

# Media Coverage

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## **FDA adverse event revisions a positive step, says CEO**

By Nick Taylor

### **Revision to FDA guidance on adverse event reporting is a positive step and forms part of a welcome increased focus on safety, says the CEO of Prism Ideas.**

At the end of September the US Food and Drug Administration (FDA) issued a final rule and draft guidance to revise its stance on the reporting of safety information arising in trials. Making the revisions was intended to speed review of safety information and protect trial participants.

In an interview with Outsourcing-Pharma, James Sawyer, CEO of Prism, highlighted two key elements of the revisions, the need to report: findings from epidemiological studies that suggest a significant risk to participants; and adverse reactions that occur at higher than expected rates.

Sawyer said both revisions are positive developments that will ultimately benefit patients. Even before the FDA detailed the revisions many companies will have already been reporting in these instances, said Sawyer, but it is good to standardise practices through written guidance.

In Europe requirements for reporting adverse events are a little different, said Sawyer. However, the global nature of the biopharm industry, and specifically the clinical trial sector, means companies will implement practices detailed by the FDA at their operations around the world.

Adopting national regulations at global operations drives harmonisation. Regulators are also seeking to formalise harmonisation, with revisions by the FDA intended to bring it more into line with the International Conference on Harmonization (ICH) and World Health Organization (WHO).

Sawyer spoke to Outsourcing-Pharma from Melbourne, Australia where he is representing UK-based Prism at AusBiotech 2010. In addition to operations in Nantwich, UK Prism has employees based in Switzerland.

From these locations Prism provides drug development consulting, such as drug safety literature reviews and annual safety reports, and medical marketing and communication services.