GHTF SG3 Session Overview

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Asia-Pacific
Economic Cooperation

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SG3 Session Outline and Goals

Existing quality system requirements of countries having developed device regulatory systems will be reviewed during this session.

Goal: Enable identification of areas suitable for harmonization and encourage convergence in regulatory practices to ensure safety, effectiveness & performance, and quality of medical devices.

Quality Management Systems: History and Evolution

Christine Nelson
U.S. Food and Drug Administration

- Why comply with quality management system standard
- What is a quality management system?
- Evolution of quality practices

ISO13485:2003 - An Overview

Gunter Frey
Member GHTF, Study Group 3

- Quality Management System Requirements
- Management Responsibility
- Resource Management
- Product Realization
- Measurement, Analysis, and Improvement
- Records & Documentation

Risk Management Principles and Activities Within a Quality Management System

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- Determination of acceptable levels of risk
- Risk analysis
- Determination of risk reduction measures
- Risk control and monitoring activities
- Case Studies

Process Validation Guidance

Christine Nelson
U.S. Food and Drug Administration

- Definitions
- How are processes validated?
- What processes must be validated?
- How to maintain state of validation
- Revalidation

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An introduction to Design Verification and Validation

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- Verification and Validation activities within the Design Cycle
- Case Studies