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Introduction: Software as a medical device

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Welcome to this issue of RF Quarterly in which global experts on software as a medical device (SaMD) address topics such as software development and the associated challenges, clinical evaluation of SaMD, safety and security risk management, digital therapeutics, and more.

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

Development and challenges

In Software development (p. 4), **Jaap Noordmans** notes that the most important activity in software development is defining the requirements because architecture, risk management, and deliverables depend squarely on the requirements. The author also discusses validation, security, and usability engineering aspects of software, emphasizing that medical device manufacturers must find a balance between user need, intended purpose, benefit-risk, clinical claims, and clinical data. The agile development method is commonly used because of its flexibility in handling changing requirements, though Noordmans cautions that it does not provide a holistic approach to support safety and performance-related characteristics.

Tahir Rizvi, **Savannah Hari**, and **Chris Gilbert** provide an overview of the quality system requirements for SaMD in Overcoming obstacles for SaMD development (p.28). They emphasize considerations for implementing an agile or hybrid development process and expand on topics unique to SaMD development, such as the importance of dataset integrity during development and approaches for proactive postmarket surveillance. They also examine the interplay between cybersecurity and risk management.

Clinical evaluation, safety, and security

One of the key requirements for SaMD manufacturers and a focus area for regulators is the evaluation of clinical safety and performance and overall benefit-risk profile of the product through a critical assessment of clinical data generated from its use. In Clinical evaluation of software (p. 38), **Zuzanna Kwade** outlines specific guidelines and standards for generating relevant clinical evidence and clinical evaluation of SaMD. However, she writes that the lack of unified industry standards for risk classification and evaluation of medical artificial

intelligence is delaying in new product registrations. Adopting the same technical documents, standards, and scientific principles across countries and regions would lead to more similar or better aligned regulatory requirements and approaches that would promote these technologies while ensuring patient safety.

In Safety risk management of software (p. 50), **Mikael Dahlke** and **Robert Ginsberg** tackle the issues around delivering high-quality software and effectively complying with regulations, especially with IEC 62304 and ISO 14971, the internationally recognized standards for medical software lifecycle and risk management, respectively. The authors provide background on dealing with risk management for SaMD, address the key challenges, and propose strategies for managing them. They also examine other safety-critical industries and offer methods for improving software quality.

Security risk management for SaMD should consider both the platform and the infrastructure in which the software and platform operate, writes **Ben Kokx** in Security risk management (p. 71). Vulnerabilities can occur in the software components, though there might also be design flaws in access controls and infrastructure, unprotected interfaces, and ways to bypass security controls. As such, security should address data protection in addition to safety and performance.

Digital health and DTx

Digital therapeutics (DTx) are a subclass of digital health, a branch of healthcare focused on improving health using internet, digital, and mobile technologies. In Digital therapeutics: Leveraging the SaMD framework for regulatory success (p. 83), **Jainam Shah**, **Geena George**, **George Cusatis**, and **Darin Oppenheimer** explore the current digital health ecosystem and how SaMD frameworks can be leveraged for regulatory success for these new software-driven, nonpharmacological therapeutics.

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