Staffing and Performance Benchmarks for Regulatory Function Highlight New Medical Device Study

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CHAPEL HILL, N.C., Aug. 17, 2012 /PRNewswire/ -- Regulatory Affairs groups face the monumental task of ensuring that companies comply with the plethora of global regulations pertaining to developing and marketing medical device products. These specialized groups largely rely on their own internal effectiveness and efficiencies to remain productive and support the organization's goals.

Optimal resourcing and staffing help Regulatory Affairs groups in the medical device industry prioritize roles and responsibilities that will be most beneficial to growth. Likewise, the effectiveness of a regulatory group also is tied to how well its responsibilities are delineated and the group itself is structured

In a recent study, Regulatory Affairs leaders said they expect the function to grow during the next three years through a combination of internal and external resources. However, few expect outsourcing and off-shoring to increase beyond current levels, according to the research project.

Research and consulting firm Best Practices, LLC conducted this benchmarking study, Regulatory Affairs Excellence: Staffing & Performance in Medical Device Companies [1], to establish meaningful metrics around Regulatory Affairs' spend, FTEs and consultants for medical device operations in the U.S. and globally. The 91-page study also examines the structure and roles of regulatory groups at medical device companies.

This study addresses critical Regulatory Affairs benchmarks for:

- Global Resource Levels - including optimal budget and staffing allocations
- Organizational Structure
- Span of Control for managers to VP
- Regulatory Submissions and Trends
- Leading & Supporting Roles of Regulatory Affairs
- Outsourcing/Offshoring for electronic storage, publishing, and translation services
- Impact of 510(k) R
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http://www.mdtmag.com/news/2012/08/staffing-and-performance-benchmarks-regulatory-function-highlight-new-medical-device-study

Links:
[1] http://www3.best-in-class.com/rr1167.htm