Essential Principles of Safety and Performance of Medical Devices and IVDs

Recap of September 11 Webinar and Setting the Scene for Today

Kenneth J. Cavanaugh Jr, PhD

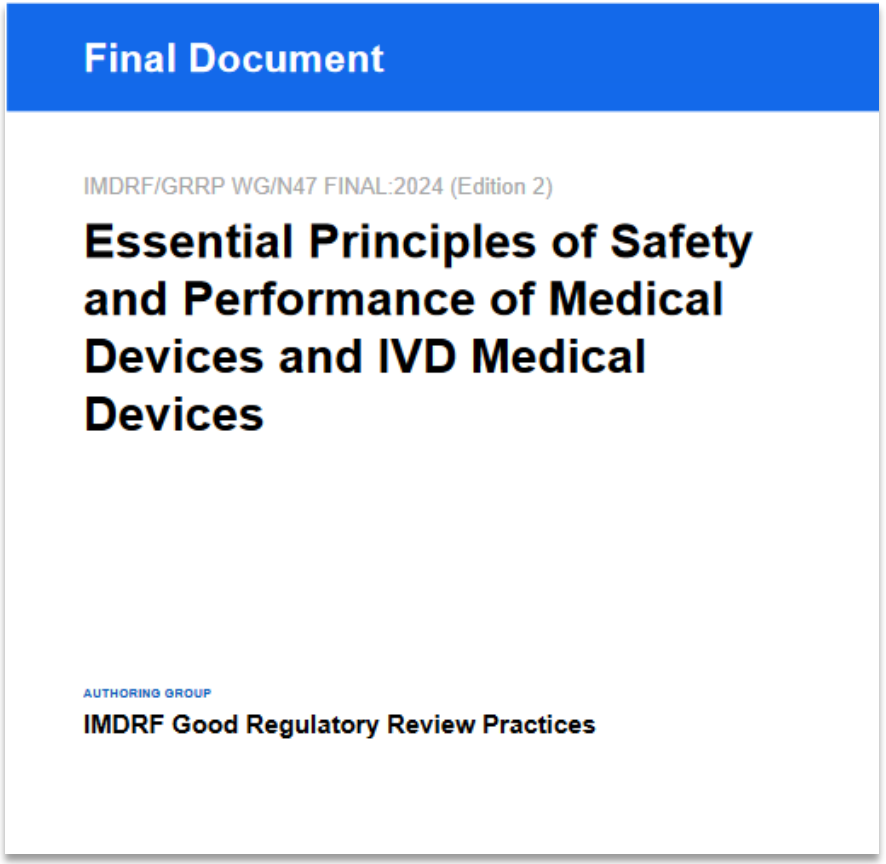
Associate Director for International Policy and Strategy, US FDA CDRH

Co-chair, IMDRF Good Regulatory Review Practices Working Group

September 19, 2024

Essential Principles of Safety and Performance

- Essential Principles (EPs) are fundamental design and manufacturing requirements for medical devices that, when met, provide assurance the device is safe and performs as intended
- Provide rigorous yet flexible framework for conformity assessment throughout the medical device or IVD life cycle



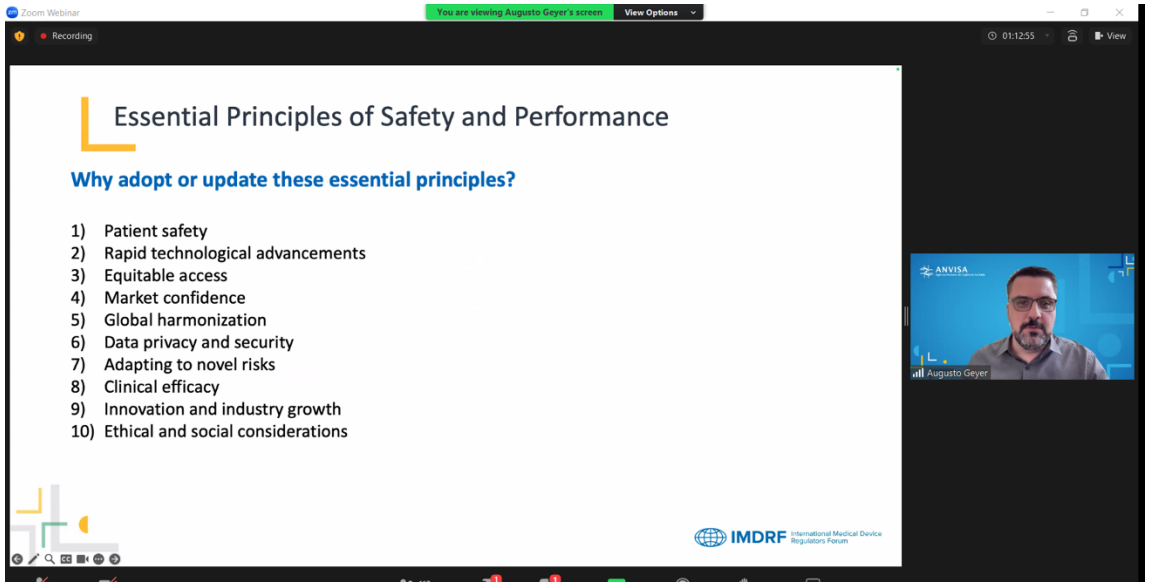
Remember This?

Key Points to Remember

- IMDRF Essential Principles (EPs) are our **blueprint** to provide safe and effective product, no matter the jurisdiction
- EPs combined with International Consensus Standards ("Standards") are our **recipe for success**
- Application of the EPs and Standards should be **flexible**
- **Manufacturers** are generally responsible for demonstrating conformity
- Implementation of EPs and Standards help regulators operationalize **reliance**

Role of Essential Principles

- Efficiently facilitate access to high-quality medical devices and IVDs
- Benefit all stakeholders in the healthcare environment
- Optimally used together with consensus standards, regulatory guidance, and other IMDRF documents

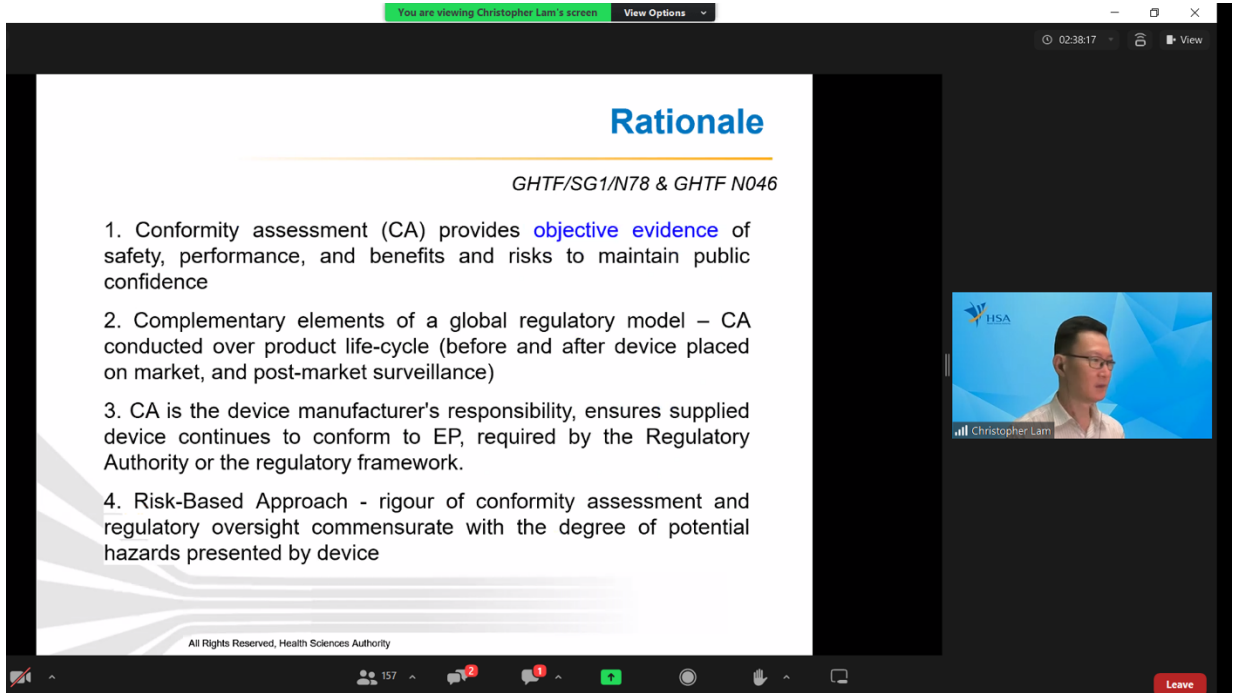


Good Regulatory Practices

- Internationally recognized processes and procedures that improve the quality and cost-effectiveness of domestic regulations
- Key characteristics:
  - Stakeholder engagement and transparency
  - Regulatory accountability
  - Clarity of process and requirements
  - Informed decision-making
  - Impact assessment
- Support EP-based regulatory framework

Conformity Assessment Using EPs

- Ensure device conforms with applicable EPs
- QMS approach – conformity with EPs should continue throughout product life cycle
- Technical documentation should facilitate efficient CA
- Consistent CA approaches can advance regulatory reliance



EP Question and Discussion Topics

- Consensus standards
  - Necessary vs voluntary
- Conformity assessment
  - Technical documentation format and contents
- Alternative approaches to demonstrate conformity to EPs
  - Identification of appropriate methodologies

Where do we go from here?

Applying Essential Principles in the Real World

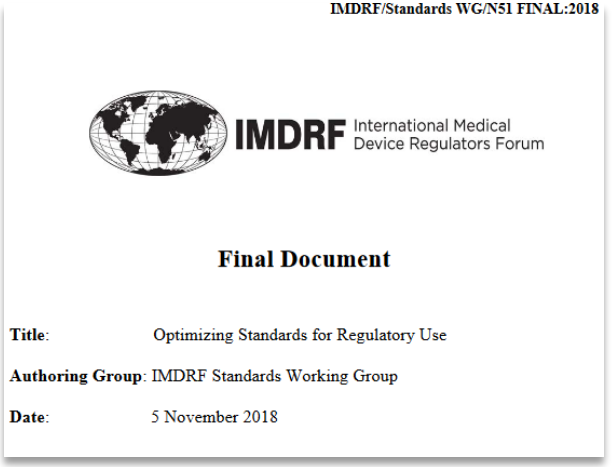
- Demonstrating conformity to an established set of EPs is a powerful regulatory approach
  - … but individual conformity assessments are often not simple

- Challenges
  - Determining EP applicability to individual devices when technologies are complex and regulatory frameworks vary
  - Pathways for demonstrating conformity to EPs are not always clear

Consensus Standards and Essential Principles

- Consensus standards can be a valuable tool in demonstrating conformity to EPs in a consistent and efficient manner

- Important considerations:
  - Optimizing utility of standards for regulatory purposes
  - Ensuring that a given standard is applicable
  - Avoiding barriers in using standards and documenting conformity to EPs



IMDRF/Standards WG/N51 FINAL:2018

IMDRF International Medical Device Regulators Forum

Final Document

Title: Optimizing Standards for Regulatory Use

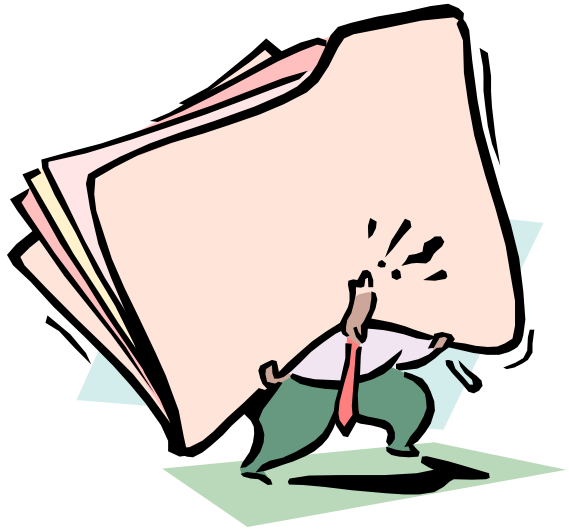
Authoring Group: IMDRF Standards Working Group

Date: 5 November 2018

What to Expect Today

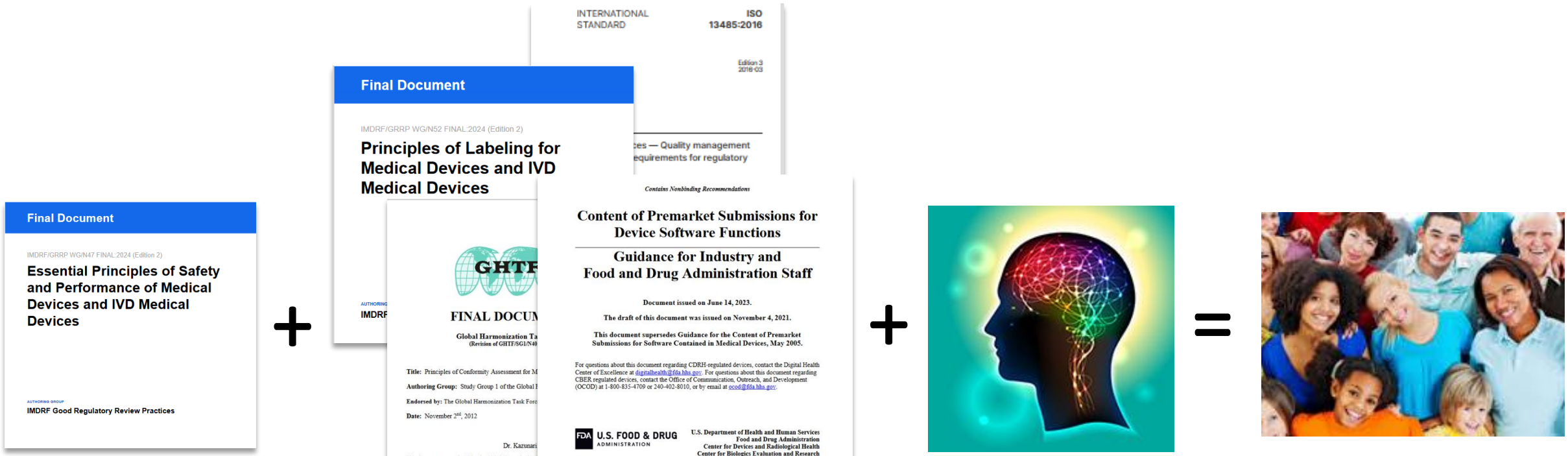
- Deeper learning about consensus standards
  - Development
  - Role within a regulatory framework
  - Application to EP conformity assessment

- Group activity (for those in the room)
  - Apply learnings to actual regulatory situations
  - Discuss observations
  - Explore different ways to think about EP application



Goal

Improved understanding of how EPs are used with other resources along with scientific judgment to enhance regulatory science



Feedback Appreciated!

We look forward to your questions at the end of this session and any feedback you have on the training

Thank you for your participation!