

# The ABC of Outsourcing

## Jonathan Trethowan of TRAC offers advice on what to look for and the questions to ask when considering outsourcing your regulatory affairs requirements

With more pharmaceutical companies than ever before opting to outsource their regulatory affairs requirements – whether in their entirety (increasingly the case for small manufacturers) or as a way of enhancing existing in house teams (where added skills and experience can be brought in to meet demand) – outsourcing is playing an increasingly important role in the pharmaceutical manufacturing sector. While the benefits of outsourcing can be significant – giving an organisation the opportunity to tap into a team of professionals or experienced individuals – it can also present companies with some real issues, which if not identified and addressed before an appointment is made can create a regulatory headache in the long run.

The most vexing question when looking to outsource is the most obvious one – how can you ensure that the people or the company you are bringing in have the right levels of experience, knowledge and expertise to really add value to your business?

Some pharmaceutical companies create problems for themselves which are only identified ‘after the event’. This is ultimately both costly and damaging, and in the most serious cases has had a negative effect on submissions and applications. Consultants providing regulatory affairs are increasingly picking up the pieces for pharmaceutical companies that have got the outsourcing process wrong – resulting in them having to redo a range of projects that were simply not done properly the first time around.

There is no question that outsourcing can be a beneficial process, but it needs to be executed effectively and requires thorough research to have been carried out before an appointment is made.

### WHY OUTSOURCE?

Even five years ago, outsourcing remained a small sector of the regulatory affairs industry. It has since developed and is playing an increasingly important role. According to industry reports, as the pharmaceutical manufacturing process becomes increasingly ‘regulated’, and the recession continues to bite, outsourcing elements of the regulatory affairs process looks set to continue to grow.

In a recent report, almost 60 per cent of small and medium enterprise (SME) manufacturers said they were engaged in outsourcing, while in the larger multi-national corporations that figure dropped to 25 per cent; there is less need for external support as a result of larger in-house teams with the necessary expertise (1).

So why outsource? Depending on the size of the business, there are a number of reasons why the outsourcing option is worth consideration:

- You may need to bring in specific expertise for a particular product or technology that you do not currently possess in-house, or may require support to complete specific submissions
- The current in-house team may be overstretched through increased workload and, as such, interim additional expertise is required
- You may be a small manufacturer who does not want to shoulder the human resources and cost burden of employing an in-house team, and would rather the flexibility to bring in people as and when you needed them, without affecting your regulatory responsibilities
- Increasing regulatory demands may have created a ‘knowledge gap’

that can be filled more effectively by outsourcing

So if the decision has been made to outsource, where do you start looking for the right support for your organisation and how do you go about ensuring that the level of expertise you believe you are bringing in is indeed what you are going to get?

### THE IMPORTANT QUESTIONS

Asking these fundamental questions can be the difference between submission success and failure, and between a positive and productive working relationship moving forward or a potentially costly and damaging delay in bringing a product to market. What is paramount is that you have confidence in the company you select and are confident that you have thoroughly researched their capability to deliver what you want. Some of the key issues and questions that you will need to address when looking to find an outsourcing partner include:

#### Previous Clients and References

You would not consider taking your car to someone who has no experience of maintaining or working with cars or without satisfied customers that you could talk to. This is also true when considering your regulatory affairs partner. Given the levels of responsibility you will place upon the consultant’s shoulders, you need to carry out your own due diligence. Ask for a list of previous clients and ensure you contact a cross section in order to get well-rounded feedback on the company and their own experiences of working with the potential provider. This will also ensure that the references are sound.

#### Success Rates with Applications

If you are pinning your hopes of a successful application with the outsourced support, you need to know what their

success rate has been previously. While each application will have its own specific needs and issues, a regulatory affairs consultancy with a high success rate will show not only a level of experience in putting together successful applications, but also in dealing with the regulatory authorities and producing consistent applications that meet the requirements of these various bodies. Ask to see some of their previous work (knowing that they are likely to remove any confidential content to protect their client) to check the quality of the work.

#### You Get What You Pay For

If the quote submitted by a regulatory affairs company seems too good to be true, then it is highly likely that it is and you would be advised to proceed with caution. If you have a significant distribution of quotes, you should ask companies to break down their costs accordingly. It is worth remembering that there are no shortcuts when it comes to making an application; if you are buying on price alone, you may have to be prepared for a rejected application that will, in the long-term, cost you more to get through a second time.

A consultancy with good experience, a good application success rate, the right level of expertise for your specific product application and a solid track record is not likely to be the cheapest on the market. However, remember why you are outsourcing in the first place and opt for the consultancy that provides you with the best service across all of the key points.

#### Membership of Professional Bodies

Find out if your potential regulatory affairs consultancy is a member of any professional bodies such as The Organisation of Professionals in Regulatory Affairs (TOPRA), or the Regulatory Affairs Professional Society (RAPS). These professional bodies play a central role in the regulatory affairs industry and an organisation that is able to not only demonstrate membership, but active participation within them, will be a positive indicator.

#### External Accreditations and Quality Standards

While it might not be directly linked to their ability to deliver regulatory affairs expertise, a company that has achieved

professional quality standards and accreditations such as the International Organisation for Standardisation (ISO) and Investors in People (IIP) will give you an indication that they see value in investing in their people and their processes.

#### Length of Time the Company has been Trading

It may sound obvious but it is important to establish how long the company has been in the market. While the internet is useful for gathering such information, websites can be designed to make consultancies look bigger or more experienced than they actually are and can create a false impression of who you would be working with. Newly established firms can have highly experienced people working for them, but finding out how long the company has been trading is important.

#### Response Times to Initial Enquiries

Given that you will need to develop a positive working relationship with your potential selected outsourcing partner, take first impressions seriously as these can act as an initial indicator as to how they will operate as a project progresses. For example, if you have to chase a response to your initial enquiry, or if you are less than impressed with the quality of the response, this should raise questions about the responsiveness of the agency further down the line.

#### Quality and Accuracy of Proposals

Do not lose sight of the reason why you are looking to outsource your regulatory affairs requirements – to bring in a range of external expertise to help your applications process and oversee the delivery of a successful submission in whole or in part.

Critical success factors in the applications building and submissions process will include accuracy, quality, knowledge and attention to detail. Look for these elements in the proposals that are supplied to you during the initial stages of the appointment process. If the consultancy you are speaking to responds with a proposal that does not provide the information you felt you had asked for, or that has errors or inconsistencies within it, this could be an indication as to how they will treat your work and application process.

#### About the author



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a PhD in Biochemistry from the University of London. Jonathan previously worked for GSK as a Protein Scientist, involved in the design and development of downstream processing steps for therapeutic proteins (monoclonal antibodies) and in regulatory affairs for several years, before launching TRAC. He is also an active member of The Organisation of Professionals in Regulatory Affairs (TOPRA). Email: [jonathan.trethowan@tracservices.co.uk](mailto:jonathan.trethowan@tracservices.co.uk)

#### Nature of the Service Provided

Ensure that the services you are looking for are actually provided by the consultancy being considered and that they can demonstrate relevant experience that reflects your specific needs, whether you require an on- or off-site resource, or are looking for project or hourly-rate based options.

#### CONCLUSION

As the regulatory affairs industry develops, and demands on manufacturers continue to grow, combined with other developments such as eCTD submissions, outsourcing regulatory projects looks likely to play a larger role within the pharmaceutical industry. Its benefits are myriad: lower costs, increased flexibility, access to specialist expertise not available in-house, and increased submission success.

However, time and care must be taken to ensure that when you are looking to outsource you bring in the right level of experience, expertise and understanding for your specific needs. The cost of getting it wrong can be painful.

#### Reference

1. *Pharma and Medical Device Regulatory Affairs*, Bharat Books, February 2010