Guide for Australian medical technology companies seeking to engage in China

First Edition
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Section 1: Reason for and scope of Guide

This Guide aims to assist small to medium-sized Australian medical technology companies (medical devices and diagnostics) that are seeking to engage with and in China.

The Guide is part of a larger project ‘Australian Medical Devices & Diagnostics to China’, which seeks to facilitate medical devices and diagnostics trade and partnership with China by breaking down the information barriers for Australian companies.

The Australian medical technology industry consists of an estimated 500 – 800 companies that are seeking opportunities in global markets and are increasingly seeking support to enter Asian markets, specifically China. Most of these companies are micro or small enterprises with a turnover of less than $2 million, with limited capability to assess overseas markets independently.

The Guide was originally conceived to provide much-needed information about intellectual property (IP) management in China and outline the types of business structures that are possible for Australian companies engaging in China, but during research phase has been broadened to provide information on the business, cultural and regulatory context and other information that a medical technology company may consider when developing their strategy for working in and with China.

The Guide includes information predominantly about mainland China, and has included a chapter on Hong Kong due to its unique positioning and role in China. Taiwan and Macau are beyond the scope of this Guide.

This Guide is not exhaustive and does not intend to take the place of professional advice (please see full disclaimer at the end of this document). Instead, it is intended to serve as a starting point for Australian companies interested in one of more of four identified strategic pathways to work in and with China:

- Research and development partnerships;
- Selling to China domestic market;
- Attracting investment from Chinese interests; and
- Sourcing manufacturing.

China is a complex and fast-changing environment, and while care has been taken to identify and present current policy, programs and regulations in this Guide (dated where possible to indicate currency of information), it should be noted that information is quickly outdated.
China-Australia Free Trade Agreement (ChAFTA)

In November 2014, Prime Minister Abbott and President Xi announced an historic conclusion of negotiations for the China-Australia Free Trade Agreement (ChAFTA), which lays a foundation for the next phase of an economic relationship between Australia and China.

It is anticipated the ChAFTA will unlock significant business and foreign direct investment opportunities for Australia. China is Australia’s largest export market for both goods and services, accounting for nearly a third of total exports, and a growing source of foreign investment. For more information, see www.dfat.gov.au/trade/agreements/chafta/

Why China?

By Australian comparisons, the statistics on China are difficult to comprehend due to their sheer magnitude. China is the world’s most populated country and is ~50 times the size of Australia at almost 1.4 billion people. It accounts for 19% of the global population. The population of the Capital, Beijing, alone almost matches the population size of Australia (~21 million in Beijing and over 23 million in Australia).

Rapid urbanisation in China is expected to result in the creation of 13 so-called “mega cities”, four mega regions, and six mega corridors by 2025. Mega regions alone will be inhabited by 211.7 million people, accounting for over one-fourth of the total urban population in 2025.

By 2020, China, surpassing the United States, will have the largest economy in the world. By 2025, China’s nominal GDP will hit $38.563 trillion. This economy will be characterised by high consumption spending, strong currency rates, and favourable trade ties.

In his first speech (Nov 2012) as Party Secretary General, China’s President Xi Jinping said as China rises on the world stage, it hopes once again to make a contribution to mankind by becoming a strong and prosperous nation.

In-keeping with the Chinese Government’s 12th Five Year Plan (2011 – 2015) (this five-year national policy mechanism is central to all Government planning) that had commenced the year prior, this far-reaching plan set the nation’s course and, as expected, the social and economic measures and priorities contained in the plan are having a deep impact on the business landscape, both within China and in countries that do business with China.

Three of the main priorities in this plan are sustainable growth, industrial upgrading and the promotion of domestic consumption. The plan’s priorities explain why certain sectors, including energy, automotive, IT infrastructure and biotechnology also receive a high degree of focus.

Under Xi Jinping’s leadership China has sought to (relatively) free up trade restrictions and currency exchange with the rest of the world.

While this was once a country of adapting existing technology, China’s new focus, coupled with increased spending and emphasis on research and development (R&D) is changing the dynamic and has opened a window of opportunity for partnering and investment in a range of areas including medical technology.

Unbeknown to many, China has quietly become the second...
largest pharmaceutical market in the world – and it is continuing to grow at a phenomenal 22% annually. Healthcare spending in China is increasing tremendously due to an ageing population, rising incidences of chronic diseases, and the government’s determination to provide healthcare to each of its citizens. These factors, combined with the Chinese Government’s focus on fostering innovation, the need for Chinese domestic companies to transform themselves through foreign partnerships and know-how, and the sheer scale of the market opportunities, are attracting more and more western biotech companies to engage with the China market. However many will attest to the fact that the rewards of doing business in China are immense but the risks are real. The basis of this risk is in the vastly different cultures and business practices of Australia and China. It is therefore incumbent upon anyone seeking to engage with China that the complexities of doing business in and with Chinese interests must be acknowledged. The degree to which Westerners can understand, respect and adapt to these differences will dictate their ability to succeed.

Complexity requires long term view

The complexities of doing business in China dictates that a long term view is more likely to be successful than a short term view. Many with experience will tell you that if you expect to have a business/partnership in China without taking the time to establish and nurture relationships, you will in all likelihood fail. The Chinese value relationships and newcomers should seek to understand both the cultural differences between our countries and the practice of guanxi (pronounced “gwan-she”) – all of which takes time.
Cultural aspects

These two distinct mindsets mean the Chinese can find some things about Australians difficult to understand, like the use of first names and direct, familiar language, even to senior people. So too, Australians can find things about Chinese difficult to understand, such as the idea that opposites can exist together (eg one country, two systems, as applies to mainland China and Hong Kong). Manners, language and culturally accepted norms all pay a part. The comments provided below are superficial compared to the subject matter they describe and should act as an indicator for further research.

A useful reference is a book titled, *Business Success in the Asian Century* by Dr Margaret Byrne, which can be found at: http://www.ugmconsulting.com/ Business-Success-in-the-Asian-Century-Cultural-Skills-Amazon.html

Guanxi

In particular, many Westerners struggle to understand the ancient practice of guanxi. Traditionally this term translated to mean relationships or connection, but more recently has, in some instances, for better or for worse, developed modern connotations as a pejorative term for corrupt practices (likened to ‘nepotism’ or the ‘under the table’ deals that are based on relationship rather than merit or transparent competition).

Guanxi is based on the notion of mutual interdependence between you and those in your network of influence and connection - family, friends, workmates, former classmates, etc. Traditionally, these relationships are nurtured and were considered to be lifelong, built up over time via a system of ‘favours’ or what is sometimes referred to in the literature as ‘deposits’ of social capital. This is a subtle and nuanced practice of establishing the ‘currency’ of guanxi, rarely spoken about overtly. It is also connected to the importance of relationships more generally, and the value of having personal introductions via a trusted friend/colleague, as the weight of such an introduction is carried by the person ‘vouching’ for another. Guanxi is not time-bound; relationships between school friends, university students, and colleagues from early stage careers are often brought into play many years, even decades, later and still retain high value in the Chinese system.

In this system, failing to return a favour (or continually drawing upon guanxi without reciprocating) can be seen as a major moral transgression. Those who transgress gain a bad reputation quickly and may find that whatever guanxi power they’ve built up rapidly evaporates.

Westerners can often see these practices as favouritism, nepotism, unfair, underhanded or corrupt whereas, more realistically this is an example of the individualist society versus a collectivist society at play.

Chinese people maintain guanxi through introductions to others who can bring some benefit to the recipient, social occasions such as dinners, small but significant offers of assistance with logistics/bureaucratic processes, also via visits with gifts during major festivals, for example, Chinese New Year. People value guanxi highly, especially in large cities in China, such as Beijing.

Language

While English is becoming more commonly used in the larger centres of modern China, you are unlikely to be able to routinely undertake business in China without the help of an appropriately skilled interpreter. Even if the person you are meeting with speaks English, restaurant staff, drivers and others service providers may not, even in major cities. In some countries it may be possible to provide, for example, the name of a hotel to a driver in written form and they will understand. In China you will need the name of the hotel in Chinese characters. This makes simply moving around in China, making appointments and general logistics complex. In the context of negotiations or more formal financial or business related activities, the cultivation of relationships with a trusted translator is critical.

Making an effort to have your business cards and ‘leave behind’ information translated will not only assist your Chinese counterpart to understand your message, it indicates respect and good will, which are appreciated. A great deal of care should be taken when translating names, business names, and materials – it is often not possible for a direct translation between English and Chinese, and working with a reputable translation company to ensure they understand the meaning and intent behind your company’s information is essential to obtaining an accurate representation in Chinese. Do not under any circumstances utilise online or automated translations of your materials.

When using an interpreter in a business meeting or to translate presentations, it pays to use a recommended translator and to brief them extensively beforehand, to avoid misrepresentation of your company. If you are planning a long-term engagement with China, employment of Chinese-speaking staff is a definite advantage. This will also indicate your commitment to the aspects of relationship mentioned above, and provide an invaluable source of culturally-sensitive advice in-house.
Business practice

The Chinese value the following in business interactions:

- Relationships (guanxi);
- Saving and giving ‘face’;
- Respect for elders, rankings and seniority;
- Patience and politeness;
- Modesty.

In Chinese culture, the notion of saving or giving face is important. Chinese people seldom make jokes of one other, especially in work place. They show respect to each other and avoid embarrassment at all cost. Avoiding embarrassing oneself or others is referred to as ‘saving face’. Being respectful of others is ‘giving face’. For example, a dinner guest would usually try a dish that the host recommends to them, no matter whether he wants to or not, to show his respect to the hospitality of the host. On the other hand, helping others to solve problems, which need extra effort or time, would be a way of giving face. It is rare to disagree publicly – contrary to the common Australian practice of engaging in what we might view as ‘robust debate’, differences of opinion or fact are seen by Chinese colleagues as disagreement and should be avoided, certainly in meetings or more formal settings. Establishing within your team who presents what information, agreement on key strategic points of discussions, for example, are useful prior to any formal business meeting or negotiation. It is uncommon to ‘brainstorm’ ideas in Chinese teams; there is usually reliance upon the most senior member of the group to provide guidance and for more junior members to follow.

Seniority

The Chinese respect hierarchy and seniority highly, especially in the work place. In respect for seniority, a request for a business meeting in China should be directed to the most senior person, with an explanation of each individual within the delegation, including their position, to assist Chinese colleagues to determine to whom it should be referred (the appropriate and equivalent level). It will be taken or responded to by a person with a corresponding level of seniority to those visiting. For example a president, CEO or chairman will meet a CEO, whereas a deputy CEO will be met by the vice president or second in charge. Don’t expect to send a senior manager to China to meet with a high-ranking government official, and if you are consistently being met by junior officials even if senior members of your organisation are requesting meetings, this response needs to be interpreted and your strategy adjusted.

Within a business meeting, you should expect to be greeted, seated (usually on the opposite side of a long table to your Chinese colleagues) and offered business cards in your order of seniority from highest to lowest and you should do the same.

Business card exchange

Business cards or name cards are given great respect by the Chinese and the ritual of exchange is used pervasively. You should give and receive cards with both hands. Upon receiving a card, you should read the card and give it due consideration. It is common to have English on one side and Chinese on the other, and you will be given the card face-up in English unless your hosts know you are fluent in Mandarin. You should do the reverse – with bilingual cards, you should present your Chinese hosts with your card Chinese-side upwards, for their ease of reading. (To ask them to read your English card when they cannot read English would be embarrassing; they would lose face.) You should not write on or deface a card you have been given.

Mingpian (name cards) are seen as a virtual representation of the person giving the card, and as such leaving them on the table where they might have food/drink spilled on them, throwing them casually into your bag, or any other action that is not respectful, is seen as rude and an impolite gesture towards that individual.

Sharing meals

It is common to be asked to dine with Chinese business people and government officials. This is a mark of respect and a chance to get to know each other. While the level of hospitality has demurred somewhat under the current leadership and austerity measures in modern China, you may expect many courses and usually in a restaurant quite separate from the office in which you are doing business (in contrast to Australia practice, of perhaps serving simple cut sandwiches at the boardroom table). Although both may be considered a ‘working lunch’, in China it is common to engage in social chat during the meal and move to business towards the conclusion of the meal.

It is a sign of politeness to accept some of everything, and sample (even a little of) all dishes served. But don’t eat or drink all of something you don’t like, since this may be taken as a sign that you want more. Empty plates commonly indicate not enough food has been ordered, which would be a great loss of face for any host who has ‘not provided’ enough hospitality for his/her guests.

Toasts

Toasting at formal Chinese events is a complex practice. Do not worry if you are unsure, as most foreigners are unaware of the complexities and
are easily forgiven for misreading the cues. Chinese people usually toast one person at a time although in less formal settings, a team or several individuals at the same level can be toasted as one. During business dining in China, hosts (in order from the most senior person to the junior) toast the guests to welcome them and show respect. They follow this order strictly as a showcase and respect for seniority, moving around the table one by one. You will have been seated in a specific order to help facilitate the hosts’ understanding of seniority, so remember to wait until you are seated, and you can determine by where your hosts are placed around the table their hierarchy also.

Your host will often start a banquet with a toast to their guest/s and/or the whole table. You may choose to reciprocate, toast for toast, or to wait until the host, his or her colleague, and other members of the hosting party have toasted. Typically, the principal guest is expected to toast a few courses after the host toasts. If you are toasting, your comments should be warm and sincere, and your toast should not be any longer than your host’s.10

When Chinese toast their guests, or when a junior person toasts the more senior, their glasses should be held in a lower position than those of the guests or seniors to show respect. If you are at a large table and cannot reach everyone’s glass to touch, it is common to simply lightly touch the bottom of your glass to the round glass centre of the table (the revolving disc bearing all the dishes), as a proxy for clinking glasses to everyone present.

**Gift giving**
Gift giving is still common to and from delegations at the end of a meeting or during a banquet, although in business meetings this is happening less often. Gifts should be inexpensive, but not too cheap, nor should they be made in China. A gift with a strong local association (or personal significance if you know your colleagues well enough to bring tailored gifts) will have real meaning for the receiver and for the giver. The best gifts will be items that are unique to Australia. The gift should be presented from most senior person to the most senior person.

However, giving a gift when your host or guest does not have one for you can cause the loss of ‘face’. If possible it’s wise to have gifts in your bag at the ready and wait for a cue from your Chinese counterpart/s.

**Keys to market success in China**
Much is written on the do’s and don’ts of doing business in China, but of all the recommendations, the themes that repeatedly appear as indicators of your likelihood of success are:

- Flexibility and willingness to adapt: Doing business in China is not like a Western country and if you treat it like you would normally, success is unlikely. Not only do both parties need to be willing to adapt and demonstrate patience with frustrations, such good will is likely to be appreciated as a mark of respect and help build trust in your relationship;
- Seeing through “Chinese eyes”: Understanding the Chinese culture, including making overt your willingness to learn from your Chinese counterparts (for example, not just presenting the Australian way of doing business as the standard practice), will assist you to build relationships, which in turn will assist your ability to build a business/partnership in China;
- Commitment to the long term: is seen as sincerity in your endeavour;
- Consistency and reliability, helps to build trust: Sending different staff to represent you each visit does not necessarily instil confidence. Relationships are often at an individual level. Don’t forget that for a Chinese person committing to a relationship with you is allowing you into their network, with all the benefits (and risk) that may bring;
- Recognition of the role of government, which permeates all aspects of life in China, from business approvals, to the heating provisions for your hotel: You will benefit from being introduced to, and getting to know, the relevant government officials in your areas of business and geography.

For all the reasons noted above, China is not a place to ‘go it alone’. The importance of partnering, extensive research and tailored advice cannot be understated.

**Layers of government, role of government**

The government of China is a complex organisation with a presence in many aspects of Chinese life. From financial planning to family housing, China’s government is omnipresent, controlling the direction of economic and social policy. Within the business spectrum China’s government is equally active, at times enacting cumbersome and opaque legislation that hinders private investment, at times working hard to facilitate the expansion of private markets.

Since 1949, China has been a one-party state, ruled by the Chinese Communist Party. The country’s legislative organ is the National People’s Congress (NPC), which convenes in Beijing for two weeks each year. When the NPC is not
sitting, the country’s permanent organ is the Standing Committee. The head of state is a President, and the State Council governs the country. The People’s Republic of China is a unitary state, which delegates certain legislative and executive powers to provincial and municipal authorities.

The government of China largely operates on three levels: National, provincial and local level. Between these three levels the Chinese government has a presence in virtually every formative aspect of Chinese life. The Chinese government plays a large role in the management of China’s economic system and a good understanding of the governmental system is crucial for businesses in China.  

In order to have a comprehensive sense of China’s business culture it is imperative to understand the various structures and organisations of China’s government.


Since China joined the World Trade Organisation (WTO) in 2001, it has become more open to trade and less autarkic, with less restriction on direct foreign investment and the lowering and removal of tariffs. 

See Section 4 on free trade and special economic zones.

State owned enterprises (SOEs)

China is dominated by companies owned by the national, provincial or municipal governments, also known as SOEs. These enterprises have enjoyed cheap loans and subsidies.

Economic Roundup reported that “While past reforms to the SOE sector were a catalyst for China’s rapid economic rise over recent decades, SOEs now lag well behind the non-state sector in terms of their productivity performance, contribution to economic growth and their role in China’s broader economic development. However, China’s state sector remains powerful; it continues to dominate many key areas of the economy, commanding a disproportionate share of the country’s financial resources through its privileged position in the political system.”

“Further market oriented reforms to the SOE sector will therefore be crucial if China is to achieve ongoing gains in productivity and to maintain a swift pace of economic development. Looking ahead, the government is expected to pursue further corporatisation and public listing of SOEs, better public asset management, while broader economic reform to China’s financial markets and government administration is likely to subject SOEs to an increasingly competitive operating environment.”

New regulations for ethical business conduct

A major focus within China recently has been reform to increase transparency, ethical conduct and considered spending, which has included new regulations for business.

In December 2013, the People’s Republic of China National Health and Family Planning Commission (NHFPC) issued Regulations on the Establishment of Commercial Bribery Records for the Purchase and Sale of Medicines, and Nine Prohibitions for Strengthening Ethical Conduct in the Healthcare Industry (Nine Prohibitions), which became effective the same day. The Nine Prohibitions re-emphasise restrictions imposed on healthcare professionals and healthcare institutions, and highlight high-risk areas such as offering improper donations, subsidies, travel and entertainment.


The rules seek to:

- Promote the implementation of the commercial bribery blacklist (the Healthcare Blacklist);
- Give blacklisted enterprises and individuals nationwide exposure by publishing the blacklist on a public website;
- Further restrict blacklisted enterprises and individuals by means such as procurement-related penalties in other provinces and a nationwide ban for repeat offenders;
- Re-emphasise restrictions imposed on healthcare professionals and healthcare institutions, and highlight high-risk areas such as offering improper donations, subsidies, travel and entertainment.
Overview of the China healthcare market

China's healthcare sector is developing at an astonishing rate. This remarkable growth is largely attributable to the country's increasing government spending, underpinned by robust economic growth, which has led to improved healthcare access and infrastructure, as well as the ongoing expansion of public insurance coverage and infrastructure for less developed parts of the country. Beyond the growth in government spending, patients' ability to afford better medical care has increased. Driving this investment is the country's rapidly-increasing middle class, and its ageing population, which are both increasing the demand for healthcare.

The Economist Intelligence Unit (2013) estimates that, by 2015, there will be more than 100 million households in China earning more than $15,000 per year, up from fewer than 35 million, with growth expected to accelerate to over 40% per year. As a result, spending is projected to grow from AU$357 billion in 2011 to AU$1 trillion by 2020. To support the expected growth in demand, the Ministry of Health's (now the NHFPC*) ‘Health China 2020 Strategy’ calls for investment of AU$62 billion in the health system.

China is also one of the world's fastest growing and most attractive pharmaceuticals markets. China has made a clear commitment to develop life sciences, with biotechnology one of seven priority industries in China's 12th Five-Year Plan (2011 – 2015). The country is injecting US$ 40 billion into life sciences development each year. This initiative emphasises innovation and quality care, designed to benefit Chinese society as a whole. However, for international companies, the emphasis on upgrading and enhancing the domestic industry can pose a challenge and threaten their current market share, given the inroads already being made by domestic players into the high-value segment.

Improving China's healthcare system – particularly for the rural population – is an important goal of the country's 12th Five-Year Plan for National Economic and Social Development (FYP), through measures such as expanding insurance schemes, increasing reimbursement for critical illness, and even pilot programs for single disease payments – all of which further contribute to increasing affordability for patients. As the government increases its emphasis on access and standards of care, facility upgrades are taking place and better reimbursement and insurance schemes are allowing a greater segment of the population to access top-quality care. Thus, mid- and lower-tier cities are now becoming viable markets for international companies.

Section 3: Commercial context for healthcare and medical technology

* Footnote: (The National Health and Family Planning Commission (NHFPC) was created from the former Ministry of Health and National Population and Family Planning Commission, as announced at the 2013 National People's Congress, see www.en.nhfpc.gov.cn)
While national standards and benchmarks are opening the door for international companies to compete in the wider marketplace where they often bring a significantly higher level of quality, price and affordability still remain critical determinants in most lower-tier markets. Current Chinese hospital payment mechanisms, unlike the healthcare technology assessment (HTA) process in Germany or France, often do not have a good scheme for allowing advanced technology, which is inevitably accompanied by a higher price tag. Thus, companies are still often competing simply on the basis of price with little room to introduce improved technologies that can deliver a better patient outcome. Alternatively, they need to delay the commercialisation process to apply and wait for a new charge code that enables higher pricing. Among other factors, this has led many companies to consider the option of introducing a value line to their product offerings.

For example, the rates of Chronic Obstructive Pulmonary Disease (COPD), are expected to grow quickly in the coming years due to high smoking rates, air quality, the ageing population and growing obesity. The World Health Organization says, in China, chronic respiratory diseases are the second leading cause of death and the prevalence of COPD in men and women in China is not very different. Frost and Sullivan advise that the changing landscape is being driven by:

- Patient demand continuing to increase as in-patient and out-patient volumes grow at double-digit rates annually.
- Patients looking for higher standards of care.
- Increasing size of the ageing population is driving the need for aged care support services across a spectrum of care.
- Local home-grown medical technology developers are becoming increasingly competitive at home and abroad with established, well-known brands.
- Recent reform measures including significant investments in modernising hospitals in both urban and rural settings.
- The influence of the government playing a bigger role in the access of the market to foreign developers.

Under the 12th FYP, the Chinese government is also emphasising investment in domestic research and development to strengthen the local medtech industry and has set a target of developing 40 to 50 innovative high-technology medical device companies.

International companies already have a strong presence in China’s high-end medical devices segment, capturing nearly three-quarters of this premium market. Of the top 10 global medical device manufacturers, all maintain a sales presence and six are currently manufacturing in China.

Trends and opportunities

Companies considering moving beyond the high-value segment ought to first consider which of their products to take into the wider, more price-sensitive marketplace where sales volumes could be much smaller per account, but the total market is much larger.

The classic example of this trend is China’s experience with drug-eluting stents (DES). Ten years ago, the Chinese DES market was dominated by international companies, but in less than a decade, domestic competitors have managed to take over this product area. It is also worth noting that Chinese companies have increased their focus on developing proprietary products. Several Chinese medtech companies are making an effort to build R&D capability by leveraging support from multiple parties. Some companies are turning to domestic manufacturing to harness the value segment’s potential. Welch Allyn Inc., for example, began to set up a facility in 2012 to fully qualify for the Community Health Center tenders program. One advantage of local production is that locally designed and manufactured products can be much more suited to the broad-based value market in China and may also be marketable for export.

Devices & diagnostics market in China

The US $17 billion medical technology market in China is one of the fastest growing in the world. It currently ranks fourth in the world and is expected to double in size by 2018.

However, on a per capita basis, China’s spending on devices is still small, indicating both a key challenge today and the potential of tomorrow as the country moves toward patterns of spending on health care more common in developed markets. Growth in device use will be underpinned by improving household economics and government policy, in the form of improving health care access, consistency in standards of care, levels of public insurance cover and a broader suite of lifestyle factors.
Distribution models and channel partners

Although different options exist for entering the Chinese market, if you wish to distribute your product via hospitals, there is no way to avoid the tendering process. Once a manufacturer “makes the list,” the next step in the journey is deciphering market segments and the optimal way to reach them. See Section 6 on reimbursement, for information on tendering.

In China, as elsewhere, delineating the most appropriate customer segmentation is a critical driver of market insight and success. China is a geographically vast country with a correspondingly wide range of economic and health care infrastructures, with patient income variations to match.

Distributors and dealers

While direct sales models may be a common practice in the US and Europe, international medtech companies have not seen much success with this model in China, relying to a greater or lesser extent on networks of distributors/dealers. At present, most international companies rely more heavily on distributors/dealers to address harder-to-reach segments of the market, while focusing internal efforts on supporting key accounts and a few brand-critical market-related activities, such as academic sponsorship and clinical support.

The division of functional responsibility between manufacturer and distributor/dealer has led to a range of interesting mixed-model strategies. Medtronic, for example, relies on a number of dealers to manage sales relationships as well as product inventory and delivery. They task their own sales force with academic and clinical support: providing sponsorships for continuing education, inviting national ‘key opinion leaders’ to hospitals for demonstration surgeries, and offering technical training opportunities for physicians from less developed regions.

Frost and Sullivan advise that the three key opportunities for medical devices over the next decade are:

- **Infrastructure build-up creates demand for products and services**
  Reform measures that led to the building and upgrading of hospitals across the country from 2009 to 2011 have increased capacity for the Chinese healthcare system and have increased demand for new devices and treatments.

- **Products designed with the Chinese market in mind improve adoption**
  Historically, products sold in China were developed for other markets by multinational companies. The growing importance of China as a growth driver, and the previous market failures has forced these companies to develop products tailored to China’s healthcare system.

- **Growth in local manufacturing gives rise to new competitors**
  Significant growth in local manufacturing capabilities for sophisticated medical equipment and implants is giving rise to new competitors. In the near future, value-based products from China could compete in other emerging and established markets as well.
Section 4: Government provisions and support for companies

Special economic, technology and free trade zones

Since the 1970s China has progressively established a multilevel range of designated zones that encompasses Special Economic Zones (SEZs), Coastal Development Areas, Free Trade Zones (FTZs), and more recently Economic and Technological Development Zones, High-Tech Industrial Development Zones (HTIDZ). While each will have their own advantages and disadvantages, generally speaking these zones have government policies that are more oriented toward free-market principles and economic policy more flexible and some provide conditional government incentives.19

Even as long ago as 2008 the World Bank20 that the “SEZs and industrial clusters have made crucial contributions to China’s economic success” and provided pilot zones and role modelling for the rest of the country. It was then estimated that the SEZs, including the industrial parks and zones made up an estimated 22% of the Country’s GDP, about 46% of the foreign direct investment and about 60% of exports, generating more than 30 million jobs. HTIDZs hosted about half the country’s high-tech firms and incubators and have accounted for half of China’s high-tech industrial output and a third of exports.

Just as with its cleantech aspirations, China has announced to the world its intentions of becoming a global hub for biotech. The 12th FYP emphasises investments and subsidies the central government plans to offer in the biotech sector. Incentives are being extended to foreign companies to get them to build R&D capabilities domestically, a process that may set in motion a global re-balancing of pharmaceutical drug discovery and commercialisation that may well dwarf what happened in cleantech.21

Geographical biotech hubs

China is pursuing a model similar to that used in the US (laboratory space, capital, academic research), but with a confidence and alacrity that could only come from a centralized economy.

The biopharmaceutical clusters of China can be divided into four areas (see Figure 2 below).
• Northeast Cluster – Beijing, Tianjin, Liaoning, Hebei, Shandong
• Central East Cluster – Shanghai, Suzhou, Taizhou, Hangzhou, Nanjing
• Central West Cluster – Chongqing, Chengdu, Xi’an, Wuhan
• Southern Cluster – Guangzhou, Shenzhen, Hong Kong.

With more than 100 life science parks located in China, it is difficult to characterise the wide spectrum of clusters and companies, however many have specific focus on areas of speciality and it is worth visiting and researching what each offers before deciding where to locate your company/laboratory. Many parks are now offering space in conjunction with local government grants to facilitate commercial ventures (see Burnet’s case study on Nanjing BioPoint Diagnostics in Section 12 as an example).

In addition, the government, both nationally and at a provincial level, has sought to create industry clusters around specific industries. There are some 22 national biomedical centres, including bio-parks such as:

• Zhongguancun Science Park (Beijing Municipality);
• Shanghai Zhangjiang Hi-Tech Park (Pudong New Area, Shanghai Municipality);
• Tianjin Economic-Technological Development Area (Tianjin Municipality);
• Guangzhou International Biotech Island (Guangzhou Development District, Guangdong Province);
• Shenzhen Hi-Tech Industrial Development Zone (Guangdong Province);
• Hunan Changsa National Economic and Technical Development Zone (Hunan Province).

• Wuhan East Lake Hi-Tech Development Zone and BioLake Wuhan (Hubei Province)
• Suzhou Biobay, Suzhou (Jiangsu Province)
• Wuxi New District, Wuxi
• Chengdu Hi-Tech Industrial Development Zone

Other growing clusters, include:
• Jinan Pharm Valley (Shandong Province) (www.ukspa.org.uk/members/jhtbi)
• Xiamen Bio Bay (Fujian province) (www.xmbio.gov.cn/html/en.html)

While coastal areas have led the way in SEZs, as they have been industrialising for many years, more recently China’s inland provinces and cities are more assertively offering a wide variety of investment incentives.

**Shanghai Pilot Free Trade Zone**

In late 2013, China announced the piloting of a new form and potentially more radical form of FTZ in Shanghai, drawing interest from around the world. Backed by Chinese Premier Li Keqiang, the FTZ is expected to be a testing ground for a number of economic reforms, with its tax-free period of 10 years for businesses, and the permitting of yuan convertibility and unrestricted foreign currency exchange in the area.

There is a special focus on encouraging development of the medical industry, particularly by wholly-owned foreign medical groups. This is designed to encourage the creation of greater research, import and local production of medical devices and provision of hospital services by the private sector in an area heavily dominated by government control (see Figure 3 below).
While not the first FTZ in China, it appears to the first of its type and oriented toward currency and investment. The establishment of the Shanghai Pilot FTZ has prompted commentators to speculate that Shanghai may in the future rival Hong Kong as the financial and trade ‘gateway’ to China.

Further details are expected to be announced as they are developed. Further to the initial details available at the 2013 launch of the Pilot FTZ, a December 2013 announcement from the People’s Bank of China said companies with operations within the zone could issue yuan-denominated bonds, thereby opening access for overseas firms to Chinese investors and make it easier to raise funds. The official (English) website can be found at: www.en.shftz.gov.cn

Medical devices in the Shanghai FTZ

The Pilot FTZ is expected to create opportunities for medical device manufacturers with the liberalisation of three sectors: hospitals, health insurance companies and capital equipment leasing. Further the zone encompasses the main port for the import of medical devices – Waigaoqiao – and is where the Pudong Medical Trade Association is located.

Importing of devices is set to be cheaper due to reduced tariffs and tariffs can be waived in leasing of equipment.  

Support programs in Australia

From Australia, companies and researchers seeking markets and partnerships in China, may be able access support via a range of programs:

Export Market Development Grants (EMDG) scheme, a key Australian Government financial assistance program for aspiring and current exporters. The scheme supports the export of intellectual property and know-how outside Australia. For more information, see www.austrade.gov.au/export/export-grants/what-is-emdg

Research & Development Tax Incentive

The R&D Tax Incentive provides Australian entities with a 40% or 45% tax incentive, which is refundable for companies with turnover under $20 million, for eligible R&D activities. While provided by the Australian Government to promote in R&D in Australia, in certain circumstances the Incentive may apply to the conduct of less than 50% of an R&D project overseas, for example a clinical trial, where it cannot be conducted in Australia. An ‘advance finding’ is required to approve the claim and more information can be found at: www.business.gov.au/grants-and-assistance

Australia-China Science and Research Fund (ACSRF)

ACSRF was recently extended by AUD$10 million over four years from 2014-15, “in recognition of the long-standing and highly successful nature of the Australia-China joint science and research relationship,” to build on over 30 years of bilateral cooperation.

The ACSRF supports strategic science, technology and innovation collaboration of mutual benefit to Australia and China, by building critical mass in areas of strategic priority, supports enduring partnerships between Australian and Chinese researchers, and encouraging the application and commercialisation of research outcomes for the mutual benefit of both countries. For more information about the Fund, see www.industry.gov.au/science/internationalcollaboration/acsrf/Pages/default.aspx

Chinese local government grants and incentives

Like Australia, the Chinese government has a focus on attracting both foreign investment and more importantly, international scientific talent to its country.

To this end, a series of science and technology plans and programs were put in place to enhance the contribution of science and technology to China’s economic growth.

While largely designed to attract entrepreneur and technology returnees to China, these grants are also open to foreign companies and individuals as well.

Generally, any company which possesses strong IP and established scientific and technological innovation can apply. These grants range from RMB 1 -2 million+ plus in-kind support in the form of free laboratory space, office space and apartment rental, as well as access to venture capital and debt funding.

Many provinces and cities provide these grant programs and many will have different names. For example, in Nanjing the grants are called “321” grants, in Suzhou “1000 plan” grants and in Ningbo they are called “3315” grants.
Section 5: Market access – regulatory

Disclaimer: although this section has been written with utmost care to differentiate current requirements from draft requirements, it is intended as a generic guidance document only. Particular requirements and pathways can vary from device to device (especially with future publication of new CFDA announcements). Therefore, we stress that before taking any regulatory actions, it would be essential to verify the most up-to-date CFDA provisions and guidelines prior to commencing any registration projects.

Regulatory considerations for medical technology

This section aims to provide an overview of Chinese government approvals – a mandatory requirement for the marketing of imported medical devices (including in vitro diagnostics devices (IVDs)) in China – including mapping the key players and various pathways to regulatory approval, and the ongoing compliance needed to ensure continuity of business.

Regulation and reform

The Therapeutic Goods Administration (the TGA) is responsible for regulating therapeutic products in Australia. In China, similar authority is held by its China Food and Drug Administration (CFDA), formerly known as the State Food and Drug Administration (SFDA).

Since joining the International Medical Device Regulators Forum (IMDRF) in 2013, the CFDA has been actively promoting harmonisation and streamlining of the regulatory framework in China. This has led to the revision of its top tier regulation, Regulation for the Supervision and Administration of Medical Devices, effective since 1 June 2014. The key changes include:

- Certificates are valid for five years (previously four years);
- Class I devices now adopt a filing approach for both Good Manufacturing Practice (GMP) requirements and product registration, removing the need for technical review;
- Class II and III device registration should be supported by clinical trial data, unless they are named in the List of Exempted Devices;
- Allowance for on-site Quality Management System (QMS) audit (where necessary) of device manufacturers outside of China;
- Emphasis on risk evaluation and regulatory control throughout the device’s life-cycle, strengthening post-market monitoring and reporting;
- Prohibition on contract manufacturing of selected high-risk devices (currently only enforced on domestic manufacturers);
- Allowance reprocessing of single-use devices that are not in CFDA’s predefined list; and
- Introduction of medical device application fees (previously imported devices applications were free-of-charge).

Consequently, all underlying supporting provisions and guidelines are undergoing rapid revamping to keep consistent with the Regulation, deeply impacting both pre-market and post-market compliance requirements in China.
Working with the CFDA

The CFDA’s headquarters is located in the capital, Beijing. It is responsible for processing all new device filing/approvals as well as any subsequent variations for imported medical devices and high-risk domestic devices. The provincial and prefecture arms of the CFDA are respectively responsible for class II and class I domestic devices, as well as for monitoring clinical trials and distributors.

The CFDA authorises the Centre for Medical Device Evaluation (CMDE) to conduct technical reviews. CMDE is divided into four scientific and technical review offices, each responsible for a specific range of medical devices.

Manufacturers may consult CMDE and/or CFDA on device-related questions. All technical questions should be directed to the CMDE, whereas those that are regulatory in nature should be addressed by the CFDA. Formal face-to-face meetings can be arranged through the China Centre for Food and Drug International Exchange (CCFDIE).

Similar to most Asian markets, a non-Chinese manufacturer* must appoint a Chinese legal entity as its legal representative (also referred to as the Sponsor or Local Market Representative). Unlike other markets however, the manufacturer, not the Sponsor, is the product registration holder. This makes it relatively simple to switch Sponsor without affecting continuity of business. The Sponsor must act on behalf of the manufacturer to demonstrate compliance with local regulation in all stages of supply, from obtaining product clearance prior to distribution, to vigilance reporting once a product has been released to the market.

The Manufacturer or Sponsor may appoint a registration agent to correspond with CFDA and CMDE on all matters relating to product applications. Such an agent must be well versed with Chinese medical device regulation, technical guidelines and application procedures. Working with reputable partners who have an established working relationship with the Chinese authorities is the best strategy in minimising complications and facilitating a smooth regulatory process.

The Sponsor is also required to provide ongoing technical support to products distributed in China and to report all adverse events to CFDA, formally this responsibility was shared with the after-sales agent. Sponsors may appoint third parties (for example, local distributors) to help perform these duties following successful pre-market filing/registration.

Pre-requisite to market entry
In addition to appointing Chinese agents mentioned above, manufacturers wishing to enter the Chinese market must also demonstrate the device can be legally supplied in its country of origin. This means Australian manufacturers must first have their devices included on the Australian Therapeutic Goods Register (ARTG) for marketing inside Australia. Please note than an “export only” ARTG inclusion will not be sufficient in its usual form and requires extra information.

The TGA issues two kinds of certificate, the Certificate of Free Sale (CFS) and the Export Certificate. For the purpose of Chinese registration, the CFS is more appropriate. The full details for the product and the manufacturer must be explicitly stated on the CFS and be aligned with those to be included on the Chinese registration certificate.

Other than Class III or active implantable medical devices and Class IV IVD devices, it is not typical for ARTG certificates to include such detail. However, a separate “Export Only” ARTG inclusion can be obtained with the required information. The CFS application should refer to both the original ARTG inclusion and the export-only version to ensure all relevant information has been captured.

Note that certain products exempted from ARTG inclusion may be classified as medical devices in China, thus they still require a CFS. All technical data and regulatory documents provided in a language other than Chinese should be accompanied by a simplified Chinese translation. All translated documents should be accompanied by the original version.

Regulatory pathways for imported medical devices

Chinese classification and product technical specifications
Medical devices (including IVDs) are classified into three categories according to their risk profile:

- Class I medical devices are low-risk devices for which safety and effectiveness can be ensured through routine administration;

*Footnote: Domestic manufacturers are directly responsible for the safety and quality of their products, hence no Sponsor is required. Their regulatory pre-requisite and pathways are summarised in below.
• Class II medical devices are moderate-risk devices for which strict control is required to ensure their safety and effectiveness; or

• Class III medical devices are high-risk devices for which special methods are required to strictly control their safety and effectiveness.

Adopting the international convention, the risk profile of a device is dependent on its intended use, structure and specification, as well as the mechanism of action. However, this does not mean for a given device, the Australian risk classification is directly translatable into a Chinese classification.

China combines the European rule-based classification system with the category-based system used in the US. A device’s risk classification depends on the applicable classification rule (similar to the Medical Devices Directive rules in Europe), the applicable classification code (similar to product code in the US) and the generic product name. The CFDA device classification documents (named below) can be referred to as reflecting the most current thinking on risk level associated with a particular device:

- Medical Device Classification Principles;
- Catalogue for IVD devices;
- Catalogues for Medical Device Classification (separately for Class I, II and III).

In the past, there has been much confusion over the various published catalogues, each covering the range of generic names under a particular product classification code. As these catalogues are not mutually exclusive, it is not uncommon that multiple classification codes (and sometimes generic product names) to be appropriate for a particular product. To avoid such confusion, the newly published catalogues have been consolidated by risk classification rather than by classification code.

The risk classification ultimately decides the applicable regulatory assessment pathway and quality system requirements (Figure 4). Generally speaking, Class II and Class III device registration must be supported by in-China type testing and (where applicable) clinical data and undergo technical review by the CMDE. In the revised Regulation, imported Class I devices would only require filing appropriate documentation with the CFDA.

Pre-market filing for low risk devices

Only medical devices within the scope of the description and intended use given for a particular product category named in the Catalogue of Class I Medical Devices would be considered Class I by the CFDA. From June 2014, the Class I devices were exempted from technical review. The local Sponsor may file the regulatory dossier with the CFDA, and once accepted, would receive overnight device listing and approval to market.

The contents for a Class I filing dossier has been finalised in the CFDA Announcement No. 2014-26: CFDA Gazette on the Matters related to Filing of Class I Medical Devices in May 2014, including:

- Form for Class I medical device filing;
- Risk analysis report;
- Product technical specifications;
- Product self-testing report (in accordance with the above specifications);
- Clinical evidence report;
- Original and draft Chinese translation of Instruction for Use (IFU) and labels;
- Manufacturing process and manufacturing site(s);

Chinese medical device classification and premarket requirements

<table>
<thead>
<tr>
<th>Class 1</th>
<th>Class 2</th>
<th>Class 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Filing with CFDA</td>
<td>STED for technical review</td>
<td>STED for technical review</td>
</tr>
<tr>
<td>Type testing</td>
<td>Clinical Trial Data (unless exempted)</td>
<td>Type testing</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Clinical Trial Data (unless exempted)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Clinical Trial Approval (selected high-risk device)</td>
</tr>
</tbody>
</table>

Figure 4: Chinese medical device classification and premarket requirements
- Free Sales Certificates from country of origin;
- Business registration certificate from the Chinese sponsor;
- Declaration of conformities (to Chinese regulation and standards).

The bolded items are unique to China and need to be gathered or generated specially for the CFDA. Though the above checklist is more comprehensive than previously required for Class I registration, most items are readily available from the device’s technical file.

Once the CFDA verifies the format and completeness of the regulatory dossier, the Class I Medical Device Filing Certificate will be issued with an official Filing Number. This should be captured on the Chinese labels and IFUs. No renewal is required for Class I filing.

**Pre-market registration for higher risk devices**

In addition to the documents requested for Class I device filing, class II and III devices need to provide additional information to support their safety and effectiveness, including:

- Chinese Essential Requirements Checklist (not required for IVD reagents);
- Verification and validation testing reports;
- Type testing report (by authorised Chinese testing centres); and
- Justification for exemption from clinical trials or (if required) in-China clinical trials.

The application dossiers for Class II and III devices are subjected to full technical review by the CMDE. The CFDA assumes all medical devices imported are manufactured and controlled under a quality management system appropriate to GMP requirements from its country of origin without further certification. Some medical device manufacturers may be selected for on-site QMS audit if deemed appropriate by CMDE during an application review.

**Type testing by authorised Chinese testing centres**

The CFDA authorised testing centre are responsible for verifying the completeness and accuracy of the Product Technical Specifications (PTS) by conducting type testing. The testing methods as specified are assessed by the testing centre on their compliance with applicable Chinese national and industrial standards. Passing such testing could be technically challenging in certain areas where the applicable Chinese standards are different from their international counterparts (typically caused by a lag in adopting the most recent version of the international version).

For example, most of the global markets have adopted the third edition of the electrical safety standards, IEC 60601-1:2005, nonetheless, China currently (at the time of going to print) only recognises the second edition, as the Chinese electrical safety standards GB 9706.1-2007 is identical to IEC 60601-1:1998. Consequently, medical devices designed in accordance with the third edition may face difficulties in passing type testing.

The sample(s) selected by the manufacturer for type testing should be representative of the entire range of device(s) pending registration. For Class III IVD reagents, CFDA Order No. 5: Provision for In Vitro Diagnostic Reagents Registration further demands that samples must be drawn from three consecutive batches.

**Clinical trial requirements**

Previously, non-Chinese medical devices have been able to leverage the clinical evidence report used for market approval in its market of origin, where most Class II and III IVD reagents have been, and will continue to, require in-China clinical trials for registrations. From October 2014, Class II and III medical device applications require in-China clinical trials, unless listed in either:

- The List of Class II Medical Devices Exempted from Clinical Trials; or
- The List of Class III Medical Devices Exempted from Clinical Trials.

Alternatively, clinical trial exemption may also be granted if one of the following criteria is satisfied:

- The safety and efficacy can be proven through non-clinical assessment; or
- The safety and efficacy can be demonstrated through analysing and evaluating data obtained from clinical trials or clinical application of a substantially equivalent device.

In practice, such exemption would be based on substantial equivalence to a device available in China (typically from the same manufacturer).

For those that require in-China clinical data, the key points for Chinese clinical trials are:

- The trials should be conducted at qualified clinical institutes. Data for Class II medical devices and IVD reagents must be generated from
two qualified clinical institutes, whereas those for Class III should employ three institutes;

- All clinical trials must have ethics committee approval and a satisfactory type testing report for commencement. Selected Class III high risk implantable/absorbable devices in the CFDA's predetermined list must have their clinical trial plan pre-approved by the CFDA prior to commencing trials in China;

- Chinese Good Clinical Practice (GCP) guidelines have been established for medical devices and IVD reagents respectively and should be followed accordingly;

- It is mandatory to notify the local (e.g. provincial) FDA office of clinical trials underway in their jurisdiction, and local FDA officers may audit the clinical sites;

- All adverse events should be monitored and reported (see below).

For imported devices exempted from clinical trials, the manufacturer should submit a rationale for exemption, as well as the clinical evidence report used in its country of origin, for Chinese registration. For imported IVD devices not exempted from clinical trial requirements, the manufacturer should supply the clinical evidence report as well as clinical report generated from targeted clinical trials conducted in China.

**Timeframe for CMDE review**

The review timeline shown below is applicable for initial device registration of as well as significant changes to Class II and Class III.

The official review timeline from submission to obtaining the registration certificate is approximately four to five months for Class II, and six months for Class III, not including any time taken by the applicant in responding to review questions. This timeframe does not consider the optional QMS audit or consultation with Medical Device Expert Committee (typically only required for technically challenging products).

Starting in late 2013, the CFDA implemented a streamlined review process, which limits the number of question-and-answer cycles. Only one set of formal review questions would be issued by the CMDE reviewer in writing. The manufacturer should submit a full response within the allocated timeframe or request an extension (up to one year is allowed). Based on the adequacy of the response, the reviewer could either make a decision, or request simple clarification.

**Regulatory pathways for outsourcing to China**

While there are certain advantages in manufacturing in China (as further explored in Section 10), there are also many factors at play in selecting one’s manufacturing partner, for example:

- The partner’s relationship with competitors;
- Protection for your product design and IP;
- Control over manufacturing process and quality of production;
- Product branding and positioning in international markets; and
- Availability of government grants and policies encouraging medical technologies.

Where other sections of this Guide have given insights into various IP and business considerations, it is crucial to also understand the regulatory consequences that would follow the legal appointment of a manufacturer in China.

As opposed to the aforementioned imported device pathways, products physically produced in China for direct supply to the Chinese market should be registered as domestic medical devices. Partial outsourcing of manufacturing steps should only be commissioned with a full understanding of the applicable regulatory requirements and associated responsibilities of all parties concerned. Such requirements and responsibility would best be assessed on a case-by-case basis depending on the particular device type(s) and proposed manufacturing arrangements.

![Figure 5: Timeline for a Class II/III submission](image-url)
For premarket assessment of domestic devices, the level of the CFDA authority that is responsible depends on the risk classification of the device, as shown on the table below.

<table>
<thead>
<tr>
<th>Domestic devices</th>
<th>Device Market Clearance</th>
<th>Manufacturing GMP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class I</td>
<td>Device Filing with Local FDA</td>
<td>GMP Filing with Local FDA</td>
</tr>
<tr>
<td>Class II</td>
<td>Local FDA conducting Technical review</td>
<td>Local FDA conducting: QMS Audit Issues manufacturing certification</td>
</tr>
<tr>
<td>Class III</td>
<td>National CFDA conducting Technical review</td>
<td>Issues registration certification</td>
</tr>
</tbody>
</table>

The CFDA in Beijing is responsible for the product registration of Class III devices, whereas the local FDA (e.g. prefectural, municipal or provincial) is responsible for Class II device registrations and Class I device filings. The administrative process and technical review timeline is in-line with those specified for imported devices.

Compared to non-Chinese devices, domestic manufacturers must be audited and certified to Chinese GMP standards. The local FDA is also responsible for the GMP certification. Previously, the GMP certificate must be obtained before a manufacturer can apply for product registration, however, with the new regulations, the domestic manufacturers may apply for market clearance with prototype devices produced prior to obtaining GMP certification.

Though the GMP requirements are mostly in-line with ISO 13485, China has no formal mutual recognition agreements with other jurisdictions, nor has it adopted the Medical Device Single Audit Program (MDSAP). Consequently, it is not possible to abridge the QMS application with certificates or audit reports from European notified bodies, Australia’s TGA, the US’s FDA or any other jurisdiction.

For Class I device manufacturers, GMP filing is required once the completeness of the QMS documentation is verified. For Class II and III device manufacturers, the QMS documentation is assessed and may require an on-site audit before the GMP certificate can be issued.

Similar to Class II and III device registration certificates, the GMP certificates for domestic manufacturers are valid for five years. All associated registration certificates are listed on the appendix to the GMP certificates. Any additional products would trigger a variation application to the GMP certificate.

**Innovative Device Pathway**

In order to increase the availability of premium technology in the Chinese market, the CFDA has published the *Special Review and Approval Procedure for Innovative Medical Devices* effective from March 2014. This fast-track regulatory process is available to innovative products meeting all three of the following eligibility criteria:

- **Chinese patent**
  The applicant must hold a Chinese (invention) patent for innovative technology or be licensed to use such a patent in China. Alternatively, the applicant could have a patent application under review with preliminary approval from the China Patent Regulatory Authority.

- **Innovative product**
  The product must be the first-of-its-kind in China and technically advanced in the global market; it should fundamentally improve product functionality and/or safety when compared to predicate devices and have significant clinical value.

- **R&D progress and records**
  The applicant should have a prototype developed under a controlled process with a fully traceable R&D dossier.

This fast-track approval process means that the registration application has priority over other device applications and the applicant is granted permission to communicate or consult with the CFDA to get guidance prior to submission and during the scientific review/approval process.

Typically, preliminary patent reviews would be granted 18 months from submission lodgement, whereas full approval takes approximately three years. Therefore, the fast-track pathway is an encouragement for multinational manufacturers to consider Chinese patents more seriously. As China is a member of the Paris Convention, international applicants can take advantage of the priority right – i.e. the first filing date can be leveraged from the first internal filing date if the Chinese patent application is submitted within 12 months.

For more details on Chinese patents, please refer to Section 7 on intellectual property provisions.

Despite the initial time and resources invested into patent applications, this direct line of communication to the CFDA throughout the application
preparation and review process could save much frustration in the ‘race’ to commercialisation. In a country where relationship building is crucial to a company’s credibility and commercial success, the chance to engage the regulator early in the design and innovation process would be highly valuable.

### Ongoing post-market compliance

The CFDA and its local branches monitor post-market compliance by conducting:

- Sampling of devices in the market place for labelling and technical conformance;
- Certification and auditing on medical device enterprise (e.g. distributors) and traceability of devices supplied;
- Surveillance on medical device users (e.g. hospitals and clinics);
- Coordinating review for particular groups of devices (especially after serious adverse events reports for this kind of devices);
- Re-evaluated product clinical experiences and adjusting risk classification accordingly.

To conform to the most current Chinese regulation, manufacturers should maintain post-market vigilance and well-defined procedures to receive feedback from and direct ongoing regulatory actions to its partners in China.

### Pre-Market Approval vs Registered Device

<table>
<thead>
<tr>
<th>Pre-Market Approval</th>
<th>Registered Device</th>
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<tbody>
<tr>
<td>• Class I</td>
<td>• Renewal</td>
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<tr>
<td>• Class II</td>
<td>• Variation</td>
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<tr>
<td>• Class III</td>
<td>• Technical</td>
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<tr>
<td>• Innovative</td>
<td>• Administrative</td>
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</table>

**Figure 7: Pre and post-market pathways**

For Class I medical devices (and IVDs), manufacturers should monitor any CFDA classification update that may affect its products.

The in-China sponsor or domestic manufacturer is responsible for post-market surveillance report, including the reporting and investigating adverse events in China. For high risk Class II and III devices, a summary adverse events report is mandatory for certificate renewal.

For Class II and III medical devices, Medical Device Registration Certificates are valid for five years and need to be extended six months prior to their expiry. After the marketing authorisation/license is issued, if there are some changes or amendment to the license, the sponsor needs to file these changes to the CFDA or its subsidiaries and get approval. Different types of change have different filing requests by the CFDA.

Any variations to the product or administrative details must be first approved in its market of origin before they can be approved in China. Technical variations are assessed for their associated risks and mitigation. Significant product or production changes may require type testing and/or clinical trial to be conducted. On the other hand, change to administrative details (e.g. a new authorised in-China representative) does not need to be supported by technical documentation.

Variations to the following items are considered significant and must be reviewed and approved by the CFDA (or provincial FDA for domestic registrations) as Variations to Approved Items:

- Product name;
- Model number;
- Specifications;
- Structure and components;
- Indications;
- Technical requirements;
- Manufacturing site changes.

The following changes are administrative in nature and can be filed with the CFDA (or provincial FDA for domestic registrations) as Variations to Registered Items:

- Name and address of applicant [manufacturer];
- Name and address of Sponsor.

Significant changes requiring technical review, typically take a few months for approval. Simple administrative changes are assessed without detailed technical review and can be approved within a few weeks.

### Adverse events and recalls

After product launch, domestic medical device makers and China agency of foreign device manufacturers should track their product quality and monitor the adverse events (AE), and re-evaluate their products if necessary. This is required according to the regulations in the footnote below.
The medical device makers or their agency must report the severe adverse events (SAE) to the CFDA's provincial affiliates and the CFDA within timeline required by government (for death, reporting within five working days, for serious injury or possibly leading to serious injury or death, reporting with 15 working days). Additionally, when the domestic and foreign medical device makers renew their product marketing authorisation, the renewal application dossier must include the AE report.

China’s NHFPC (formerly MOH) publishes the regulations for medical device recalls, which took effect 1 July 2011. This regulation gives the definition of medical device recalls and defects, as well as making clear that the medical device maker is responsible for the control and removal of medical device defects and taking charge of product safety.

Medical device distributors and hospitals/units using medical devices should immediately suspend the sales and use of the devices if they find the devices they are distributing or using are with defect and accordingly inform medical device makers or suppliers. Meanwhile, the defect should be reported to local and relevant provincial FDA, which is responsible for the supervision and administration of device recalls. The CFDA takes charge of management in the event of a nationwide device recall. Hospitals should also report to local provincial healthy authority at the same time.

Medical device manufacturers should establish device quality management system (QMS) and device adverse event monitoring system to collect and record device quality issues and device adverse events. Device makers should analyse the collected information and investigate and assess the potential defect related to devices and report the collected device adverse events to the CFDA. In terms of the defect severity, the recall can be divided into three levels:

- First class recall: the use of the device possibly causes or has caused severe health hazard;
- Second class recall: the use of devices possibly causes or have caused a temporary or reversible health hazard;
- Third class recall: the use of the device causes little possibility of health hazard, but still needs to be recalled.

A device recall has two types: one is called as initiative recall; the other is a recall mandated by CFDA.

The CFDA revises the product classification catalogue from time to time and adjusts particular device classifications depending on market experience gained over time. Should the risk classification change for a particular category of devices, the manufacturer will need to submit a variation application to CFDA.

**Labelling**

The CFDA issues regulations for use and labelling. The instructions for use and labelling for medical devices and the amendments to them should be consistent with the package submitted to CFDA/PFDA for registration (class II and III device) and filing (class I device). When the applicant submits a product registration or filing application to the CFDA, they also need to lodge a usage instruction and labelling (in simplified Chinese) for review and approval (class II and III device). More information can be found in the ‘CFDA Order No. 6: Regulations for Package Insert and Labelling of Medical Devices, 30-Jul-2014’ at www.cfdadevices.com/regulations.html
Section 6: Market access – reimbursement

Reimbursement and tendering for contracts

Unlike Australia, there is little reimbursement available for medical devices and diagnostics in China and the system that does exist is somewhat complicated, especially with its tendering system for certain types (highly priced) of medical devices.

Reimbursement amounts can differ depending on the specific province/municipality and can also differ between different hospitals in the same province/municipality.

Getting listed on the reimbursement catalog is preferred to assure the sales of your medical device in China. Reimbursement and medical device pricing is regulated by the National Development and Reform Commission (NDRC) and the National Health and Family Planning Commission (NHFPC).

The Chinese consumer see products from Japanese, German and the US as being of high quality and Australian are held in high esteem as well.

Tendering

Tendering in China is full of diverging methods and varying scoring systems. Complex as it may seem, a December 2012 regulation issued by the NHFPC (formerly the MoH) mandates that all public hospitals participate in the provincial centralised procurement process for high-value consumables, replacing a more localised system that gave greater discretion to cities and hospitals to select the devices that met their needs. Because this two-year tendering cycle is the only route to market in provinces where it has been adopted, success in these provincial tenders is critical to market access and financial performance.

How the health tendering system works

The process is quite similar from province to province:

- A policy/tender list is announced;
- manufacturers enroll;
- qualification review takes place;
- ceiling price is set;
- manufacturers submit bids based on the set ceiling price.

Most provinces employ a two-round qualification system before settling on the results and awarding the winning bidders.

The tendering process confers the right to sell, but does not come with guaranteed volume. While the tendering process does serve the purpose of filtering the number of manufacturers that a hospital can choose from for specific products, there will always be multiple winners. There are filters in place that may lead to disqualification from a tender, but the purpose of understanding the tendering process, is not necessarily to learn how to get in, but to prevent from being left out.

Successfully tendering at the provincial level only allows a device manufacturer to compete for a place on a hospital’s list of approved devices. But once approved, the manufacturer, or its distributor/sales representative, must still persuade individual physicians of the relative benefits of the product over any competing devices that have also been approved for that hospital. Surgeons will then discuss these various product options with their patients, but as such, there’s no guarantee that they will use a particular device or product.
The bid process itself starts with the setting of a ceiling price; this can happen in a number of ways. Take, for instance, Guangdong and Inner Mongolia: in Guangdong, the ceiling price is decided by an expert tendering team and is based on both the historic and current market price of a product. In Inner Mongolia, on the other hand, the ceiling price is set based on the lowest stable purchase price of Inner Mongolia’s medical and health institutes from the previous year.

After the ceiling price is set and the bidding process is completed, an expert panel will score all submissions based on detailed tender evaluation criteria. This is where things get a bit more complicated. For medical device companies, the key to tendering is to avoid being the worst, so to speak, with either the highest bidding price or the lowest overall score.

As the tendering system evolves, there could be nuances and improvements in some provinces.

Since the tender evaluation criteria are decided at the provincial level, increased participation from the manufacturer provides multiple opportunities to help shift the conversation from price to quality, as well as ensure greater fairness throughout the scoring process. Furthermore, in most provinces a number of the criteria tend to be subjective (e.g., brand reputation, and even company scale), therefore being in good repute with the tender evaluation panel is key to maximising the odds of success and obtaining an achievable price point during the process.

Hospital listings could have partial variations in the future. For example, medical device companies could face groups of hospitals in negotiations, instead of individual hospitals as before. Such changes will give hospital groups stronger bargaining power to push for lower prices. There are also other experimental schemes mixed in, which can further cloud the pricing alternatives and hospital selection criteria.

**Beyond tendering**

While, for simplicity, cities can be classified into a tiered system based on administrative status, the socioeconomic diversity and demographic makeup within these tiers can vary massively. Take, for instance, Hangzhou and Guiyang, both provincial capitals classified as Tier 2 cities. Whereas Hangzhou has a GDP per capita of over $10,000, the equivalent figure in Guiyang falls just under $4,000. Clearly, Hangzhou commands a degree of disposable wealth that can support a much higher level of medical care than Guiyang.

As a consequence, in cities such as Hangzhou, doctors typically have a higher share of in-city patients and often, a more defined set of preferences toward equipment and products. Guiyang, on the other hand, is more of a magnet for the surrounding towns and villages, which creates very different demand dynamics. Here, the patients are often referrals and levels of insurance (and hence affordability for the patient) can vary significantly. Therefore the types of products and sales will vary greatly between these two Tier 2 cities.

But defining customer segmentation isn’t just a matter of re-classifying cities in a more sophisticated fashion. A stratified system of hospitals also exists within these cities, making a complex system even more so. Thus, even within the same city, different segments will co-exist and multiple sales models and approaches in each territory may be required to deliver the optimal quality and quantity of market presence.

**Pricing and reimbursement**

Reimbursement mechanisms and pricing is complicated since it is designed to meet different requirements at provincial/ municipal level. In general, reimbursement schemes treat the medical devices differently by classifying them into two types: implantable or disposables.

Only medical devices that are approved (by the CDFA) and put in the pricing formulary (reimbursement catalogue) regulated by government could get reimbursed under the medical insurance coverage. Because of variety, we take Shanghai as an example to explain pricing and reimbursement process in one city.

**Rise of the private healthcare sector**

China is experiencing unprecedented demands on its healthcare system and the role of private healthcare is increasing, to supplement services that the public health system is unable to cover. As of 2013, China had 9,800 private hospitals, representing almost half of the total number of hospitals in the country29. However, private hospitals still severely lag behind their public peers due to low utilisation, talent shortages and incomplete social insurance coverage. As part of China’s ongoing healthcare reform initiatives, the Chinese government has set a goal to increase the share of patients treated by private hospitals to 20% by the end of 201530.

The recent official launch of Shanghai International Medical Center (SIMC) (the first international private hospital jointly funded by private capital and government capital) will, it is hoped, mark a new chapter in China’s hospital reform efforts.
Two additional high-end hospitals are in the pipeline in Shanghai. The Shanghai New Hongqiao International Medical Centre will focus on high-end medical services and is expected to launch its operations in 2015. In addition, a premium cancer hospital will be established by Concord Medical Services Holdings Limited, a privately-owned medical institution in China listed on the New York Stock Exchange. Regulatory approvals have been granted and the hospital is expected to launch its operations in 2018.

Historically, China’s private hospitals have struggled and only a select few have managed to achieve recognition in the market. The United Family Healthcare (UFH) brand is one of the more renowned hospital brands. UFH currently operates two private hospitals and satellite clinics in Beijing and Shanghai. The two private hospitals have internationally board-certified Western doctors and enjoy premium medical facilities. Established in 1997, Beijing UFH was the first foreign-invested hospital and the first internationalised standard hospital in China and is one of the few successful examples of its kind in China.

More recently (July 2014), China announced it would allow for the first time foreign ownership of a hospital, in some part of the country. A statement issued jointly by the National Health and Family Planning Commission and the Ministry of Commerce said that investors will allow for the first time foreign ownership of a hospital, in some part of the country. A statement issued jointly by the National Health and Family Planning Commission and the Ministry of Commerce said that investors will be allowed to set up new hospitals or acquire existing ones under a new pilot program in Beijing, Tianjin, Shanghai, Jiangsu, Fujian, Guangdong and Hainan.

**Improving equity and accessibility of healthcare**

One of the top priorities for healthcare reform is to improve equity and accessibility of quality healthcare. There is an intense pressure on resources at China’s top medical institutions. According to the latest statistics, the country’s medical institutions have an average utilisation rate of 90% at any given time and the top hospitals’ utilisation rates rarely fall below 100 percent.

The recent relaxation of regulations that allow doctors to work in more than one facility and to operate their own clinics are encouraging the sharing of doctors across hospitals. The recent draft published by the National Health and Family Planning Commission (NHFPC) in January 2014 allows for doctors to practice in multiple locations and therefore alleviate pressures on tier 3A hospitals.

In response to the Chinese government’s ongoing crackdown on improper payments to doctors by pharmaceutical companies to prescribe certain drugs, SIMC is implementing a compensation system whereby doctors’ income will be based primarily on consultation, attendance and treatment, rather than kickbacks from medication and lab tests. SIMC also requires that the portion of hospital income attributable to drugs sales may not exceed 8% of the total cost.

There has been criticism of SIMC for its hefty consultation fees of RMB1,200 (approximately US$200). In comparison, the cost of most patients’ consultations at public hospitals rarely exceeds RMB50, and is significantly less if the patient is enrolled in the national health insurance program.

SIMC has addressed this disparity through cooperation with insurance companies. Recent information indicates that 35 insurance companies, comprising 70% of the local market, have entered into arrangements with SIMC. SIMC will cooperate with insurance companies to streamline payment procedures. These arrangements should enable more patients in commercial insurance schemes to have access to SIMC.

SIMC’s investment model may set a precedent for the increasing number of private investors looking to invest in China’s growing private hospital sector. To facilitate these investments, the Chinese government appear to be relaxing its restrictions on private and foreign investment in this sector. In the past, healthcare providers required a minimum of 30% Chinese ownership. However, this requirement has now been relaxed to allow for 100% ownership for investors from Hong Kong, Macau and Taiwan. The recent health reforms published by the State Council indicate that the goal is to further relax limits on foreign investment in hospitals, but no specific timeline has been provided.

In light of these developments, the sentiment for foreign investment in the private healthcare sector looks to be on the rise.
Section 7: Intellectual property (IP) provisions

General patent environment

China has a sophisticated but young patent system, which was developed in the late 1980s and is based on European law. Rights are enforceable, for the Chinese and for foreigners, and while there are still enforcement issues, indications over the past 20 years are that the Chinese government is working towards a stronger and more enforceable patent system. Prospects for further improvements in the patent system are good with increasing evidence that the Government, courts and administrative agencies are improving.

It took countries with strong patent systems, like Japan and South Korea, 30 to 40 years to get to the same point. The drivers for this rapid progress in the patent system are both external and internal to mainland China.

As China has opened up to international trade, and recognised the value of attracting overseas innovation, the patent system has taken on greater importance. The protection of patents, has until recently been a notorious and major barrier for international businesses to bring their intellectual property to China. In 2012 more patent applications were filed in China than in any other country. In raw numbers, 652,777 patent applications were filed in China followed by 542,813 in the United States and 342,796 in Japan.

Internal drivers for effective patent protection are also now stronger than ever. For example, 82% of Chinese invention patent applications filed in 2012 were made by Chinese applicants.

Value of patents in China

Opportunities in China for Australian medtech companies are extensive and include industry collaboration, academic and research collaboration, clinical trials, manufacturing and sales. Increasingly, for companies wanting to take advantage of these opportunities, Chinese patents are considered an essential foundation stone upon which partnerships and collaborations should rest.

Chinese patents can also provide significant value for companies doing business in China in more tangible ways. For example, companies that can achieve ‘High and New Technology Enterprise (HNTE)’ status qualify for a lower corporate tax rate (15% instead of the standard rate of 25%). To qualify for the HNTE status, the enterprise must renew its qualification every three years and own the core IP for its main products.

The Chinese government also provides incentives for companies involved in R&D by subsidising the costs of patent applications filed by Chinese applicants. These subsidies vary from province to province but can cover a substantial portion of costs involved in patent preparation and filing.

Australian companies can structure their businesses to take advantage of these tax rates and subsidies. For example, Chinese subsidiaries of Australian companies may qualify for HNTE status and for patent filing subsidies. To this end, an Australian company could transfer its Chinese patents to its Chinese subsidiary while keeping ownership of the non-Chinese patents off-shore. Companies that do business in China on a regular basis could also potentially offset patent costs by trading patent rights to their Chinese manufacturers, whose patent costs are subsidised.
Strategies for protecting intellectual property

The patent system was introduced in China in 1985 and so is still relatively young, but it is broadly based on European systems (particularly the German one) and the standard of examination is relatively high.

The process of obtaining patent protection in China (see Figure 1) now involves an average two to three years once the Chinese national phase has commenced, at an indicative 20-year cost of AU$20,000 - AU$50,000. Patent rights are therefore generally of good quality, reasonable cost and timely.

How long will it take, how much will it cost?

As a starting point the following are suggested strategies for developing a patent filing and management strategy for China.

Standard and/or utility patents

There are three types of patent applications in China:

- **Invention (standard)**
  Provides a 20-year term for innovative technical solutions in the form of articles or processes.

- **Utility Model**
  Provides a 10-year term for a new technical solution to the shape or structure of an article.

- **Design Patent**
  Provides a 10-year term for novel designs that are industrially applicable with respect to the shape, patterns or colour of an article.

The importance of Utility Model patents has now become widely recognised by multinationals. The advantages of utility models compared to Invention patents are:

- They are not subject to substantive examination and can be granted relatively cheaply and quickly (e.g. without one year of filing);
- It is easier to meet the threshold for inventive step;
- They can be more difficult to invalidate.

It is possible to file for both a Utility Model and Invention patent for the same invention simultaneously. This allows the invention to be patented within a year of filing (via the Utility Model) and the patentee can then take infringers to court. The Utility Model patent can then be replaced when the Invention patent is granted, thus providing a full 20-year protection for the invention.

For patents applications entering China via the PCT route, however, the applicant can only file it as either a standard patent or utility model application. This means that Australian companies wanting to take advantage of the dual option must do so by filing directly in China within 12 months of the provisional filing rather than using the PCT route.

Inventor-ship and ownership

It is important for all companies wanting to do business in China to be diligent and take steps to avoid potential problems concerning inventor-ship and ownership of its patent applications.

For inventions developed by a company in Australia, the ownership should be relatively straightforward, assuming that entitlement properly flows from the inventor(s) to the company (e.g. through employment contracts or assignment of IP rights from the inventor(s)).

The company may want to consider the option of assigning or licensing rights in its Chinese patent applications to a Chinese entity (for example, to take advantage of the tax breaks or incentives for patent filings discussed above).

For any given patent family, it is

![Figure 8: How long will it take, how much will it cost?](image-url)
possible to assign or license rights in the Chinese application whilst maintaining ownership of the rights for corresponding applications filed in other jurisdictions.

Where inventions are developed in China, for example through outsourced R&D or a joint venture, the patent ownership may be more complicated. To avoid potential problems, issues such as the following need to be considered.

If the R&D for an invention is carried out in China, it may be necessary to first file the patent application in China before it can be filed anywhere else. For example, it may be necessary to file a provisional application with the Chinese Patent Office rather than the Australian Patent Office.

The default rule is that the party who makes improvements to a technology based on the licensed patent or technology automatically owns the IP rights on such improvements. When outsourcing R&D, therefore, it is critical for companies to secure the right to apply for patent applications up front in a written agreement. The contract should clearly specify existing patent rights obtained before entering into the agreement and ownership of possible future rights generated after the entering into the agreement. The distribution of future IP rights must also be agreed upon in advance.

In the case of joint ventures, each party is an independent entity that wields control over its own technologies and facilities. As such, unless otherwise stipulated in a joint venture agreement, the right to apply for patents is co-owned by both parties.

When a Chinese employee contributes to an invention which results in the granting of a patent to his or her employer, the employer is required to award remuneration to the creator-employee for the patented invention. For this reason, employers should insert in employment contracts a provision that quantifies the amount of remuneration to be awarded to employees for their invention, and such remuneration must be ‘reasonable.’

It is also good practice to include express provisions in employment contracts regarding confidentiality, patent ownership, non-compete and non-solicitation to avoid future disputes.

Due diligence
A rigorous due diligence process will be required to assess opportunities and threats arising from indigenous Chinese patent filings.

In terms of opportunities, patent landscape analyses of Chinese patent filings may provide valuable access to ideas and collaborative opportunities. In terms of threats, indigenous patent filings should be analyses from a ‘Freedom to Operate’ perspective, particularly for companies who are preparing to offer products or services to the Chinese market.

A great deal will depend on the reliability and past record of those with whom you do business in China. Much of the risk can be reduced by thorough preliminary checking and not being seduced by promises which a Chinese ‘partner’ cannot fulfil.

Promises can range from the ability to enter into ‘illegal’ contracts, secure local subsidies through to remitting funds, securing premises and obtaining government contracts. The choice of legal structure, restrictions on transfer of capital, royalties and dividends, the security of local workers and even the ability to execute documents all have their particular Chinese requirements.

A fundamental requirement is a network of trusted advisors in China to assist with legal, accounting, regulatory, enforcement and government contact issues, that can bring a carefully cultivated network of advisors based on personal relationships, with strong local experience and demonstrated track record.

Partnering
For the reasons outlined earlier in this Guide about the unique complexity of China and the benefits of partnering, IP protection is an area where the right partner can provide significant benefits. Finding a trusted Chinese partner will assist in further protecting your patent rights, but providing an in-country ally to represent your mutual interests, who is closer to market intelligence, and has language and cultural understanding of the opportunities and threats.

Other types of IP protection
This section has focussed only on IP in the form of patents; however other forms of IP are recognised and widely used in China.

Trademarks
China’s trademark law was first adopted in 1982 and subsequently revised in 1993 and 2001. The new trademark law extended registration to collective marks, certification marks and three-dimensional symbols, as required by TRIPs. China joined the Madrid Protocol in 1989, which requires reciprocal trademark registration for member countries, including Australia. China has a ‘first-to-register’ system that requires no evidence of prior use or ownership, leaving registration of popular foreign marks open to third party. However, the Chinese Trademark Office has cancelled Chinese trademarks that
were unfairly registered by local Chinese agents or customers of foreign companies.

**Copyright**

Unlike the patent and trademark protection, copyrighted works do not require registration for protection. Protection is granted to individuals from countries belonging to the copyright international conventions or bilateral agreements of which China is a member. However, copyright owners may wish to voluntarily register with China’s National Copyright Administration (NCA) to establish evidence of ownership, should enforcement actions become necessary.

**Unfair Competition**

China’s Unfair Competition Law provides some protection for unregistered trademarks, packaging, trade dress and trade secrets. The Fair Trade Bureau, under the State Administration for Industry and Commerce (SAIC) has responsibilities over the interpretation and implementation of the Unfair Competition Law. Protection of company names is also provided by SAIC. According to the TRIPs Agreement, China is required to protect undisclosed information submitted to Chinese agencies in obtaining regulatory approval for pharmaceutical and chemical entities from disclosure or unfair commercial use. China’s State Drug Administration and Ministry of Agriculture oversee the marketing approval of pharmaceuticals and agricultural chemicals, respectively.

**Licensing into China**

As China’s economy and intellectual property system continue to mature, there is an increasing demand by Chinese businesses to in-licence technology from foreign companies. Due to the differences between Australia’s and China’s legal system and business environments, some notable considerations for technology licensing are provided below.

> ‘Regulations on Technology Import and Export Administration’ apply to licensing and other ‘technology imports’ into China. They are compulsory and cannot be contracted out of. Various other laws also apply.


Key features of the Regulations include:

- Warranties required by law in favour of the licensee;
- Assignment and sub-licensing are treated differently from what is normal in Western countries;
- Contractual treatment of improvements by the licensee is also unusual; and
- There is a need to register licences and get approval for certain technologies.

**Warranties**

Licensors are required to warrant the reliability and completeness of the technology, and they may not disclaim or limit these warranties by contract. With careful drafting, the scope of the warranty can be restricted.

**Improvements**

As a general rule, great care needs to be taken when the licensee will work on improving or further developing the licensed technology. Unless the Chinese licensee is paid to carry out further development, the default rule is that the licensee owns resulting intellectual property rights. If the IP is jointly owned, the licensee will have the right, in China, to commercialise the jointly owned IP independently of the licensor.

Clauses that restrict a licensee’s right to make/own/use improvements are generally prohibited under Chinese law, unless reasonable consideration is paid in return.

Under Chinese court interpretation of the relevant laws, a number of improvement-related limitations are considered illegal monopolisation of a technology and an illegal impediment to technological improvement.

**Employees**

Where licensees do agree to assign developed IP to the licensor, they have to have the right contracts in place with their employees, or the employees may own the IP.

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Footnote: “The information in this section on licensing in China is extracts from DibbsBarker’s white paper ‘Licensing into China: tips and traps’”
Other restrictions
There is also a prohibition on requiring licensees to source supplies or components from the licensor or its nominee, and on requiring patent royalties where patent rights have expired or are invalid.

The entire licence agreement will be void if it includes any clause with the effect of restricting the licensee’s right to challenge the validity of the licensed IP.

Confidentiality
It is not possible to obtain an injunction from a Chinese court to prevent threatened breaches of confidence, although it is possible to obtain damages if a breach occurs. Take practical steps to ensure the licensee is only given the information it really needs e.g. consider sending technical personnel for an initial “show how” training period, rather than sending complete product designs and specifications.

Governing law
Choice of law and the method of dispute resolution are major issues when licensing into China. While it is possible to choose foreign law for a licence agreement (but not a joint venture), a licensor cannot use foreign law to evade mandatory rules under Chinese law, or to evade public interest obligations in China.

Chinese contract law requires that contracts have a valid arbitration clause specifying the arbitration body. Arbitration outside China can be chosen, but it can be difficult to enforce the resulting award against a Chinese licensee. Arbitration can be elected in Hong Kong under either English or Hong Kong law, as such arbitral awards are enforceable in mainland China.
Section 8: Establishing commercial operations in China

Business structures in China

The choice of corporate structure is a decision that is potentially crucial for the success of Chinese ventures. Deciding which corporate structure to use should be guided by the consideration of the following: The control of decisions and the ability to retain the profits of the corporate entity; the value of partnering with a local business with established networks and knowledge of local markets, business etiquette, laws and government affairs; and how much capital you are willing to commit.

Business structures that Australian companies can use to establish in China are types of Foreign Invested Enterprises (FIEs):

- Wholly Foreign-Owned Enterprise (WFOE, pronounced Woofee), which are the most common;
- Contractual Joint Venture (CJV);
- Equity Joint Venture (EJV); or
- Foreign-Invested Partnership Enterprises.

An Australian company may also opt to establish a representative office (RO), however the activities of the RO are limited to liaison and the office cannot engage in profit-making activities, issue invoices or enter into agreements. The RO is limited to four foreign employees and is not a limited liability company.

Wholly foreign-owned enterprises

As suggested by their name, a WFOE would be wholly owned by the Australian company and does not require a local investor. They are usually structured as limited liability companies, though may also take other forms, including partnerships.

WFOEs provide greater control to foreign, in this case Australian, investors and avoid the need to find and deal with local partners. A WFOE is not able to be used if you want to invest in restricted markets, nor will they provide the benefits of local partners, such as local knowledge or relationships.

Minimum-registered capital

Previously, the minimum capital requirement for a WFOE was RMB 30,000 (or RMB 100,000 if there was only one shareholder). Following the release of the new Company Law in 2013, which took effect on 1 March 2014, these requirements have been removed in some cases. For example, the minimum capital requirement is waived in the Shanghai FTZ. Local interpretations can also vary depending on the industry and region in China.

Regulations for WFOEs were amended recently to allow companies up to 10 years to pay.

Approval

Approval of WFOEs takes place at the central level (by the Ministry of Commerce, or MOFCOM), provincial or local level, depending on the investment and business scope. Applications will usually be decided within 90 working days, and must include: an establishment application; a feasibility study; articles of association; candidates for board positions; a legal certification and a certificate of good credit; a list of materials to be imported; and other documents as required.

Upon receiving initial approval, a WFOE must obtain a business licence from the relevant level of the State Administration of Industry and Commerce (SAIC) (www.saic.gov.cn/english), apply for an Organization Code at the Technological Supervision Bureau, register with the Land and Resources Department (the equivalent of Australia’s titles
office) where needed, the Public Security Bureau, Finance authorities, Statistics Bureau, Customs, Foreign Exchange Administration and the state and local tax authorities.

**Contractual joint ventures**

CJVs, and their counterparts EJVs, are commonly used for foreign investment into China, being the only structures that foreign companies can use to invest in ‘restricted’ markets.

A CJV is contractually created between Chinese and foreign investors. CJVs provide considerable flexibility, as matters such as allocation of profits/losses, risk and management (including the right to appoint board members) are contractually negotiated between the parties. The CJV may also be established as a separate legal entity to limit the liability of the contributing investors.

This model also allows foreign investors to more easily access the established local networks and knowledge of their Chinese partners.

**Minimum-registered capital**

The minimum registered capital is dictated by the relevant investment’s location and industry, with the CJV contract defining the amount of registered capital and percentage share contributed by each investor. For CJVs with separate legal status, foreign investment must generally account for at least 25% of the registered capital in order to be treated as a foreign invested enterprise.

**Approval**

A CJV requires the approval of the MOFCOM or an authorised local counterpart. The investors must submit, amongst other things: an application for establishment; the joint venture agreement; a feasibility study prepared jointly by the investors; and a list of candidates for all board positions.

MOFCOM usually reviews the application within 45 working days and considers whether the CJV would: be detrimental to China’s sovereignty or national interests; endanger state security; violate local laws, administrative regulations and national industrial policies; or cause or contribute to environmental pollution.

A CJV must also obtain a business licence from the relevant level of the SAIC and register with the relevant tax authorities and other relevant authorities.

**Equity joint ventures**

EJVs are similar to CJVs, except that:

- EJVs must be established as a limited liability company (equivalent to a private company in Australia) with separate legal status; and
- The distribution of profits, losses and management is determined in proportion to each party’s investment.

**Foreign-Invested Partnership Enterprises**

In 2010, the PRC provided a new structure to consider - the foreign-invested partnership (FIP) – based on the ‘Administrative Measures on the Establishment of Partnership Enterprises’ in China by Foreign Enterprises or Individuals (called the FIP measures) and the ‘Administrative Provisions on the Registration of Foreign-Invested Partnership Enterprises’ (FIP registration procedures).

**Minimum-registered capital**

The ratio of registered capital to the total investment in an EJV, CIV and WFOE by the investors is set by regulation and must be:

<table>
<thead>
<tr>
<th>Total Investment in the EJV</th>
<th>Registered Capital</th>
</tr>
</thead>
<tbody>
<tr>
<td>$3 million or less</td>
<td>At least 70% of the total EJV investment</td>
</tr>
<tr>
<td>More than $3 million and up to and including $10 million</td>
<td>At least 50% of the total investment or $2.1 million <em>(whichever is greater)</em></td>
</tr>
<tr>
<td>More than $10 million and up to and including $30 million</td>
<td>At least 40% of the total investment or $5 million <em>(whichever is greater)</em></td>
</tr>
<tr>
<td>More than $30 million</td>
<td>At least 33.3% of the total investment or $12 million <em>(whichever is greater)</em></td>
</tr>
</tbody>
</table>

*Figure 9: Ratio of registered capital to the total investment*
FIPs are similar to partnership structures in other countries. Broadly speaking, a partnership provides more structural flexibility than other structures, such as EJVs, or CJVs.

**Cash repatriation**

China has additional restrictions of the repatriation of cash outside of China. Withholding tax applies of 10% to dividends paid to non-resident shareholders unless lower rate is available in the applicable tax treaty. Registered capital may only be decreased in limited circumstances, which are generally associated with the decrease in scale of the business. This can pose limitations on the repatriation of cash of a non-profit making entity.

**Tax incentives**

Projects in the “encouraged” category, designated by the government, are usually eligible for preferential treatment. In general, apart from possible tariff exemption quotas for self-utilised capital imports for encouraged projects, companies engaged in encouraged projects may apply for certain tax incentives.

The principal incentives include a 15% preferential tax rate applicable to new high-technology enterprises and a 50% super deduction for qualifying R&D expenditure.

There also is a geographically based incentive focused on new high-technology enterprises established in or after 2008. The incentive (in addition to the 15% rate that applies to all new high-tech enterprises) is a two-year tax holiday followed by three years of tax levied at a 12.5% rate. The 15% preferential tax rate also is granted to encourage businesses in the western region until 31 December 2020.

**Income tax reduction or exemption for qualified transfer of technology**

China has offered an incentive since 2008, giving a preferential tax rate on profits derived from qualifying transfer of technology. The rate varies between zero and 12.5% as opposed to the normal corporate tax rate of 25%. The incentive rate is an exemption from tax for the first RMB 5 million of income and a 50% exemption on income beyond RMB 5 million. The ‘patent box’-type incentive goes beyond patents to allow income from certain types of commercial ‘know-how’, such as process innovation, to qualify for the lower rate.

To enjoy a preferential enterprise income tax reduction or exemption, a technology transfer should satisfy the following conditions:

- The party to the technology transfer that enjoys the preferential treatment shall be a resident enterprise as prescribed in the Enterprise Income Tax Law;
- The technology transfer shall fall within the scope stipulated by the Ministry of Finance and the State Administration of Taxation;
- A domestic technology transfer shall be recognised by a department of science and technology at or above the provincial level;
- A technology transfer to a foreign country shall be recognised by a commerce department at or above the provincial level;
- Any other requirement stipulated by the competent department of taxation under the State Council.

**Negotiating commercial agreements with Chinese companies/partners**

While business arrangements in China are built on trust, there is a growing acceptance of the benefits of written agreements. It is recommended that commercial agreements are in writing to promote understanding of what has been agreed and to provide some legal recourse to each party.

Documents are likely to be considered invalid in China if they are not in Mandarin and/or they do not comply with local regulations and law. Ideally you will need a bilingual lawyer and a qualified translator. It is not uncommon for disputes and confusion to result from poor translations. Your lawyer will ensure that the terms of your agreement are lawful and appropriate, and assist you to conduct due diligence to ensure the Chinese company has a valid business license, check its official Chinese name, address, ownership and legal representative.

All litigations in China are performed in Mandarin. Therefore courts request any documents that contain a language other than Mandarin to be translated. For the sake of saving time and money, you might choose a bilingual agreement.

Commercial agreements should be signed by the Chinese company’s legal representative and be stamped using the company’s official chop or seal (see below). All Chinese company’s have an official chop which is registered with the Public Security Bureau (PSB). You may also request that each page of the agreement be stamped separately, to ensure that pages are not replaced after the signing.
Company “Chop”
In China, Chops are used as the official seals of a company or organisation. If a letter or document does not have the Chop, it’s not considered official. The Chop makes an otherwise legitimate agreement official. It gives power. Without it, a document – no matter what else is on it – is just a piece of paper.40

Consequently the Company’s Chop should be kept safe and locatable at all times. An Australian Company might choose to hold the Chop in Australia and carry it to China when needed.

Disputes and jurisdiction
To agree on the manner of solving disputes is useful. Without any agreement on this, it will be deemed as choosing the People’s Court (i.e. litigation as the manner of solving disputes). There may be more than one court that is entitled to accept the filing. The parties may choose one of them.

Default and liquidated damage
Unlike the US, where you can nominate ambit amounts as the liquidated damage, in China you need to agree on specific terms on how to measure damages, or, if it is unlikely to be measured, the specific terms stating a significant damage may be caused due to the default and set a fixed and defensible number.
If you are seeking investment or partnership from/in China you will need to consider which strategy (equity financing, technology licensing), what type of investor, and which structure you will utilise (WFOE, JV, RO), and how you will mitigate the risks and challenges associated with engaging with participating Chinese companies and investors. Obtaining on-ground advice and support is key to this success, as is being informed and sufficiently flexible to take advantage of the funding and partnering opportunities now available in China.

The decisions that you will make to establish partners or attract investment should depend on your individual business plan. See Appendix A for a business plan pro forma. The population of this plan will require both on-the-ground research and the involvement of specialist advisors. Because of the complexity of the China market, you would be wise to engage with an advisory firm already operating in it, or those with multinational operations in China.

Chinese venture capital

With such exponential market demand for biotech innovation and products, life science venture capital funds (VCs) and other strategic investors in China have been busy doing deals. The Chinese VC sector, established only ten years ago, has invested significantly into life science ventures, with innovations having risen to an average of $1 billion per year (Dow Jones Venture Source, Q3 2013). Chinese VCs investing in life sciences have tended to focus their investments in traditional organisations such as those engaged in clinical research and drug delivery, but in the past few years their interest has expanded to the new growth opportunities available in the medtech sector.

The environment for investment/investors is complex with both sophisticated and not so sophisticated investors now exploring opportunities in the biotech space. ‘War stories’, both positive and negative, still continue to frame many Australian businesses’ perspectives on China, and in so doing, often distort the real picture.

Alternative sources of financing

In order for Chinese biotech companies to fill their pipelines quickly with high-value products and reduce their development risks, they are increasingly looking outward to ‘in-license’ technologies from the West. Armed with large sums of investor money and management teams with significant Western experience, Chinese companies are buying or licensing Western assets to incorporate into their pipelines, as a key component of their business strategies. Additionally, Chinese local government authorities seeking new sources of revenue are also keen to offer grants, tax incentives, and world-class research facilities to attract research companies from Australia and elsewhere to their locations and technology parks.

China also now has a growing number of angel networks, foundations, and family investment offices (SOHOs) all interested in investing in foreign biotech innovation companies. As more Western life sciences businesses are prioritising, entering and growing businesses in China, more and more Chinese companies and VCs are seeing the value in funding and
in-licensing earlier-stage innovation from the West. Foreign investors, in the form of US denominated funds, as well as the VC funds of pharmaceutical giants, have also established large in-China life science funds to invest in both local and foreign biotech innovation, and develop China business models for their investment portfolios.\textsuperscript{7}

**Trade support**

Australia, via the Australian Trade Commission and various state government offices, has excellent representation in China and can assist Australian companies with information and in-country support, as well as providing and administering the Export Market Development Grants (EMDG) scheme, a key Australian Government financial assistance program for aspiring and current exporters. The scheme supports the export of intellectual property and know-how outside Australia.

For more information, see www.austrade.gov.au/export/export-grants/what-is-emdg

**To fund in-China operations**

To fund in-China operations, Australian companies would be best advised to establish a Chinese partner or entity. Regardless of Government-provided tax incentives or grants to attract foreign technologies and business, specialist advisors are recommended to help you operate effectively within the Chinese market. Advisors may be members of AusBiotech, or sourced through referrals from groups like Austrade or associations such as the China-Australia chambers of commerce (AustCham). See Section 14 for more information and contact details.

In-country investors are very domestically oriented and will often require a direct correlation to Chinese business to be attracted to your investment opportunity.

**To fund ex-China operations**

Chinese investors will be more attracted to invest directly into Australian companies if there is an option for part ownership of an asset, and if they see a link or opportunity from the business which is relevant to the Chinese market.

There are an increasing number of investment funds in China. At this point in time most are focused on Chinese business, but China has a long history of direct foreign investment into Australia, albeit in mining and property, that has built a level of comfort for the Chinese in investing in Australia. China is also keen to develop health technologies and investors more and more are seeing the value in investing in new technologies as well as attracting these technologies into their home market to benefit the Chinese people. The challenge for Australian companies is making the connections and building the relationships.

**Industry forums**

No matter which country you are seeking investment from industry forums provide an excellent way of meeting and presenting to investors to attract investment and partnership opportunities. AusBiotech stages Asia Biotech Invest each year in May or June in Hong Kong, featuring companies presenting their investment opportunity to the highly-sophisticated Hong Kong investment community and increasingly from investors from mainland China.

**Australian listed companies**

A number of Hong Kong and China-based fund managers regularly invest in listed Australian life science companies. You will need to present your investment opportunity to them, either directly or as part of an industry forum. A number of Australian life science companies now have substantial portions of their shares held by investors in Asia.
Section 10: Manufacture of medical technology in China

Accessing manufacturing capability

Assuming you’ve decided to manufacture in China for product sales or clinical trials (in China and/or for export), finding the right manufacturer in the manufacturing mecca of the world has no simple one-size-fits-all process. The complexity of niche medical devices will narrow your options somewhat, but it’s really a matter of commencing the search and, as with many aspects of doing business in China, finding the right advisors.

While China excels at lower-end commoditised manufacturing, depending on the material being used, some types of advanced manufacturing may not be possible. Having local support in China is essential, therefore, to start the search Australian companies could start with advice from their in-country partner or already established contacts, look to locations where governments may be offering incentives, or look to dedicated science parks for advice.

Alternatively the industry associations named in Section 14 of this Guide may also be able to offer advice.

Companies such as Invetech, for example, is a contract product development and manufacturing company, which supports manufacture of new and complex instruments and medical devices. Invetech has operations in Australia and China and works closely with co-located sister company, Leica Microsystems, who provide ISO13485 certified manufacturing.

Developing a check-list

You should develop a check-list of items that are important and relevant for your product. The following provides a suggested check-list of the considerations you might make in selecting a manufacturer:

- What types of products do they manufacture?
- Is the location of the manufacturer suitable? Consider the logistics and transportation route. Do you need to be close to a port, for example?
- Is the manufacturer suitable with regard to your product volume?
- Ask what standards they are certified to (i.e. ISO13485 or CE mark). Which notified bodies are they audited and certified by? What experience do they have with exporting?
- What class of clean room do they have? What is their hygiene and environmental control? What capacity do they have?
- Ask questions about quality management systems. How do they manage traceability and material control from their suppliers?
- What are your plans for sterilisation (if relevant)? Consider the options for contract sterilisation.

Once a suitable manufacturing partner has been identified with the assistance of on-ground support in China, arrange to visit the potential manufacturers. On this visit you may wish to establish, ask, check or discuss the following:

- Negotiating price.
- Drafting a plan including a risk analysis with contingency plan.
- Establishing a confidentiality agreement.
- Performing a quality audit, looking at systems and processes in more detail. Asking to view certification certificates.
- View sterilisation processes, if relevant and/or performed in-house.
- Commence developing a supplier agreement or contract.
- If you are supplying the raw materials a customs hand book will need to be established. Material going in must match material going out in order to avoid the customs duty (17%) and VAT (17%).
- If the subcontractor is to supply the material, tight controls and material specifications will need to be put in place.
The Australian Bureau of Statistics’ Trade in Goods and Services 2014 data showed that Australian exports to China increased 25.4% in the past year to $9.1 billion.

China has various inspection and certification requirements for imported goods and heavier restrictions and conditions for the import of medical products. To import products into China, a registration certificate (either a Medical Device Registration Certificate or an Import Medical Device Registration Certificate) must have been granted by the CDFA (See Section 5).

According to the Regulations for the Supervision and Administration of Medical Devices issued by CFDA (Article 11), a registration certificate is required before applying for customs formalities. See eng.sfda.gov.cn/WS03/CL0767/61641.html

A China Compulsory Certification (CCC) can apply to a broad range of products, including some medical devices with electrical components for safety conformity.

### Customs Duties

The customs value of imported goods is determined by Customs on the basis of the transaction value, as well as the costs of transport, charges associated with transport, and the cost of insurance incurred prior to unloading of such goods at the port or place of entry within the Customs territory of the People’s Republic of China.

The transaction value of import goods is the price actually paid or payable for the import goods by the buyer when sold by the seller for export.

For more information, see: [english.customs.gov.cn/](http://english.customs.gov.cn/)

### Section 11: Customs regulations for exporting from Australia to China

The seven sub-categories of medical devices that require the CCC are listed below:

1. Medical x-ray diagnostic equipment;
2. Haemodialysis equipment;
3. Hollow fibre dialysers;
4. Blood circuit pipings in vitro for blood purification equipment;
5. Electrocardiographs;
6. Implantable cardiac pacemakers;
7. Artificial heart-lung machines.

When a medical device requires a CCC, the company must conduct product testing in Chinese labs and an on-site audit of the legal manufacturer is also required.

For details of the application procedure, please visit [export.gov/china/doingbizchina/eg_cn_027466.asp](http://export.gov/china/doingbizchina/eg_cn_027466.asp)
Section 12: A case study - Nanjing BioPoint Diagnostic Technology Ltd

The Burnet Institute, with headquarters in Melbourne and offices in many countries in the region, has been active in the public health and medical research space in China for over 20 years. Following a recent decision to expand its China program, Burnet developed a long-term strategy for securing an independent stream of income for its China operations, which included the establishment of a commercial biotechnology venture in China, with Burnet’s share of future profits allocated towards support of public health projects. With its strong focus on translational research and commercialisation of medical technology that has enormous potential in both the domestic China and global markets, Burnet was ideally placed to ‘experiment’ with this business model. Burnet identified one of its diagnostic technology projects as being appropriate for this purpose, and began actively searching for funding to realise this venture in China.

Colleagues at the Australia-China Association for Biomedical Sciences (ACABS) brought to Burnet’s attention the grant opportunity awarded by the Nanjing Government aimed at fostering innovation and attracting commercially viable projects to establish operations in a local life science park. This “321” scheme is actively promoted throughout many provinces in China, with varying levels of funding and in-kind support offered, predominantly targeting the return of Western-trained and educated Chinese expatriates, although foreign individuals (‘natural persons’, not companies) are also eligible to apply. The application process was entirely in Chinese language, online, and it was essential to work in close partnership with trusted ACABS colleagues once the opportunity had been identified through to successful awarding of the grant.

In late 2013, Burnet announced the successful registration of a commercial company (WFOE) in China, Nanjing BioPoint Diagnostic Technology Ltd, established via this grant from the Nanjing Government and investment from the Institute. Based in Nanjing, the capital city of Jiangsu province – Victoria’s sister state – this new company will undertake research and development of novel diagnostic tools in areas of unmet medical need, and represents another strategic step forward in Burnet’s ongoing expansion of its overall China operations.

With help from ACABS colleagues the Burnet entered into the competitive process November 2012 and was awarded a RMB1.3 million (approx. AU$240,000) grant in April 2013. The application process consisted of an initial online proposal application (with a heavy emphasis on the business plan and commercial viability of the project), and following shortlisting several months later, presentation in person at a panel interview in Nanjing. Once awarded the grant, there were a number of additional milestones such as successful registration of the company, capital investment, and sourcing of further investment for the project, all undertaken with significant support of local officials in both the Investment Bureau and the science park where the company was to be located, as well as a team of advisors and lawyers in Australia and China.

The grant provided the new venture with laboratory and office space within the Jiangsu Life Sciences & Technology Innovation Park on the outskirts of Nanjing as ‘in kind’ support for three years, as well as an allowance for renting an apartment that will be very useful for frequent visits from Melbourne-based staff to the new facility. During 2014, Burnet entered into an agreement with a Beijing-based Chinese investment group to provide Nanjing BioPoint
with the necessary funds to complete the research and development phase and move into manufacturing of the device.

Burnet also established a company structure in Hong Kong, to facilitate the investment in Nanjing BioPoint (while retaining its WFOE status) and the eventual repatriation of profits.

From late 2014, the Burnet began to host BioPoint’s new Nanjing-based research and development staff for advanced training in Melbourne, and commenced an expanded program of diagnostics research and development drawing on both Australian and Chinese expertise. It is anticipated that the device funded under this grant will be the first of several products to utilise the platform of Nanjing BioPoint Diagnostic Technology, which will be a fully integrated business undertaking the commercial development of innovative diagnostic tools, with the capacity for manufacturing, sales and distribution of products long-term.

**Key reflections:**

Determining your company’s criteria for establishing a presence in a particular location is a useful process: for Burnet, this included consideration of the Jiangsu-Victoria link, existing relationships with key government and academic partners in Nanjing, and cost of establishment (ie second and third tier cities offer unique opportunities compared with Beijing or Shanghai). For other companies industry profile or access to particular markets may influence choice of location. For Chinese staff, identifying opportunities for leveraging their guanxi/ existing connections and relationships (eg University alumni) is valuable.

This particular 321 scheme utilised a ‘matching fund’ arrangement for the grant, but the breakdown between in-kind and cash contribution was not clear to Burnet at the time of application. In fact the requirement changed further during the application process to be cash-only for this particular grant. This has significant implications for the initial investment required by the applicant, if successful, particularly when combined with the requirement that the company be registered/owned by an individual not an organization. For obvious governance reasons, Australian companies are unlikely to shift large sums into personal bank accounts of individual staff members, nor feel comfortable transferring these funds to local Chinese bank accounts in an individual’s name. It is advisable to look very closely into the detailed conditions of such grants, and if possible talk to colleagues who have previously applied via similar grant mechanisms before initiating the application.

As this funding scheme was restricted to individuals, and could not be awarded to companies/ organisations in the first instance, this had implications for applicants in terms of IP ownership, financial risk, company structure, legal and tax arrangements and so forth, as all paperwork associated with both the grant and the company needed to be in the individual’s name, and access to personal details, such as bank accounts and details of home property ownership back in Australia, were documented. With the differences in business cultures and governance procedures this was more challenging for foreign applicants than Chinese applicants.

Due to the application process and all associated company paperwork being handled in Chinese language, it was absolutely critical for Burnet to have a team of trusted and bilingual advisors. This resulted in a large team of advisors (on business structuring, liaison with government officials, securing investment, etc.) and lawyers in Australia, Nanjing/Shanghai, and Hong Kong. Close monitoring and proactive project management of the application process and then establishment of company structures was critical. This necessitated a coordinated team approach, with individuals with specialist knowledge and skills, as well as operational knowledge of working in China, working together over a lengthy period of time. Resourcing numerous trips to Nanjing, Shanghai, Hong Kong and Beijing was also required.

Investing in thorough due diligence, risk assessment, and building strategic relationships are all critical. The establishment of this company, while central to Burnet’s long term vision for its China operations overall, was initiated at this particular time largely due to the opportunity of the grant being identified by our ACABS colleagues. Up to this point Burnet had done extensive research into the possibilities, and no doubt could have continued to do so for years. But, in what could perhaps be summarised as the strategy of ‘research, research and research, research, research and then research some more - then jump’ and with the support of Burnet’s Board of management, extensive due diligence and risk assessment was undertaken and ultimately a decision was taken to ‘take the leap’. It has been complex, time and resource-consuming, but an extremely valuable learning experience. With our team of trusted advisors in place and ever-developing relationships on the ground, we reached a point of confidence in moving forward and would encourage other Australian biotech companies to engage in a similar process of thorough research followed by decisive action to make the most of similar funding opportunities.
Section 13: Hong Kong

Hong Kong is a former British colony that reverted to Chinese rule in 1997. Hong Kong became the first Special Administrative Region of the People's Republic of China, under the constitutional principle of “one country, two systems”. It has a different political system from mainland China and independent judiciary functions under the British-style common law framework. Hong Kong has one of the highest per capita incomes in the world but also the highest income inequality among advanced economies. Due to its recent history, English and Cantonese are widely spoken, unlike mainland China. Most signs and services are bi-lingual.

Not surprisingly, Hong Kong ranks as the third most important leading international financial centre, after London and New York City, and has a vibrant stock exchange (Hong Kong Stock Exchange or HKex). Mainland China has two exchanges, Shanghai and Shenzhen. As at end-July 2013, 747 mainland enterprises were listed on the HKex, with a market capitalisation of about US$1,534 billion – about 55.8% of the market total.

The Hong Kong and Chinese governments agreed in April 2014 to allow international investors to trade Shanghai ‘A’ shares via the HKex while mainland investors will be able to trade Hong Kong ‘H’ shares via the Shanghai Stock Exchange, subject to quotas both ways.

The prevalence of English makes Hong Kong an easy place for Westerners to do business, along with its low taxation regimes and free trade.

Hong Kong’s history - geographically and geopolitically - has positioned it a stepping stone for overseas enterprises keen to access mainland China, and for mainland businesses keen to access global markets.

Hong Kong entrepreneurs, who share the same culture as their counterparts in the mainland, also have a great deal of experience doing business there. Hong Kong is leveraging these strengths to help enterprises interested in China. Hong Kong is the mainland’s most important entry point, handling about one-fifth of China’s foreign trade. There may be benefits in registering a company in Hong Kong to hold interests in China.

Hong Kong, with its direct access to China, is developing as a pivotal hub in the Asia Pacific region, and this is especially important from an Australian perspective as a regional neighbour. Private investment by Chinese and Hong Kong-based venture capitalists has burst forth in recent years, peaking at $1 billion in 2010 and reaching $573 million in 2011.

More than 50 Hong Kong fund managers currently invest in Australian public biotech companies, and it is expected that this interest will grow vastly in the coming years.

The regulatory process in Hong Kong is completely different from mainland China. No mandatory pre-approval is required as Hong Kong does not have any overarching legislation that regulates the manufacture, import, sale or use of medical devices. Instead, the Hong Kong Ministry of Health maintains a system for voluntary listing of devices. It should be noted that this applies to medical devices sold in Hong Kong only; to sell into mainland China requires CFDA approval (see Section 5).

Hong Kong is renowned for the high professional standards of its healthcare personnel and its widespread use of advanced medical technologies and equipment. Hong Kong’s per capita healthcare spend is among the highest in Asia and research funding and infrastructure is in place to support R&D activities by biomedical companies.

Medtech businesses seeking opportunities for expansion, can contact InvestHK’s Innovation & Technology team can assist: www.investhk.gov.hk/business-opportunities/biomedical.html
Section 14: Industry and support organisations

This Section provides a list of the major support and industry organisations providing support to medical technology firms in China. The Section gives a description of what they do and outlines how they can assist Australian companies.

The Australian Trade Commission (Austrade)
The Australian Trade Commission - Austrade - contributes to Australia’s economic prosperity by helping Australian businesses, education institutions, tourism operators, governments and citizens as they:

- Develop international markets;
- Win productive foreign direct investment;
- Promote international education;
- Strengthen Australia’s tourism industry; and
- Seek consular and passport services.

Austrade achieves this by generating market information and insight, promoting Australian capabilities, developing policy, making connections through an extensive global network of contacts, leveraging the badge of government offshore and providing quality advice and services.

Austrade aims to create value for the Australian business sector, and do it in a way that represents a good investment for the taxpayer. Austrade seeks to do all this in a way that meets or exceeds all appropriate standards of ethical behaviour.

Austrade currently has 12 offices in China (including Hong Kong and Macau). With a comprehensive mix of information and customised services to help Australian companies do business within China and understand foreign regulations and business practices. Services are designed to assist firms looking to grow their business in China and Hong Kong. Austrade also works to promote the Australian education sector within China and Hong Kong and attract productive foreign direct investment into Australia.

For more information on Austrade’s support and activities in China, please visit www.austrade.gov.au/Export/Export-Markets/Countries/China/Market-profile

To view individual ‘doing business’ country profiles, visit: www.austrade.gov.au/Export/Export-Markets/Countries

For Australian exporters and education institutions – contact Austrade on 13 28 78 (Australia only), +61 2 9392 2035 (from outside Australia) or email: info@austrade.gov.au

AustCham Greater China
The Australian Chamber of Commerce Greater China (AGC) is the peak body comprised of the four Australian Chambers of Commerce (AustCham) in the region – namely AustCham Beijing, AustCham Shanghai, AustCham South China (Guangzhou) and AustCham Hong Kong and Macau.

The chambers work to strengthen and promote Australian businesses, government and community relationships in China by providing their members with the information, resources and contacts they need to succeed in the region. The chambers aim to promote Australia as a creative and reliable provider of innovative, high quality business solutions.

The chambers are run on a not for profit basis and operate independently from government. They are funded entirely by membership, sponsorship and chamber activities and are governed by an annually elected board of directors.

For more information on AustCham Beijing, see: www.austcham.org, AustCham Shanghai, see...
CCCMHPIE has built up platforms for Export Fair, the second largest Chinese Commodity Import and Products Hall at the Guangzhou organiser of the Medicinal and Health Products. In addition, CCCMHPIE is the medicinal products export bases. The government strategy to develop into international markets as well as companies in their efforts to break into the small and medium-sized companies is to facilitate the tendering of export quotas and implements export products for medicinal and health products, and formulates quality standards for the spectrum of functions. It organises government to perform a broad range of services.

CCCMHPIE is entrusted by the government to perform a broad range of functions. It organises the tendering of export quotas and formulates quality standards for export products for medicinal and health products, and implements government programs to assist the small and medium-sized companies in their efforts to break into international markets as well as the government strategy to develop medicinal products export bases.

In addition, CCCMHPIE is the organiser of the Medicinal and Health Products Hall at the Guangzhou Chinese Commodity Import and Export Fair, the second largest fair in the world. Over the years, CCCMHPIE has built up platforms for Chinese and foreign companies to develop strong and healthy business relationships.

For more information, please visit www.cccmhpie.org.cn/English

Through a memorandum of understanding (signed in May 2014) with AusBiotech, CCCMHPIE has offered to encourage and support increased interaction between Chinese and Australian life science companies and have (by arrangement with AusBiotech) offered access to visitor office facilities in Beijing. CCCMHPIE has a range of specialist sub-committees and is considering the formation a medical devices sub-committee. CCCMHPIE can assist with the conduct of due diligence.

Membership fees are RMB $8000 per annum and international companies are permitted to join.

China Association for Medical Devices Industry (CAMDI)
Dr Jiang Feng, CEO

CAMDI was founded in 1991 and registered with the Ministry of Civil Affairs of People’s Republic of China. It is an industrial and non-profit organisation whose members consist of companies and individuals engaged in manufacturing, distributing, R&D, testing and education training of medical devices. It is operated under the supervision of the State-owned Assets Supervision and Administration Commission of the State Council and the China Industrial Economy Federation. It also receives further guidance from the Ministry of Civil Affairs, the Development and Reform Commission and the State Food & Drug Administration. Currently, there are 15 branches and professional committees supporting over the 4,000 member companies of CAMDI.

The mission of CAMDI is to represent and provided common benefits of its members, safeguard the legal rights of members, and promote the safety and effectiveness of medical devices as well as the development of Chinese medical devices industry, while complying with the state laws and regulations.

For more information, please visit www.camdi.org/en

Standard membership fee is RMB $2,000 per annum. Premium memberships are also available for interested organisations.

Through a memorandum of understanding (signed in April 201p) with AusBiotech, CAMDI has pledged to: promote cooperation in the area of medical devices, especially where it will assist industry development; and facilitate interaction between Australian and Chinese parties and officials, scientists and technologists working in the medical technology sector.

Shanghai Medical Instrument Trade Association (SMITA)
Ming Rong Pan, Chairman

SMITA was founded in 1987 as a non-profit professional organisation that was voluntarily formed by manufacturing and trading units in Shanghai medical circle, R&D and servicing units, and colleges and schools.

With regard to industrial work and professional work, SMITA is governed by Shanghai Municipal Economic Commission and Shanghai Economic Commission respectively. SMITA has more than 700 members and covers over 30 categories or over 3,000 varieties of equipment and material.

SMITA’s basic purpose revolves around “service, intermediary and coordination”.

For more information, please visit www.smianet.com/english

Through an MOU with AusBiotech (signed July 2014) SMITA has agreed
to encourage and support increased interaction between Chinese and Australian medical device companies through access to visitor office facilities in Beijing and to identify projects that can attract funding to support medical device collaboration between China and Australia.

The membership fee is RMB $2,500 for the first year and then lowers to RMB $1,500 per annum.

Companies seeking information from SMITA will require English translation.

Hong Kong

Hong Kong Medical & Healthcare Device Industries Association (HKMHDIA)

Mr Albert Lee, Chairman

HKMHDIA was incorporated in June 2003 to represent the interests of the medical and healthcare device industries in Hong Kong. It was previously named Hong Kong Medical and Healthcare Device Manufacturing Association, as most of the members were manufacturers or contract manufacturers. The association has adopted its current name in November 2007 as the membership base has grown substantially in terms of both size and range, covering the entire value chain in the medical device industries such as design house, components manufacturers, traders and companies which provide testing and certification services.

HKMHDIA’s works to contribute to the local knowledge-based economy and to assist the technology industry by:

- Helping the medical and healthcare device industries to build internal competencies;
- Setting and observing professional and industrial standards;
- Facilitating national and international cooperation;
- Supporting and advising on medical device policies and regulations;
- Ensuring that safe and effective medical devices ultimately benefit the public.

For more information, please visit www.medicaldevice.org.hk

HKMHDIA plays an active role in promoting its members’ expertise and consulting local and international regulatory impacts to its members. It also seeks sponsorship and support from the government for better development of the medical device industry.

Memberships are available for Australia-based companies to join. The fee amounts to HK $2,000 for a one-year membership or HK $3,500 for a two-year membership. Registration details and forms can be found at www.medicaldevice.org.hk/en_member2.php

Hong Kong BIO (HKBIO)

Prof Albert Cheung-Hoi Yu, Chairman

HKBIO was founded by pioneering scientists with extensive life science backgrounds and multi-cultural experience in research and development, engineering and business. HKBIO is an independent non-profit organisation with the goal to promote best practice, raise awareness across the biotechnology industry while providing added value benefits to its members, whether they are students, researchers, entrepreneurs, industry bodies, public or private sector representatives.

HKBIO’s mission is to develop, cultivate and promote the professional and institutional disciplines of biotechnology in Hong Kong and China for the benefit of members, the public and the global community.

For more information, please visit www.hkbio.org.hk

HKBIO has through an MOU with AusBiotech (signed in June 2012) agreed to encourage and support increased interaction between Hong Kong and Australian biotechnology companies through access to visitor office facilities in Hong Kong and to identify projects that can attract funding to support biotechnology collaboration between Hong Kong and Australia.

The membership fee is HK $3,000 per annum for corporate entities. Registration details and forms can be found at www.hkbio.org.hk/html/JoinHKBIO.html

Australia

Australia Chinese Association for Biomedical Sciences

President: Dr Ruchong Ou
Secretary: Dr Eddie Yan

The Australia Chinese Association for Biomedical Sciences Inc. (ACABS) is a professional not-for-profit organisation, established by Australian Chinese Scholars in the fields of biological and medical sciences. The organisation has professional members in the fields of biological and medical research, clinical practice, education and biotech. It has strong connections with Chinese universities and biotech companies. ACABS is a national organisation with the headquarters in Melbourne. It has more than 100 members and an additional 200 associates in Australia and China.

Objects of ACABS:

- To foster friendship and collaboration, and to strengthen the communications among Australia Chinese scholars;
- To encourage contributions to the advancement of science and technology; and
- To advocate and carry out exchange and collaboration between Australia and China in biomedical science, technology, education and training, and clinical services.

ACABS is able to utilise its connections in China to help Australian companies to enter the Chinese market. It is familiar with Chinese business culture, establishing linkages with potential investors and developing business strategies. For more information, please visit: www.acabs.org.au
Section 15: Contributors

This Guide and the broader project, of which it is part, are supported with funding from the Australian Trade Commission as part of the Asian Business Engagement (ABE) Plan.

The Guide was developed by AusBiotech, Australia’s industry organisation, working on behalf of members for almost 30 years to provide representation and services to promote the global growth of Australian biotechnology. AusBiotech is a well-connected network of over 3,000 members in the life sciences, including therapeutics, medical technology (devices and diagnostics), food technology and agricultural, environmental and industrial sectors.

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Dr Jenny Petering  
Partner, FB Rice (Chair)

Jenny is one of the leading practitioners in the Australian biotechnology space. She has extensive experience in managing international patent portfolios, including strategic planning, due diligence, infringement and patentability advice, and coordinating opposition proceedings. Jenny is regularly singled out by industry reviews of the world’s leading patent prosecutors both for her exceptional technical ability and her commitment to clients.

She acts for a broad range of clients including universities, hospitals, co-operative research centres and research institutes as well as corporates ranging from start-up companies to multinational. They all have one thing in common in that they work on cutting-edge biological advancements.

She is also a member of the Monash University IP Board and a Senior Fellow in the Faculty of Law at Monash University. Jenny is a registered Australian Patent Attorney.

Helen Fisher  
Corporate & International Tax Partner, Deloitte

Helen leads Deloitte’s life sciences industry group in Australia, having had many years’ experience in the life sciences/biotechnology and healthcare industry, providing tax consulting and compliance services to publicly listed and large multinational companies. As lead tax partner on a number of clients, Helen has a proven track record of delivering strategic solutions by capitalising on opportunities and managing tax risks. Helen brings the right technical expertise to help clients obtain the best commercial outcome. Helen has advised on licensing deals, demergers, implementing offshore structures, intellectual property management and location, supply chain management projects, assisting in negotiations with various tax authorities on tax accommodation and capital raisings.

Helen is passionate about the life sciences, biotechnology industry and has a deep understanding of the life cycle of biotechnology and medical device companies and the tax issues they face.

Robin Chambers AO  
Chambers & Company International Lawyers

Robin has been the Senior Partner since its establishment in 1984. He has served as Chadbourne & Parke’s Special Counsel – China since 2003. He was formerly General Counsel of CRA Limited (now Rio Tinto Limited) for 14 years and lead lawyer on major mining projects in Australia involving billions of dollars of equity investment and export sales contracts. His practice primarily involves acting as the Leader Lawyer on international projects, with particular focus on China. Robin was appointed as lead lawyer to the Chinese Government’s AUD$420 million Channar joint venture investment in 1984, which was China’s first major overseas investment. Mr Chambers has advised a number of major Chinese state-owned enterprises on their investments in Australia over 30-year period. He has also advised U.S., European and Australian corporations on a range of projects in China. He has leading-edge experience on the negotiation and documentation of numerous joint ventures in Australia and overseas, together with project management experience coordinating the participation of numerous interested parties at all stages and the project financing of major projects by international banking syndicates. His involvement extends to projects in more than 30 countries.


Meg Hooton, Senior Director, Therapeutic Delivery Unit, Asia Pacific, Unit Head North Asia, Quintiles

Meg was appointed Head of the North Asia Project Management Group in November 2011 and serves on the Asia Pacific and Greater China Quintiles’ management teams. Since taking this role Meg has strategically aligned China, Hong Kong, South Korea and Taiwan.

With over 20 years’ experience in Asia Pacific Meg has concentrated her career in the healthcare sector with a focus on research and development. Working in partnership with MNCs, regional and local pharmaceutical, biotech and medical device companies Meg brings a customer centric approach to the delivery of full service clinical trials to support regulatory applications across multiple markets.

Prior to joining Quintiles Meg held various positions in Bristol-Myers Squibb including leadership of early development commercialisation teams. She qualified as a Registered Critical Care Nurse in Australia and holds a Bachelor of Arts (Asian Studies) from Monash University. Meg is based in Singapore after working in Beijing for a number of years.

Rob Scott  
Director - China BlueSky Partners

Rob Scott is a Director of China BlueSky Partners, an advisory firm based in Shanghai and focused on assisting Australian technology companies to access and receive investment from the China market.

Rob was the former Queensland State Leader of Ernst & Young’s
China Business Group working for Australian clients entering the China market and for major Chinese companies facilitating their investments in Australia. He has a 15 year history of successfully working in the international trade and investment sector, assisting companies in their international expansion, venture capital raising, and business planning/structuring.

Rob holds a MBA from QUT and a Bachelor of Commerce from Griffith University with Chinese studies completed at the Shanghai International Studies University.

Luke Treloar
Senior Manager, Management Consulting, KPMG Advisory (China)

Luke is an American, and has over seven years’ experience in China-market business and financial consulting assisting both multinational and mainland China companies. He is a fluent Mandarin speaker, and has a strong understanding of the opportunities and challenges of doing business in China.

Luke’s professional experience and core specialty is highly focused on the challenges and unique opportunities associated with doing business in Mainland China. This has involved market entry strategies, fund raisings, international public listings, operation-turnarounds, exit strategies, and entrepreneurial projects.

Luke has advised numerous American firms on market entry strategies, due diligence, business and financial modeling, and risk assessment. Correspondingly, he has advised leading western research institutes and investment funds on China-market life science projects. Notably, he led a partnership organisation of Research Triangle Park (RTP), North Carolina medical device, pharmaceutical, and biotech companies in their efforts to pursue China business opportunities.

Dr Neale Jones
Partner, L.E.K. Consulting

Neale is a Partner with L.E.K. based in the Sydney office. He has over 12 years of experience in strategy consulting in Europe, Australia and the Asia Pacific region. After joining L.E.K.’s London office in 2001, Neale returned to Sydney in 2006. He has extensive experience advising clients from across the European and Asia Pacific life sciences and healthcare services sectors, supporting both private and public sector clients to address their most important strategic issues including corporate strategy development, R&D optimisation, business unit strategy, product commercialisation strategy including international expansion / new market entry and evaluating acquisition opportunities.

Neale has led over 50 separate engagements for healthcare & life sciences clients over the past five years, including a range of engagements for Australian healthcare clients assessing opportunities to enter the Chinese market. More broadly, Neale collaborates closely with colleagues from across L.E.K.’s Asia Healthcare & Life Science practice, in particular its offices in China and Japan. He brings to bear L.E.K.’s depth of understanding into Chinese healthcare market dynamics.

Neale holds a D.Phil in Chemistry from the University of Oxford and a Bachelor of Science (Honours) from the University of Sydney.

Duncan Hart
Duncan Hart Consulting (Melbourne)

Duncan initially practised for 20 years as a solicitor and a barrister mainly in the areas of intellectual property, insurance and commercial law. He became managing partner of a legal practice (Ross McCarthy 1988-1999) followed by three years as Regional Managing Director of one of Australia’s largest law firms (1999-2002) in Melbourne.

As a Regional Managing Director he was responsible for managing offices in three Australian cities and two in South East Asia. He also oversaw a number of the firm’s specialist practice groups ensuring they were optimally managed, supported, and resourced. His revenue responsibility exceeded $50 million.

Since retiring as Regional Managing Director he has practised as a consultant (2002 –2014) to companies, government and professional service firms in Australia and Asia.

His educational background includes legal (LL.B) and a Masters of Business Administration (MBA) degrees from the University of Adelaide; I also attended the European Summer School of Management in Scotland in 1997.

He has served as Chairman of the South Australian Law Society Office Management Committee, Chairman of the American Chamber of Commerce Export Committee, Chairman of the American Chamber of Commerce Export Group and as a Board member of the Mary Potter Hospice. He has also served as an elected local councillor of the Unley City Council and is a director of Professional Services Australia, and a former director of Epilepsy Action.

He is admitted as a barrister and solicitor in both Victoria and South Australia and maintains a current practising certificate.

Lisa Renkin
Burnet Institute (Melbourne)

International health specialist Lisa Renkin is a Senior Fellow at the Burnet Institute. Lisa’s expertise spans 20 years of responding to health and development needs, with a focus on effective HIV and health systems initiatives throughout the developing world.

Lisa is currently the head of Burnet’s China program and is leading the expansion of the Institute’s integrated
biotech and public health program. This role incorporates technical involvement in the planning and implementation of programs as well as strategic leadership of our Institutional profile and portfolio of activities throughout China. She has lived and worked in various parts of China over the past 12 years and speaks some Mandarin.

Lisa is a member of a number of technical and industry specific advisory groups, and is actively involved in promoting Victorian and Australian biotechnology, life sciences, research and health development expertise in international settings. She has recently project-managed the successful establishment of Burnet corporate structures in Hong Kong and more recently an R&D and commercialisation facility in Nanjing, Jiangsu province. She is member of the Board of the Australia China Business Council (ACBC), Victoria branch.

Dr Julian Chick
COO, Admedus

Currently the COO of Admedus Ltd (formerly Allied Healthcare Group), Julian is an experienced corporate executive with 12 years’ experience in senior management with roles as Chief Executive Officer, Head of Business Development, plus running early and late stage research & development (R&D) projects. In the past ten years Julian has raised over $200 million for R&D projects across medical devices and therapeutics.

Julian has had five years’ experience as an investment adviser and financial consultant with Prudential-Bache Securities, BNP Paribas and Salomon Smith Barney. He was also the principal analyst with Foursight Associates reviewing healthcare and biotechnology investment opportunities for private equity investors and venture capitalists. Julian has a PhD in Muscle Physiology.

For the past two years Julian has been part of the management team at Allied Healthcare Group, which has a sales and distribution team and recently received approval for its Class III medical device for congenital heart repair, CardioCel. Julian has established businesses and run operations, collaborations and licensing in and out of China over the past nine years.

Dr Anna Lavelle
Chief Executive Officer,
AusBiotech Ltd

Anna was appointed inaugural Chief Executive Officer of AusBiotech Ltd in June 2005. Previously Anna was an executive with the Australian Red Cross Blood Service (ARCBS) commencing in 1998 as Director responsible for Strategic Planning and Business Development. In 2002, Dr Lavelle was appointed Director of Intellectual Capital and was responsible for management of the national R&D program, evaluation of emerging technologies and international and national business development activities including technology transfer and IP management.

Prior to joining ARCBS, Dr Lavelle held positions of Chief Executive Officer of a public health organisation, Industry lobbyist for a member organisation and was an academic at Monash University, Melbourne. Dr Lavelle holds a Doctor of Philosophy in Genetics from the University of Melbourne.

Lucy Xiao
Consultant – Asia Services,
Brandwood Biomedical

Educated in China and Australia and with qualifications in both Biomedical and Mechanical engineering, Lucy is well versed in every step of the medical device life-cycle from conceptual design to post-marketing activities. Combining technical knowledge and regulatory expertise, Lucy supports both Australian and international clients in quality and regulatory requirements, specialising in Asian markets.

Lucy is bilingual (English and Mandarin) and is experienced in direct interactions with regulatory authorities in Greater China. Clients also benefit from the Asian regulatory intelligence she supplies with real-time regulatory announcements and trends of the fast-changing regulatory landscape in China.

Lorraine Chiroiu
National Communications Manager,
AusBiotech (Project Manager)

Lorraine has worked as a dedicated advocate for the biotechnology sector since joining AusBiotech more than five years ago. In this role she works closely with public policy impacting the sector at state and Federal levels and provides communication via various mediums to inform AusBiotech members and key stakeholders about industry news and writes regularly for a range of industry publications.

She has recently led the project management of two significant industry resources: the revised Code of Best Practice for Reporting by Life Science Companies; and the development of the Guide for Life Science Company Directors.

Lorraine has previously worked in Corporate Affairs for a multinational US-based pharmaceutical company, where she led a project in Singapore. She has also worked in communications roles for The Pharmacy Guild of Australia and The University of Melbourne.

Lorraine has an undergraduate degree in public relations, majoring in journalism, a postgraduate diploma in marketing management, and an MBA from the Asia Pacific’s top-ranking program at the University of Melbourne’s Melbourne Business School.
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Appendix A: Business planning checklist for China

The following business planning checklist is provided to prompt your thinking about the types of considerations you might wish to make when considering the China market and/or in preparing your business plan. It has been developed by Rob Scott, a Director of China BlueSky Partners, an advisory firm based in Shanghai and focused on assisting Australian technology companies to access and receive investment from the China market. AusBiotech has been permitted to reproduce the checklist, however, copyright belongs to and all rights are reserved by China BlueSky Partners (www.chinablueskypartners.com)

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(1) Planning

1.1 What is the main reason you have chosen China as a market (i.e. market growth; reduced supply costs; increased global profitability; vertical integration, etc)?

1.2 What is your Vision/Mission Statement for where you want your China operation to be in five years?

1.3 What locations have you considered within China? Why have you chosen these locations? Have you considered the benefits/costs of alternative locations (e.g. other regions or cities)?

1.4 What industry do you plan to operate in? Have you researched the key factors (current structure; success factors; competitors; and distribution channels) for the industry in which you will be operating?

1.5 Please define the proposed scope of your business (i.e. investment/exporting/sourcing)? Is this a natural extension of your current operation or a completely different venture?

1.6 What is the value proposition of your business to the China market (integrate products/services; provide customers a one-stop shop solution; lower cost opportunity)? How is this positioned against current market offerings?

1.7 Detail the key strengths, weaknesses, Opportunities and threats for your offering in China.

1.8 How does the business make money? What is the revenue model (i.e. manufacturer/developer; direct to market; distributor/reseller; licensor?)

1.9 What is your budget for your new venture in China?

1.10 What are your three main strategic objectives and KPIs for the China business over the next three years? What are three main short-term (12 month) objectives and KPIs (if different from the above)?

(2) Products and Services

2.1 Describe (in full detail) your main products/services (i.e. features/benefits)?

2.2 What unmet and specific needs do they satisfy within the China market?

2.3 What percentage of your income and profits will the sales of these products/services comprise of your total global revenue?

2.4 For each of these main products/services, list the following:

   1) Your unique selling point;
   2) Your target customers;
   3) Your key suppliers;
   4) Your main rivals/competitors (include other major competitors entrants not already in China);
(3) China Market Analysis

3.0 What is your estimate of the current market for your product/service within China? What is the basis of this estimate (i.e. desktop research, primary MR, partners/supplier estimates, etc.)?

3.1 What is the level of current interest within the China market for your product/service? Have there been any major demand shifts/trends within the China market in the last 12 months that you can leverage?

3.2 What future opportunity/threats do these trends offer for you? (e.g. fragmenting competition, locally available skills, rapid market growth, etc.) – how will these play out over the short (12 months) and mid to long-term (i.e. 2-5 years+)?

3.3 How does the type (supplier, license, etc.) and strength of the relationships with your partners/suppliers help you business? Will your current/proposed model remain the same through the next three years?

3.4 Are all your proposed product/services already in China, or is China a ‘greenfield’ site for your type of offering?

3.5 If established, do you know the approx. % market share of your major competitors in China?

3.6 Is the market growing and what is the forecast growth in the next five years?

3.7 How do these competitors satisfy or fail to satisfy the market’s needs?

3.8 Are there barriers to entry for other competitors to enter the market? (i.e. distribution, costs, credibility, etc.)

(4) Sales and Marketing

4.1 What are the key product attributes valued by your China customers (i.e. price, quality, added value; or other factors – location, etc)?

4.2 On a scale of 1-5, how would you rate your products meeting these needs? How about your competitors?

4.3 What locations in China have you identified for your product/service? Why?

4.4 What market segments (current and future) in China have you identified for your products/services? Why?

4.5 What is your expected break-up of sales between major customers and the rest? (e.g. 80/20 or 20/80)

4.6 How would describe the typical end user for your product/service?

4.7 What is your expected market penetration in China over the next five years? Is this realistic? Why?

4.8 How will the company be branded/perceived in the market/s? How will this branding be achieved?

4.9 Do you or will you engage external agencies for outsourcing and what will they do? (design/development, production, reselling)

(5) Strategy

5.1 Describe your current China market strategy (i.e. cost vs. value; domestic vs. international; penetration vs. premium). What changes have you made to your domestic strategy to cater for the China market?

5.2 Detail the regions/provinces/cities you will be targeting for China market entry – or (if online model) what is the main mechanism by which you will reach consumers?

5.3 Describe your planned business model for the (i.e. organic; M&A; license/franchise).

5.4 How will the company run its overseas operations (i.e. direct export, licensing, WFOE, JV, separate geographic division offices)?

5.5 If you are looking for a Chinese partner or acquisition target, what size, location, capabilities and/or experience/value do you require?

5.6 Describe your China distribution strategy (direct; OEM, distributors; retailers; resellers, other)?
5.6 Describe your R & D/Commercialisation strategy for China as appropriate to your business?

5.7 Describe your China operations strategy (internal/external – production/delivery; increases/decrease in capacity/investment; production techniques; economies of scale; production schedule).

5.8 What is your strategy and timeframe for exiting your China business?

(6) IP/Legal

6.1 What actions have you undertaken to protect your intellectual property (IP) in China? (current or pending patents, TM, copyright, trade secrets, NDAs/employee contracts, etc)

6.2 What is your IP strategy for China? Have you sought professional advice in this regard?

6.3 Will you be applying for any IP in China? If so what aspects of your business will be protected and how?

6.4 Will any intellectual property (IP) be developed/ transferred to China as part of this investment?

(7) Management

7.1 Who are your key management and staff you will need to make the company successful in China? What are your perceived difficulties in recruiting them?

7.2 Does your existing management team possess previous experience working in China (or other Asian countries) or managing companies there? If so please detail.

7.3 How do you intend to retain and compensate your key Chinese management/staff (i.e. share options, incentive schemes)?

7.4 Will these hires be expats, returnees, or local staff? Does your China HR strategy cater sufficiently for each group?

7.5 What other staff and management do you require to run the China business in the future and when will they be hired? With what required qualifications and experience?

7.6 What will your Chinese organisational structure look like now and in three years?

(8) Operational Risks

8.1 Are you aware of all the risks and challenges of undertaking investments in China? (financial; partners; people; corruption; suppliers; competition; developing economy and regulatory system, etc.)?

8.2 What strategies/contingencies have you put in place to minimise each of these risks? (e.g. financial control systems, IT backup systems, etc)? Are your resources either in Australia or China sufficient to manage these effectively?

8.3 How will you manage key operational issues - company set up, employment of staff, IP, etc.?

8.4 Have you completed adequate due diligence on your prospective JV partner/acquisition target?

8.5 Are all your proposed contracts compliant with all relevant Chinese laws and other government regulations?

8.6 Will you be structured as a separate business in China? If so how (i.e. Registered Office, Wholly Foreign Owned Entity or JV)? What will the relationships be between your parent and Chinese subsidiary? Have you considered transfer pricing and other cross-border tax issues?

8.7 Have you obtained all the necessary business licenses and government approvals for the investment?

8.8 Have you already engaged high quality advisors to assist you on the key aspects of the transaction?

(9) Financials

9.1 Detail the budget for the first three years (i.e. the total cost of the investment over this period).

9.2 What are your projected revenues and growth (number of units/sales, etc) over the next three years for the China business?

9.3 When do expect to receive this revenue (i.e. ongoing, seasonally, etc) and what are your terms of trade?

9.4 What is your projected NPAT (Net Profit After Tax) for the next three years?

9.5 What is your expected gross margin on sales? Will this change over the next three years?

9.6 What are your expected major fixed and variable expenses (wages, marketing, admin, R&D, etc)? Will these change over the next three years?

9.7 Do you have any (current or future) other revenue sources (related companies, consulting, bank interest, etc.)?

9.8 What are your interest and depreciation costs (if any)?

9.9 What production/revenue targets do you have to hit to break-even?

9.10 Are all these funding requirements covered by the registered capital for your Chinese entity? If not, does the China company need further capital and by when?
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