

QUALITY MANAGEMENT SYSTEMS (QMS)

THE VALUE OF QUALITY MANAGEMENT SYSTEMS

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Fundamentals / 1

- A Quality Management System (QMS) is a collection of business processes focused on achieving quality policy and quality objectives to meet customer requirements. The technique is used in a wide range of businesses, including those who manufacture medical devices.
- A QMS controls three managerial processes: quality planning, quality control and quality improvement.
- The international standard applicable to the design, production, installation and servicing of medical devices is ISO 13485 *Medical devices quality management systems - Requirements for regulatory purposes*. It is widely used.



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QMS Regulatory Requirements

- Medical devices regulations require manufacturers to have a QMS which, for most medical device risk categories, is subject to regular independent audit.
- A manufacturer shall establish, document and maintain a quality system to control the design & manufacture of its medical devices. The manufacturer's management shall demonstrate responsibility for, and commitment to the QMS.
- Procedures describing each element of the quality system shall be recorded and maintained in a Quality Manual.
- Product-specific technical information shall be recorded and maintained under the control of the QMS.



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Quality Manual / 1

- The QMS documents within a quality manual all the procedures and records needed to ensure its products are safe, perform as intended, and meet the requirements the various regulations it needs to comply with.
- The quality manual incorporates, for example:
 - The manufacturer's quality objectives, quality policy, quality plans, and quality records as well as evidence of management commitment.
 - The name and address of the manufacturer and of the manufacturing site/s covered by the QMS.
 - An overview of the types of medical devices covered by the QMS.
 - The manufacturer's organisational structure together with the responsibilities of managerial staff.

continued



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Quality Manual / 2

- The method of monitoring the effective operation of the QMS and its ability to achieve the desired quality of the design and performance of its medical devices.
- Procedures to control, verify, & validate the design and manufacture of specific device types, including risk assessment & management processes, such that the devices meet the requirements of applicable medical devices regulations, during their lifetime.
- Where the design, manufacture, processing, and/or final inspection and testing of the medical devices, or elements thereof, is outsourced to another party, the method of monitoring such activities.



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Other Procedures under QMS Control

- Any tests & inspections undertaken during and after manufacture of particular devices, together with a procedure to calibrate any test equipment and trace its use to the product or sub-assembly that has been tested.
- The post-marketing surveillance plan for the devices, including, where applicable, a plan for the post-marketing clinical follow-up.
- A description of the internal auditing procedure and follow-up activities.



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Single Audit Program / 1

- Medical devices are exported widely. Therefore, manufacturers have to comply with a multiplicity of different medical devices regulations, many requiring the manufacturer's QMS to be audited by the importing country's RA. The administrative burden placed on both the manufacturer and the various RAs, results in increased taxes & product selling prices.
- For many years, industry and regulators have discussed co-ordinating their regulatory activities so as to eliminate multiple audits of the manufacturer's QMS. There are examples within a multi-member 'single market', such as the EU, of this approach as well as in bilateral agreements (e.g. USA & UK in the '90s).



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Single Audit Program / 2

- In 2012, the International Medical Device Regulators Forum (IMDRF), the successor to the GHTF, began to develop a ‘Medical Device Single Audit Program’ (MDSAP).
- The objective is to develop a standard set of requirements for auditing organizations performing regulatory audits of medical device manufacturers’ QMS.
- This action will complement the current ISO13485 revision process under which IMDRF seeks modifications to achieve a harmonized standard among its members.



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Single Audit Program / 3

- The Working Group has developed a standard set of requirements, such as:
 - Requirements for Medical Device Auditing Organizations for RA Recognition.
 - Competency and Training Requirements for Auditing Organizations.
 - RA Assessor Competency and Training Requirements.
 - Guidance on RA Assessment Methods of Auditing Organisations Processes.
 - MDSAP Assessment and Decision Process for the Recognition of an Auditing Organization.
 - Regulatory Authority Assessment Method for the Recognition and Monitoring of Medical Device Auditing Organizations.



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Single Audit Program / 4

- Outside the IMDRF scope, but building on the IMDRF MDSAP guidance documents, the US is leading a MDSAP Pilot Program (excluding design dossier reviews).
- Other participants are:
 - Australia's Therapeutic Goods Administration (TGA).
 - Brazil's Agência Nacional de Vigilância Sanitária (ANVISA)
 - Health Canada
 - Japan's Ministry of Health, Labour and Welfare, and the Japanese Pharmaceuticals and Medical Devices Agency.



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Thank You



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