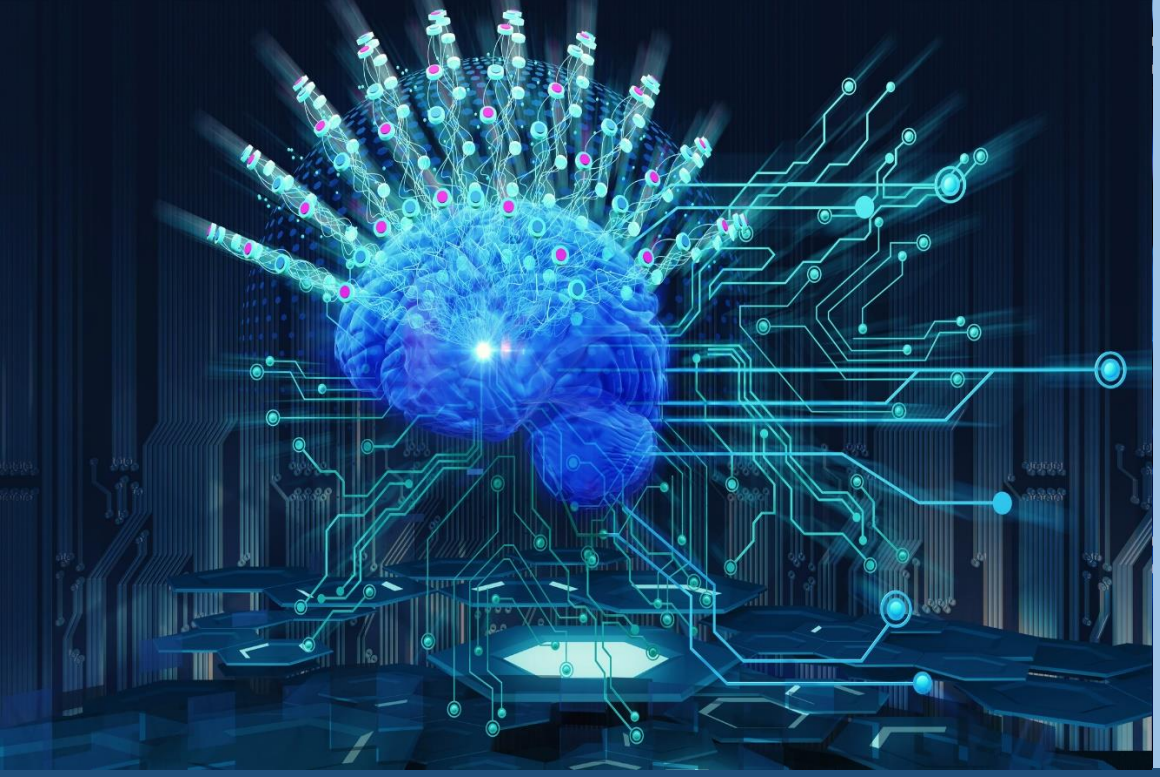

REGULATORY FOCUS

March's REGULATORY FOCUS: Regulatory intelligence

Renée Matthews

Feature articles during March focused on regulatory intelligence (RI), including first-hand accounts of setting up a dedicated process for RI monitoring and developing an in-house RI database, as well as an examination of the implications of the US Food and Drug Administration's (FDA's) new integrated review template for RI. Also included were articles on the importance a global unique device identification (UDI) system, the FDA's Bad Ad program, and the importance of written communication skills in career advancement.

RI process, storage, and review

Supporting and understanding the scope and value of RI is key to the success of an integrated RI program, **Dinar Suleman** and **Rosanne Middleton** note in A multiprong approach to organizational regulatory intelligence: One company's experience. Growing that RI function can be challenging, but Suleman and Middleton describe step-by-step how they established a dedicated, in-house RI function in a company after it was divested. They detail how they defined the process for regulatory surveillance/monitoring and highlight the importance of communication, cross-functional team engagement, and doing regular reviews and analyses during that stage. They also report on the impact of the new RI

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function on the organization and how it grew to populate organizational dashboards and strategic planning tools.

In Advantages of developing and deploying an in-house regulatory intelligence database, **Sean Schofield, William Waggoner,** and **John Joines** share their experience in developing and maintaining an in-house RI database at a contract research organization. They suggest companies with a global regulatory presence stand to benefit from having such a database, especially if it is flexible, customizable, sufficiently interactive. The system structure should support diverse users who can both access content and provide feedback for improving the system. This collaborative effort serves as a system of checks and balances to ensure the business-critical content is optimized for timely delivery of projects.

Access to regulatory precedent is essential for formulating a regulatory strategy, and there many publicly available sources of precedent, including company documents and marketing application review files. In FDA's new integrated review template and implications for regulatory intelligence, **Emily Huddle** provides a valuable outline of available review summary information for devising regulatory strategy, as well as tips on how to search across review summaries. Huddle also addresses the impact of the FDA's new integrated assessment template on information disclosed within the review documentation. She suggests this improved transparency will contribute to increased predictability of regulatory success, which will benefit a range of stakeholders, including patients.

Labels and device identification, prescription drug promotion

A significant amount of time and money has been spent in the US to create the national UDI system, AccessGUDID. Other jurisdictions, including the EU, Australia, China, Saudi Arabia, and South Korea, are also addressing their UDI regulations. In The importance of the device label to a global UDI system, **Terrie Reed, Dennis Black, Rich Kucera,** and **Shivum Bharill** suggest jurisdictions standardize labeling requirements so the UDI and data in UDI databases (UDIDs) match the information on the device label and the UDID metadata are represented as consistently as possible across jurisdictions. They note that reducing cross-jurisdiction variance as the global UDI system expands could pave the way for formalizing a global medical device data repository.

The FDA's Bad Ad program has been in place for just more than 10 years and remains focused on ensuring prescription drug promotion remains truthful, balanced, and accurate. In The FDA, prescription drug promotion, and its Bad Ad Program, **Ankur Kalola** provides an overview of the program and discusses its results to date based on the number of promotional pieces submitted to the Office of Prescription Drug Promotion, reports of potentially false or misleading promotion, and compliance actions.

Writing skills and career advancement

In Good writing skills as a cornerstone for career advancement, **Nancy Singer** underscores the importance of strong written communication skills to assist in regulatory career advancement. Singer provides tools and techniques for writing clear, accurate regulatory documents, among them, identifying the reader so information can be precisely targeted or customized; organizing the information; and using online grammar, proofreading, and formatting tools. Singer leaves the reader with a valuable takeaway: Write to inform, rather than impress.

Upcoming in REGULATORY FOCUS

What's coming in April?

Articles during April will focus on Regulatory Career Development. Look for this topic and more throughout April at REGULATORY FOCUS.

And May?

For the May issue, REGULATORY FOCUS will have an update on the EU Medical Device Regulation and the In Vitro Diagnostic Regulation. The submission due date for articles has been extended to 12 April 2021. To contribute to the issue, email rmatthews@raps.org.

Call for articles: June monthly issue

In June, REGULATORY FOCUS will present the annual issue on Nutrition in Health and Disease Management, and the Gut Microbiome. The submission due date for articles is 3 May 2021. To contribute, email rmatthews@raps.org.

Upcoming in RF QUARTERLY

REGULATORY FOCUS launched the inaugural issue of RF QUARTERLY in mid-March. The new publication replaces the former quarterly article series. Each issue will include original content, developed around a theme, as a member-exclusive addition to regular monthly REGULATORY FOCUS articles. The themes for the rest of 2021 will be:

- Artificial Intelligence in Regulatory Affairs (June)
- Quality and Compliance in Regulatory Affairs (September)
- RAPS 2021 Convergence (December)

To contribute to the September or December issues of RF Quarterly, email rmatthews@raps.org.

For more information, see Guidelines for Authors and the 2021 Editorial Calendar.