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"Can You Handle the Truth?"

## **"Monitoring and Ensuring Pharmaceutical Compliance"**

**Cutting Edge Information, 2008, 104 pages, \$7,695**

**Review by Norman M. Goldfarb**

"Monitoring and Ensuring Pharmaceutical Compliance" covers the trend towards creating centralized compliance departments to manage compliance from research through marketing and sales. Department of Health and Human Services (DHHS) Office of Inspector General (OIG) regulatory action has led compliance departments to focus their attention on marketing and selling activities, but many also watch the people who watch the people conducting clinical research.

Compliance departments at the fifteen pharmaceutical and biotech companies surveyed are small, with an average of 6.5 personnel (range of 1 to 16). However, half are led by a chief compliance officer ("C level") or vice president with executive-level stature. On average, they spend 33% of their time monitoring and reviewing, 14% training other departments, and 16% developing standard operating procedures (SOPs) to monitor and review against. One of five principles of success for compliance departments is to collect feedback about whether the compliance burden is too onerous or too trivial.

The report is available at <http://www.cuttingedgeinfo.com/>

### **Reviewer**

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