

EXPERT OPINION IN BIOANALYSIS

How CROs can gain a Competitive Advantage in the Bioanalysis Market



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Introduction

Today's bioanalysis outsourcing market is growing rapidly and, as CROs grow and evolve to meet market needs and market challenges, they also need to consider how they can offer additional value to their sponsors in the face of increased competition.

Effective CROs are adapting their offerings to meet the growing biologics space, whilst optimizing their processes to be more efficient in delivering timely methods, audits, and results to sponsors whilst adhering to the regulatory expectations. Making your teams more effective enables you do to much more work with the same resources and frees up employees to support emerging techniques - and this is all possible through the adoption of process control through software, such as LES (Lab Execution Systems) and ELN (Electronic Laboratory Notebook) systems.

A little background history

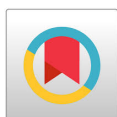
In the 1990s through to the early 2000s the vast majority of bioanalysis was being performed on small molecule drugs and the adoption of liquid chromatography-mass spectrometry (LC-MS) was the main impact on the field. The barrier to entry for a CRO was relatively low and those with an LC-MS capability could provide a viable commercial offering to the marketplace, so long as they had the right relationships with pharmaceutical clients and could prove the ability to deliver reliable results. CROs were small, niche and had only captured a small percentage of the total bioanalysis market.

Today's market

Fast forward to today and the majority of regulated bioanalysis is outsourced. The global bioanalytical services market is anticipated to reach USD 3bn by 2025 [1], with some estimates showing growth of 10-15% over the same period [2].

The rich mid-late stage pipelines of biologics, coupled with steady small molecule pipelines, is behind much of this expected growth. 2017 saw the highest number of new drugs approved to date and market forecasts show a 10% growth in revenue from biologics, which is the result of a strong late stage biologics pipeline.

The Pharma R&D Annual Review (2017) [3] shows that the overall pharmaceutical pipeline is at its largest with 2017 having over 14,000 pipeline projects, that is up over 8% on the previous year. Over 7,400 of that pipeline is in preclinical and over 2,000 are in Phase 1 clinical trials, up 11 percent on 2016. There are now more organizations to work with, with over 4,000 pharma organizations reporting active



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pipelines, which is an 8.6% increase on 2016 [3].

The key takeaway from all these numbers and percentages is that there is a greater than ever need for bioanalysis and the trend is likely to provide even more projects for CROs between now and 2020. So, how can CROs gain an advantage in this competitive, and growing, market?

China

Now the world's second largest economy, China is a market with great potential for pharma. However Chinese regulators often require Phase 1 trials against a Chinese population, even for drugs approved in other markets. This means bioanalytical testing in China is growing rapidly to support clinical trials for existing western therapies, new entities and the Chinese medicine market.

Unsurprisingly over the last ten years the Chinese bioanalysis market has grown rapidly with local CROs, affiliated laboratories and international CROs all now delivering services to the Chinese and international marketplaces. To address the concern over maintaining quality standards, the China Food and Drug Administration (CFDA) has overhauled its regulations and announced a comprehensive submission inspection framework and a new self-inspection requirement which permits sponsors to withdraw any submissions if data integrity or compliance issues are found.

Chinese bioanalysis services are now arriving at an international standard and if the pace of regulations is maintained, with much-needed improvements to sample shipping and import rules, then we should expect to see a rise in China-based bioanalytical CROs operating on the open market.

Regulations

After years of emphasis on how to apply regulations to this sector, there seems to be a mature consensus in well-established western markets on how to apply these to promote confidence in results, processes and data accuracy. This means that CROs have a pattern to follow which can include the tools and processes used in labs to drive the workflow and data analysis from method development to final report. How mature processes are in this space and how efficient an organization is at implementing and executing them can be a valuable differentiator for customers looking for efficient turnaround times and low-risk partners. Sponsors now have an expectation that, as a minimum, their partner CROs can demonstrate that they will conduct bioanalysis to the same standards and regulations as they can do in-house.

Regulators have a good handle on how to validate both paper-based and electronic data, with recent discussions at WRIB 2017 were held on just this topic. Even the most rudimentary paper-based workflows need software systems to control LC-MS systems, or to process chromatography data. Implementing new electronic workflows are only extending coverage of current validations, whilst removing the manual paper-based elements.

Evolve and improve

We have established that business development teams at bioanalytical CROs have a rich market to win business in, but the competition is strong and a business needs clear differentiators.

Sponsors are comparing CROs with the competition and the following areas feature prominently:

- Analytical resources
- Assay development expertise
- Biomarker capabilities
- Flexibility in reporting
- Geographic coverage
- Innovative pricing
- Low costs

- Method development turnaround time
- On-time delivery of results
- Communication
- Technical expertise

Increasing capabilities

The industry is responding to the growth of bioanalytical testing of large molecules by offering new services to supplement current capabilities. New techniques, such as ligand binding assays, flow cytometry, and immunoaffinity assays, are now supporting biologics projects. The adoption of new systems such as high-resolution mass spectrometry, micro-flow LC-MS and nanoflow LC-MS systems to increase selectivity and sensitivity of experimental analysis are becoming ever more important to support biologics and biosimilar projects. This means more techniques for CROs to learn, develop against, and support. When you couple the increased complexity of the services being offered and the volume of studies being requested, you can quickly arrive to the conclusion that you need to grow your organization to deliver these capabilities. New bioanalytical labs and facilities, populated by more employees are appearing each year, newly enlarged organizations then generate more internal work, management, overheads and operational costs. Attracting the right talent to these labs and running these assays is an industry challenge. Today's bioanalytical scientists expect to have an organization that can support their role with training and programs that go beyond on-the-job, in-the-lab training, and with mature software and processes that help them to be efficient and effective in their role. However, increasing headcount and instrumentation on its own is not the answer.

Be more efficient

Scaling to meet demand builds new inefficiencies on top of existing issues within an organization. A must is to maintain the quality of results and the processes delivering them. As teams grow, the number of projects delivered also increases, and it becomes harder than ever for a QA department to find deviations from the method, investigate and report. As you scale, rework increases, continuing the waste and slowing down a CRO's ability to deliver more with existing resources.

A good indication of a problem is that you are having to handle unbillable rework or have been required to grow the size of the QA and Project Management teams supporting bioanalysis. It doesn't need to be this way, and mature bioanalysis CROs are implementing ELN and LES systems to ensure that methods are followed, deviations tracked and report generation can be achieved with fewer resources and quicker than before.

Business analysis we've had done with bioanalysis CROs has shown some startling statistics. Below are some anonymized examples (see if you can find your own organization in here).

North American CRO

Spends 21,500 hours a year managing their paper-based processes, requiring a dedicated team of 12 analysts to manage it and a dedicated QA team to review every paper record to find deviations, taking days to locate records for regulatory audits.

North American Multinational CRO (just one site)

Runs over 400 studies a year processing 300,000-400,000 samples a year. They spend over 214,000 hours a year managing their paper processes, with 124 analysts and a dedicated QA team and again taking days or weeks to locate records for audits.

Canadian CRO

Runs over 300 studies a year. They spend over 120,000 hours managing paper processes. Loses over \$1m in revenue annually due to retests, and \$740,000 a month due to lost productivity.

How software can have an impact

It is therefore unsurprising that the adoption of tools such as ELNs [4] and LES is now happening at pace within the bioanalysis industry, mirroring the adoption of tools and working practices that are typical at sponsor pharma and biotech organizations. On average systems such as these can add 33% extra capacity to the CRO, free up analysts for more important top-line work and can reduce the reporting time for audits to just minutes. When selecting an ELN or LES solution it is important to consider selecting a tool that makes it easy for regulators to review. This means consistent ways of producing items such as exception reports and system audit logs. This goes beyond a generic ELN offering towards a dedicated bioanalysis solution which provides workflows such as this out of the box.

A bioanalysis solution can provide tools to aid with method development, method execution, QA reporting, equipment validation, sample management and study report generation. They are designed to improve the time to perform a workflow but also to eliminate errors and to capture allowed deviations from the method and present these during an audit in a standard format.

If you are spending days away from the lab, helping round up paper and trying to explain deviations from processes to auditors, or are part of that QA group perhaps it's time to take a look at improving your quality and throughput with a bioanalysis software solution.

What's coming next?

The bioanalytical sector is necessarily conservative in adopting new software or workflow approaches when compared to other areas of the pharma research cycle. However, taking a look over the fence into clinical research and preclinical research is helpful in predicting trends which will later on be adapted to the needs of this sector.

Reduce operational costs

The biggest trend in the research and development software community is a shift from self-managed on-premise software to software which is delivered and maintained by the vendor in the cloud for the price of the offering.

This enables companies to reduce the need for buying and maintaining expensive hardware systems and employing teams of IT personnel to look after them. It also allows for rapid deployment of new functionality, keeping up with the latest regulations and security patching.

The challenge in this space is finding software vendors that can demonstrate the right maturity of service so that they provide a validated solution via the cloud, which implies audited controls on the software vendor's development teams and partners, code checking, and automated steps for the validation of systems.

Novel technologies

One of the biggest emerging 'buzzes' today is around Blockchain technology, which underpins many of the digital currencies such as Bitcoin. Blockchain, put simply, provides an immutable shared audit log of every event that has occurred to that data, throughout the data chain. The theory is that this technology can provide an audit of how a test was performed, how it was handled, and by what equipment. Today this is an area of investigation and will probably be part of the basis of future software offerings in the bioanalysis space.

Personalised medicine

Someday soon, it will be necessary for an individual to view and use their bioanalysis data with input from their clinician to drive their treatment forwards. This poses the greatest challenge to the industry-to move from a closed black-box approach to one of greater openness. Steps towards this are occurring slowly, but the bioanalysis data represents a key dataset in interpreting trial outcomes.

I can foresee patients enrolling on a personalised medicine premium with their health provider and part of this would be to perform bioanalysis to help tune the patient's treatments to their individual needs. This will impact how results are documented, explained and annotated and of course the processes and software used in bioanalysis over the next few years.

Conclusion

If CROs are to gain a bigger market share in such a competitive bioanalysis market, they require a robust data management solution that improves workflow efficiency, simplifies the application landscape for the scientist and addresses the significant QC burden of each study – because of this, I expect to see the rate of CRO software adoption increasing significantly in the coming years.

The complexity of systems for defining, testing, analyzing and reporting on sample analysis runs makes bioanalysis a prime candidate for advanced data management and automation of common workflows and reports. To enhance both the speed and quality of their bioanalysis, CROs need a solution that can bring significant efficiency improvements, integrate with other lab informatics and can cope with the specific needs of the broad range of studies performed.

Ideally, CROs will look to implement a single solution for the capture, storage and reporting of bioanalysis study data that can integrate with existing laboratory infrastructure. With a single platform, CROs can increase quality, reduce study- and turnaround times, ultimately increasing their capacity and competitiveness in the market.

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