Johnson & Johnson MEDTECH

Industry Perspective
SaMD Regulatory Challenges

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SaMD – Industry Perspectives Regulatory Challenges

- Nature of software is different than other medical devices
  - Iterative changes planned and unplanned
    - High volume of submissions
  - Evolving risks (ie cybersecurity)
  - Delivery methods (not physical supply chain channels)
- Need to develop expertise and capacity
  - Regulators and industry
- Need to develop risk-based fit-for-purpose approaches

Considerations

- Qualification – Am I regulated as a device?
  - Per IMDRF meets the definition of device
  - Definition varies by jurisdiction (US and EU very different)
  - Interpretation also varies by jurisdiction
  - Focus HA use of resources
- Classification – If I am a device what is my risk classification?
  - IMDRF proposes a risk classification (significance and state of the healthcare condition)
  - While appropriate it is difficult to align with traditional risk classifications for devices
- Clinical Evaluation – What kind of data is needed to support?
  - IMDRF proposes an approach
  - Not generally implemented or understood
- Artificial Intelligence
  - There are some differences, but the approach should be the same

Global Landscape

- Drivers of patient access to safe and effective products
  - Good Regulatory Practices
  - Global convergence/predictability of requirements
    - Exclude low risk functionalities
    - Multiple function approaches
  - Minimization of country-specific requirements including certifications
  - Leveraging and increase in recognized standards
  - Capacity building
    - Reliance and recognition (number of staff)
    - Technical training (expertise of staff)
    - Infrastructure (ability to review software per regulatory requirements)
  - Novel regulatory approaches to life cycle management

Thank you

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