



New Developments in the Standards Community – Quality Management & Sterilization

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Conference*

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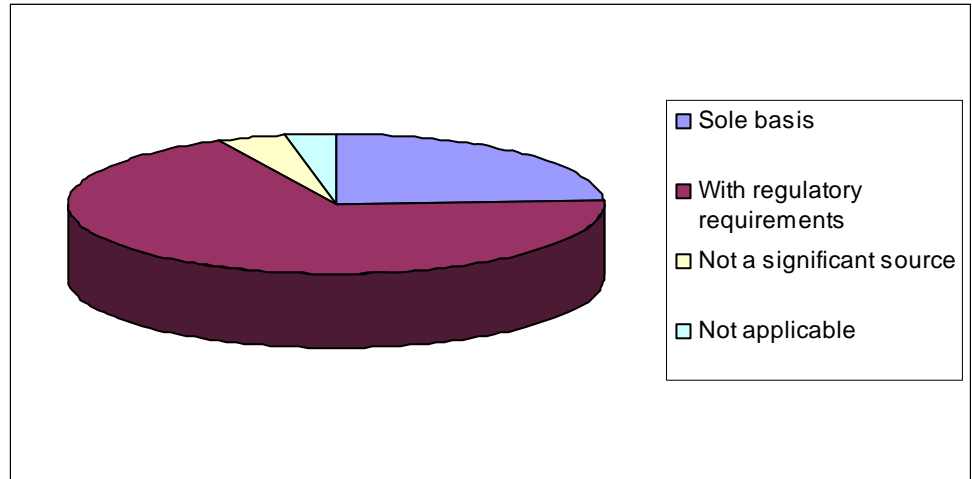
Agenda

- ISO TC 210 – Quality Management & related general aspects
 - Linkage with risk management
 - ISO 13485:2003
 - Labelling & symbols
 - Small bore connectors
- ISO TC 198 – Sterilization of Healthcare Products
 - Standards for development, validation and routine control
 - Risk management linkage
 - Quality Management Linkage

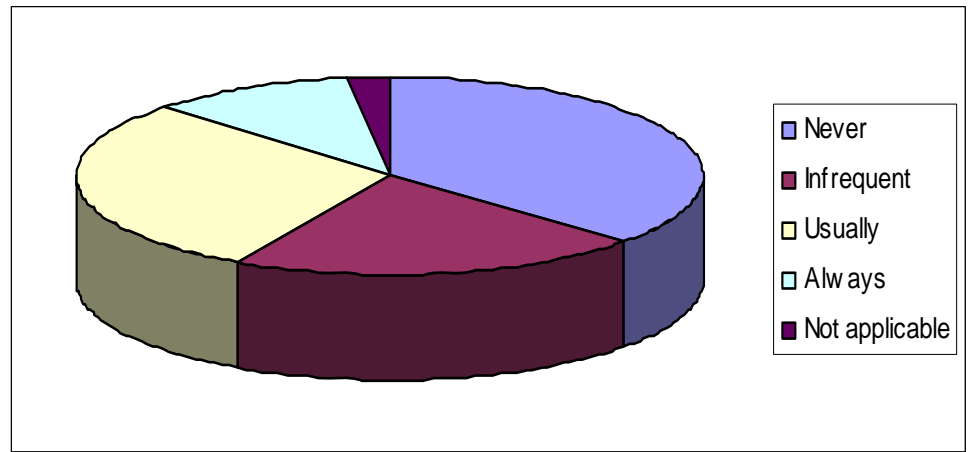
	ISO TC 210	ISO TC 198
• Number of published ISO standards	• 13	• 42
• Participating countries:	• 30	• 28
• Observer countries:	• 18	• 19
• Working groups	• 3	• 14
• Joint WGs/Panels	• 4	• 1
• Cooperative relationships	• IEC TC 62 • GHTF	• CEN TC 204 • CEN TC 102

Responses to ISO TC 210 Questionnaire – ISO 13485:2003 & ISO TR 14969

Percentage of respondents using ISO 13485:2003 as basis for their QMS

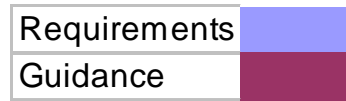
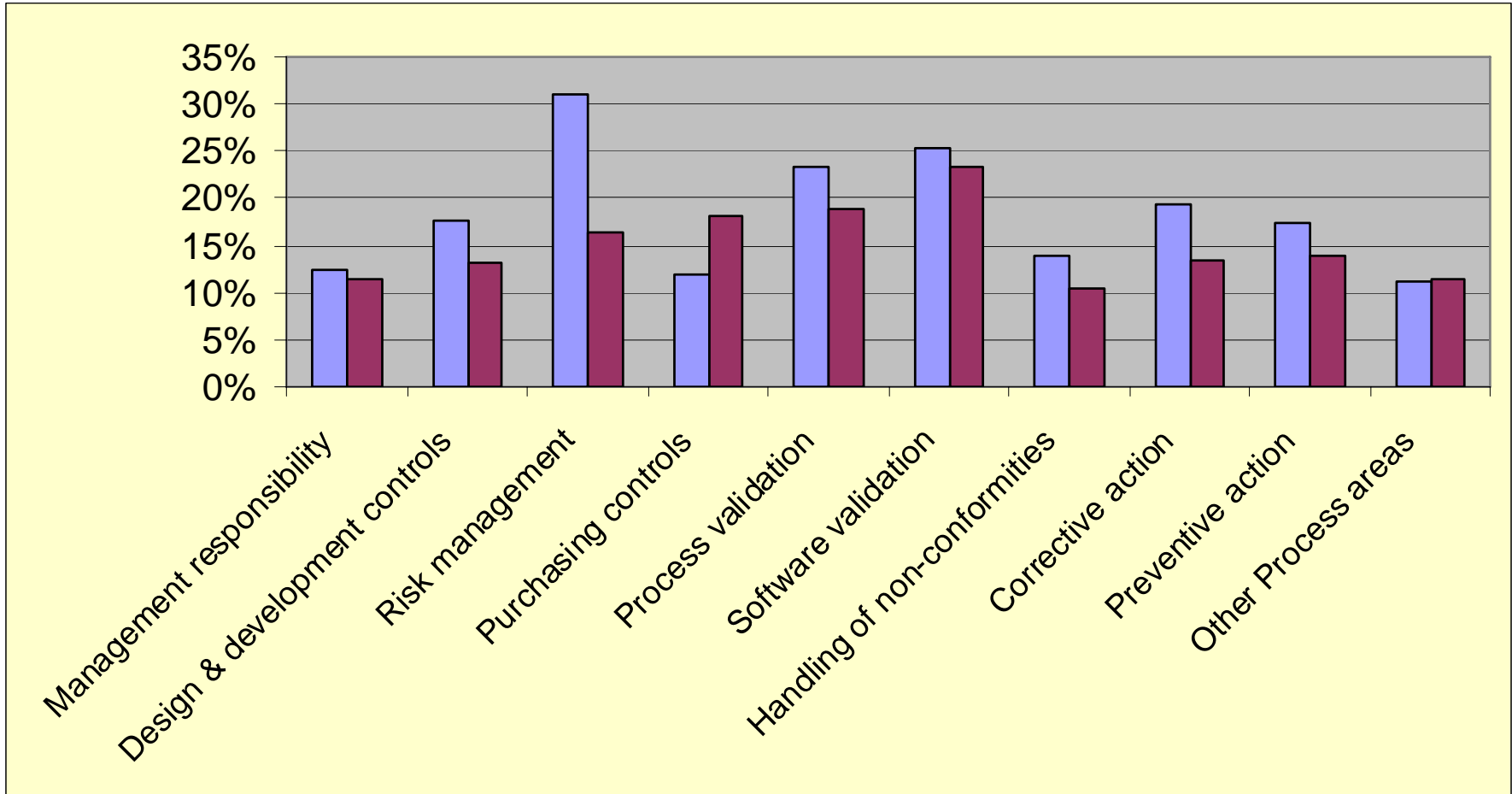


Percentage of respondents using ISO TR 14969:2004 for QMS guidance





Percentage of respondents supporting additional requirements or guidance on particular QMS elements in ISO 13485 or ISO TR 14969



Provision of information to device users is a risk control measure

- ISO TC 210 is
 - defining internationally recognised symbols for a number of key items of information
 - developing a new standard on validation of symbols

Small bore connectors

- International concern at the occurrence of a number of incidents and near incidents associated with inappropriate connection of different medical devices
- Issue affects a large number of different types of medical device and exceeds the scope of any existing ISO or IEC Technical Committee
- Expertise within ISO/TC 210 in risk management and quality management
- ISO TC 210 facilitated a meeting of interested parties in 2006
 - Participants concluded that ISO/TC 210 was best placed to lead this effort
- ISO TC 210 has sought approval for
 - a new work item on small bore connectors, to be undertaken jointly with IEC/SC 62D,
 - amendment the scope of the Technical Committee to clarify its responsibility in this regard.

Sterilization standards

- Sterilization process – risk control measure
 - Reduces probability of a micro-organism being present on a medical device
 - Achievement of the required probability is a customer and regulatory requirements
 - Required probability is predicted from validation of the sterilization process
 - Effective delivery of the sterilization process is demonstrated by routine control measures
- Standards for development, validation and routine control describe consensus on how to demonstrate achievement of required probability
- Sterilization standards do not reference ISO 14971

Sterilization standards (cont ...)

- Common template for standards for development, validation and routine control
 - Published
 - General requirements
 - Ethylene Oxide
 - Radiation
 - Moist heat
 - Aseptic processing
 - Liquid chemical sterilants
 - In preparation
 - Dry heat
 - Low Temperature Steam Formaldehyde
 - Under revision
 - General requirements
 - Liquid chemical sterilants
 - Aseptic processing



Quality management system elements in sterilization standards

- Consistent with regulatory expectations

Documentation requirements

- Document control
- Control of records
- Management responsibility
 - Authority and responsibility
 - Sterilization contractors
- Product realization
 - Purchasing
 - Identification and traceability
 - Calibration
- Measurement, analysis and improvement
 - Control of nonconforming product and corrective action