

Guidelines on outsourcing practice in life science

Outsourcing of selected part(s) of the drug development process increases substantially every year among both small and large drug developing companies. Services can be found in both the private and public sectors, represented by companies, science park facilities and university core facilities.

This guide aims to support the outsourcing companies in their selection of service providers, by establishing some simple practical advice. The guide has been developed in collaboration with service providers, drug developing companies and outsourcing consultants. The outsourcing process can be long, sometimes up to a year before the actual project is initiated, and is described step by step below.

• How do I define the outsourcing project?

This first step sets the stage for the entire process. Be careful to define what *shall* and what *shall not* be included. Decisions to be taken include who is going to be responsible for each action point, what level of quality is needed, time schedule and milestones. Furthermore, clear definitions of the end product as well as the quality of the product have to be specified. The user rights of results, intellectual property rights and publication rights should also be considered at this stage, for the end product, but also for the improvements of the products and processes. This procedure is identical when purchasing services from either a private or public provider, but will influence the selection.

To set the correct level of quality requirement of the service, it is important to have a clear picture of the aim of the project; what needs must be met

- internally: should the level of quality be sufficient to secure a hypothesis? If so, consider if it also has to be valid for the financiers of the project.
- by authorities: should the level of quality meet regulatory demands for e.g. clinical trials, for registration, or other purposes?
- by potential customers: should the level of quality be sufficient for e.g. big pharma?

It is important to have sufficient knowledge of the activity to be outsourced in order to establish the requirements and evaluate the service provider. If not available in house it is advisable to consult professional help in the definition of the project and in the evaluation of the proposals. This is especially important for long term projects and the use of clinical trial projects. Keep in mind that the responsibility for the quality of the product or the analysis in the future lays with the outsourcing company – the buyer - not the service provider. This means that future audits are performed on the

product developing company. Some activities may require a quality system in-place at the outsourcing company.

A request for proposal (RFP) is prepared based on the definition of the outsourcing project, and is sent to selected service providers. Keep in mind that a well prepared RFP will result in good precision of the resulting quotes.

- **Who do I contact and how?**

In order to find suitable service providers, use your existing networks and databases such as www.toolsofscience.eu. Going beyond your personal networks is helpful, especially to get a feeling of a reasonable cost and time for the project. Recommendations from your network are invaluable.

As soon as you have a list of providers, call them and ask them if they have the possibility to perform the service. You will know if they are available, and also get a first impression of the company.

Is geography a concern? Remember that distance is normally not an advantage but could be handled if the benefits are unquestionable. However, there are hidden costs in working on a far distance. Such cost could be direct cost as travels for meetings and audits, shipment of material as well as indirect cost (e.g. time for supervision over phone, delays or extra work caused by differences in language or culture).

Ask for meetings with the selected providers, where you will go through some of the main questions you have regarding the assignment and the provider. This meeting will shorten the list of potential providers even more, as well as provide more input to the definition of the outsourcing project. Aim for two to four providers. More than four will cause undesired extra work load for all parties.

Send the request for proposal to the selected companies. In case you need a confidentiality agreement, it shall be signed before the request for proposal is sent out.

- **How do I evaluate the proposals?**

Before doing the evaluation of the proposals, think through the different criteria that have to be met, and multiply it according to weight, e.g. if the physical distance to the provider is not very important, multiply its grade with 1, and if the timing of the project is extremely important, multiply it with 10.

Usual criteria are:

- Quality track record
- One-stop-shop (can the provider perform all services themselves, or do I need several providers?)
- Time for the different deliveries
- Technical capabilities and competence
- Cost, including the hidden costs which can be huge (e.g. milestone payments, royalties).
- The total cost, including e.g. the transport from the provider, storage

- Communication skills of the provider (e.g. do we understand each other? Do they reply quickly to my questions?)
- Distance
- Language
- Responsiveness
- Project management structure

From the weighted criteria, make a selection of one or two candidate companies.

Example:

Criteria	Weight	Company A		Company B	
		Grade (0-100)	Multiplied value	Grade (0-100)	Multiplied value
Quality track record	7	50	350	90	630
One-stop-shop	2	80	160	20	40
Time for deliveries	9	80	720	60	540
Cost	8	50	400	10	80
Sum			1 630		1 290

In this example, Company A seems to be of more value for this specific project (1 630 points in comparison to Company B 1 290 points).

Do not forget to listen to your “gut-feeling” and try to be objective about the perceived transparency for each specific company. Is there a match between what the service provider says and what you see?

- **How do I assure quality?**

Professional support in the evaluation of quality assurance (QA) processes is of great value for a successful project. There are consultants for the QA session. Remember that the responsibility for the quality of the products lies with the outsourcing company.

Visit the service provider to get a first-hand-feeling for how they work. Does it seem likely that they can keep the correct quality level? Will they respond to your demands? Do they have a quality level certified by an external (private or public) organization? It is helpful to hire a consultant to support you in the evaluation of the provider’s quality system. Be sure to check all parts of the quality system: does the company have all the necessary permissions? Your presence during the audit is very valuable.

- **Which agreements do I need?**

- “Pre-contractual ” agreements such as memorandum of understanding, letter of intents, heads of agreements and term-sheets if any, in order to define limit and general goals of the activity
- Confidentiality agreement/secretcy agreements/non disclosure agreements (NDA) in order to define what is back-ground knowledge and what knowledge will be developed after the outsourced activity

- Material transfer agreement (MTA), which regulates e.g. how the procedures shall be performed, the purpose of the assignment, time plan, contacts and responsibilities
- Study protocol could be part of the business agreement or separate to define exactly what, which, how and when the outsourced activity will be realized from a scientific/technical point of view
- Research contract/cooperative research agreement/service agreement that define juridical and business aspects (e.g. value of activities, responsibilities, time, contact persons, law applicables, etc) that will be realized
- Dedicated IPR agreement if any could be separate of part of the business agreement and defines juridical and economical aspects related to potential previous knowledge produced
- Quality and audit agreement could be part of the business agreement or separate. The purpose is to define the final quality level and the possibility for the client to audit the provider facilities
- Research exemption agreement (typical for public research centers (could be part of the business agreement or separate) that will permit to public research center to use for research purposes potential previous knowledge that will be patented by the client

If the contract is not clear in the above mentioned aspects, your project can be much more expensive than predicted. It is important to specify what happens if the service provider, the subcontractor or the outsourcing company goes bankrupt. When a CRO undertakes to use a certain technique or competence, be sure to add this into the agreement. Sometimes the success of a method depends on a certain person, and the access to this person should also be included in the agreement. If the CRO will be using subcontractors, it has to be specified what they will deliver, and who's responsibility it is to guarantee that the subcontractor delivers the correct product of the right quality and at the right time. The definition of check-lists could be a useful way to monitor all these aspects.

Also try to include a plan for possible failures and what to do if things do not work out according to the plan (e.g. research work that does not result in success within a reasonable time frame, quantity of material is not fulfilled, timing is not fulfilled, recruitment of patients or staff does not keep up to speed).

Other aspects to making your outsourcing project successful:

- Your project is often more successful if you collaborate with the CRO in a partner-like collaboration, as opposed to using the CRO as a simple provider. Involve the CRO in the discussions, in finding solutions to challenges etc.
- The service provider shall have one person who has the main responsibility for the project and one contact person for each specific partial project
- Use consultants as soon as your company's internal competence is not sufficient, this will save time and money
- A QA consultant can be of great value
- You have the possibility to influence and value the project team. In case you are not satisfied, see to that the persons are exchanged.

- Schedule regular meetings and ensure continuous communication with the project team.. Do not hesitate to give feedback on the work.
- Remember that the perception of the progress and result is based upon your expectations. Make sure your supplier is aware of and share those expectations in all critical parts.
- Be aware that you will need to collect all material that will be produced: if necessary insert specific clauses in contracts that permit you to access lab books, raw data, methodologies, etc.

The key to success is information exchange and a continuous open communication.

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