Rising demand is expanding scope and workload of regulatory affairs function

First benchmark study characterizes state of regulatory affairs function

- The scope of the regulatory affairs function has expanded rapidly to handle a broad and growing range of pre- and post-approval responsibilities.

- In response, head count within the regulatory affairs function has been growing steadily, with most functions tending to hire from within and using minimal outsourcing support.

- On average, 39% of regulatory staff have more than 10 years of experience, compared to 9% for clinical staff.

- Most regulatory functions are centrally managed, with 60% based at company headquarters, and 24% and 16% based regionally and locally, respectively.

A growing volume of global drug development and commercialization activity has dramatically increased the workload for regulatory affairs professionals during the past decade. The expanding volume of submissions filed across a larger number of countries has required more interactions with, and more coordination among, regional regulatory agencies and health authorities. Post-approval, regulatory affairs professionals have had to accommodate higher levels of disclosure and more demanding post-launch and product lifecycle management activities.

To date, few quantitative analyses have characterized the structure and capacity of regulatory affairs functions. Recently, Tufts CSDD undertook the first systematic assessment of global regulatory affairs performance, summarized in this Tufts CSDD Impact Report. The study found that the regulatory function is handling a high and growing volume of cross-functional activity, depending heavily on internally-grown staff possessing high levels of experience and low turnover. As more and more of the clinical function continues to be outsourced, regulatory affairs personnel will need to coordinate closely and communicate effectively with external service providers. They will be challenged further to handle a growing workload as their companies seek to improve R&D efficiency in an operating environment marked by ever-rising costs.