Intelligent and efficient **regulatory resourcing**

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In the current pharmaceutical climate, regulatory professionals and indeed regulatory departments are being stretched, with increasing workloads and new requirements and territories, but with little, if any, additional headcount. In light of this, our June edition offers a range of focus articles concentrating on resources spanning the continuum from maximising existing internal activities to outsourcing in its various guises.

Strategy has been defined as "the match an organisation makes between its internal resources and skills and the opportunities and risks created by its external environment." Our aim for this edition is to highlight that resource issues are not the sole preserve of regulatory directors, project managers and human resource departments, but can, and should, be a topic for every regulatory professional in their daily work.

We first look to internal resources and to the fundamental topic of decision-making. Ronan Donelan of Quintiles presents some best practices in this area and highlights that training in the science of decision-making is a worthwhile investment for the regulatory profession.

Continuing the internal resource focus and in the first of a two-part series, Hans van Bruggen of Netherlands-based *e*CTD*consultancy* BV considers the lack of global harmonisation and the potential improvements which can be made. Populating systems with information in a transparent manner requires transparent business processes and separation of content and context of use. Tools can significantly impact the solutions, but as important are the configuration and processes applied by the business – both of which need to be tuned to a wider context of use to future-proof activities. Part II of this paper will focus more on the transparency and consistency which can result in better efficiency and flexibility.

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Next we have the benefit of two articles which look at outsourcing and the trends in recent years. Christopher Carr from Pharmalink Consulting discusses the need to adapt to the constantly shifting regulatory landscape to capitalise on the opportunities and overcome the associated challenges. Despite internal coping strategies such as changes in department structures, the outsourcing of regulatory activities to external service providers in order to support business models is being increasingly utilised. Christopher looks to the trends which have influenced this outsourcing and to the different mechanisms which can be exploited: centralisation and streamlining of regulatory activities; a move towards long-term outsourcing partnerships; the outsourcing of regulatory intelligence; and the outsourcing to more cost-effective centres of expertise.

Ash Ramzan and Carolyn Beeden of Woodley BioReg Limited expand on this concept and the trend of outsourcing and their article looks to the use of consultants, freelancers, "people placers", off-shoring and consulting companies. They surmise that the future of regulatory affairs resourcing includes a more consolidated approach with direct employees supported by a combination of consulting companies and individual experts/consultants. There is also a welcome evolution of new flexible and adaptable solutions to maximise company budgets while delivering seamless resources, available over longer periods of time as and when required.

Our focus features are balanced with other high-quality articles on different topics, the first of these exploring the use of real world evidence gathered from observational/noninterventional studies and pragmatic trials. In addition, we have an article on the benefits of process analytical technology (PAT), and how to make PAT-based submissions. This is followed by a veterinary meeting report on this year's EMA/IFAH-Europe Info Day, and a useful article for the medical devices sector on proposed changes to *in vitro* diagnostics legislation.

We hope that the combination of these articles will encourage you to take time from a busy schedule and enhance your regulatory skill base.