OUTSOURCING WITH CRO's

Flow Cytometry and Beyond

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Introduction

Scientists across sectors are feeling the eroding effects of tight budgets and shrinking staff. For many, this has meant managing burdensome workloads and making difficult decisions about the scope and size of research projects and clinical trials. Outsourcing is a broad term that describes business agreements in which services are contracted out to an independent business or service provider, but the term outsourcing is not always associated with positive images. Many scientists in the pharmaceutical and biotechnology sectors are coming to recognize outsourcing as an asset as contract research organizations (CROs) step in and provide critical technical and scientific expertise for these research sectors.

What are CROs?

CROs provide services across the biomedical research landscape, including animal models, assay development and validation, toxicological and safety services, drug discovery, diagnostics, genomics, clinical study support, and biologics production. CROs vary in size and expertise, with some larger CROs offering a wide variety of general services, and smaller boutique CROs specializing in technically demanding areas like flow cytometry and cell sorting. CROs are typically located near hubs of biomedical or pharmaceutical research, and this proximity can be a critical factor for scientists needing research support for highly perishable samples.

CROs are becoming a critical part of the research infrastructure, and scientists in academia, biotech, and the pharmaceutical industry are becoming more comfortable working with CROs. This surge in demand has resulted in a flood of CROs into the marketplace. Scientists are now confronted with the challenge of finding trustworthy CROs that can perform specific services within a reasonable time frame, price point and provide high quality and reliable results.

This guide provides a resource for scientists interested in identifying and working with CROs that are well suited to the scientific services being sought. The guide also presents essential information about forming successful scientist-CRO partnerships and incorporating CRO services into long-term research endeavors.

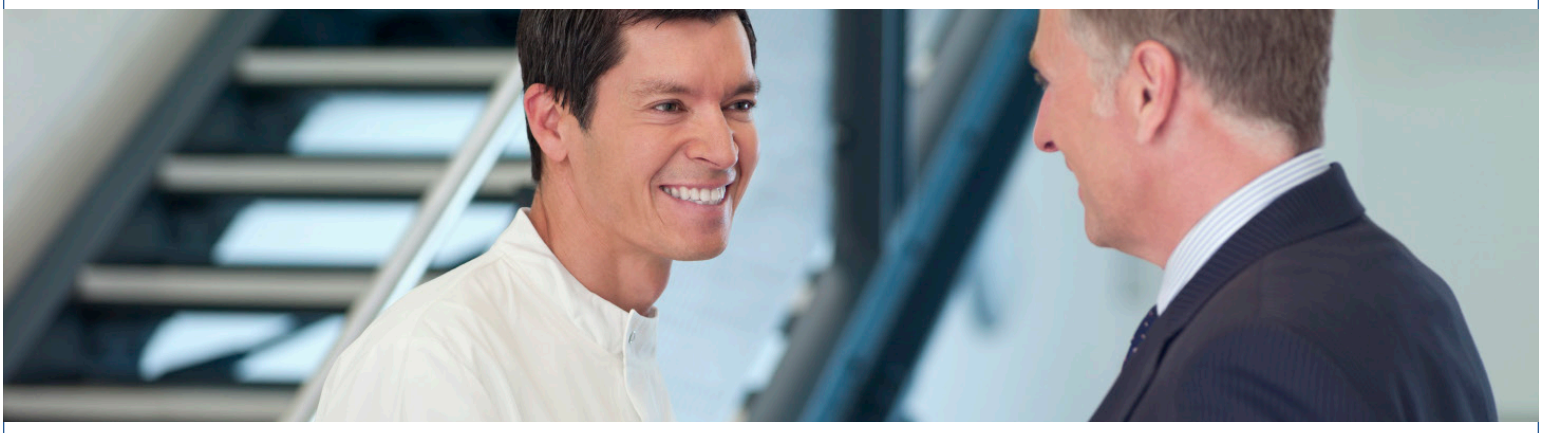
Considerations for Finding a Potential CRO

Most researchers have some awareness of CROs. You may know of colleagues who work with CROs, or you may have acquaintances who have taken jobs in CROs after leaving positions in academia or the pharmaceutical industry. Nonetheless, you may be uncomfortable with the idea of handing off your precious clinical samples to a CRO, or you may think using a CRO is not a cost effective option.

You must first recognize that not all CROs are created equal. In the case of flow cytometry CROs, some organizations are dedicated specifically to flow cytometry services while others offer flow cytometry as an option from a menu of broad services including sequencing, antibody purification, and mass spectrometry.

If you are intrigued by the idea of contracting a CRO for flow cytometry work, consider these five items to help you make a confident and well-informed decision.

1. Due Diligence — As a potential CRO customer, you must take the time to research CROs. Talk to colleagues and find out who else in your scientific community uses CROs. Scientific meetings are another way to discover and interact with CROs. Get customer references from CROs and contact the



references to learn more about their contracting experiences. You may even find scientists who have used specific CROs by conducting literature searches using the CRO name as a search criteria. The more time you spend talking to other scientists who have used a given CRO, the more informed you will be about the quality and reliability of the organization.

2. Respect — An outstanding flow cytometry CRO should be a respected business with an impeccable reputation. Research the history of the company, and look for success metrics like awards and recognition from the scientific and CRO communities. Trade publications and websites also profile CROs and can give you more information about how an organization is managed. CROs with a strong scientific record may feature research publications to which they have contributed data. Consider which factors are good indicators of the CRO's reputation.

3. Expertise — Successful CROs take pride in hiring and retaining experienced scientists and technicians with strong research backgrounds and years of technical expertise. Seek out this information from a prospective CRO and decide for yourself if you feel comfortable working with these scientists. Working with a CRO is like collaborating with another lab in some ways. You should take the time to research your potential research partners in the same manner as you would for a collaboration.

4. Location and logistics — Convenience and proximity may be an important factor if you need to hand off fresh samples as soon as possible to a CRO for flow cytometry analysis. In contrast, you may be accumulating a collection of samples over several months from a single trial, and you'll need your CRO to take on this shipment and storage of these samples until they can be run together. Whether you need your CRO to process and stain samples quickly or store them long term, take all these factors into consideration when weighing the importance of a CRO's location.

5. Nimbleness — Is a potential CRO ready to take on new customers? Can the CRO scale up your staining protocol to handle hundreds of samples at a time? Make sure to speak with someone at a CRO that can give you a realistic perspective of the CROs capabilities. Nimble and well-managed CROs can take on new customers within a relatively short period of time, whereas less experienced or larger CROs may place customers on a wait list for several weeks or months. Gaining insight into a CRO's workload capacity is a strong indicator of how the CRO runs its operations.

Taking the Next Steps

You have spoken with colleagues and exchanged emails with CRO representatives. Now you are ready to seriously consider working with a CRO to manage and run all the flow cytometry assays for your next big clinical trial. You may still feel apprehensive about entrusting your valuable samples to these new hands. How do you safeguard your research and develop a productive relationship with your CRO?

Think about these 5 P's to make the most out of your new CRO partnership

Prepare. Selecting the right CRO takes time and due diligence. Preliminary research may help you narrow down your options to two or three potential CROs, but you may need to spend further time meeting with these contenders to decide which organization can handle your project. You may want to meet with a CRO scientist in person to gauge their expertise and comfort level with your assays. You will probably want to know what instruments they use and how they monitor the function of their cytometers. As a potential customer, you should feel comfortable requesting as much information as you deem necessary to make an informed decision about a CRO.

Plan Everything. Communication is the bedrock of a successful relationship with a CRO and this begins when you explain your assay needs and determine if the CRO will need time for assay development. The success of your work with a CRO begins with your effort to describe your protocols and research plans in explicit detail. Seemingly trivial details, like the types of buffers used or the sources of fluorescent antibodies could prove to be essential to the completion of your flow cytometry request. Scheduling details also assure that a CRO can be properly staffed to handle your samples at the correct time points. Details matter so no one is confused, frustrated or disappointed

Taking the Next Steps

Point of Contact. You will be exchanging large amounts of information with the CRO, and this two-way relationship is most successful when you have an open line of communication with a person responsible for managing your project within the CRO. You should identify your key contact person as soon as possible. Make sure you are comfortable working with this person and invest time in building this relationship. Spend time understanding the role of other CRO team members working on your project. This is critical especially when unexpected results arise and you want to have a fruitful discussion about such issues.

Pick a Time and Problem Solve. You should schedule a regular meeting time with the CRO team to discuss progress, look at data, and troubleshoot issues that may arise. This type of meeting may happen in person, by web conference, or over the phone. Regular meetings help keep everyone in the loop and prevent problems from languishing for weeks. These meetings are also helpful for understanding the workflow of your project at the CRO and how changes in your research plans can be adapted to by the CRO team. Projects rarely go exactly as planned, but both you and the CRO team will feel more in control of the project through regular communication.

Praise. Good CROs invest significant capital and time into building high quality operations staffed with experienced scientists and technicians and run under the strictest standards. CROs can only continue offering their superior services if the research community and pharmaceutical industry supports them. If you have a great experience with your CRO, spread the word, and give credit where credit is due.

You may consider a CRO as a reasonable option for short term service requests, like a basic immunophenotyping assay or a toxicology analysis. If you are satisfied with your experiences with a CRO for these one-time services, you should consider how a CRO could bolster your lab's research productivity for larger, long term projects. CROs can help you realize your vision to perform translational studies that assess the clinical potential of your preliminary results. CROs are also well-suited for all levels of clinical trials and are well-versed in the regulatory processes involved in such studies.

What should you consider if you want to transform your relationship with a CRO from being just a service provider to a research partner? Think about your long-term research needs and start discussing your plans with your CRO. You can tap into the wealth of experience that CROs have on the clinical and regulatory fronts, and you can realize new research goals that may have seemed unattainable.

1. What are your long term needs?

Do you need to develop a set of novel assays and have them validated for clinical use? Are you then planning to use these validated assays for a series of clinical studies? A

CRO is an efficient and effective partner for these needs and provide critical research planning and regulatory guidance throughout the duration of your research study. CROs also excel at project management and can work with you on developing a reasonable time line for all the elements of your project.

2. Do you need technical expertise without the headaches of a collaboration?

Research collaborations can be mutually beneficial arrangements under the right conditions. Unfortunately, collaborations usually result in unequal divisions of labor and tenuous negotiations for authorship on research papers. How can you avoid these pitfalls? Partnering with a CRO can offer you many of the rewards of a research collaboration with the added benefit of having a formal business arrangement between you and the CRO that spells out the nitty gritty details of who does what and who gets credit for the work. CROs are also eager to expand the scope of their technical expertise and will want to work with you to develop or adapt novel assays like mass cytometry.

3. Do you need to assure that your assays are reproducible?

Experimental reproducibility is becoming an issue of major concern in the biomedical research community. Some researchers of high impact papers are now being asked to cooperate with reproducibility efforts that target their key findings. In your own lab, you may have worked tirelessly on developing a novel assay that could be of great use to the research community, but you fear that the assay results may not be reproduced in another scientist's hands. A CRO is a powerful partner for backing up your research labors and working out the details of an assay in such a way to assure reproducibility through the development of a robust protocol. CROs develop clearly written protocols that include numerous controls and account for a multitude of experimental variables. Rather than thinking of a CRO as a service provider, consider their expertise in assay development and validation and let them help you make a robust assay protocol.

Realize Your Potential

This guide provides you with compelling reasons to consider working with a CRO to improve your research productivity and realize new goals. CROs are becoming formidable research partners for scientists across sectors and are transforming how large projects are developed and carried out.

Take time to think about how a CRO can help you work toward goals that you may have considered overwhelming or even impossible. With a CRO, your research potential can reach new heights.

Quantifying Biological Response
Through Cytometry