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Establishing a Successful CRO–Client Relationship

How to avoid common problems between the client and CRO.

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In recent years, pharmaceutical companies have focused on core competencies and relied on contract research organizations (CROs) to support their analytical and manufacturing-support requirements.

In today's economic environment, more and more pharmaceutical companies are using the services offered by CROs. Outsourcing analytical services can reduce overheads by circumventing the need to invest in expensive technology and equipment, thus generating cost savings for the company. The CRO can

provide expertise using up-to-date technology supported by an extensive knowledge of the current regulations. Outsourcing also can save time, which is often critical because any delay in production processes, batch releases, or obtaining approvals from regulatory bodies can severely damage a company's prospects.

It is essential that CROs work in close collaboration with their clients, providing smart solutions to their analytical needs, establishing and transferring methods quickly, and ensuring that information transfer is efficient, secure, and confidential.

The key attributes that a CRO should have to support fast turnaround of projects are the following:

- technical know-how
- experience and a history of successful method transfer
- extensive knowledge of the regulatory requirements
- efficient quality systems with requisite documentation in place
- secure storage and transfer of data
- flexible approach to incorporate last-minute changes.

If a CRO has these core capabilities and maintains a good relationship with the client, it will be able to successfully establish manufacturing support and batch release methods.

This article highlights the importance of the CRO–client relationship through a case study, which demonstrates how partnership and support during the project can result in a timely delivery during late-stage development.

CASE STUDY

A CRO was approached with an opportunity to develop, validate, and transfer several analytical methods to support its marketing authorizations. The ultimate intention was to use the validated assays for in-process or manufacturing support testing and batch release. The timelines for completing these projects were very aggressive considering that some of the methods required did not exist earlier, although the customer already had the reagents in place. Table 1 lists some of the problems that may arise during contract analysis, and some of the ways to avoid these problems.

Table 1. Key elements of a good CRO–client relationship and how to avoid common problems

Project problem	Problem solved	Lesson
Method transfer	Establishing a clear understanding of the client's requirements and expectations from the start of the project.	Establishing a clear understanding of the client's requirements and expectations from the start of the project.
Method validation	Establishing a clear understanding of the client's requirements and expectations from the start of the project.	Establishing a clear understanding of the client's requirements and expectations from the start of the project.
Method transfer	Establishing a clear understanding of the client's requirements and expectations from the start of the project.	Establishing a clear understanding of the client's requirements and expectations from the start of the project.
Method validation	Establishing a clear understanding of the client's requirements and expectations from the start of the project.	Establishing a clear understanding of the client's requirements and expectations from the start of the project.
Method transfer	Establishing a clear understanding of the client's requirements and expectations from the start of the project.	Establishing a clear understanding of the client's requirements and expectations from the start of the project.
Method validation	Establishing a clear understanding of the client's requirements and expectations from the start of the project.	Establishing a clear understanding of the client's requirements and expectations from the start of the project.

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SET-UP

The first task was to set up effective lines of communication. At the start of the project, face-to-face meetings were found to be beneficial. However, telephone and video-conferencing facilities also helped during the initial discussions. The remit of the project was understood and agreed, because knowing exactly what the client wanted was essential to provide the best service. The client was asked to provide as much information as possible upfront about the products, processes, supporting analytical methods, aims, and timelines to avoid any surprises later in the collaboration.

In addition to the technical issues that were discussed, contracts, confidentiality, and technical agreements were rapidly established to document the project's remit and responsibilities. A single point of contact was assigned at each site to facilitate information exchange. Any subsequent agreed contractual changes (amendments) were processed quickly to prevent delays in the project timelines.

FEASIBILITY ASSESSMENT

Transferring a pre-existing method (if not defined by a pharmacopeia) or establishing a new method often requires a technical feasibility study or trial run, which allows the CRO to provide a proof of concept of the intended method. The reagents or methods supplied by the customer can be checked and any supplementary consumables or equipment found to be necessary to produce a robust method, considered fit for purpose, can be sourced. This process allows for an assessment of the typical time constraints for performing the testing. If the initial projected timelines appear unrealistic, contract or protocol amendments can be made at this stage.

If the outcome of the feasibility assessment is favorable, then the data can be securely transferred to the customer for approval, and results may be formally documented in the form of a feasibility report if required.

In this case study, a two-week feasibility project was performed for assays that had not been developed previously. In the case of customer-established methods transfer to the CRO, this time was used to test the methods and perform comparative data analysis with the customer's previously derived in-house data. Once the customer was

satisfied with the trial and feasibility tolerances and agreed acceptance criteria, the project could proceed.

EXPERIENCE

A CRO must have the requisite experience in performing rapid methods development, validation, and transfer, and routine sample testing. In this case study, the CRO had 15 years of experience in developing, establishing, and routinely operating these types of assays. Time efficiencies often can be introduced during method transfer by planning hands-on training in advance in the receiving laboratory. This is not always necessary but can be advantageous because any geographic, environmental, or analyst variation between the two laboratories can be quickly accounted for by doing so. Experience has shown that when biological products are involved, even fully validated assays and products are often not as robust as initially perceived when transferred to another laboratory.

The CRO also must be up to date with the latest regulatory requirements. In this case study, the parameters and acceptance criteria for validation and acceptable inter-laboratory variation limits for the comparative analysis for method transfer were discussed with the client before initiation. Recommendations were made to the customer and regulatory support was offered. It is vital that development, validation, and transfer protocols are scrutinized, agreed, and signed off by all concerned parties before the initiation of the practical aspects of the project.

COMMUNICATION

As the project progressed, both organizations kept each other informed on a weekly basis, and at critical times, on a daily basis, which meant that any last-minute amendments to the method could be incorporated quickly and unexpected results could be acted upon immediately. A flexible working approach and service provision is necessary when dealing with such high-priority projects. The CRO was therefore enabled to react quickly to the client's needs and allocate resources to the project as required, becoming an extension of the customer's team.

SYSTEMS

Another advantage in outsourcing to a CRO is that the tools and systems are already in place for analysis. Extensively validated software (e.g., laboratory information management systems for sample traceability), fully 21-*CFR*-compliant instrumentation software, and spreadsheets for data analysis can be quickly adapted to produce a flexible data format per client needs. Analytical and report templates are also available.

Experienced teams for quality assurance checking of data were deployed at critical time-points so that analyses could be checked immediately as results were produced, and teams for checking and reviewing produced documents were set up at the client site to enable fast turnaround for document approval. The customer was satisfied and assured that their project tasks and reporting had been carried out to the appropriate level of science, quality, and integrity.

CONTINUING SUPPORT

As the CRO–client relationship grows, the CRO acts as an extension of the client's business. The CRO becomes a stakeholder in the well-being of the client's business objectives.

In the case study discussed, the CRO delivered the projects on time and within budget. The CRO–client relationship overcame the many problems posed with obtaining equivalent materials, equipment for the methods-transfer exercises, and many changes to the project scope after initiation.

Even after the customer has obtained marketing authorization, the CRO testing facility should remain available and flexible to allow for variability in production times during the manufacturing process, allowing the customer to meet its manufacturing objectives. This is of course within the remit of the CRO's quality system and customer's product license stipulations. For example, to support a client's production process, the CRO may need to work odd hours (night shifts) to provide urgently required real-time data necessary for the client to progress to the next manufacturing stage of the product.

The continued relationship increases the opportunity of a mutual understanding of the issues that can arise and further develops trust between the two organizations. This may lead to a more collaborative approach with joint planning and forecasting.

The CRO may get the opportunity to become a preferred supplier for manufacturing support and batch release testing. Once the relationship has reached this stage, an ongoing contractual agreement to cover all testing may be set up and the CRO can organize work from the customer to give assurance that its testing is centrally placed in its testing schedule.

Building a good working partnership between the client and CRO and maintaining this ongoing relationship results in time and cost savings, providing added value to both businesses.

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