RF Quarterly

Volume 1 • Number 3

Introduction: Quality and compliance

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Welcome to the fall issue of RF Quarterly in which international experts from the US, EU, and Saudi Arabia examine quality and compliance and their governing regulations, with specific focus on data integrity, quality system design and management, current good manufacturing practice (cGMP), and postmarketing activities in relation to medical devices, pharmaceuticals, and biologics.

Pragmatism, integrity, and QMS

Data reliability in all formats and parts of an operation is critical for ensuring product reliability, but if the information in the regulatory dossier is not accurately translated into working documents, the integrity of the data generated will be compromised. In Data integrity and compliance with GxP: A pragmatic approach (p. 4), **David W. Husman** offers useful, hands-on guidance for ensuring data integrity while emphasizing that computer data are only a small part of the broader landscape. Other factors, such as appropriate governance, a culture of compliance and integrity, and effective procedures are critical to drive consistency in the execution of those tasks.

Compliance with US Food and Drug Administration (FDA) cGMP regulations is crucial for ensuring the safety and effectiveness of pharmaceutical, biologic, and medical device products on the US market. The regulations require establishment of a quality management system (QMS) for maximizing conformity with policies and procedures, promoting efficiency and accuracy, and ensuring product safety and efficacy. In Current good manufacturing practices and quality system design (p. 19), **Joscelyn Bowersock** and **Richard Vincins** examine the impact of an effective QMS, noting that manufacturers with robust QMS processes can more readily ensure quality in product development, manage risk, and initiate continuous improvement activities. That could translate into fewer product failures and recalls and shorter and fewer FDA inspections. The authors caution that regulations change, so manufacturers must stay informed and have regulatory intelligence operations to provide timely updates to leadership and compliance teams.

In Medical device quality management systems (p. 41), **Gert Bos** underscores the importance of the QMS, but for medical device companies, which need to be able to control the design, manufacturing, and supply processes so that devices are safe and effective and conform to agency regulations globally. The recognized international standard for medical device quality management systems is ISO 13485:2016, although some countries still use the 2003 iteration and others, such as the US, have their own requirements. Bos provides a detailed his-

torical context for the standard and an overview of its requirements. He describes the QMS validation process and emphasizes that all supplier products and services should be strictly controlled so that they meet the manufacturer's standards.

Postmarketing, compliance, and CAPA

Product development and regulatory registration are part of the overall product lifecycle. Ongoing maintenance and reporting are necessary throughout a medical device's lifetime to ensure compliance with the quality system requirements. In Medical device compliance and postmarketing activities (p. 54), **Ryan Burke** and **Elizabeth Goldstein** provide an overview of medical device postmarketing requirements, which include establishing processes for registration, medical device reporting, and device tracking, among others, as well as postmarket surveillance and postapproval studies for certain application types. The authors highlight the importance of unique device identification (UDI) in the tracking process and also share valuable guidance on exporting medical devices from the US.

In PMS and the role of CAPA in the medical device regulatory cycle: A Saudi perspective (p. 68), **Mohammed Majrashi** examines the role of CAPA in quality management, with a focus on practices in Saudi Arabia. He stresses the importance of having robust PMS to ensure continued, safe production and use of medical devices while keeping abreast with globalization and the expansion in new technologies. CAPAs and a UDI system should be incorporated into the quality management system, and the PMS system should include reactive and proactive components. In addition, strong communication with healthcare practitioners and the public is crucial, as is harmonization between regulators for fluid exchange of data and information and knowledge sharing.

Biologics manufacturers are required to comply with the FDA's preapproval and postapproval requirements, and noncompliance may include a request for a risk evaluation and mitigation strategy, medication guide, or postmarketing study, writes **Anne Marie Woodland** in Biologics compliance (p. 72). Compliance with these regulations should be based on a QMS and risk management to capture changes during product development and process validation. Woodland details the regulations and approval pathways for biologics, and outlines useful advice on addressing chemistry, manufacturing, and controls changes, safety reporting, and good clinical and laboratory practice for biologics.

I thank the authors for their generosity in sharing their knowledge and expertise with the RAPS regulatory community and hope their insightful articles and will serve as useful guidance and resources in your work. As always, I also thank my RAPS colleagues for their contributions in making this issue possible.

Upcoming issues of RF Quarterly

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- Software as a medical device (March 2022)
- Regulatory history (June 2022)
- Strategy in regulatory affairs (September 2022)
- RAPS 2021 Convergence (December 2022)

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Citation Matthews R. Introduction: Quality and compliance. RF Quarterly. 2021;1(3):1-2. Published online October 2021.