

Analytical Testing Labs



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Analytical Testing Laboratories: Adapting & Responding to the Current Business Climate

By: Cindy H. Dubin, Contributor

Today's economic downturn has led to a reduction in funding for early stage projects. However, significant growth in outsourcing throughout the past several years means it is unlikely that biopharmaceutical companies will cut back on outsourcing non-core capabilities, such as analytical testing. Contract laboratories are significantly increasing these capabilities to better serve biopharmaceutical companies as they continue to seek ways to reduce cost, optimize speed, and increase the flexibility of their research and development programs.

Based on these biopharmaceutical objectives, total spending on contract analytical services is \$9.3 billion annually, distributed evenly across process/formulation development, analytical development and testing, and the manufacture of clinical trial materials, according to PharmSource.

In addition, more companies are moving their work out of the United States and into China, India, and Europe

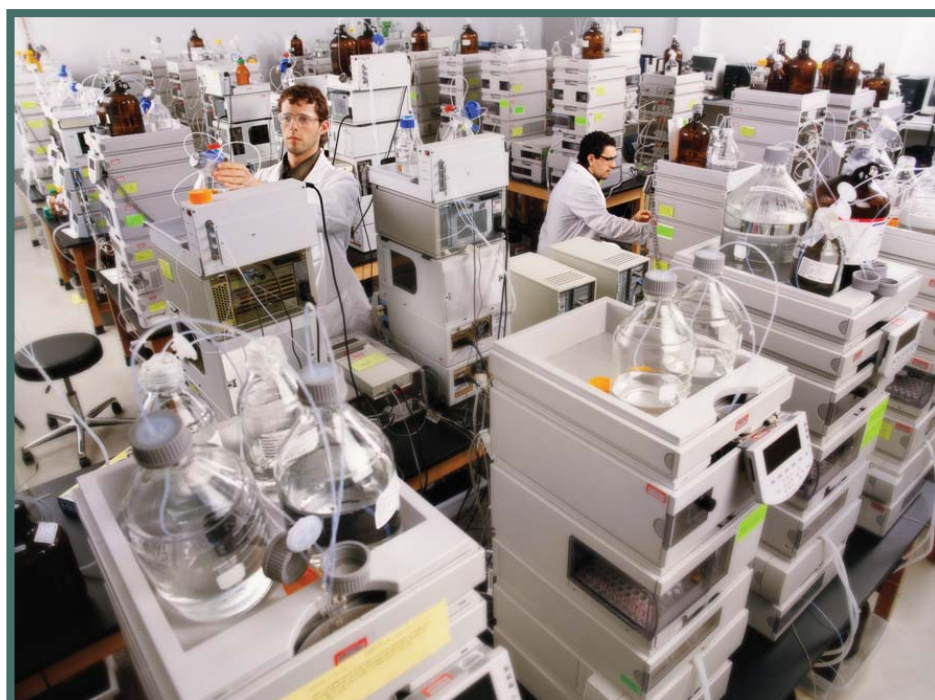


Figure 1. PPD cGMP laboratories have more than 230 high-performance liquid chromatography (HPLC) instruments to provide analytical capabilities such as method development, validation, stability and QC testing for clients.

as biotech and pharmaceutical companies fight the effects of today's economic recession. It is expected that the global CRO market will grow 14% per year over the next 3 years, making global contract research a \$35-billion industry by 2013, according to Business Insights.

"The growth of the European CRO market is expected to be spurred by the need for pharmaceutical and biotech companies to control costs and accelerate product development," says Frost & Sullivan Industry Analyst Ranjith Gopinathan. "From early drug discovery

through post-launch services, pharmaceutical companies are moving their non-core functions to external providers,” he adds.

As a result, PPD, one of the leading global contract research organizations, is extending its presence in Europe by expanding its analytical testing services. Just two years ago, PPD acquired AbCRO, a European contract research firm offering Phase II-IV clinical services, to penetrate key Central and Eastern European markets. Additionally, PPD just opened a contract research facility in Athlone, Ireland. According to Magdalena Mejillano, PhD, Vice President of cGMP laboratory services for PPD, the facility expands the company’s global scientific expertise, laboratory capacity, and supplies network to meet growing client demand in Europe, the Middle East, and Africa. The 18,000-square-foot analytical testing laboratory and clinical supplies business will conduct testing and release of clinical and marketed products spanning all phases of drug development.

PPD has already hired 21 employees in Athlone and plans to create approximately 250 jobs at the facility to include PhD-level scientists, analytical laboratory staff, and other clinical development professionals. The company is investing up to \$19 million to develop the 35,000-square-foot campus.

To date, PPD has applied to the Irish Medicines Board (IMB) for manufacturer licenses to support both investigational medicinal products and marketed products and laboratory

certifications for quality control of medicinal products. As of March 1, PPD’s license applications have been assessed, and the quality system and premises inspected by the IMB.

Specialty Pharma magazine recently spoke with Dr. Mejillano about the future plans for the Athlone lab, the specific services it offers to US- and European-based companies, and the advantages of conducting business in Ireland.

Q: *In today’s economic environment, what trends are you seeing in analytical testing?*

A: We are seeing an increasingly competitive environment given today’s economic times, and the restructuring of pharmaceutical companies is impacting outsourcing decisions, which has delayed some projects. These changes are making analytical testing providers like PPD rethink how we can best adapt and respond to the challenging business climate. One of the primary reasons for opening our Ireland-based lab was to increase our flexibility to meet the changing needs of our clients more effectively. Outsourcing for laboratory services remains strong, and once pharma completes its restructuring, we are optimistic that outsourcing will pick up again. When that happens, we believe we are well positioned to deliver a full range of analytical testing services to our clients throughout the US and Europe.

Table 1. Global spending on analytical development and testing for large-molecule drug substances by analytical activity (US millions).

Batch Release	\$103
Stability	\$84
Methods	\$134
Viral Clearance	\$98
Microbiology	\$11
Characterization	\$221
Raw Materials	\$122

Source: PharmSource Information Services, Inc., The Market for Contract Analytical and Development Services, 2009.

Q: *What made Ireland enticing to PPD?*

A: Our decision to establish operations in Ireland was driven by several factors. First, this location creates an opportunity to offer the advantages of geographic proximity to our clients in Europe and bring streamlined program management and study oversight and ease of sample shipments. Second, European regulations require that companies looking to market products in Europe have to perform release testing at a European-based analytical lab. In addition, we needed a stronger presence outside the US to better service our growing client base in Europe and the Middle East. Finally, Ireland offers very attractive business incentives and a highly skilled, educated workforce to support our recruitment efforts. Many pharmaceutical and biotech companies have also located operations in Ireland, which creates a strong pool of potential clients for us.

Q: *What challenges and/or obstacles do you face in establishing this lab and carrying out work there?*

A: One of the challenges in establishing our Ireland lab is to make sure we have aligned our capabilities and services with what our clients are looking for. We need to maintain a certain level of flexibility in our business plan, which means we may need to accelerate offering services that were originally planned for later this year to respond to market demand and client needs. Another challenge is making sure that business opportunities are additive to what exists in the United States and our labs do not compete for the same business.

Q: *What services will the Athlone lab offer?*

A: We will offer fully integrated product and analytical development services, including method development; validation; stability, release, and quality control testing, for small and large molecules with an emphasis on inhalation products. One of our business strengths is inhalation product testing for nebulizers, nasal sprays, metered dose inhalers, and dry powder inhalers. In addition, we will also provide cGMP global clinical supplies services, including secondary packing, labeling, storage, and distribution, as well as regulatory consulting, product licensing and marketed product support, and qualified person services.

One of our near-term plans is to

establish large-molecule services for biopharmaceutical clients. Large-molecule testing is a relatively untapped and rapidly emerging business opportunity, and we have now accelerated its implementation based on client needs. In addition, we are actively assessing other client requests for various services like raw materials testing, impurity identification, and extractables and leachables.

Q: *What makes the PPD lab unique compared to others in that region?*

A: There are a handful of analytical contract labs in Ireland, mainly smaller niche facilities. PPD is unique in that we will offer small- and large-molecule testing capabilities, including inhaled products. In addition, we will provide integrated services for clinical and commercial product release testing, Qualified Person (QP) release, and a logistics center for distribution of these supplies in one location. PPD also offers the advantage of having a strong corporate presence in Europe with a global infrastructure for CMC regulatory support and clinical programs.

Q: *What are your long-term objectives for the Athlone lab?*

A: It depends on the market demand and client requirements. We will grow as the market dictates and add capabilities as our clients need them. We are optimistic the Athlone facility will enable us to capture additional market

share from European, Asian, and Middle Eastern companies needing to market their products in Europe, as well as US-based companies seeking to commercialize their products in this region.

Q: *What is the one mistake PPD must avoid as it moves forward in Athlone?*

A: We must avoid not calibrating our pricing according to what the market can bear. We are still trying to understand the competitive nature of the contract laboratory industry in Europe, the cost structure of our Ireland lab, and how to strike the right balance between being competitive while maintaining operating margins.

Q: *What do you specifically want the Specialty Pharma audience to know about the lab?*

A: The laboratory in Ireland is an extension of our US lab in terms of small- and large-molecule testing. We will take full advantage of our technical expertise and experience we have built for almost 20 years and continue to provide high-quality data and service to our clients. The Ireland lab is part of our near- and long-term vision to create “one lab, multiple locations,” wherein we can offer our clients the flexibility of using any or all of our labs operating under the same systems, processes, operating procedures, and culture. ♦