



Tufts Center for the Study of Drug Development

TUFTS UNIVERSITY

Impact REPORT

ANALYSIS AND INSIGHT INTO CRITICAL DRUG DEVELOPMENT ISSUES

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.