

Contract Research Organization

Holland Code: IEC

Background

A contract research organization (CRO) is a company or organization that offers a wide range of pharmaceutical services primarily to the pharmaceutical and biotechnology industries. The government defines a CRO as a corporation that assumes, as an independent contractor with the sponsor, one or more of the obligations of a sponsor to design, select, monitor, evaluate, and/or prepare materials to be submitted to the Food and Drug Administration [21 CFR 312.2(b)]. Services can include but are not limited to: product development, formulation activities, phase I through IV activities, data entry and management, project management, institutional review board (IRB) approval, statistical analysis, and other required activities necessary to apply for a New Drug Application (NDA) or an Abbreviated New Drug Application (ANDA). In addition to medications, CROs serve as contractors for sponsors of medical devices. Pharmacists can play an integral role in each step of the process through direct management or oversight, and as a team member. There are a variety of career paths within CROs for pharmacists. This profile provides aggregate data of those respondents employed in CROs.

Respondents indicated that 30% of their time is spent on research activities. Fifteen percent is spent on project/case management and 10% spent on data management. An additional 8% and 8% spent in two areas: business/organization/department management and service (such as committee work).

Characteristics

A total of 13 CRO pharmacists responded to the survey. Sixty-two percent reported having a PharmD degree. Forty-six percent had obtained an advanced degree, such as an MS (23%) or PhD (15%). Thirty percent had been through a residency, and an additional 10% completed a fellowship. Ten percent indicated having some type of certification. Additionally, 10% have completed some other type of training. Respondents' average age was 40 years old. More than half (60%) of respondents were female. Income data show 50% earn less than \$100,000 and 30% earn more than \$120,000. The average time worked per week was 36 hours.

The majority of respondents indicated that they were satisfied with their work, with 33% indicating "extremely satisfied" and 42% indicating "somewhat satisfied." Fifty percent of respondents said that they felt the work was "extremely challenging" and 42% indicated that they felt it was "somewhat challenging."

Insider's Perspective

What aspects of the job are most appealing?

Many of the respondents indicated that “flexibility in scheduling” was one of the most satisfying aspects of their work. One respondent said they enjoyed, “working with a diverse group of colleagues with varying backgrounds (medical doctors having different specialties, statisticians, medical writers, etc.)” and “exposure to the all the steps in the drug approval process and the opportunity to move into a different job within the company if desired.”

What aspects of the job are least appealing?

No one specific item stood out for this group. Several issues were mentioned including billing for time, length of hours worked, and no direct patient contact. One respondent said that they didn’t like that the job is “very highly detail oriented.”

What advice should students and practitioners consider when selecting the option of CRO pharmacist?

Many of the respondents indicated that pharmacists should be flexible in looking at their career path. One respondent stated, “Look and think outside the box.” Another indicated that it is important to “remain flexible, be positive, and maintain a personal and professional balance.”

Adapted from the American Pharmacists Association