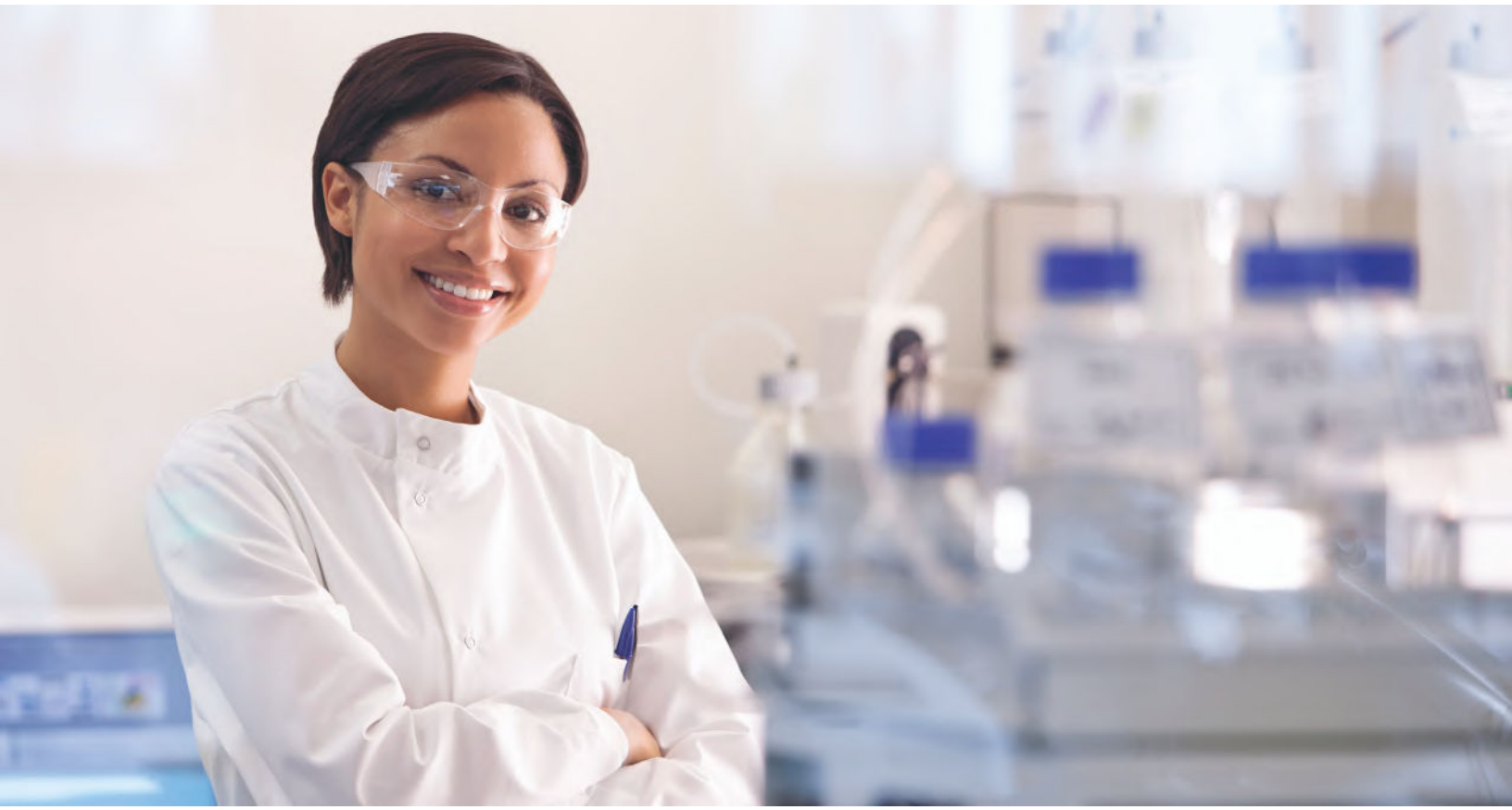
CONFIDENTLY CHOOSE A CRO TO **SUPPORT YOUR IND EFFORTS**

AT QPS WE BELIEVE IN DEVELOPING CLOSE AND LONG-LASTING RELATIONSHIPS WITH OUR CLIENTS ON THE BASIS OF TRUST AND MUTUAL RESPECT.

This mutual trust, combined with the agile approach we offer as a specialty CRO, helps improve the quality of your outsourced clinical work and reduces the degree of required oversight.



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3 SIMPLE TIPS FOR FINDING A CRO WITH IND APPLICATION KNOWLEDGE

The U.S. Food and Drug Administration (FDA) reports having received a higher number of applications for investigational new drugs (INDs) in the past few years. Only a handful of years ago, the number of IND applications received annually was hovering in the 300-400 range. Yet, in the 2018 fiscal year, the FDA received 675 IND applications. And 487 applications were submitted in just the first three quarters of 2019. This rise in IND applications is part of a trend of growing biotech investment that is boosting drug discovery and development around the globe.

Asia, in particular, has demonstrated a spike in funding. As a result, this region has quickly become a center for biotech and pharmaceutical research. According to Pharma Intelligence, nearly one-quarter (23.6%) of the world's pharmaceutical companies are now in Asia. Additionally, Market Research Future has predicted that the preclinical CRO market in Asia will see significant growth in the near future.

Biotech and pharmaceutical companies know that the stakes are high when picking a CRO partner. Therefore, sponsors need to thoroughly vet CRO candidates to ensure they will be able to provide support through preclinical testing and into Phase I and beyond. Biotech and pharmaceutical companies that want to feel confident in their CRO choice can do the following as they evaluate candidates.

1. ASK CRO CANDIDATES IF THEY OFFER A FORMAL IND PACKAGE

Preparing and filing an IND application with the FDA is a complex process. The more experience a CRO has with IND applications, the better equipped it will be to execute a strategic preclinical program and put together a thorough and professional assessment of a drug candidate. Because experience and know-how is so important, sponsors should look for a CRO partner that offers a formal IND package. Questioning prospective CROs about their IND offerings will provide insights about how routinely a CRO completes IND applications and if this service is truly in a CRO's wheelhouse.

As part of an IND application, sponsors must report on their drug's preclinical studies. Ideally, a sponsor will be able to work with a single CRO that can design, execute and perform all necessary studies. Working with one CRO, rather than multiple CROs, is preferable because it creates continuity during research studies. An experienced CRO with a formal IND offering should be able to navigate FDA preclinical study guidelines and handle all aspects of the process fluidly.

2. INTERVIEW THE RESEARCH TEAM AND LOOK FOR SCIENTISTS WITH A BROAD RANGE OF PRECLINICAL EXPERTISE

In order to complete the necessary safety evaluation for an IND application, studies in the following areas might need to be completed: genetic toxicology, general toxicology, safety pharmacology and reproductive toxicology. Conducting these safety tests requires a diverse team of skilled scientists. CRO candidates should have experienced in-house technicians, veterinarians, toxicologists, clinical pharmacologists and U.S. board-certified pathologists to carry out all safety testing. Vetting a CRO should involve interviewing the research team to learn about their qualifications, experience and processes.

From a researcher's perspective, part of preparing for an IND filing involves asking safety-driven questions and considering how a drug might be used in humans. A trained research team will be able to explain the processes they will use as they look to answer questions about a drug's dosing in humans or how long and how frequently it can be safely used.

Another research-related point to consider is that both *in vitro* and *in vivo* testing are required when filing an IND application. Typically, general toxicology studies will need to be performed in two species prior to moving to dosing humans. Together, it is important to look for a CRO with *in vitro* and *in vivo* testing as well as to access to animal models of multiple species.

With the high costs incurred in designing and carrying out preclinical tests, it is important to fully trust the expertise of the team performing the scientific research before making a sizeable investment in drug research and development.

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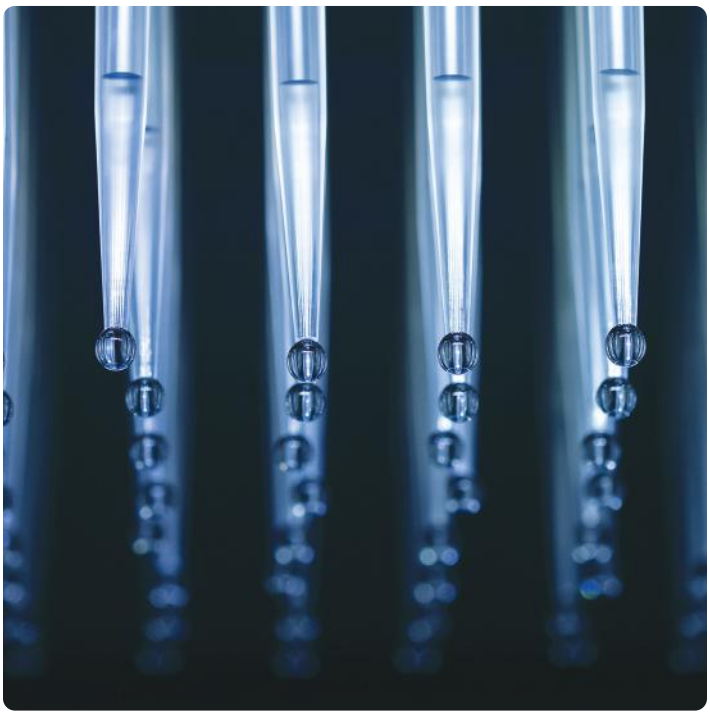
3. GIVE PREFERENCE TO FULL-SERVICE CANDIDATES WITH A GLOBAL PRESENCE

By choosing a full-service CRO with global capabilities it not only ensures mobility and opportunities to conduct testing in multiple locations, it also makes it easier to comply with quality standards set by the China FDA, Taiwan FDA, US FDA, and EMA for registration. For these reasons, any short-listed candidates should be global CROs.

Consider the benefits of doing preclinical work in one location and then having the ability to conduct clinical trials in other parts of the world. For starters, there is the potential for saving money. Opening an IND in the U.S. comes with an upfront fee and high research expenses. However, in other areas, the process is often quicker and less expensive. Exploring opportunities for conducting early research outside of the U.S. can lower costs. Of course, not only is there a possibility for cost saving, but having freedom to conduct research in more than one location will allow trials to be carried out in areas where patients are readily accessible. For example, a global CRO partner may be able to conduct cost-effective preclinical testing in Asia and then move clinical trials to the United States in order to have access to patients with specific disease indications. The point is, transferring from one location to another at different stages of research can be advantageous. But it requires a CRO that has global capabilities and can support the seamless transfer of knowledge within its organization. Therefore, when vetting CRO candidates, preference should go to full-service candidates with a global presence.

There is a promising future ahead for drug discovery and development worldwide. CROs will continue to be an integral part of new drug research and development around the world. With many options available, the importance of vetting and choosing the right CRO – one with preclinical expertise and facilities for an IND application – is becoming increasingly important. Sponsors should expect that part of a CRO's qualifications include having a formal IND service offering, a senior team of scientists and a global presence. Abiding by these standards can lead to a more fruitful partnership and help make it easier to advance promising compounds into new drugs approved for patients.



QPS IS COMMITTED TO WORKING WITH YOU

QPS has extensive experience in supporting drug development. We understand the complexities, particularly with respect to managing and conducting global clinical trials, proper bioanalysis, and monitoring the pharmacokinetics of drug candidates. We are committed to working with you personally to advance your product for the benefit of patients worldwide.

BROAD ACCESS

QPS provides clients with broad access to our preclinical and clinical development capabilities. Clients also benefit from our experience in preclinical and clinical development of a diverse portfolio of treatment modalities for a wide range of indications. Our preferred vendor agreements also provide for the establishment of client-dedicated units within our organization.

TIMELY DELIVERY

Partnering with QPS will position your company for success, enabling timely, personalized delivery of your drug candidate portfolio to the marketplace.

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TIME IS OF THE ESSENCE IN DRUG DEVELOPMENT. CONTACT THE QPS BUSINESS DEVELOPMENT TEAM TODAY!

Call +1 512 350 2827 Email infobd@qps.com

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