

Contract Research Organization

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.”

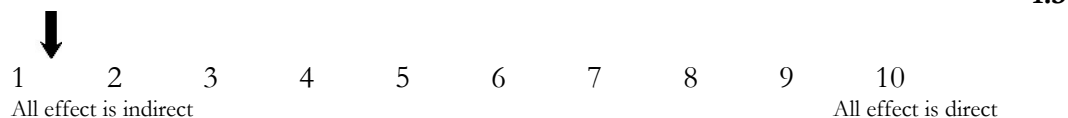
What aspects of the job are least appealing?

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?

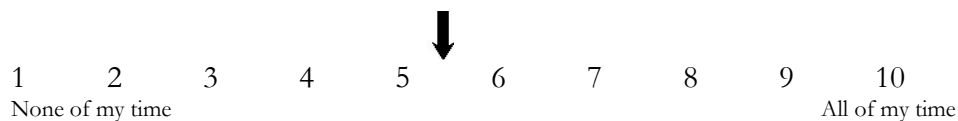
Many of the respondents indicated that pharmacists should be flexible in looking at their career path. One respondent stated, “Look and think outside the box.” Another indicated that it is important to “remain flexible, be positive, and maintain a personal and professional balance.”



Collaboration with Other Professionals

Rated as a 5.3 on the scale, CRO pharmacists have the opportunity to collaborate with other professionals. Communication with doctors and nurses in the trial is essential to make sure that all the protocols and criteria of the study are being followed. The CRO pharmacist must work to communicate accurately and concisely to ensure the study subject is being properly administered.

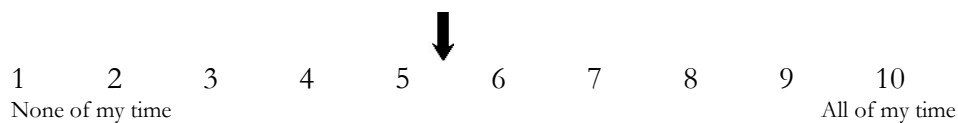
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Educating Other Professionals

The opportunity exists to educate other professionals around a number of topics in a CRO. From understanding the inclusion and exclusion criteria to data analysis, educating other professionals about these areas ranked in the mid-range.

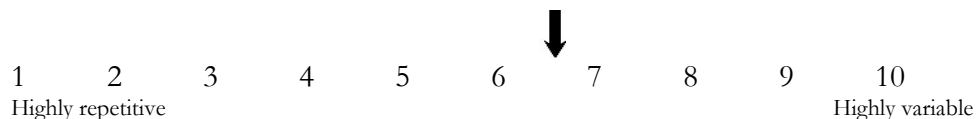
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Variety of Daily Activities

Daily activities constantly change and are time sensitive. While some tasks can become repetitive in nature, the people and processes involved often change. Challenges often arise in resolving therapy and other prescription-related problems.

= 6.6



Multiple Task Handling

Corresponding to the high range score in the factor for “variety of daily activities,” CRO pharmacists indicate that they multitask. In response to this survey, the majority of pharmacists indicate several tasks require their attention at one time.

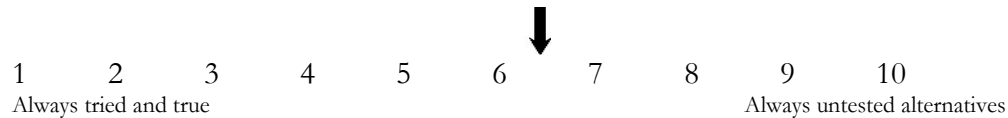
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Problem Solving

In the CRO setting, the problems encountered may or may not be overly complicated. With a rating of 6.4, pharmacists indicated that they lean toward new alternatives. This should not be taken to mean that the tried-and-true solutions are not used. It is more that every trial has a unique feature that can require one to think outside the box.

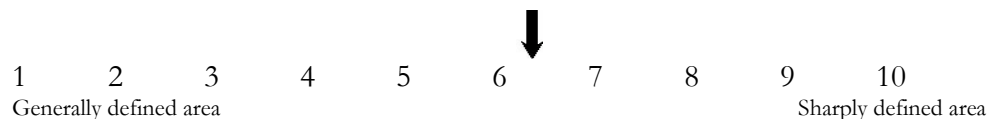
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Focus of Expertise

Some career paths in the CRO environment require a very specific, very specialized degree of knowledge oftentimes linked to the therapeutic area being examined (e.g., a pharmacist specializing in cardiovascular disease). The overwhelming amount of knowledge required of that individual would be involving the treatment of patients with the disease state while still knowing the broader ramifications of quality of life issues and other study-related areas. It appears that the CRO pharmacist balances the knowledge of both the general and sharply defined areas.

= 6.3



Innovative Thinking

Respondents rated this factor in the upper range with a 7.4 response, indicating that their practice often requires innovative thinking. Opportunities for idea generating span the entire breadth of a project.

= 7.4



Applying Scientific Knowledge

CRO pharmacists have the opportunity to exercise the scientific knowledge they gained in pharmacy school. The type of knowledge they apply is dependent upon the stage of the drug discovery/clinical trial process involved.

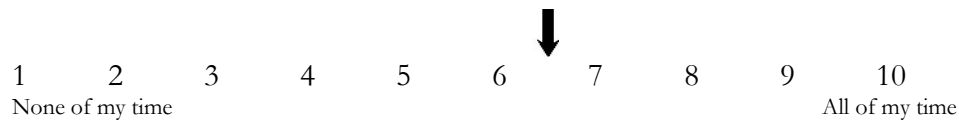
= 8.0



Applying Medical Knowledge

Applying medical knowledge was a slightly lower rating than scientific knowledge at 6.5.

= 6.5



Creating New Knowledge by Conducting Research

The CRO environment is an example of a setting that can provide opportunities for the creation of new knowledge. Again, the specific project that a pharmacist is working on influences these opportunities.

= 6.8



Management/Supervision of Others

Management/supervision of others scored lower mid-range for CRO pharmacists at 4.0. There are many times that a pharmacist works as part of a team and has sole responsibility for a given area of expertise, while at other times a pharmacist may manage the entire process.

= 4.0



Management/Supervision of a Business

The majority of classical management or supervision of business activities is the responsibility of the executives in a larger corporation. Even in small CROs, the business is driven by sponsors and those who have the responsibility in the CRO to meet and discuss projects with the sponsor.

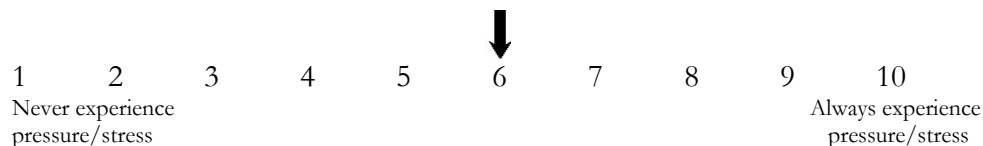
= 3.4



Pressure/Stress

Responding CRO pharmacists indicated that they experience a mid-range level of pressure or stress in their practice. A respondent indicated that there is “a lot of stress because all contracts are time sensitive and have to maintain a certain level of billability.”

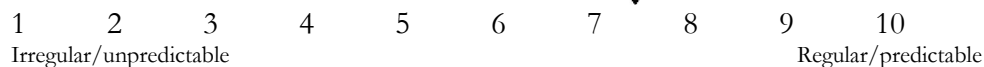
= 6.0



Work Schedule

The predictability of work schedule received a 7.4. This is somewhat dependent on the project and timelines.

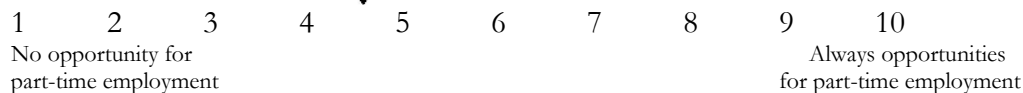
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Part-Time Opportunities

Receiving a mid-range rating in the survey at 4.6, respondents indicated that they can be offered the opportunity for part-time positions. With today's pharmacist training and the more complex regulations for clinical trials, CROs are often looking for people to "fill in the gaps" on specific projects.

= 4.6



Job-Sharing Opportunities

Job-sharing received a low range response at 3.0.

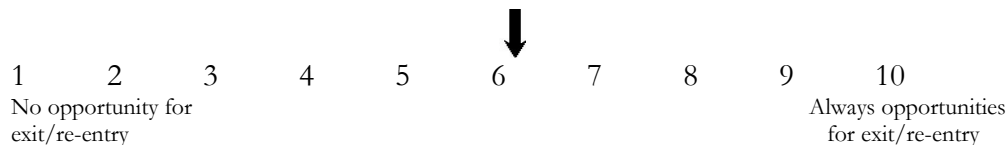
= 3.0



Exit/Re-entry Opportunities

Exit/re-entry opportunities are exactly mid-range in this practice environment.

= 6.2



Parental Leave Opportunities

Parental leave opportunities ranked 7.8 in the areas of work-related options. This was tied for the highest rating of any critical factor by this group.

= 7.8



Leisure/Family Time

With a work schedule that is more regular and predictable, respondents indicated that they are better able to plan for leisure time or time with their families. However, specific projects may impact one's ability to take time off if the project is nearing completion of milestones in the process.

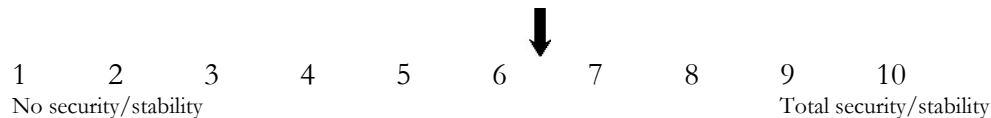
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Job Security

CRO pharmacists agree that, on the whole, they are enjoying adequate job security. As the research process and clinical trials arena becomes more and more complex, CROs continue to expand and the roles that pharmacists play also become higher in demand.

= 6.4



Opportunities for Advancement

Respondents indicated a high mid-range rating relative to the opportunities to advance within a CRO. Career advancement can often be limited by the size of the organization with broader opportunities across larger organizations.

= 6.6



Opportunities for Leadership Development

Leadership can be characterized by the possession of vision and initiative—vision to guide an individual or organization to a goal and initiative to take the steps necessary to get to that goal. These skills are often critical components of personal career development. In this survey, respondents indicated that this factor fell in the high mid-range area at 7.9.

= 7.9



Community Prestige

CRO pharmacists fall mid-range regarding community prestige. CRO pharmacists themselves are not necessarily well known for the work that they do unless one is employed at the corporate headquarters.

= 5.0



Professional Involvement

Tied for the highest rating factor by this group, CRO pharmacists have a high-range rating on the opportunity to be professionally involved in meetings and events in their profession. Professional involvement of individual pharmacists is critical to the development of the profession as a whole.

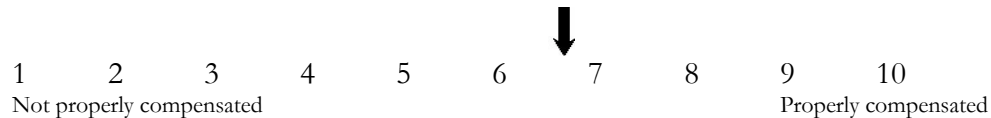
= 7.1



Income

Respondents indicated that they are in the upper mid-range of being properly versus not properly compensated for their professional services. Many advised those looking at career opportunities that it is worthwhile to investigate what CRO pharmacists do to determine if it is the right fit.

= 6.7



Benefits (vacation, health, retirement)

CRO pharmacists gave their benefits an equal rating to their income in the survey. Respondents indicated that they usually receive a benefits package that includes bonuses, health coverage, and retirement plans.

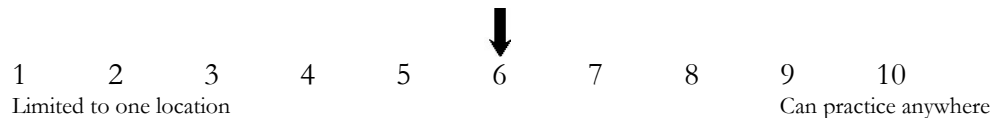
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Geographic Location

The CRO environment provides an interesting situation for pharmacists. There are a limited number of locations if one is interested in working in the corporate headquarters of a CRO. However, there are corporate offices across the United States and in some cases employment can be home-based.

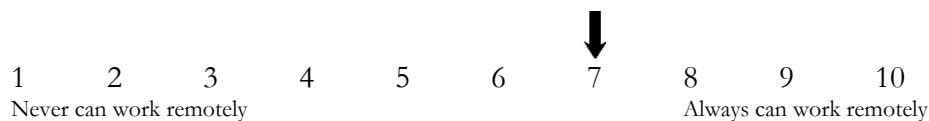
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Working Remotely

Autonomy in the CRO environment can depend on the particular project and the stage of the project. However, respondents indicated that they have a high level of autonomy regardless of the project's phase. Some decisions, mostly administrative, may require further consultation with other team members.

= 7.0

**Autonomy**

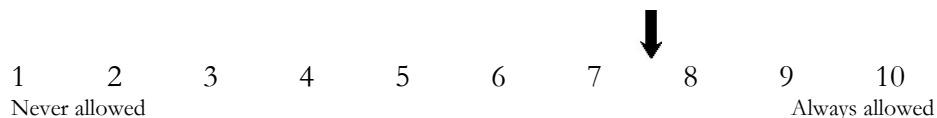
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**Self-Worth**

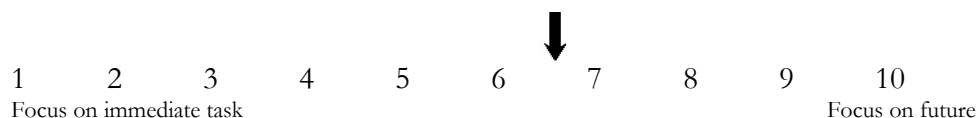
In general, the focus of the CRO pharmacist is to move the process of drug discovery and clinical trial activity to fruition. Seeing a project reach milestones and goals provides the opportunity to see how one's work impacts the health care of others.

= 7.4

**Future Focus**

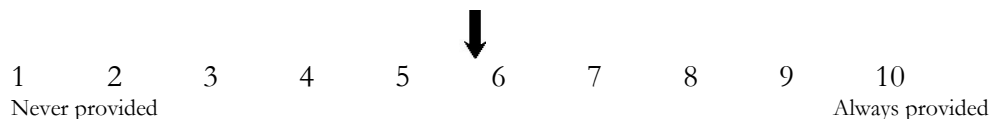
Most projects have a future focus because the goal is to successfully complete the project for specific decision points, such as "go/no go" assessments or processing an NDA to the FDA. In addition, some tasks in the CRO environment can be viewed as very immediately focused and are time sensitive.

= 6.5

**Professional Prestige**

Professional prestige, to an extent, is related to the earlier factor on collaboration with other professionals. CRO pharmacists do have the opportunity to publish work and present information at national meetings.

= 5.6



Mean Scores for Critical Factors

1. Interaction with people	2.0
2. Performing physical assessments	1.4
3. Interpreting laboratory values	1.9
4. Continuity of relationships	3.9
5. Extent to which effect is direct	1.3
6. Collaboration with other professionals	5.3
7. Educating other professionals	5.4
8. Variety of daily activities	6.6
9. Multiple task handling	7.3
10. Problem solving	6.4
11. Focus of expertise	6.3
12. Innovative thinking	7.4
13. Applying scientific knowledge	8.0
14. Applying medical knowledge	6.5
15. Creating new knowledge by conducting research	6.8
16. Managing others	4.0
17. Managing business operations	3.4
18. Pressure/Stress	6.0
19. Work schedule	7.4
20. Part time opportunities	4.6
21. Job sharing	3.0
22. Exit and re-entry	6.2
23. Parental leave	7.8
24. Free time for leisure/family activities	7.4
25. Job security	6.4
26. Opportunities for advancement	6.6
27. Opportunities for leadership development	7.9
28. Community prestige	5.0
29. Professional involvement	7.1
30. Income	6.7
31. Benefits (vacation, health, retirement)	7.4
32. Geographic location	6.0
33. Working Remotely	7.0
34. Autonomy	7.8
35. Self-Worth	7.4
36. Future focus	6.5
37. Professional prestige	5.6
38. Unique practice environment	8.1
39. Advanced degree	6.7
40. Entrepreneurial opportunity	4.7
41. Additional training	6.2
42. Interacting with co-workers	8.0
43. Travel	3.0
44. Writing	5.5
45. Working with teams	8.2

Reference

Schommer JC, *APhA Career Pathway Evaluation Program for Pharmacy Professionals 2012 Pharmacist Profile Survey*. February 2013

Professional Organizations

American Pharmacists Association (APhA)
2215 Constitution Ave, NW, Washington, DC 20037
Tel: 800-237-APhA Fax: 202-783-2351
www.pharmacist.com

Drug Information Association (DIA)
800 Enterprise Road, Suite 200, Horsham, PA 19044
Tel: 215-442-6100 Fax: 215-442-6199
www.diahome.org

Society of Clinical Research Associates (SoCRA)
530 West Butler Avenue, Suite 109, Chalfont, PA
Tel: 215-822-8644 Toll-Free: 800-SOCRA92
www.socra.org