February's REGULATORY FOCUS: Global and regional harmonization and alignment

Renée Matthews

Feature articles during February included a range of topics focused on harmonization and alignment across global and regional regulatory entities, including electronic submissions through the European Medicines Agency (EMA), tools for updating the EU In Vitro Diagnostic Regulation (EU IVDR) template, China's new PAC regulation, Project Orbis and improving patients access to new therapies, as well as a report on medtech companies' preparation for EU Medical Device Regulation (EU MDR) implementation.

The EMA facilitates a range of regulatory submissions and application processes through different systems, but it is a laborious system for first-time applicants, who must first create several different accounts and assign roles before they can actually initiate a submission. In Navigating the maze of electronic submissions at EMA, regulatory experts **Maurice Bancsi** and **Beatriz Criado** provide a valuable step-by-step guide for first-time applicants setting up for the electronic submission process. The guide outlines setting up the separate accounts for the EMA and eSub accounts, getting the EMA account number,

©2021 Regulatory Affairs Professionals Society

and establishing user access to the SPOR (Substance, Product, Organization, and Referentials), IRIS, and EudraCT platforms.

Still in Europe and focusing on harmonization of processes, IVDR regulatory affairs consultant **Annette Hormann** offers advice for regulatory professionals on updating existing templates to meet the new EU IVDR requirements and showing compliance with the safety and performance requirements of EU Regulation 2017/746. In Tools for updating the IVDR template for demonstrating scientific validity, Hormann takes the reader through the steps, but emphasizes that ultimately, it is the appropriate use of supporting documentation – flow charts and tables, for example – containing device or IVD product data that will ultimately help professionals update the template to demonstrate how a product meets scientific validity requirements.

China's National Medical Products Administration recently issued a new regulation on postapproval changes (PACs). In addition to complying with the requirements in the Drug Registration Regulation regarding classified, risk-based change management for manufacturing processes, the regulation details the responsibilities for the manufacturing authorization holder (MAH), the national and provincial regulatory agencies, and emphasizes that the MAH bears the main responsibility for the PAC change activities. In China's new PAC regulation: Closer alignment with global best practices regulatory affairs specialist **Yingying Liu** provides an overview of the regulation and its annexes for PACs and discusses their impact on manufacturing site change management, change classification determination and consultation, and reporting categories. Lui notes that more guidance is needed, but nevertheless, the regulation provides much-needed clarity and aligns the Chinese regulatory system more closely with international best practice legislation.

Project Orbis, an initiative of the US Food and Drug Administration's Oncology Center of Excellence, is a pilot program providing applicants with a framework for concurrent submission and review of oncology products among international partners. The aim is to ensure equitable access to new medicines for all patients by allowing drug manufacturers to register new products earlier and in as many countries as possible. In Project Orbis: Maximizing patient access to new medicines, global regulatory strategists **Narissa Mulchan** and **Allison Guy** summarizes Genentech's experience with the pilot from November 2019 to December 2020. They note that as Project Orbis and other regional review procedures become more routine, it may be useful to establish new global standards to optimize clinical trial design to make them more amenable to simultaneous international review.

With the end of the transition period for the EU MDR coming up in May 2021, many medtech companies producing devices in the EU have to put the necessary processes in motion to comply with the new demands. This means gathering as much data as possible to establish patterns and extent of resource allocation, especially in terms of time, cost, and personnel. In EU MDR survey:

Time investment, costs, and personnel resources, **Veronika Schweighart**, a clinical data management specialist, and **Catherine Higginson**, specialist in clinical data capture and market research in the medtech sector, report on a 2020 survey they conducted among medical device manufacturers to assess the true costs of the EU MDR to companies. The results show that the regulation requires considerable resources on the part of manufacturers in terms of time, costs, and personnel, and that postponement of the regulation's validity date to May 2021 had not seemed to alleviate the situation. The authors caution, however, that the new regulation should not be viewed as a mere cost driver, but as a potential catalyst for long-term innovation.

Upcoming in REGULATORY FOCUS

What's coming in March?

Articles during March will focus on regulatory intelligence. Look for this topic and more throughout March at REGULATORY FOCUS.

And April?

For the April issue, REGULATORY FOCUS will look at Regulatory Career Development. The submission due date for articles has been extended to 12 April 2021. Topics could include the following:

- What does it mean to work in a regulated environment? (technical knowledge vs. compliance mindset)
- Pathways to regulatory affairs (including quality, compliance, or intelligence as possible areas of focus, and looking at pathway options, such as college, as a new hire, or transitioning from other departments)
- Credentialing (perspectives from RAC holders, pathways, and pursuing and maintaining credentialling)
- Specializing in regulatory healthcare compliance (fraud and abuse)
- Life as a regulatory professional (at a small or large company; as a consultant)
- Transitioning product lines/specialties (commonalities and differences)
- Transitioning from specialist, to manager, to director, to VP (tactical knowledge, strategic thinking)
- Reaching beyond your company – contributions to the profession (writing articles, presenting at conferences, chapter leadership, organizational participation)

To contribute to the issue or suggest a topic not listed above, email rmatthews@raps.org.

Call for articles

May monthly issue

For the May issue, Regulatory Focus will have an update in the EU Medical Device Regulation and the In Vitro Diagnostic Regulation. The submission due date for articles has been extended to 30 April 2021.

To contribute to the issue or suggest a topic not listed above, email rmatthews@raps.org.

Upcoming in RF QUARTERLY

REGULATORY FOCUS is launching the RF QUARTERLY series this March to replace the former quarterly article series. Each RF QUARTERLY will include original content, developed around a theme, as a member-exclusive addition to regular monthly Regulatory Focus articles. The themes for 2021 will be:

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

To contribute to the June RF QUARTERLY or any of the other upcoming issues of RF Quarterly, email rmatthews@raps.org.

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