



# ISO 13485:2016 Are You Ready For This?



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# Agenda

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- ▶ Transition Requirements
- ▶ Overview of Changed/New/Deleted Requirements
- ▶ Questions & Answers



# Transition Requirements

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- ▶ ANAB, the accreditation body based in the United States, has published Heads Up 340 relating to the transition process for CBs and CB clients.
  - ▶ The revised ISO 13485 was published on 1 March 2016. IAF Resolution 2015-13 details a transition period of three years from the date of publication.
  - ▶ A certification body had to apply to migrate its accreditation. Once approved, CBs can issue certificates to ISO 13485:2016.
    - ▶ PJR is approved/accredited to issue ISO 13485:2016 certificates.



# Transition Requirements

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- ▶ As this is a three-year transition plan, PJR is encouraging clients to transition on their recertification audit. No additional audit time is added for clients that transition on recertification.
- ▶ If clients transition on a surveillance audit, then 0.5 day of on-site time is added.
- ▶ The last possible day for an ISO 13485:2016 transition audit is 1 December 2018. This will allow sufficient time for corrective actions, audit package review and certification decision.



# Overview of Changed/ New/ Deleted Requirements: 0.1 General

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- ▶ Includes more detail regarding the types of organizations covered by ISO 13485:2016 and the life-cycle stages covered:
    - ▶ Life-cycle stages: organizations involved in design and development, production, storage and distribution, installation, servicing, final decommissioning and disposal of medical devices and design, development and provision of associated activities.
    - ▶ Types of organizations: can be applied to suppliers or external parties providing product (e.g. raw materials, components, subassemblies, medical devices, sterilization services, calibration services, distribution services and maintenance services) to such organizations.
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# Overview of Changed/New/Deleted Requirements: 0.1 General

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- ▶ **ISO 13485:2016** requires the organization to:
  - ▶ Identify its role under applicable regulatory requirements;
  - ▶ Identify the regulatory requirements that apply to its activities under these roles;
  - ▶ Incorporate these applicable regulatory requirements within its quality management system.



# Overview of Changed/New/Deleted Requirements: 0.2 Clarification of Concepts

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- ▶ “As appropriate” is deemed to be appropriate unless an organization can justify otherwise. A requirement is considered appropriate if it is necessary for:
  - ▶ Compliance with applicable regulatory requirements
  - ▶ The organization to manage risks
- ▶ Use of the word “risk” pertains to safety or performance requirements of the medical device or meeting applicable regulatory requirements.
  - ▶ This extends beyond product realization.



# Overview of Changed/New/Deleted Requirements: 0.2 Clarification of Concepts

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- ▶ “Documented” is understood to mean established, implemented and maintained.
- ▶ “Product” is also understood to mean service.





# Overview of Changed/New/Deleted Requirements: 0.3 Process Approach

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- ▶ Added requirements really drive the process approach to quality management:
  - ▶ Understand and meet requirements;
  - ▶ Consider processes in terms of added value;
  - ▶ Obtain results of process performance and effectiveness;
  - ▶ Improve processes based on objective measurement.



# Overview of Changed/New/Deleted Requirements: 1 Scope

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- ▶ This section again reiterates the expanded applicability of the standard in terms of life-cycle stages and inclusion of suppliers and external parties.
- ▶ Clarifies that outsourced processes are the responsibility of the organization and are to be accounted for in the organization's QMS by monitoring, maintaining and controlling the processes.
- ▶ Clarifies that requirements in sections 6 and 8 (as well as 7) can be justified as non-applicable.



# Overview of Changed/New/Deleted Requirements: 3 Terms and Definitions

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- ▶ Many new terms and definitions have been added. Just the most important ones are being reviewed here:
- ▶ 3.2 Authorized representative: natural or legal person established within a country or jurisdiction who has received a written mandate from the manufacturer to act on his behalf for specified tasks with regard to the latter's obligations under that country or jurisdiction's legislation.



# Overview of Changed/New/Deleted Requirements: 3 Terms and Definitions

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- ▶ **3.4 Complaint:** Written, electronic or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, usability, safety or performance of a medical device that has been released from the organization's control or related to a service that affects the performance of such medical devices.
  - ▶ This is different than the ISO 9001:2015 definition.



# Overview of Changed/New/Deleted Requirements: 3 Terms and Definitions

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- ▶ **3.5 Distributor:** natural or legal person in the supply chain who, on his own behalf, furthers the availability of medical device to the end user.
  - ▶ There may be more than one in a supply chain.
  - ▶ Persons involved in such activities such as storage, transport, etc. on behalf of the manufacturer, importer, or distributor are not distributors under this definition.



# Overview of Changed/New/Deleted Requirements: 3 Terms and Definitions

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- ▶ **3.7 Importer:** Natural or legal person in the supply chain who is the first in a supply chain to make a medical device, manufactured in another country or jurisdiction, available in the country or jurisdiction where it is to be marketed.



# Overview of Changed/New/Deleted Requirements: 3 Terms and Definitions

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- ▶ **3.10 Manufacturer:** Natural or legal person with responsibility for design and/or manufacture of a medical device with the intention of making the medical device available for use, under his name; whether or not such a medical device is designed and/or manufactured by that person himself or on his behalf by another person(s).
  - ▶ Multiple notes have been added under this definition.



# Overview of Changed/New/Deleted Requirements

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- ▶ Note that italicized font used in ISO 13485:2003 to call out medical device-specific requirements is no longer used.





# Overview of Changed/New/Deleted Requirements

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## ▶ 4.1 General Requirements

- ▶ 4.1.1: The organization shall document the role(s) undertaken by the organization under the applicable regulatory requirements.
  - ▶ Manufacturer
  - ▶ Authorized representative
  - ▶ Importer
  - ▶ Distributor



# Overview of Changed/New/Deleted Requirements

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## ▶ 4.1 General requirements

- ▶ 4.1.2a: The organization shall determine the processes needed for the quality management system and the application of these processes throughout the organization taking into account the roles undertaken by the organization.
- ▶ 4.1.2b: Apply a risk based approach to the control of the appropriate processes needed for the quality management system.



# Overview of Changed/New/Deleted Requirements

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## ▶ 4.1 General requirements

- ▶ 4.1.4 a-c: Changes to QMS processes shall be evaluated for their impact on the QMS, evaluated for their impact on the medical devices and controlled in accordance with ISO 13485 and regulatory requirements.



# Overview of Changed/New/Deleted Requirements

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## ▶ 4.1 General requirements

- ▶ 4.1.5: When the organization outsources a process that affects product conformity:
  - ▶ Monitor and control the process
  - ▶ Retain responsibility for conformity to ISO 13485:2016, customer and applicable regulatory requirements
  - ▶ Controls shall be proportionate to the risk involved and the ability of the external party to meet requirements
    - Controls shall include written quality agreements.



# Overview of Changed/New/Deleted Requirements

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## ▶ 4.1 General requirements

- ▶ 4.1.6: Organization shall document procedures for validating computer software used in the QMS.
  - ▶ Software shall be validated prior to use and in response to changes in the software or its application.
  - ▶ Approach for software (re)validation shall be proportionate to the risk associated with the use of the software.
  - ▶ Maintain records.



# Overview of Changed/New/Deleted Requirements

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- ▶ **4.2.3 Medical Device File:** For each medical device (family), organization shall establish and maintain (a) file(s) containing/referencing documents required by 13485 or applicable regulatory requirements. File contents:
    - ▶ General description of device, intended use/purpose, labelling, instructions for use;
    - ▶ Specifications for product;
    - ▶ Specifications or procedures for manufacturing, packaging, storage, handling and distribution;
    - ▶ Procedures for measuring and monitoring;
    - ▶ Requirements for installation (as appropriate);
    - ▶ Requirements for servicing (as appropriate).
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# Overview of Changed/New/Deleted Requirements

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- ▶ 4.2.4 Control of documents: Required procedure needs to address preventing deterioration or loss of documents.
- ▶ 4.2.5 Control of records: Organization is required to define and implement methods for protecting confidential health information contained in records in accordance with regulatory requirements.



# Overview of Changed/New/Deleted Requirements

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## ▶ 5.6 Management Review

- ▶ 5.6.1 General: Organization must document procedures for management review. Top management must review the QMS at documented, planned intervals.
- ▶ 5.6.2 Inputs: New inputs include feedback (previously customer feedback), complaint handling and reporting to regulatory authorities.





# Overview of Changed/New/Deleted Requirements

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- ▶ 6.2 Human resources: The organization must document process(es) for establishing competence, providing needed training and ensuring awareness of personnel.



# Overview of Changed/New/Deleted Requirements

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- ▶ **6.3 Infrastructure:** The organization must document the requirements for the infrastructure needed to prevent product mix-up and ensure orderly handling of product.
- ▶ Infrastructure was clarified to include information systems.
- ▶ Maintenance was clarified to be applicable to equipment used in production, controlling the work environment and monitoring/measurement.



# Overview of Changed/New/Deleted Requirements

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- ▶ 6.4.1 Work environment: The organization shall document the requirements for the work environment needed to achieve conformity to product requirements.
- ▶ 6.4.2 Contamination control: For sterile medical devices, the organization must document requirements for control of contamination with microorganisms/particulate matter and maintain required cleanliness throughout assembly/packaging.



# Overview of Changed/New/Deleted Requirements

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- ▶ 7.1b Planning of product realization: Organization needs to provide resources specific to the product, including infrastructure and work environment.
- ▶ 7.1c: Organization shall determine required handling, storage, distribution and traceability activities.



# Overview of Changed/New/Deleted Requirements

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## ▶ 7.2 Customer-related processes

- ▶ 7.2.1: Determination of requirements related to product: The organization must determine any user training needed to ensure specified performance and safe use of the medical device.
- ▶ 7.2.2. Review of requirements related to the product: This review must occur prior to the organization's commitment to supply product to the customer and ensure that applicable regulatory requirements are met and any user training previously identified is or will be available.



# Overview of Changed/New/Deleted Requirements

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## ▶ 7.3 Design and development

- ▶ 7.3.2 Design and development planning: During design and development the organization must document:
  - ▶ The review(s) needed at each design/development stage;
  - ▶ The methods to ensure traceability of design and development outputs to design and development inputs;
  - ▶ The resources needed, including competence of personnel.
- ▶ The requirement for management of interfaces was eliminated.



# Overview of Changed/New/Deleted Requirements

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- ▶ 7.3.3 Design and development inputs: Inputs relating to product requirements must be determined/records maintained. Inputs shall include:
  - ▶ Usability requirements
- ▶ Requirements shall be able to be verified or validated.



# Overview of Changed/New/Deleted Requirements

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- ▶ **7.3.5 Design and development review:** Design review records must include the identification of the design under review, the participants involved and the date of the review.





# Overview of Changed/New/Deleted Requirements

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- ▶ **7.3.6 Design and development verification: Organization is required to document verification plans that include methods, acceptance criteria and, as appropriate, statistical techniques with rationale for sample size.**
- ▶ **When the intended use of the medical device requires connection/interface with another, then the verification shall include confirmation that design outputs meet design inputs when connected/interfaced.**
- ▶ **Records of results and conclusions of verification and necessary actions must be maintained.**



# Overview of Changed/New/Deleted Requirements

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- ▶ 7.3.7 Design and development validation: Organization is required to document validation plans that include methods, acceptance criteria and, as appropriate, statistical techniques with rationale for sample size.
- ▶ Rationale for choice of product used for validation shall be recorded.
- ▶ When the intended use of the medical device requires connection/interface with another, then the validation shall include confirmation that design outputs meet design inputs when connected/interfaced.
- ▶ Records of results and conclusions of validation and necessary actions must be maintained.



# Overview of Changed/New/Deleted Requirements

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- ▶ New requirement, 7.3.8 Design and development transfer: Organization must document procedures for transfer of design and development outputs to manufacturing. Procedure must ensure that outputs are verified as suitable for manufacturing before becoming final production specs and that production capability can meet product requirements. Results/conclusions of transfer shall be recorded.



# Overview of Changed/New/Deleted Requirements

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- ▶ **7.3.9 Control of design and development changes:** The organization must determine the significance of the change to function, performance, usability, safety and applicable regulatory requirements for the medical device and its intended use.
- ▶ The review of design and development changes shall include evaluation of the effect of the changes on constituent parts/WIP/delivered product, inputs/outputs of risk management and product realization processes.



# Overview of Changed/New/Deleted Requirements

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- ▶ **New requirement, 7.3.10 Design and development files:**  
Organization must maintain a design/development file for each medical device (family). File must:
  - ▶ Include or reference records generated to demonstrate conformity to the requirements for design/development
  - ▶ Include or reference records for design and development changes.



# Overview of Changed/New/Deleted Requirements

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- ▶ 7.4.1 Purchasing process: New criteria for evaluation and selection of suppliers must :
  - ▶ Be based on the performance of the supplier
  - ▶ Be proportionate to the risk associated with the medical device
- ▶ Organization needs to plan the monitoring and re-evaluation of supplier, including their ability to meet requirements for purchased product. Results of monitoring shall be an input to the supplier re-evaluation process.
- ▶ Nonfulfillment of purchasing requirements shall be handled based on risk associated with the purchased product and compliance with applicable regulatory requirements.
- ▶ Records relating to selection, monitoring, and re-evaluation of suppliers must also be maintained.



# Overview of Changed/New/Deleted Requirements

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- ▶ 7.4.2 Purchasing information: Purchasing information must include, as applicable, a written agreement that the supplier notify the organization of changes in the purchased product prior to implementation of any changes that affect the ability of the purchased product to meet specified requirements.



# Overview of Changed/New/Deleted Requirements

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- ▶ 7.4.3 Verification of purchased product: When the organization becomes aware of any changes to the purchased product, the organization must determine whether these changes impact the product realization process or the medical device.





# Overview of Changed/New/Deleted Requirements

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- ▶ **7.5.2 Cleanliness of product:** The organization shall document requirements for cleanliness of product or contamination control of product if... product cannot be cleaned prior to sterilization or its use, and its cleanliness is of significance in its use.



# Overview of Changed/New/Deleted Requirements

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- ▶ **7.5.4, Servicing activities:** The organization shall analyze records of servicing activities carried out by the organization or its suppliers:
  - ▶ To determine if the information should be handled as a complaint;
  - ▶ As an input to the improvement process, as appropriate.



# Overview of Changed/New/Deleted Requirements

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- ▶ 7.5.6, Validation of processes for production and service provision: Requirement for organization to document procedures for validation of processes.
  - ▶ These procedures must include revalidation/criteria for revalidation and approval of changes to processes.
- ▶ Requirement for a documented procedure for validation of computer software remains. Specific approach used must be proportionate to the associated risk and the effect on the ability of the product to conform to specifications.
- ▶ Records of results/conclusions/necessary actions from validation activities shall be maintained.



# Overview of Changed/New/Deleted Requirements

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- ▶ 7.5.7, Particular requirements for validation of processes for sterilization and sterile barrier systems: Concept of sterile barrier systems introduced. Processes need to be validated prior to implementation and following product/process changes.
- ▶ Records of results/conclusion/necessary actions from validation shall be maintained.
- ▶ Reference to ISO 11607-1 and -2.



# Overview of Changed/New/Deleted Requirements

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- ▶ 7.5.8, Identification: If required by regulatory requirements, the organization shall document a system to assign unique device identification to the medical device.
- ▶ The organization shall document procedures to ensure that medical devices returned to the organization are identified/distinguished from conforming product.



# Overview of Changed/New/Deleted Requirements

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- ▶ 7.5.11, Preservation of product: Organization must protect product from alteration/contamination/damage during processing/storage/handling/distribution by:
  - ▶ Designing and constructing suitable packaging and shipping containers
  - ▶ Documenting requirements for special conditions needed if packaging alone is not sufficient.
  - ▶ If special conditions are required, they must be controlled and recorded.



# Overview of Changed/New/Deleted Requirements

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- ▶ 8.2.1, Feedback: Organization must document procedures for a feedback process, including production and post-production activities.
- ▶ Feedback gathered shall be a potential input into risk management for monitoring and maintaining product requirements as well as the product realization or improvement processes.



# Overview of Changed/New/Deleted Requirements

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- ▶ **8.2.2, Complaint Handling:** This is a new section. A document procedure is required for timely handling in accordance with applicable regulatory requirements.
- ▶ Justification for not investigating a complaint needs to be documented.
- ▶ If the investigation reveals that activities outside of the organization contributed to the complaint, then relevant information needs to be exchanged between the parties.
- ▶ Records shall be maintained.





# Overview of Changed/New/Deleted Requirements

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- ▶ 8.2.3, Reporting to regulatory authorities: New requirement that if applicable regulatory requirements require notification of complaints that meet specified reporting criteria of adverse events or issuance of advisory notices, the organization shall document procedures for providing notification to the appropriate regulatory authorities.
- ▶ Records of reporting to regulatory authorities shall be maintained.



# Overview of Changed/New/Deleted Requirements

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- ▶ 8.2.6, Monitoring and measurement of product: Records need to identify the test equipment used to perform measurement activities.



# Overview of Changed/New/Deleted Requirements

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- ▶ 8.3, Control of nonconforming product: The documented procedure must also define the responsibilities and authorities for the identification, documentation, segregation, evaluation and disposition of nonconforming product.
- ▶ The “evaluation” must include a determination of the need for an investigation and notification of any external party responsible for the nonconformity.
- ▶ Records of the evaluation/investigation/rationale for decisions must be maintained.



# Overview of Changed/New/Deleted Requirements

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- ▶ Actions in response to nonconforming product detected before delivery (now in 8.3.2) are separated from actions in response to nonconforming product detected after delivery (now in 8.3.3).
- ▶ 8.3.2: Nonconforming product accepted by concession only if justification is provided, approval is obtained and applicable regulatory requirements are met.
- ▶ 8.3.3: The organization shall document procedures for issuing advisory notices in accordance with applicable regulatory requirements. Procedures shall be capable of being implemented at any time. Records shall be maintained.



# Overview of Changed/New/Deleted Requirements

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- ▶ 8.4, Analysis of data: The required procedure shall now include determination of appropriate methods, including statistical techniques and the extent of their use.
- ▶ The analysis of data needs to include input from audits and service reports, as applicable.



# Overview of Changed/New/Deleted Requirements

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- ▶ **8.5.2, Corrective action and 8.5.3, Preventive action:**  
Required procedure(s) need(s) to include a verification that the corrective/preventive action does not adversely affect the ability to meet applicable regulatory requirements or the safety/performance of the device.



Thank you for your time and  
attention!

Questions?  
Feedback...