January's REGULATORY FOCUS: The impact of disruption on the global regulatory

By Renée Matthews

Feature articles during January focused the effects of disruption on global regulatory practice. In context of the COVID-19 pandemic, authors examined expedited approval pathways for tests kits in southeast Asian countries; the role of digital promotional strategies in minimizing the impact of the pandemic on advertising, promotion, and labeling; and the importance of continuing soft-skills training during remote working. Under the broader framework of disruption, a group of authors identified changes in industry regulations as a disruptive trend and explored how digital transformation can help companies meet new regulatory compliance demands. Also included in the issue were articles on medical device software under the EU Medical Device Regulation (MDR) and on the new Dietary Guidelines for Americans.

COVID-19, changing regulations, and disruption

Regional regulatory authorities in southeast Asia moved rapidly to introduce pathways for accelerated approval of in vitro diagnostic (IVD) test kits after COVID-19 spread from China in early 2020. Some countries already had expedited pathways in place; others had to develop and introduce the alternate

pathways within the confines of strict quarantine restrictions. In COVID-19 IVD test kits: Expedited response by Asian regulatory authorities, regulatory affairs specialist **Anisha Panth** describes the pathways and measures taken. She emphasizes the need for a harmonized application process to further streamline future emergency responses so that manufacturers can prepare a single application for distributing product in the region.

Another early impact of the pandemic was the shift from print to digital promotional strategies by regulatory advertising and promotion (AP) professionals. Some pandemic-related changes to the AP review process now seem standard. However, in Impact of the COVID-19 pandemic on aspects of regulatory advertising and promotion, regulatory advertising and promotions manager **Olivia Walker** recommends that sector professionals examine and assess solutions to those early challenges to establish best practices going forward and for dealing with future crises.

Soft skills have an important role in defining one's employability and advancing both personal and team success. In Soft skills training during a pandemic: Why it's important, and how to do it, professional development specialist **Nancy Singer, JD, LLM, RAC, FRAPS,** discusses how training during the pandemic can help employees – and by default, companies – achieve goals while also giving them the opportunity to connect with colleagues and build morale while working remotely. Singer, who is a member of the RAPS Board of Directors, provides tools and techniques for regulatory managers to create a virtual training program on soft skills, with a focus on effective communication.

Regulatory compliance specialists **William Buzzeo** and **Michelle Gyzen** expand the scope of regulatory disruption to include changes in industry regulations as a driver of disruption. In Transforming regulatory strategy to meet the evolving compliance landscapes, the authors focus on the impact of regulatory changes on pharmaceutical and life sciences organizations' ability to meet compliance demands for medical devices. They argue that digital transformation – and specifically, a technologically advanced data strategy – can help companies meet compliance expectations and maintain business value.

New regulations, guidance, and guidelines

The EU MDR has been published with new medical device software (MDSW) requirements, along with qualification guidance to determine if software is MDSW and guidance for MDSW classification. However, the change to EU MDR has introduced new problems for clinical evaluation because the current EU Medical Device Directive guidance for clinical evaluation is still in use. In Medical device software under the EU MDR, medical devices expert **Leo Hovestadt** outlines new guidance for clinical evaluation of MDSW and for equivalence, legacy devices, and the notified body's clinical evaluation assessment report. Hovestadt suggests the EU MDR should be closely studied as it is a source for useful solutions for clinical evaluations. In addition, he notes that under the guidance for MDSW qualification and classification, proper application of Rule 11 could help avoid assignment to a higher-risk classification.

For the first time, the 2020-2025 dietary guidelines from the US Departments of Agriculture and Health and Human Services are organized by life stage to include infants and toddlers and expanded advice for pregnant and lactating women, according to **Haiuyen Nguyen**, a specialist in dietary supplement regulations, in New US dietary guidelines expand nutrient considerations for life stages. The guidelines to provide a customizable framework for diet and healthy eating across the lifespan and with specific recommendations for each life stage as well. Nguyen notes although the guidelines are intended for health-focused professionals, they are readily accessible for the general public as well.

Upcoming in REGULATORY FOCUS

What's coming in February?

Articles during February 2021 will focus on a range of topics on Global Regulatory Harmonization. Look for these topics and more on the REGULATORY FOCUS site throughout February.

We will accept submissions until 12 February 2021, especially articles on initiatives by national regulatory authorities for developing work-sharing arrangements or describing the progress and challenges in the global adoption of International Council for Harmonisation standards. To contribute to the issue or suggest a topic, contact Renée Matthews at rmatthews@raps.org.

And March?

For March, REGULATORY FOCUS will look at Regulatory Intelligence.

Call for articles

April monthly issue

For the April issue, REGULATORY FOCUS will look at Regulatory Career Development. The submission due date for articles is 15 March 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 members, pathways, and pursuing and maintaining credentialling)
- Specializing in regulatory healthcare compliance (fraud and abuse)
- Life as a regulatory professional (small or large company or 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.

RF QUARTERLY

REGULATORY FOCUS is launching the RF QUARTERLY series this Spring 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 (Spring)
- Artificial Intelligence in Regulatory Affairs (Summer)
- Quality and Compliance in Regulatory Affairs (Fall)
- RAPS 2021 Convergence (Winter)

For the Spring RF QUARTERLY focusing on Global Clinical Trials, we are seeking articles on the following topics:

- Preparations for the upcoming EU Clinical Trials Regulation
- Implementation of the FDA guidance on patient-focused clinical development
- Reporting clinical trial changes to the FDA during the COVID-19 pandemic
- Ensuring diversity clinical trials
- Experience with the EU Voluntary Harmonization Procedure
- How to get alignment of FDA, EMA, and PMDA on global registration trials
- Approaches to first-in-human trials for rare diseases (especially with gene/cell therapies)
- Inclusion of ex-US investigators under INDs

We would also be interested in articles on topics not mentioned here, but that fall within the broader context of the issue theme.

The submission deadline for articles is 10 February 2021. To contribute to the Spring RF QUARTERLY or any of the other upcoming issues of RF QUARTERLY, email rmatthews@raps.org.

Also see Guidelines for Authors and 2021 Editorial Calendar

Citation Matthews R. January's REGULATORY FOCUS: The impact of disruption on the global regulatory community. January 2021. REGULATORY FOCUS. Regulatory Affairs Professionals Society.