C/M/S/ Cameron McKenna

Outsourcing - lifesciences

Like any business area, companies in the Lifesciences sector have a need for outsourcing functions from time to time. Of course, the usual areas ripe for outsourcing (e.g. HR, IT, Financial Services) are as relevant in this sector as any other, but there are a number of key strategic areas specific to Lifesciences companies that are also outsourced and which are done so for specific purposes.

Reasons for outsourcing

The reasons (or, indeed, requirements) for outsourcing a particular function depend very much on the nature of the company itself.

> “…even though the specific function could continue to be carried out in-house, for various reasons, it may be more appropriate for the function to be carried out by a separate service provider…”

A start-up company may well find that it does not have the resources or experience to develop, say, a patented compound and to explore its full potential in the relevant therapeutic field. A larger, more established company's reason for outsourcing may be, for example, that although the specific function sought to be outsourced relates to its core business (e.g. drug development) clinical trial management, say, may well be better and more efficiently provided by experienced contract research organisations (“CRO”) specifically geared up to provide the services on a national or international basis.

For large companies or multi-nationals, it may also be that even though the specific function could continue to be carried out in-house, for various reasons, it may be more appropriate for the function to be carried out by a separate service provider – albeit with close contractual supervision (the contract here replacing the management role previously carried out in-house by the company). Our lawyers have recently advised a large pharmaceutical company on the outsourcing of the management and running of its internal sterile and solid dose manufacturing functions to a company specifically set up to provide this function. We have also recently advised on the outsourcing of the Royal Mail's employee health services division to Sema. We advised not only on the HR and TUPE issues but also on the detailed service level requirements the provider had to deliver to ensure a seamless transition with a minimal loss of control for the company.

Outsourced functions

What many people would see as normal contractual activities of a Life Science company is in reality an example of outsourcing. Areas for outsourcing in the Lifesciences sector include:

Research and Development ("R&D")

A key function of any life science company, R&D, although carried out largely in-house, is also outsourced. Examples of outsourced R&D are:

- simple contract research may be outsourced to universities or small R&D companies in order to access specific expertise and/or to add to an early stage development programme (e.g. pre-clinical testing etc)
- discrete areas of research may be sponsored through PhD students or carried out by universities. The requirement may simply be to acquire results but may also be to create goodwill and also perhaps tap into a future seam of new potential employees

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Collaboration (including licensing and development)

Joint R&D in a specific field is a form of outsourcing. Here the parties may contribute either cash, intellectual property, expertise in the field, access to a market that the other party is wishing to break into and other key functions for the development or commercialisation phase (e.g. experience in setting up and running clinical trials or regulatory expertise, etc).

Clinical trials

The clinical trial process is a key step in bringing a drug or device to the market. Clinical trials can be expensive and may require a great deal of time, resources and expertise to organise. Whether you are a start-up company or a larger established organisation, it is not uncommon for this process to be outsourced. As trials will be key to your core business there is little scope for error and a great deal of care and consideration needs to be put into the selection of the relevant service providers as follows:

- appropriate clinical trial investigators with specific patient populations need to be identified
- sites with the specific facilities and resources
- CROs with experience and with key personnel in the relevant field are vital both for management and monitoring
- regulatory professionals for both report writing and assistance in completing the regulatory dossiers may also be needed if all these resources are not available in-house
- laboratories for sample testing etc.

Manufacturing
Many organisations will not have this function fully in-house and so a suitable manufacturer may be required. The supplier must be able to deliver the required specification and be in compliance with Good Manufacturing Practice (GMP) as well as meeting other commercial requirements.

Co-promotion
Where a marketing authorisation for a medicinal product is being or has been granted, it may be that another party is better placed to promote and sell the product in a specific market. This may be because they have already an established presence in the specific territory or have experience in this field. "Outsourcing" this aspect of your sales and marketing function thereby gives you access to the relevant skills experience and market.

"The extent of this "due diligence" will of course vary depending on the type of outsourcing to be undertaken and the level of legal and commercial risk associated with it."

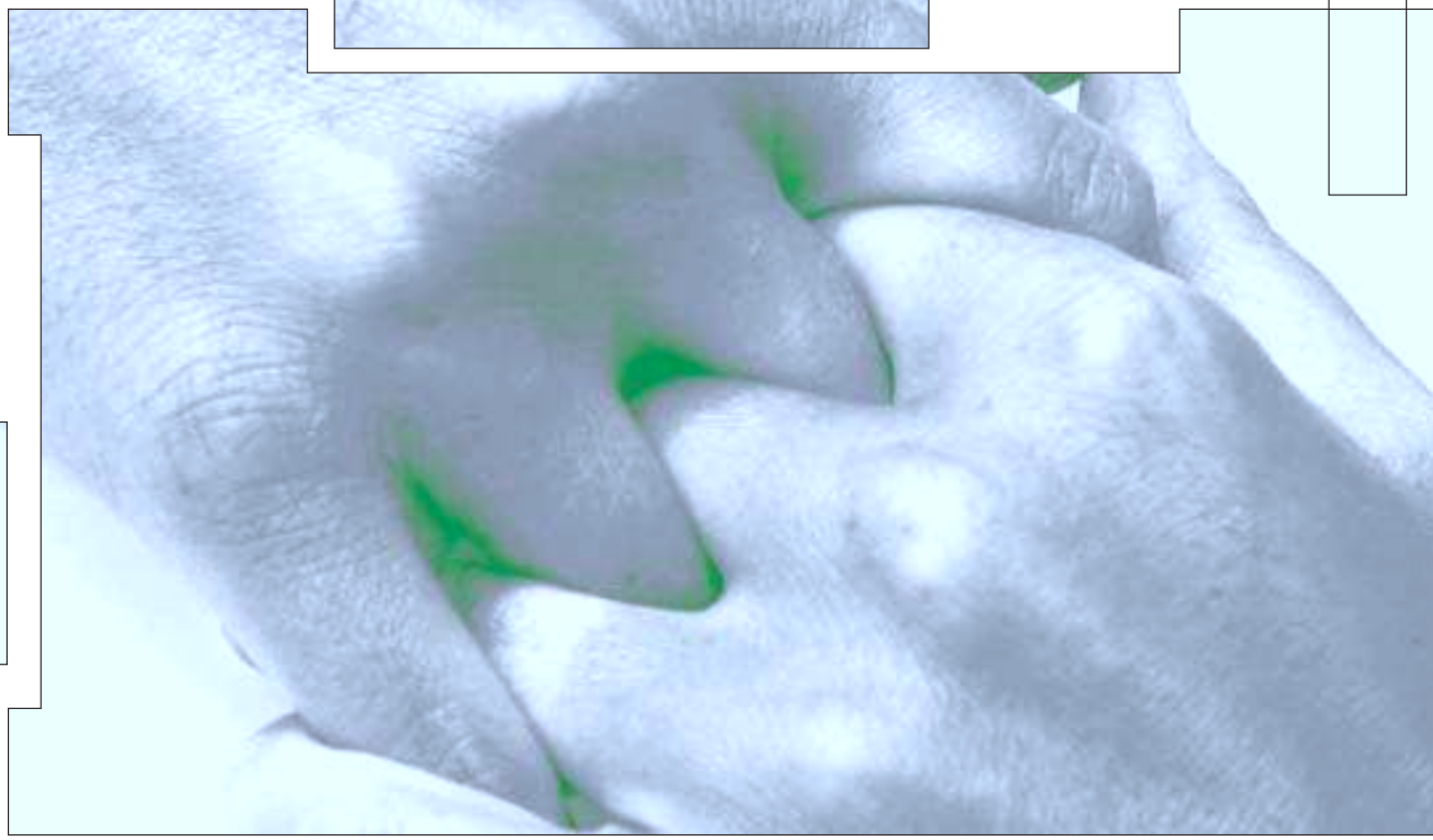
Outsourcing relationship

Key in all the identified examples of outsourcing, is the need to ensure from the outset that: the reason for the outsourcing is clearly understood; the most appropriate and suitable providers are identified; the deliverable requirements are set; and the legal and commercial risks identified. From this platform the key contractual framework can be designed and structured to ensure all your requirements are met from a functional, commercial and legal perspective.

The extent of this "due diligence" will of course vary depending on the type of outsourcing to be undertaken and the level of legal and commercial risk associated with it. For example, simple contract research where little risk is involved can simply require a standard form agreement with little negotiation. On the other hand, where a multi-national, multi-centred, Phase III clinical trial is being undertaken, the choice of CRO is critical. It may be that a detailed service specification needs to be drawn up and a CRO contract ▶

drafted to be attached to an invitation to tender ("ITT") with CROs being invited to bid for the project. Quality, efficiency and expertise are required for this process. It may be that personnel attending the "beauty parade" are required to be actively present or involved in the project on an ongoing basis and not just being the marketing face in order to win the project. These areas all need to be specifically drafted for in the service agreement.

Where a development and licensing arrangement or co-promotion arrangement is being considered, a great deal of careful consideration must go into the choice of the "partner" so as to ensure the desired objective and goals are achieved. The detailed and complex nature of the agreement that will be required must deal with all aspects of a relationship on an ongoing basis from the research programme, funding arrangements, ownership and commercialisation of intellectual property, regulatory responsibilities, royalties and revenue streams, liabilities and termination rights.



How can we help?

The Lifesciences team at CMS Cameron McKenna have a great deal of experience in advising companies in the Lifesciences sector on all aspects of their outsourcing arrangements.

> "...the agreement that will be required must deal with all aspects of a relationship on an ongoing basis..."

We are regularly involved at an early stage in this process depending on the nature of the outsourcing arrangement (be it the simple contract research to a major clinical trial management programme or licensing and development or co-promotion arrangement). We can provide valuable experience and participate actively in the whole process of the outsourcing arrangement. We can provide both customers and suppliers with:

- assistance and advice on the initial identification of the outsourcing need and the areas upon which it will impact the current business operations together with changes required to manage and offset the new arrangements
- drafting and negotiation of contractual documents to effect the outsourcing arrangements together with any ITT sought to attract bids
- continuing advice and assistance on ongoing compliance issues regarding performance of the outsourcing arrangements

If you would like to find out more about outsourcing in the lifesciences sector and how CMS Cameron McKenna can help you please contact the following members of our Outsourcing Group:

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For more information on outsourcing and to receive updates on new developments as they arise, register to Law-Now, our free email information service.

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