Essential Principles of Safety and Performance of Medical Devices and IVD

Summary

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Essential Principles (EPs) are the **Blueprint/Cornerstone** for safe and effective devices

Imagine using these LEGO bricks …

to build this complex skyscraper …

- Like blueprints guide complex construction, **EPs provide a framework** that ensures devices are safe, effective, and meet regulatory requirements that are based on EPs.
- **Standards offer the direction** on how to achieve this vision by providing the technical details and requirements for demonstrating conformity.
- Manufacturers should have the **flexibility to choose** alternative methods for demonstrating conformity. This ensures adaptability without compromising safety and performance.

Flexibility in voluntary standards drives **innovation**

Standards should not be mandatory or modified

Applying standards should be adaptable, enabling manufacturers to use alternative methods to demonstrate conformity, when necessary, along with a clear rationale.

Standards should be applied with flexibility

Only parts of a standard may be relevant to a specific product or process. Manufacturers should be allowed to determine applicable portions using a clear rationale.

Adaptation to evolving technologies

As new technologies emerge, manufacturers need the flexibility to conform to EPs using different methods, scientific judgment, and common sense.

Essential Principles and voluntary consensus standards benefit all stakeholders

1 Patients

- Gain **confidence** in the safety, efficacy, and quality of medical devices
- Benefit from **innovative devices** with shorter development time and faster access
- **Timely access** to life-saving devices improves overall health outcomes

2 Health Authorities

- **Consistent** evaluation and approval of devices across jurisdictions
- Promotes efficiencies and supports **innovation** in regulatory processes
- Provides **harmonized framework** that supports global regulatory efforts and collaboration

3 Industry

- Provides **clarity** on safety, performance, and quality requirements
- Promotes a transparent, efficient, and **predictable regulatory environment**
- Supports **innovation** driven by patient needs
- **Reduces regulatory redundancy** that utilizes more of our finite resources

Common regulatory processes and use of voluntary consensus standards **simplify** regulatory work, reducing duplication across product lifecycle

This improves **efficiency** and **accelerates timely access** to innovative therapies and diagnostics that improve health outcomes

Essential Principles apply across total device lifecycle

Pre-Market Phase

EPs guide the specifications, design, and testing to ensure devices meet the safety and performance requirements.

Market Entry

Standards and conformity assessments provide assurance that devices conform to EPs before they are launched in the market.

Post-Market Surveillance

- Ongoing evaluations ensure that devices continue to perform safely and effectively after they are in use.

- Redesigns may be necessary to address any new risks or findings.

Key takeaways

- EPs & voluntary consensus standards provide a common language for communicating safety, efficacy, and quality across stakeholders.
- EPs & voluntary consensus standards create a framework for collaboration & harmonization across jurisdictions, which facilitates easier application of reliance principles.
- By adhering to voluntary consensus standards, manufacturers and regulators can rely on consistent processes that facilitate timely access to innovative devices.
- It’s best practice to embrace EPs to drive innovation while ensuring safety and effectiveness.
- Flexibility supports innovation and faster access to cutting-edge therapies and diagnostics.

Q&A

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