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Regulatory Affairs Workload at Drug Development Firms Has Increased Dramatically, According to Tufts Center for the Study of Drug Development

BOSTON – March 11, 2010 – A growing volume of global drug development and commercialization activity during the past decade has dramatically increased the workload for regulatory affairs professionals at pharmaceutical and biotech companies, according to a study recently completed by the Tufts Center for the Study of Drug Development.

The study, the first systematic assessment of global regulatory affairs performance, found that the regulatory affairs function within drug development companies has grown steadily, with most departments tending to hire from within. This comes at a time when a growing number of those companies are outsourcing more of their clinical trial work to external service providers.

Findings from the Tufts CSDD analysis were reported in the March/April Tufts *CSDD Impact Report*, released today.

“As more of the clinical function continues to be outsourced, regulatory affairs personnel will need to coordinate closely and communicate with external service providers. They will be challenged to handle a growing workload as their companies seek to improve R&D efficiency in an operating environment marked by ever-rising costs,” said Tufts CSDD Senior Research Fellow Ken Getz, who conducted the study.

Based on data from mid-size and large pharmaceutical and biotechnology companies with global drug development operations, the study also found that:

- * Regulatory affairs functions support, on average, 100 major projects per year, two-thirds of which are in clinical research phases.
- * On average, 39% of regulatory staff has more than 10 years of experience. This compares to 9% for clinical staff.
- * Annual average internal staff turnover for regulatory affairs groups was 6.5%, compared to 21% for clinical groups.
- * Companies report that only 5% of staff are contract employees, who are engaged most frequently in connection with dossier compilation.

About the Tufts Center for the Study of Drug Development

The Tufts Center for the Study of Drug Development (<http://csdd.tufts.edu>) at Tufts University provides strategic information to help drug developers, regulators, and policy makers improve the quality and efficiency of pharmaceutical development, review, and utilization. Tufts CSDD, based in Boston, conducts a wide range of in-depth analyses on pharmaceutical issues and hosts symposia, workshops, and public forums, and publishes the *Tufts CSDD Impact Report*, a bi-monthly newsletter providing analysis and insight into critical drug development issues.

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Contact: Tufts Center for the Study of Drug Development
Peg Hewitt – 617-636-2185
peg.hewitt@tufts.edu

Business Communication Strategies
Peter Lowy – 617-734-9980
lowy@bus-com.com