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 23% of their time is spent on research activities. Sixteen percent is spent on data management with an additional 14% spent equally in two areas: project management and consulting/advising sponsors. Ten percent is spent on business management.

Characteristics

A total of 23 CRO pharmacists responded to the survey. Seventy-four percent reported having an entry-level pharmacy degree with 49% reporting a PharmD degree. Forty-eight percent had obtained an advanced degree, such as an MS (22%) or PhD (26%). Thirty percent had been through a residency, with an additional 22% having a fellowship. Nine percent indicated having some type of certification. Additionally, 4% have completed some other type of training.

Respondents' average age was 43 years old. More than half (61%) of respondents were female. Income data show 25% earn between $80,000–$100,000, while 62% earn $100,000 or more per year, with 13% earning more than $170,000. The average time worked per week was 43 hours. Respondents represented 12 states.

The majority of respondents indicated that they were satisfied with their work, with 48% indicating "extremely satisfied" and 48% indicating "somewhat satisfied." Thirty-nine percent of respondents said that they felt the work was "extremely challenging" and 61% indicated that they felt it was "somewhat challenging."

Insider's Perspective

What aspects of the job are most appealing?
Twenty-six percent of the respondents indicated that "flexibility in scheduling" was the most satisfying aspect of their work. This was followed by 17% who felt that interacting with colleagues was appealing. An additional 13% like the research perspective.
One respondent from North Carolina summed this up by stating the position is "research-based, fast-paced, in a multidisciplinary environment." Another respondent from Massachusetts liked "being involved with the government agencies and providing important research, in a timely manner, to potentially guide policy decisions."

A Colorado respondent enjoyed being in the "health care technology sector [because it is] a very challenging new environment [involving] cutting-edge product development."

What aspects of the job are least appealing?
No one specific item stood out for this group. Three issues all received 8% mention as least appealing: billing for time, length of hours worked, and no direct patient contact. A couple of respondents provided one word responses to the question of least appealing aspects of their practice. One Pennsylvania pharmacist simply stated "timeliness" as a concern while the other, from Florida, stated "travel."

What advice should students and practitioners consider when selecting the option of CRO pharmacist?
More than half (57%) of the respondents indicated that pharmacists should be flexible in looking at their career path. One respondent from Wisconsin stated, "Look and think outside the box." Another from Rhode Island indicated that it is important to "remain flexible, be positive, and maintain a personal and professional balance."

Critical Factor Ratings

Interaction With Patients

CRO pharmacists indicated that the lack of interactions with patients was one of the least appealing aspects of the job. The rating is in the low range of the scale.

= 2.5
σ = 1.7

Conducting Physical Assessments

This factor is the lowest rated factor by CRO pharmacists. At 1.3, respondents rarely conduct physical assessments. Those who work on phase III or IV of a trial may have access to assist with assessment activities.

= 1.3
σ = 1.4

Interpreting Laboratory Values

CRO pharmacists have a slightly better opportunity to spend some time interpreting laboratory values compared with the above factor. Again, this is dependent on the specific project that is being managed.

= 1.9
σ = 1.8

Continuity of Relationships

CRO pharmacists have the opportunity to get to know their sponsors and other health professionals on a personal level, especially when working on long-term projects. Some sponsors request specific CRO staff to work on projects because of previous experience. CRO pharmacists develop a working knowledge of the idiosyncrasies of their sponsors and the government requirements for a given therapeutic area.

= 3.9
σ = 3.4

Helping People

Not surprisingly, CRO pharmacists ranked this factor 2.6 showing that these pharmacists feel they have more of an indirect effect on the well-being of patients. In fact, some would say that the indirect effect in clinical research in the long run can directly impact other professionals interaction with patients by providing new discoveries brought to the market.

= 2.6

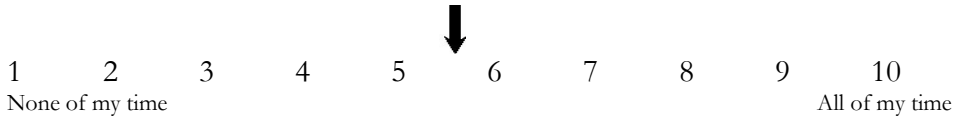
σ = 2.4

Collaboration With Other Professionals

Rated as a 5.6 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. A respondent from Minnesota indicated that "interactions with colleagues from a variety of professional backgrounds is important."

= 5.6

σ = 3.1



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.

= 4.6

σ = 2.7

Variety of Daily Activities

CRO pharmacists ranked this as tied for the second-highest factor in the survey for the group. 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. A respondent from Florida indicated that "there is diversity of work, flexibility, strategic thinking, and direction changes."

= 8.2

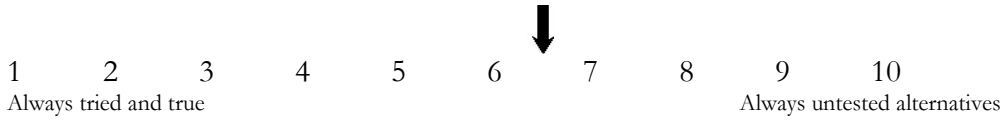
σ = 1.9

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.

= 7.2
σ = 2.8

Problem Solving
In the CRO setting, the problems encountered may or may not be overly complicated. With a rating of 6.5, 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.

= 6.5
σ = 1.6



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
σ = 2.2

Innovative Thinking
Respondents rated this factor in the upper range with a 7.8 response, indicating that their practice often requires innovative thinking. Opportunities for idea generating span the entire breadth of a project.

= 7.8
σ = 1.3

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.

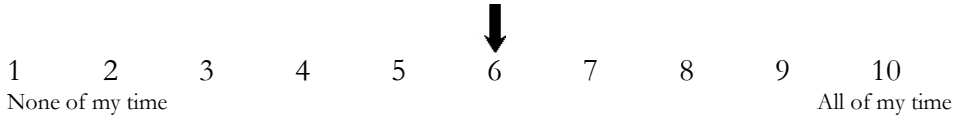
= 7.3
σ = 2.0

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

= 6.5
σ = 2.6

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.

= 6.0
σ = 3.3



Management/Supervision of Others
Management/supervision of others scored mid-range for CRO pharmacists at 4.7. 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.

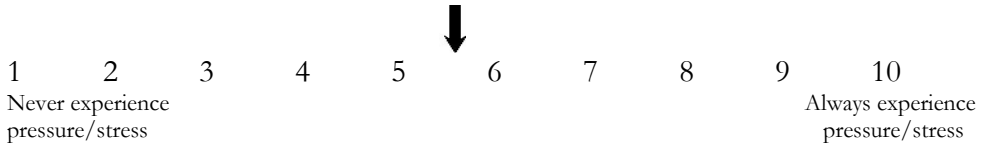
= 4.7
σ = 2.9

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.

= 3.7
σ = 3.0

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

= 5.6
σ = 2.4

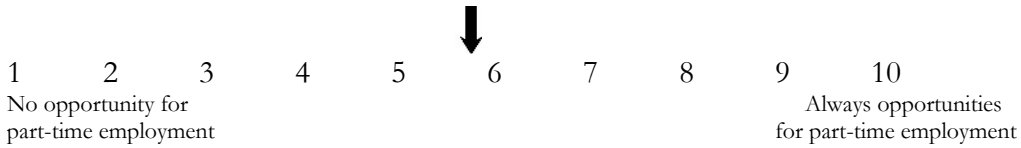


Work Schedule
The predictability of work schedule received a 6.4. Respondents indicated a mid-range response. This is somewhat dependent on the project and timelines.

= 6.4
σ = 2.6

Part-Time Opportunities
Receiving a mid-range rating in the survey at 5.8, 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.

= 5.8
σ = 3.6



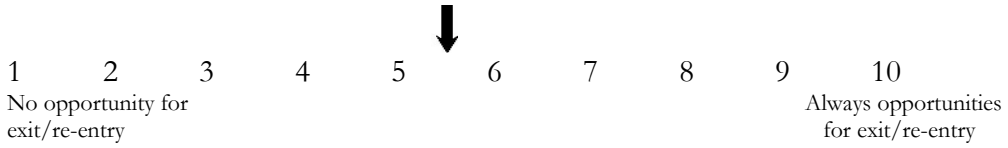
Job-Sharing Opportunities
Job-sharing received a low range response at 3.4.

= 3.4
σ = 3.0

Exit/Re-entry Opportunities

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

= 5.5
σ = 3.1



Parental Leave Opportunities

Parental leave opportunities ranked 8.3 in the areas of work-related options. This was tied for the highest rating of any critical factor by this group.

= 8.3
σ = 2.8

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.

= 7.3
σ = 2.5

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.

= 7.1
σ = 2.7

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.

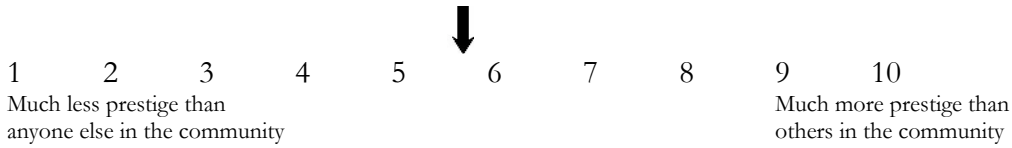
= 7.9
σ = 1.9

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 7.6.

= 7.6
σ = 2.4

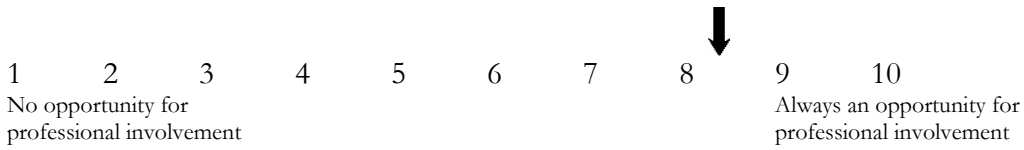
Community Prestige
CRO pharmacists fall mid-range regarding community prestige. CRO pharmacists themselves are not necessarily well known for the work that they do unless one is employed at the corporate headquarters.

= 5.7
σ = 2.3



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.

= 8.3
σ = 1.9



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.

= 7.7
σ = 2.1

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. This factor was rated the highest by this group of respondents.

= 7.7
σ = 2.9

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.

= 6.4
σ = 3.1

Autonomy
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.

= 8.0
σ = 0.8

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.

= 8.0

σ = 1.8

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.

= 7.0

σ = 1.9

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.

= 7.1

σ = 1.9

Unique Practice Environment

CROs tend to provide a unique practice environment for pharmacists. In fact, this factor tied as the second-highest rated factor by these respondents. The unique side is the diversity in projects and flexibility of the practice.

= 8.2

σ = 1.8

Advanced Degree

For the CRO pharmacist, an advanced degree can be required if the individual chooses to pursue management positions in the organization or specializes in a unique area. As stated earlier, 48% have some type of advanced degree with more than 60% having a residency, fellowship, or certificate training.

= 6.7
σ = 3.6

Entrepreneurial Opportunity

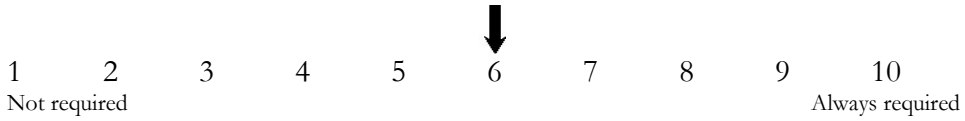
Entrepreneurial opportunity was rated mid-range for the respondents. This will differ tremendously based on the CRO itself. Start-up companies will provide greater opportunities than well-established corporations. However, even in the larger organizations, entrepreneurial opportunities do exist.

= 5.7
σ = 3.0

Additional Training

Surprisingly respondents were mid-range with the rating of this factor at a 6.0. Perhaps this is because many have advanced degrees. In addition, internal training may not be considered by the respondents as a needed additional training although many of the CROs have comprehensive training programs that all employees complete.

= 6.0
σ = 3.1



Interacting With Colleagues

As one would suspect, CRO pharmacists interact with coworkers on a daily basis.

= 7.9
σ = 1.9

Travel
CRO pharmacists, for the most part, have lower needs to travel for their day-to-day activities. Opportunities do exist to meet with sponsors, although with newer and more sophisticated telecommunications many meetings can take place from the office.

= 3.5
σ = 1.5

Writing
Respondents were in the upper mid-range regarding writing. Many projects require some type of written report. In addition, depending on how an organization processes billable hours, some writing may be involved with this process as well.

= 6.7
σ = 2.2

Working With Teams
Not surprisingly, respondents indicated that they have a tendency to work in teams. This reinforces the idea that drug discovery research and clinical trial activities are multifaceted, needing many skills and expertise from a variety of people.

= 7.7
σ = 1.9

"On Call"
Respondents indicated a low "on call" need for the positions. Specific project activities may require an "on call" status, but these are not commonplace.

= 2.2
σ = 2.6

Work on Holidays
Respondents rated this in the low-range because many corporations observe holidays and provide time off for employees.

= 2.0
σ = 1.6

Work on Weekends

Respondents indicated that they fall in the lower range on this factor.

= 2.5

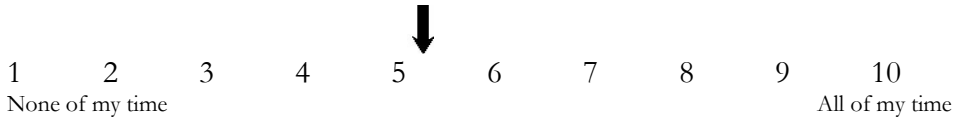
σ = 1.9

Presentations

Presentations ranked in the mid-range. There are times when presentations are made to sponsors and to other team members regarding the status of a given project. In addition, there is ample opportunity to work with a school of pharmacy and present information about specific aspects of both the drug discovery and clinical trial processes.

= 5.2

σ = 2.1



Mean Scores for Critical Factors

1. Interaction With Patients	2.5
2. Conducting Physical Assessments	1.3
3. Interpreting Laboratory Values	1.9
4. Continuity of Relationships	3.9
5. Helping People	2.6
6. Collaboration With Other Professionals	5.6
7. Educating Other Professionals	4.6
8. Variety of Daily Activities	8.2
9. Multiple Task Handling	7.2
10. Problem Solving	6.5
11. Focus of Expertise	6.3
12. Innovative Thinking	7.8
13. Applying Scientific Knowledge	7.3
14. Applying Medical Knowledge	6.5
15. Creating New Knowledge by Conducting Research	6.0
16. Management/Supervision of Others	4.7
17. Management/Supervision of a Business	3.7
18. Pressure/Stress	5.6
19. Work Schedule	6.4
20. Part-Time Opportunities	5.8
21. Job-Sharing Opportunities	3.4
22. Exit/Re-entry Opportunities	5.5
23. Parental Leave Opportunities	8.3
24. Leisure/Family Time	7.3
25. Job Security	7.1
26. Opportunities for Advancement	7.9
27. Opportunities for Leadership Development	7.6
28. Community Prestige	5.7
29. Professional Involvement	8.3
30. Income	7.7
31. Benefits (vacation, health, retirement)	7.7
32. Geographic Location	6.4
33. Autonomy	8.0
34. Self-Worth	8.0
35. Future Focus	7.0
36. Professional Prestige	7.1
37. Unique Practice Environment	8.2
38. Advanced Degree	6.7
39. Entrepreneurial Opportunity	5.7
40. Additional Training	6.0
41. Interacting With Colleagues	7.9
42. Travel	3.5
43. Writing	6.7
44. Working With Teams	7.7
45. "On Call"	2.2
46. Work on Holidays	2.0
47. Work on Weekends	2.5
48. Presentations	5.2

Reference

Schommer JC, Brown LM, Sogol EM. *Career Pathway Evaluation Program 2007 Pharmacist Profile Survey*. June 2007.

Professional Organizations

American Pharmacists Association (APhA)
1100 15th Street NW, Suite 400, Washington, DC 20005
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

NOTE: For further pharmacy organization information, please visit the American Association of Colleges of Pharmacy Web site at www.aacp.org and click on the "Related Pharmacy Organizations" link.