

Essential Principles of Safety and Performance of Medical Devices and IVDs

*Recap of September 11 Webinar and
Setting the Scene for Today*

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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

Final Document

IMDRF/GRRP WG/N47 FINAL-2024 (Edition 2)

Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices

AUTHORING GROUP

IMDRF Good Regulatory Review Practices

Remember This?

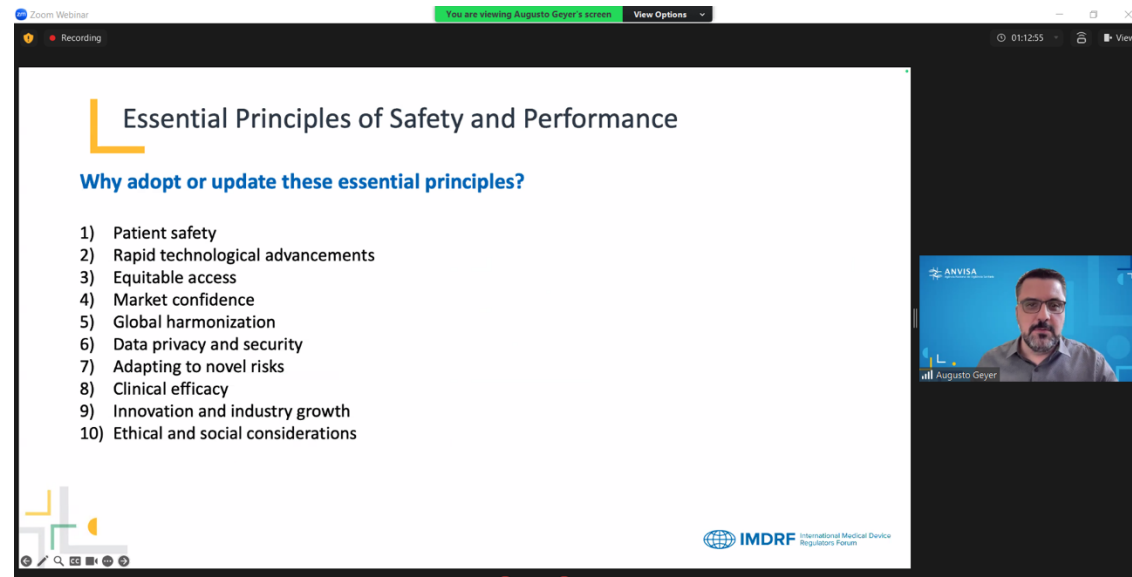
Key Points to Remember



- 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



The image is a screenshot of a Zoom webinar. The main content is a slide with the following text:

Essential Principles of Safety and Performance

Why adopt or update these essential principles?

- 1) Patient safety
- 2) Rapid technological advancements
- 3) Equitable access
- 4) Market confidence
- 5) Global harmonization
- 6) Data privacy and security
- 7) Adapting to novel risks
- 8) Clinical efficacy
- 9) Innovation and industry growth
- 10) Ethical and social considerations

The slide also features the IMDRF logo (International Medical Device Regulators Forum) in the bottom right corner. A video thumbnail of a speaker, Augusto Geyer, is visible in the bottom right corner of the Zoom window. The Zoom interface shows 'Recording' in the top left, 'You are viewing Augusto Geyer's screen' in the top center, and 'View Options' in the top right. The time '01:12:55' is displayed in the top right corner.

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

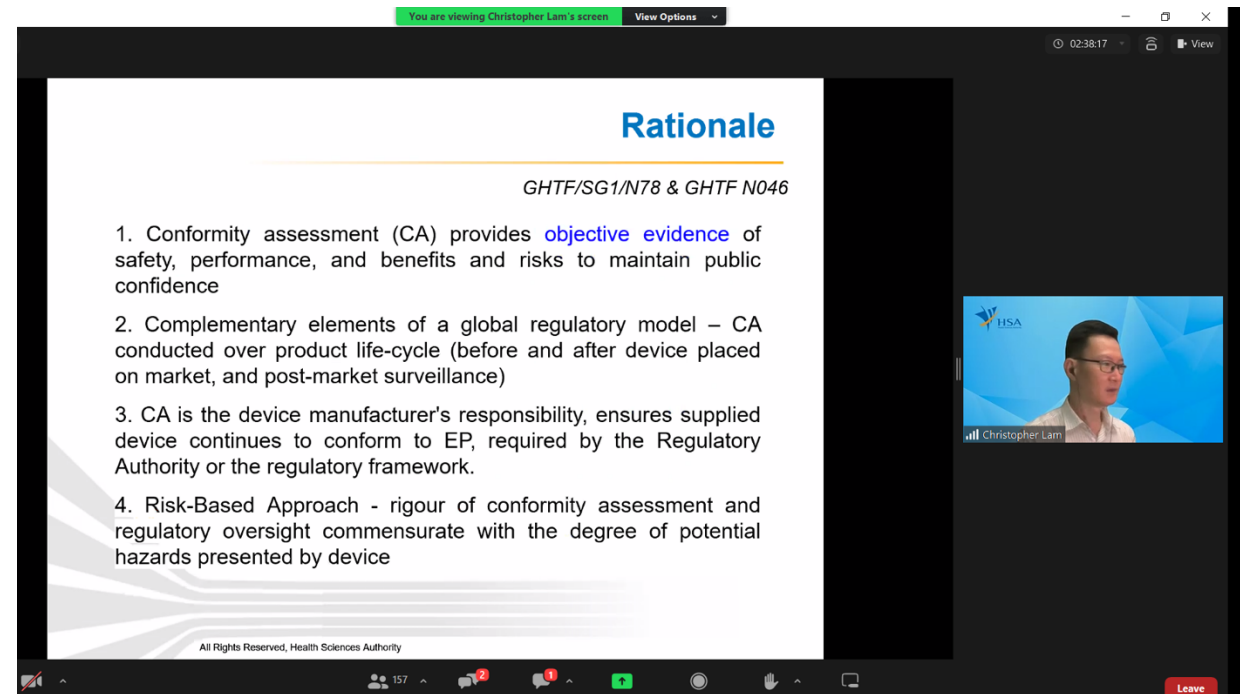


Introduction to Essential Principles: Good Regulatory Practices

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September 11, 2024

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



The screenshot shows a Zoom meeting interface. At the top, a green bar indicates "You are viewing Christopher Lam's screen" and a "View Options" dropdown. The main content is a slide titled "Rationale" in blue text, with a subtitle "GHTF/SG1/N78 & GHTF N046". The slide lists four points:

1. Conformity assessment (CA) provides **objective evidence** of safety, performance, and benefits and risks to maintain public confidence
2. Complementary elements of a global regulatory model – CA conducted over product life-cycle (before and after device placed on market, and post-market surveillance)
3. CA is the device manufacturer's responsibility, ensures supplied device continues to conform to EP, required by the Regulatory Authority or the regulatory framework.
4. Risk-Based Approach - rigour of conformity assessment and regulatory oversight commensurate with the degree of potential hazards presented by device

At the bottom of the slide, it says "All Rights Reserved, Health Sciences Authority". On the right side of the Zoom window, there is a video thumbnail of Christopher Lam, with his name "Christopher Lam" and the HSA logo visible. The Zoom meeting controls at the bottom show 157 participants, a chat icon with a red notification, and a "Leave" button.

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



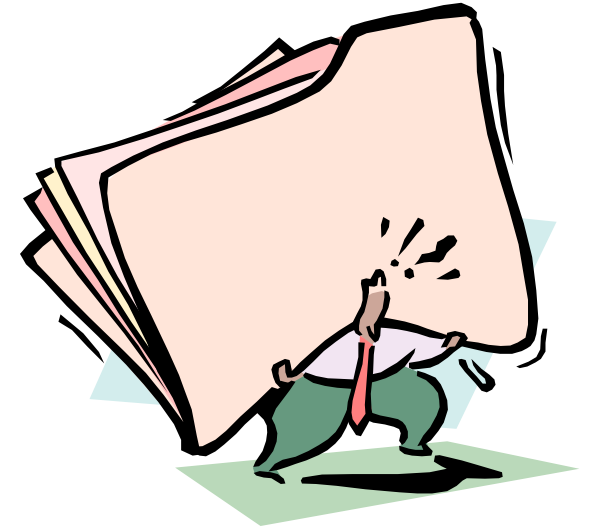
Consensus Standards and Essential Principles

- 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



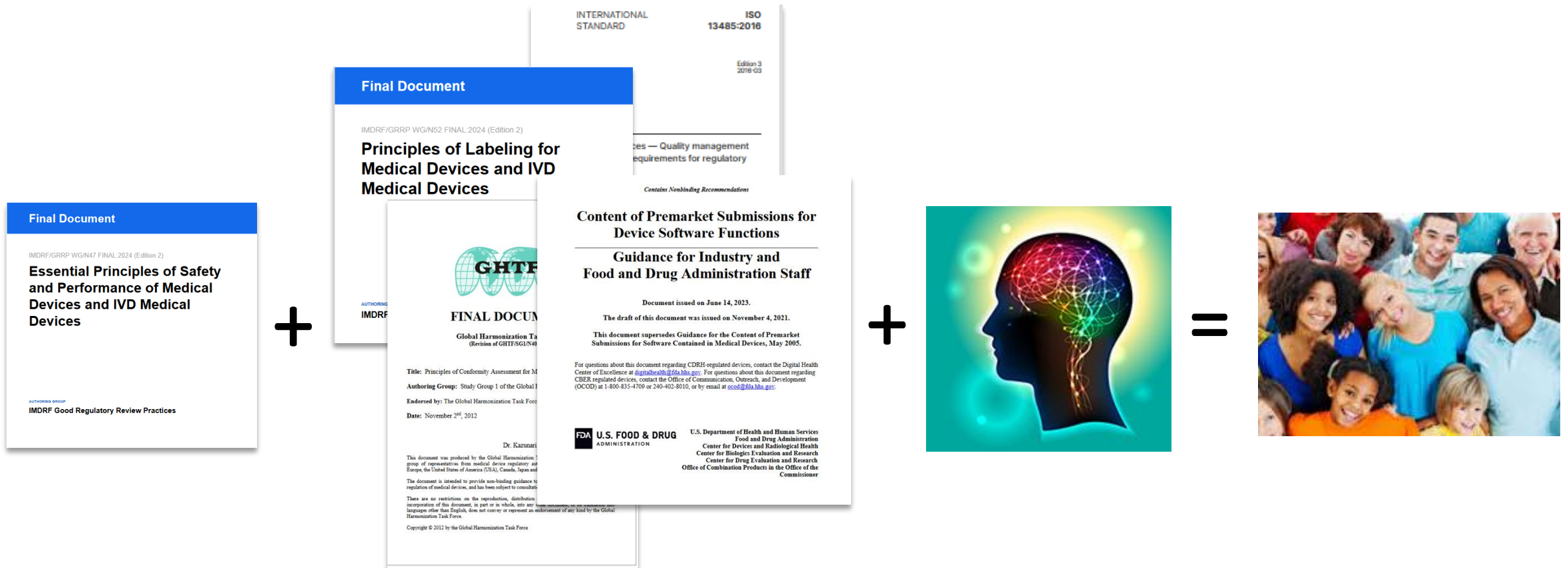
What to Expect Today

- 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!

