Outsourcing strategies in Bioanalysis

“One thing is certain, the nature of outsourcing is changing rapidly and in 5–10 years’ time, bioanalysis will be unrecognizable to current proponents.”

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The world of quantitative bioanalysis of pharmaceuticals is changing rapidly. We are seeing a shift in the types of analytes measured from predominantly small molecules to a variety of molecular types, including proteins, peptides, antibody–drug conjugates and other novel constructs [1–3]. This is requiring changes in skill sets for bioanalysts and in the technologies they use. Concurrent to this major change, there is an ongoing shift in pharmaceutical (Pharma) companies increasingly outsourcing their bioanalytical activities [2]. This special focus issue of *Bioanalysis* explores the development of outsourcing strategies, how they are implemented by different organizations, what is required for the strategy to be successful, what are the effects on the companies involved and their staff (including training, recruitment and retention) and where this might be going in the future. Insightful and thought-provoking articles and interviews are derived from a variety of experts and leaders in the field with backgrounds in Pharma companies, Contract Research Organizations (CROs) and as consultants.

A number of articles explore the development of different models for outsourcing. Many Pharma companies have utilized CROs for several years to predominantly perform the analysis of samples derived from large clinical studies, which they do not have the in-house capacity to support themselves [3,4–7]. This typically involves the transfer of a method developed and validated by Pharma compa-

nies to CRO. This model is considered transactional and is usually negotiated on a study-by-study basis. Due to the ongoing success of these arrangements and the requirements from Pharma companies to reduce fixed costs, now in many cases, this has often progressed to an arrangement where the bioanalytical support for preclinical toxicology, including studies used for regulatory filing and method development and assay validation are routinely outsourced [5,6]. In some cases, this also includes the support by the CRO of first-time-in-human clinical studies and the development and validation of the associated clinical analytical method [6]. While this approach is still at its heart transactional, it may expand to covering the outsourcing of bioanalytical support for whole drug-development programs, rather than on a study-by-study basis. In a limited number of cases, some Pharma companies have progressed to a model where they outsource all their preclinical and clinical bioanalytical activities, with little or no in-house bioanalytical capacity or expertise, other than those overseeing the work at CROs [6–9]. This model can include teams at the CRO, dedicated to the work of a particular Pharma company and requires the harmonization of processes between the parties. Furthermore, CRO staff may have a seat at the table at what were previously considered internal Pharma meetings, such as the clinical study management team. This arrangement requires a lot of trust and effort to set up and maintain and moves beyond the transactional arrangement

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to a much more in-depth partnership between the parties. It is notable that this latter model is the norm for smaller biopharma companies who have little or no in-house bioanalytical capability, or expertise and therefore must rely on and trust the capabilities of the CRO completely [7,10]. Interestingly, this change has enabled some Pharma companies to focus its internal capability on more research-orientated studies and provide an increased resource pool to support bespoke bioanalytical method development [3,5–6].

This shift to increased outsourcing and the parallel availability of high quality CROs, providing support at reasonable prices has inevitably led to senior management and procurement groups in Pharma to increasingly consider bioanalysis to be a commodity with price being the principle factor [3–7,10]. This acceleration in outsourcing is in turn leading to a shift away from experienced and highly analytically skilled in-house bioanalytical groups in biopharma companies. Where once these groups were seen to be the innovators and the mainstay of the industry who would attract the best talent, the pendulum for these activities has in many cases now shifted to the CROs [7,10–11]. It is observed that where in the past, staff would regularly move from CROs to big Pharma companies, the reverse is now routinely the case. Furthermore, these changes in the model used for outsourcing have in turn led to differences in the relationship between the parties involved, with CROs increasingly taking the lead on technical and regulatory issues [4,9,11]. However, one thing that comes through clearly in all the articles is the prime importance of good communication between all parties, regardless of the model used for outsourcing.

These changes inevitably lead to speculation about the future of bioanalysis. There will always be a requirement for the provision of high quality circulating con-

centration data for decision making and regulatory filing. However, the way this data is generated is going to continue to evolve. Will obtaining bioanalytical data continue to move toward the commoditized model? Will this in turn, inevitably lead to a lack of staff in Pharma companies with bench bioanalytical expertise who are able to select CROs, oversee their work and integrate the data into projects and regulatory documents? Will these responsibilities therefore reside with the CRO, rather than with Pharma companies and if so what are the implications for regulatory submissions? Could this lead to a change in not only the outsourcing model, but also the nature of CROs themselves? Will we see increased competition between CROs for samples, skilled staff, expertise and technology development? Will the inevitable downward pressure on prices mean that new models appear? Will we see an increase in mergers and acquisitions of CROs? If so, what is the impact on data quality and pricing? Does this make the development and implementation of fully automated solutions for bioanalysis a real possibility? One thing is certain, the nature of outsourcing is changing rapidly and in 5–10 years' time, bioanalysis will be unrecognizable to current proponents. We hope you enjoy reading these insightful articles and that they provoke your own responses and discussions.

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