

"Benchmarking Drug Safety and Pharmacovigilance"

Cutting Edge Information, 2010, 155 pages, \$7,695.00

Review by Norman M. Goldfarb

"Benchmarking Drug Safety and Pharmacovigilance" offers important perspectives on drug safety and pharmacovigilance programs for pharmaceutical and biotechnology companies, as well as service providers.

The report has four sections:

- Executive Summary
- Drug Safety Budgets and Outsourcing
- Structure and Staffing
- Drug Safety Activities

Over 100 charts and figures, accompanied by interpretative discussion, provide important insights, such as the following:

- The most expensive drug safety functions are (a) case management and (b) regulatory report development and submissions, each accounting for an average of 28% of spending. Other activities include risk mitigation strategy, signal detection, medical services, regulatory report development and submission, regulatory consulting and training, safety technology services, project management, literature review, and due diligence.
- The FDA is applying more resources to safety, especially through its Sentinel Initiative, which is not yet operational. There are signs that the FDA is becoming more open, i.e., not using safety-related inquiries to trigger audits, but most companies try to stay off the FDA's safety radar.
- Most companies spend \$300,000 to \$700,000 per product on drug safety programs.
- Few companies outsource risk mitigation strategy, signal detection, and medical services functions.
- About half of clinical operations departments have some oversight of the drug safety group.
- Almost half of companies begin drug safety operations in pre-clinical. The others presumably consider drug safety to be part of other functional groups (starting with legal) until the drug safety group takes over.

In the development of this report, analysts surveyed people at 27 companies. The report presents data in aggregate form and also broken out by company size (small, medium and large), with biotech companies placed in a separate category.

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

Reviewer

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