Introduction: Regulatory strategy

Welcome to the September issue of RF Quarterly in which global regulatory experts write about the key elements of regulatory strategy throughout the product lifecycle; chemistry, manufacturing, and controls (CMC) regulatory strategy; the application of project management strategies to postapproval CMC submissions; and medical writing strategies for aligning regulatory documents with strategic goals.

We thank the authors for their generosity in sharing their knowledge and expertise with the RAPS regulatory community and hope their articles will serve as useful guidance and resources.

Teamwork, knowledge, and adaptability
Good regulatory strategy strives to reconcile plans to develop and gain approval for a product with a company’s overarching business objective to produce a profitable safe, effective, and accessible health product for patients. Achieving that requires teamwork, underscored by a balance of hard and soft skills among team members and collective adaptability in navigating the challenges in the global regulatory environment. Knowledge of regulatory requirements in different regions or countries is paramount.

In Elements of global regulatory strategy — The basics (p. 4), Neal E. Storm and Monica Batra explore the role of the global regulatory professional and key considerations for developing global strategy. They note that the pharmaceutical industry’s expanding global reach means drug distribution is multinational, yet the current regulatory frameworks still are largely national or regional in focus. This highlights the drug manufacturer’s responsibility, and specifically, the global regulatory professional’s job, to develop a globally integrated regulatory strategy to bridge the dissonant drug development requirements of regional drug regulatory authorities.

Continuing in the context of the drug development as an expanding global effort, Darin S. Oppenheimer and colleagues emphasize the importance of a well-designed and executed regulatory strategy in Introduction to regulatory strategy (p. 21). The authors provide “how-to” advice for identifying the strategic requirements for devising drug development and postmarketing plans. They detail the critical elements for a successful strategy and address expectations regarding filing, efficacy, safety, and labeling, among others, as well as strategy implementation and risk management.

CMC, project management, writing
Regulators make benefit-risk decisions based on the three pillars of quality, safety, and efficacy, with CMC applied throughout the product development spectrum, write Stephen Antonelli and Michael Craig in CMC regulatory strategy (p.31). They
provide a comprehensive guide for navigating the CMC regulatory landscape and understanding the multiple considerations needed to generate a strategy that is efficient cost-wise and in time to approval. Although the emphasis is on product registration and post-approval changes in the US, EU, and Japan, a separate section for countries with emerging markets is included.

In *Application of project management strategy to postapproval CMC submissions* (p. 42), Emily A. Rapp and Rebecca Imperial present opportunities for using a project management framework when strategizing for CMC regulatory submission projects. They discuss Project Management Body of Knowledge nomenclature, project performance domains and constraints, and provide examples of scenarios that may be encountered during a submission project. The authors recommend templates that could be useful to manage each hypothetical situation but emphasize the templates can be tailored to meet the needs of their users.

Putting any regulatory strategy into action will always require written documents, writes Kathryn Wekselman in *Medical writing strategies: Aligning regulatory documents with strategic goals* (p. 53). The author provides some best practices to align regulatory documents with strategic goals so that regulators will understand what a sponsor is trying to achieve, why the goal is important, and how the totality of available information supports the desired regulatory action. Key elements of successful regulatory medical writing include adopting the perspective of a regulatory agency audience, using clear structure and language, and leading teams skillfully.

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**Acknowledgment**

I thank the following colleagues for their assistance in preparing and publishing this issue: art director Simon Fong; designer Connie Hameedi; Denise Fulton and Gloria Hall for editorial support and guidance; Ryan Connors, and Nicole Duran for marketing support; and Ravi Gaddipati for web production support.

**Citation**


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