

Why should I use a regulatory consultant?

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WHY?

Have you ever heard the phrase 'Legislation is getting easier'? no, me neither!

It seems that almost every day new pieces of legislation are introduced and this is particularly the case in the Chemical Industry. The regulation of chemicals covers their production, transport, storage, use and disposal and all are key areas for legal compliance for companies operating in the chemical and associated industries. Because of the hazardous properties inherent to many chemicals, this is understandable. The risks associated with non-compliance in this area are significant: in relation to health and safety; environmental impact; reputational damage; and prosecution.

Ensuring legal compliance requires a thorough understanding of the chemicals involved, their hazardous properties, how they are manufactured and used and the specific legislation that applies to them. This legislation may be national, regional or global and may differ considerably from one country to another. Keeping abreast of legislation is a difficult task in itself and many companies struggle to do so, particularly if they operate at a regional or global level.

In some areas, such as plant protection products and biocides (non-agricultural pesticides), it is essential to have a good understanding of not only the core legislation and implementing legislation, but also the guidance on how this legislation should be interpreted, as well as being aware of the status of ongoing discussions on the expected future trends in the implementation of the legislation. In the biocides area in which I work, for example, there is constant interpretation and discussion at EU level and this is reflected by discussion documents which appear on a quarterly basis to coincide with the ECHA/Competent Authority meetings. It is important for industry not only to be aware of these discussions, but to also have an input to them.

In addition, for companies supporting active substances or products over the regulatory hurdles associated with this legislation, expert scientific and regulatory input is needed to generate the dossiers that must be submitted. These dossiers are assessed before active substances or products can be placed on the market. Because of this, in addition to regulatory specialists, experts in the areas of toxicology, ecotoxicology, analytical chemistry, residues, efficacy and exposure modelling (both human and environmental) need to be employed. Taking the example of biocides, a detailed knowledge on how the products are used is needed, particularly in relation to looking at potential exposure to products as diverse as disinfectants, preservatives, insecticides, insect repellents and even embalming fluids. New regulatory requirements are regularly introduced, such as the assessment of potential endocrine disruption (ED) properties (1).

While some larger companies may have the expertise available in-house, many find that these requirements are beyond their available expertise or that sufficient resource is not available. This is where employing a good quality consultancy firm with expertise in the particular legislation is 'a must'. Historically, in some circles there has been a resistance to using consultants ('the C word'). Thankfully, this mind-set is now becoming a thing of the past and companies have either changed their opinion on the use of consultants or, if not, may no longer be in existence.

It may have been joked in the past that a consultant would ask to borrow your watch and then charge to tell you the time; whilst still getting a laugh (or at least a giggle), this has become a dated view and the true value of good consultancy firms is now well recognised.

WHO?

Selecting a good regulatory consultant can be a difficult task, particularly if you have not worked with consultants in the past. Referrals are always a good indication that a consultant has a good reputation, so ask companies in your sector, supply chain or in your industry if they can recommend a consultant.

It is also important to identify a consultant with the appropriate skills, experience and expertise in the particular field that you need. Some consultancy firms offer a wide range of regulatory services, while others specialise in particular aspects of the field. It is important to identify the services you are looking for: are you needing just one area of the legislation to be addressed, for example an environmental risk assessment, or are you looking for a much broader range of services, which may include regulatory strategy or taking on-board a full dossier submission from start to finish? Do you want the consultant to be involved in training your team or monitoring any studies that may be required? And don't forget about follow up work such as post-submission support to handle questions from the Regulatory Authorities.

The geographical range of the consultancy is also something to consider; some firms specialise in individual countries or regions, while others have a global offering. This is obviously important on multinational or global projects, where experience in several geographic regions is critical. Language skills and local knowledge is important, so having a local office can be key to getting approvals in some regions. Industry-specific experience is also likely to be important, particularly with regard to how products are used and potential routes of exposure.

The size of the consultancy is also important. Some firms have been set up by a single individual, and while this can result in lower operating costs, it may mean that peer review of reports and documentation may not be possible. There is also the risk of lack of cover if the consultant is away on vacation or otherwise not able to provide support. Even with larger consultancies, it is important to check that there are a number of staff available to cover specific areas such as toxicology or ecotoxicology to ensure that work will not stop during periods where one specialist is unavailable or where workloads are high.

For high-level work, technical advocacy may be required and in most cases consultants should have experience in dealing with regulatory bodies on a regular basis (sometimes daily). This includes national bodies (for example the UK's HSE and France's ANSES), pan-European entities (ECHA and the European Commission) as well as key regulatory bodies such as EPA in the US. Some regulatory consultancies offer legal support, while others are happy to work with a range of legal firms. The same goes for testing services as some regulatory consultancies are part of contract research organisations (CROs) and can offer in-house testing. More commonly, consultancy firms will work with a number of CROs and can recommend the firms with most experience in the particular studies required.

Client consultant relationships are important and can lead to the consultant being seen as part of your team. This relationship can go on for many years with trusted advisors – so it is important to identify a consultant with whom you get on and can work closely with.

A point to remember is that in life you generally get what you pay for - you may need to consider that a cheap offer by a consultant is not necessarily always the best and be cautious of consultants offering their services at a discount.

HOW TO BECOME A REGULATORY CONSULTANT?

Historically, many consultancies have recruited staff from industry, regulatory bodies (such as Government Authorities) or from CROs. More recently, as the industry matures, an increased number of firms are taking on new graduates to train through to becoming consultants. In the area of regulatory affairs, there is a clear demand for graduates with an MSc or a PhD in chemistry, biochemistry and biological sciences. One problem with recruiting in this area is that not many degree courses include modules on regulatory affairs, which means that the role may not be on the radar for new graduates. Good on-the-job training of new recruits is essential and most competent regulatory firms have training programmes in place to develop new entrants through to becoming accomplished consultants.

The skill set required to be a good consultant is varied: in addition to the scientific and practical regulatory knowledge, soft skills such as interpersonal skills are important to facilitate the relationship between consultant, client and regulatory body a good sense of humour and patience also help!

REFERENCES

1. Andrew D., Scott, S., Ellis, S. and Elsmore, R. (2019) Regulation of endocrine disrupting chemicals in the EU. *Chimica Oggi - Chemistry Today* - vol. 37(3) May/June 2019. ■

