ISO 13485:2016 QUALITY MANAGEMENT SYSTEMS STANDARD

Overview

About the Instructor

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- **Aaron Ramsey**
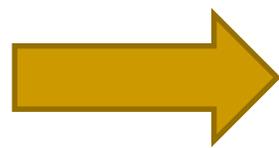 - ❑ Lead Service Manager of Quality, Purdue MEP

- Experience:
  - ❑ Quality, operations, project management, and machining
  - ❑ Manufacturing, Pharmaceutical, and Medical Device industries

- Skills & expertise:
  - ❑ Lead Auditor Certified – ISO 9001:2015 / ISO 13485:2003
  - ❑ NSF HACCP training

About Purdue MEP

- **Who we are:** Purdue Manufacturing Extension Partnership (MEP)

  - ❑ Division of Purdue Technical Assistance Program.

  - ❑ Our staff consists of subject matter experts (SMEs) from a wide variety of business and manufacturing sectors.

- **What we do:**

  - ❑ We work exclusively with Indiana businesses, **primarily manufacturers**, to maximize performance through **streamlined processes, increased profitability, and increased competitiveness.**

  - ❑ We offer public workshops, on-site training, and consulting services.

  - ❑ Through these services Purdue MEP clients report **new sales, product and market growth, cost reductions, and job growth.**

ISO 13485 Background & Overview

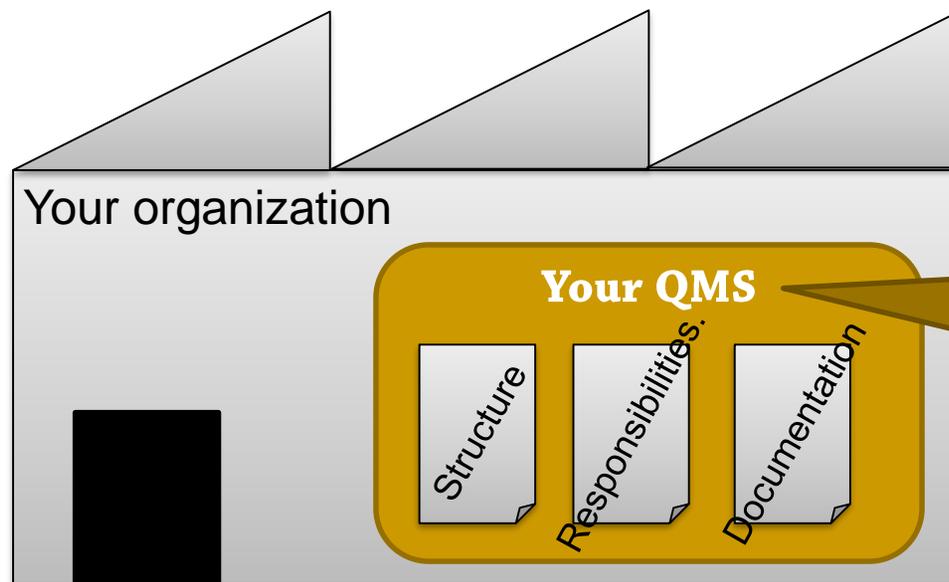- The ISO 13485 standard
- ISO certification

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ISO 13485:2003 Overview
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What is ISO 13485 ?

- **ISO 13485** is an **International Organization for Standardization** (ISO) standard that represents the requirements for a comprehensive **quality management system** for the design and manufacture of **medical devices.**

Quality Management System

- **What is a quality management system (QMS)?**
  - A **system to establish policy and objectives and to achieve those objectives** (ISO)

Your organization

Your QMS

Structure

Responsibilities.

Documentation

ISO 13485:2016 sets out the **basic requirements** of a quality management system.

About ISO 13485

- Designed in particular for medical device manufacturers

- Released in 2003; updated in 2016.

- Is a "stand-alone" Standard, meaning that a company can apply it without the support of any other quality system standard (i.e. the support of ISO 9001).

- The standard can be used by an organization for the design, development, production, installation and servicing of medical devices as well as for the design, development and provision of related services.

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About ISO 13485

- Based on the broader ISO 9001 standard, ISO 13485 was first implemented in Europe in 1996.

- In Europe, ISO 13485 Standard designated as EN ISO 13485:2016 is seen as the de facto standard for the medical device industry.

- Addresses most or all of the quality system requirements in markets including Europe, Australia, Japan, Canada, South Korea and Brazil, etc.

  - However, certification in Europe, for example, does not mean your ISO 13485 certification is valid in other markets such as Canada or Japan. Many countries impose their own additional QMS requirements on top of those outlined in the standard. You must meet those additional requirements – on top of ISO 13485 – to be certified to sell in those markets.

Relation to Other Standards

- Closely aligned to other management standards:
  - ISO 9001 (Quality)
  - ISO 14001 (Environmental)
  - OHSAS 18001 (Occupational Health and Safety)

- ISO/TR 14969:2004: A Technical Report intended to provide a guidance on the application of ISO 13485:2016.
  - The guidance is useful to better understand the requirements of ISO 13485 and to learn some of the different methods and approaches available to meet ISO 13485 requirements.

Relation to Other Standards

- **Differences between ISO 13485 and ISO 14001:**

  - ISO 13485 requires more attention to the regulatory requirements and it only asks for the QMS to be implemented and maintained.

  - ISO 14001 focuses on managing your organization's impact on the external environment, to reduce pollution and comply with regulations

Comparing ISO 9001 and 13485

ISO 13485

- Focuses on **meeting customer requirements** and **maintaining the effectiveness of the QMS**. Also, there are more requirements for documented procedures.

- Adds additional requirements and clarifications for organizations that need to demonstrate their ability to provide medical devices and related services that meet customer requirements and regulatory requirements.

ISO 9001

- Focuses on **customer satisfaction** and **continual improvement.**

Comparing ISO 9001 and 13485

- ISO 13485:
  - Has more emphasis on:
    - Records meeting medical device requirements
    - Risk management
    - Work environment and cleanliness
    - Complaint handling and corrective action
  - Follows the process approach introduced in ISO 9001:2000.
  - Focuses on regulations (documents, management review, awareness, resources required to meet them), defined processes, and records to demonstrate conformance.

Are ISO 13485 and ISO 9001 Equivalent?

- Other specific differences include:
    - The promotion and awareness of regulatory requirements as a management responsibility.
    - Examples of market-specific regulatory requirements include 21 CFR 820, the Quality System Regulation for medical devices sold in the United States, enforced by the U.S. Food and Drug Administration (FDA), or the Medical Devices Directive 93/42/EEC, required for doing business in the European Union (EU).

Comparing ISO 9001 and 13485

- **Other specific differences include:**
  - ❑ Controls in the work environment to ensure product safety
  - ❑ Focus on risk management activities on design control activities during product development
  - ❑ Specific requirements for inspection and traceability for implantable devices
  - ❑ Specific requirements for documentation and validation of processes for sterile medical devices
  - ❑ Specific requirements for verification of the effectiveness of corrective and preventive actions

ISO 13485 Certification

- **What does it mean to be ISO 13485 certified?**

  - An independent body has determined that the QMS meets ISO 13485 requirements.

    - ISO is **not** involved in the certification process.

    - Certification is performed by external certification bodies.
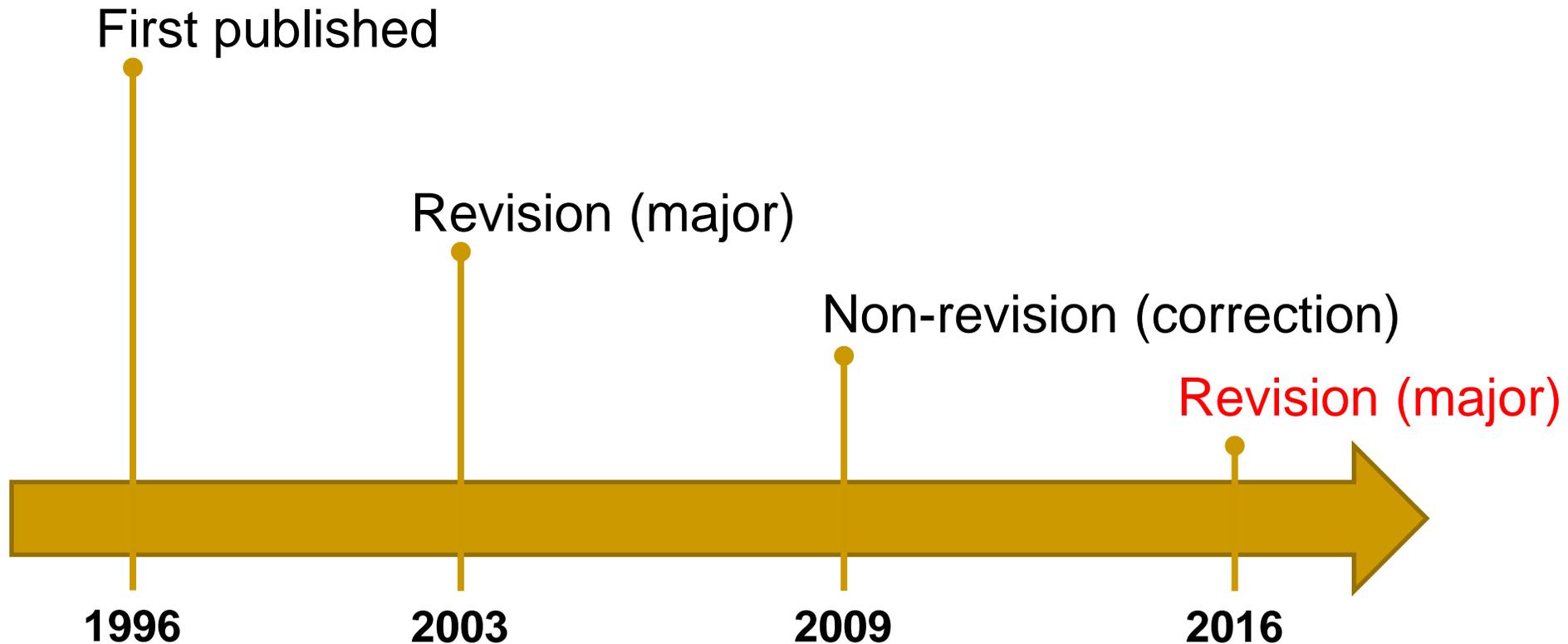
Why ISO 13485/QMS?

Benefits to the organization:

- Identifies responsibilities
- Improves quality, efficiency, and productivity
- Reduces cost
- Provides continuous assessment and improvement
- Provides access to new markets and market share

Benefits to the customer:

- Improved quality and service
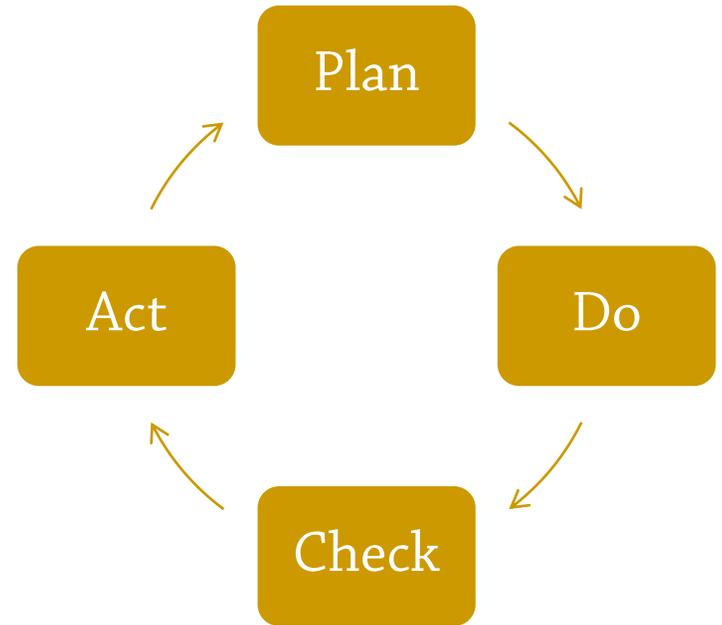- Better customer satisfaction
- Provides a standard QMS structure

ISO 13485 History

First published

Revision (major)

Non-revision (correction)

Revision (major)

1996   **2003**   **2009**   **2016**

Similarities of Management Systems

- **Use PDCA**
- **Include common elements:**
  - Planning (Objectives)
  - Document Control
  - Record Control
  - Internal Audits
  - Corrective / Preventive Action
  - Management Review

Plan → Do → Check → Act (cycle)

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Overview of ISO 13485:2016

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ISO 13485:2003 Overview
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Overview

- **Section 1: Scope**
  - Talks about the standard and how it applies to organizations
- **Section 2: Normative References**
  - References another document that should be used along with the standard
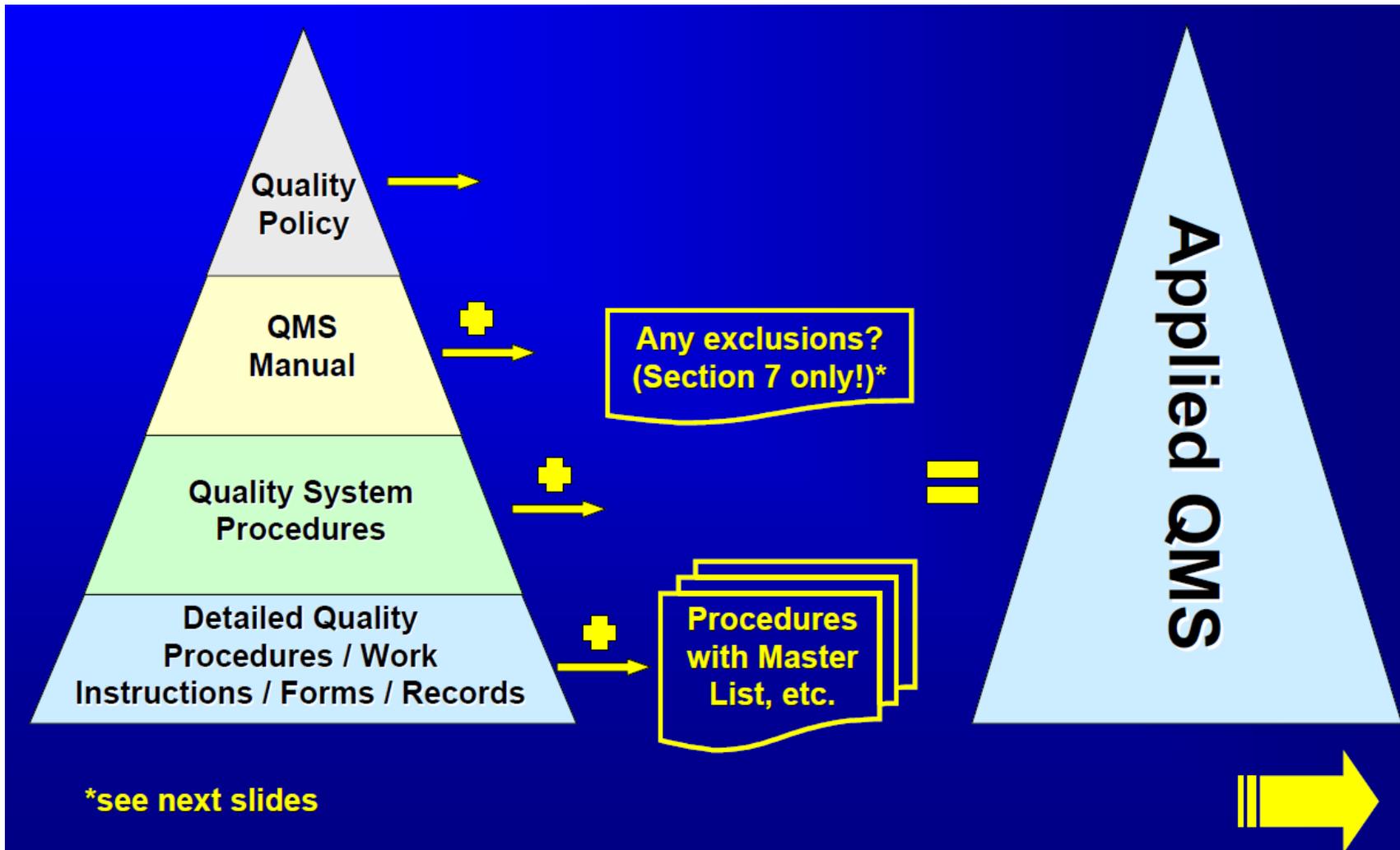- **Section 3: Terms and Definitions**
  - Gives definitions related to medical devices

Key Sections of ISO 13485:2003

Section 4.0	Quality Management System Requirements
Section 5.0	Management Responsibility
Section 6.0	Resource Management
Section 7.0	Product Realization
Section 8.0	Measurement, Analysis, and Improvement

Quality System Definition

Source: Frey, G., & Asai, H. ISO 13485:2003, An Overview

Quality Management System 4.1

4.1 General requirements

- Implementation and maintenance of an effective QMS to provide medical devices meeting customer and regulatory requirements

- Ensure control of outsourced processes

4.2 Documentation requirements

- What is to be done and by whom, when, where, and how it is to be done, what materials, equipment and documents are to be used,

- How an activity is to be monitored and measured,

- Design History File, Technical File, Complaint File, device records, etc.

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5. Management Responsibility

5.1 Management commitment

- Is demonstrated by actions ensuring processes operate as an effective network of interrelated processes

5.2 Customer focus

- Ensure customer requirements are understood

5.3 Quality policy

- Establishes commitment to: quality; continuing effectiveness of the quality management system; meeting customer and regulatory requirements

  - Should be reviewed periodically for continued applicability

5. Management Responsibility

5.4 Planning

- Includes:
  - setting quality objectives & associated targets for the quality management system AND for medical devices & related services (see 7.1 a)
  - defining timeframes for achieving targets
- An organization's QMS is influenced by varying needs particular objectives, the products provided, the processes employed, the size & structure of the organization, etc.
- ISO13485 does NOT imply uniformity in the structure of quality management systems or uniformity of documentation!

5. Management Responsibility

5.5 Responsibility, authority and communication

- Examples demonstrating Responsibility & Authority:
  - documented position descriptions, including responsibilities and authorities
  - organization charts
  - can be included in documented procedures or flowcharts.
  - Independence must be demonstrated for certain activities (e.g. internal audits, one design review participant; management representative)
- Above documents must be controlled (see 4.2.3).

5. Management Responsibility

5.5 Responsibility, authority and communication

- Within an effective quality management system communications must be:

  - encouraged

  - clear and understandable

  - bi-directional

  - at all levels of the organization

  - open and active

- **Examples:** Internal audits, external assessments, management reviews, bulletin boards, all employee meetings, suggestion boxes, etc.

5. Management Responsibility

5.6 Management Review

- Periodic assessment of the QMS for continued suitability, adequacy and effectiveness.

- **Inputs include:**
  a) results of audits,
  b) customer feedback,
  c) process performance and product conformity,
  d) status of preventive and corrective actions,
  e) follow -up actions from previous management reviews,
  f) changes that could affect the quality management system,
  g) recommendations for improvement, and
  h) new or revised regulatory requirements.

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5. Management Responsibility

5.6 Management Review

- **Outputs include:**

  a) agenda

  b) attendance record

  c) presentation materials

  d) improvements needed to maintain the effectiveness of the quality management system and its processes

  e) improvement of product related to customer requirements

  f) resource needs

  g) statement of conclusion the effectiveness of the quality management system

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6. Resource Management

6.1 Provision of resources

- **Resources can be:**
  - people
  - infrastructure
  - work environment
  - information
  - suppliers and partners
  - natural resources
  - financial resources

Adequate resources are prerequisite to an effective QMS

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6. Resource Management

6.2 Human Resources

- Personnel performing work affecting product quality and device safety and effectiveness must be competent
  - Qualifications include:
    - Education
    - Experience
    - Skills
    - EFFECTIVE Training (initial and continue)
    - Formal certification (e.g. welding, soldering)

Organization must be able to demonstrate this!

6. Resource Management

6.3 Infrastructure

- Includes:
  - Buildings
  - Work space
  - Utilities (water, electricity, waste management, etc.)
  - Process equipment (software and hardware)
  - Equipment maintenance activities & frequency
  - Supporting services (cleaning, etc.) If not considered and appropriately defined, the above examples can potentially affect conformance with product requirements!

6. Resource Management

6.4 Work Environment

■ The most significant factors within the work environment that can affect product quality are:

- ❑ process equipment,

- ❑ established work environment (controlled environments, clean rooms, etc.)

- ❑ personnel –internal and **external** ! (health, cleanliness, protective equipment/gear, i.e. static dissipating wrist bands, hoods & gowning, etc.)

"Established" means defined, documented, implemented and maintained!

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7. Product Realization

7.1 Planning of product realization

- "Product realization" describes the processes starting with
  - planning
  - determination of customer requirements
  - customer communication
  - design and development (7.3),
  - purchasing (7.4),
  - production and servicing (7.5),
  - control of monitoring and measuring devices (7.6)
  - delivery of the medical device
  - record keeping requirements

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7. Product Realization

7.1 Planning of product realization

The organization shall determine :

- ❑ product quality objectives & requirements
- ❑ definition of medical device lifetime (record retention!)
- ❑ establishing processes & documents
- ❑ resource needs
- ❑ design and development (7.3),
- ❑ verification & validation
- ❑ monitoring and inspection
- ❑ test activities and product acceptance criteria
- ❑ risk management
- ❑ records

Clause 7.1

- **Actions to address risks and opportunities**
  - Actions must be taken to address risks identified.
  - Actions taken should be commensurate with the potential impact on products or services.
  - Organization shall evaluate the effectiveness of actions.

Risk-Based Thinking

- Risk-based thinking:
  - Ensures risk is considered from the beginning
  - Makes proactive action part of strategic planning
- ISO 13485:2016 requires a **systematic approach to risk** rather than treating it as a single component of a QMS.
  - Risk is considered and included throughout the whole standard.

Benefits of Risk-Based Thinking

- Establishes proactive culture of improvement

- Assures consistency of quality of goods or services

- Improves customer confidence and satisfaction

- Assists with statutory or regulatory compliance

Risk-Based Thinking

- **Action Item: Implement risk-based thinking.**

1. Identify the risks
- Determine what is acceptable and unacceptable.
- Determine how to avoid, eliminate, or mitigate the risk.

2. Implement the plan.

3. Check the effectiveness of the action.

4. Improve if needed.

Identify/Rank/Mitigate Risks

Task	Template
Identify risks	Registry of key risks
Rank risks/determine which are acceptable and which are unacceptable	Risk evaluation matrix
Document how to avoid, eliminate, or mitigate the risk	Risk reduction action plan

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Risk Identification Tools

- Strengths-weaknesses-opportunities-threats analysis (SWOT)
- Failure Mode Effects Analysis (FMEA)

SWOT Analysis

Strengths
- Advanced technology in procurement
- Track record of successful implementation at other E&P operators
- Enhanced efficiency at each procurement stage

Weakness
- Huge data management required
- Effect on current maintained relationship with existing suppliers
- Additional investment required

Opportunities
- Reduction in administrative costs
- Integration with SAP system to deliver higher performance
- Tendering & Bidding process more convenient

Threats
- Lack of suppliers' support may prevent achieving desired benefits
- Internal staff may be rigid to work in changed system

Identify Risks

ACME Tool & Die Specialists

Registry of Key Risks & Opportunities

Source of risk /opportunity	Risk / opportunity description	Impact	Actions to address risks / opportunities	Responsibility	Deadline	Evaluation date	Evaluation results
Key Risks							
Loss of critical personnel	Unable to complete process	Missed deliveries	Cross train workers	Operations manager	Complete	Annually	Training records
Equipment failure	Unable to complete process	Missed deliveries	Find alternative source	Operations manager	Complete	Annually	Approved supplier list
Critical supplier fails to deliver	Unable to complete process	Missed deliveries	Develop critical supplier list with alternative sources	Operations manager	July 2016		Approved supplier list
Change in customer requirements	Loss of/change to orders	Reduction of schedule	Diversity customer base	Sales manager	Complete	Quarterly	Orders from new customers
Key Opportunities							
ISO certification	Potential additional customers	Increased opportunities	Develop and document processes	All personnel	August 2016	August 2016	ISO certification
Marketing	Sales prospect forms	RFQ	Evaluate potential for new sales	Sales manager	Continual	Quarterly	Additional customer orders
New technology	Competitive advantage	Improved efficiency	Review industry needs	Management team	Management review	Quarterly	Additional customer orders

ISO 14971 Risk Management

- ISO 13485:2016 requires you to focus on risk management or that you maintain a risk register.

- ISO 14971 Risk Management:

  - Provides principles, framework, and process for managing risk

  - May be a useful reference for organizations that want or need a more formal approach to risk (but its use is not obligatory)

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7. Product Realization

7.2 Customer-related processes

- Focus is on product and services to be supplied. This includes requirements related to the product:
  - design input/output for new product development,
  - customer delivery expectations vs. delivery schedules
  - customer feedback & communications relative to orders placed or product delivered
  - regulatory or legal requirements
  - design related factors included in customer orders
  - unspecified customer expectations.

7. Product Realization

7.2 Customer-related processes

- Review of product requirements prior to committing to supply:
  - ❑ product requirements defined & documented

- Review of post-marketing product performance
  - ❑ additional product information (e.g. service, additional applications, maintenance, upgrades)

Again, records are key!

7. Product Realization

7.3 Design and development

- Established procedures describing design processes and ALL design activities:
  - goals and objectives of the design and development program (i.e. what is to be developed, timeline, etc.)
  - the markets intended

7. Product Realization

7.3 Design and development

- **Design inputs** include:
  - intended use of the device,
  - Indications and contra-indications for use of the device,
  - performance claims and performance requirements (including normal use, storage, handling and maintenance),

- **Design outputs** include:
  - specifications for raw materials, component parts and sub-assemblies,
  - drawings and parts list,
  - customer training materials,
  - process and materials specifications,

7. Product Realization

7.3 Design and development

- **Design reviews** may address the following questions:
  - Do designs satisfy specified requirements for the product?
  - Is the input adequate to perform the design and development tasks?
  - Are product design and processing capabilities compatible?

- **Design verification** is necessary to ensure that the design outputs conform to

  - specified requirements (design inputs).
  - tests (bench tests, lab tests, chemical analysis, etc.)
  - alternative calculations,

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7. Product Realization

7.3 Design and development

- **Design validation** goes beyond the technical issues of verifying output met input. It is intended to ensure that the medical device meets user requirements and the intended use.

  - actual or simulated conditions

  - consider capability and knowledge of user

  - operating instructions

If production equivalent- need to document why it is equivalent!

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7. Product Realization

7.3 Design and development

- **Control of design and development changes**
  - Product design may require change or modification for many reasons.
  - Change can happen during or after the design phase
  - Changes may result from:
    - design review
    - design verification or validation
    - omissions or errors during the design phase which have been identified afterwards

- **When changes are necessary, evaluate effects on:**
  - product requirements and specifications
  - intended use
  - current risk assessment

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7. Product Realization

7.4 Purchasing

■ Supplier selection and control consists of:

- ❑ establishing criteria (product, parts, quality system, process controls, metrology, etc.)

- ❑ evaluating against those predetermined criteria

- ❑ selecting

- ❑ ongoing monitoring

The extent depends on the nature and risk associated with the product or service, and includes outsourced processes.

7. Product Realization

7.4 Purchasing

- **Purchasing information** describes the product to be purchased in sufficient detail, such as:
  - technical information and specifications,
  - test and acceptance requirements,
  - quality requirements for products, services, and outsourced processes

7. Product Realization

7.4 Purchasing

- **Verification of purchased product** to ensure specified requirements are met:
  - receiving Inspection (shipments are complete, properly identified, undamaged)
  - product incoming inspection (100%, sampling, skip lot, etc.)
  - certification of suppliers
  - certificates of conformance or acceptance test reports from supplier

Must be procedurally defined within the organization's QMS, *including actions when requirements are not met !*

Applies to *ALL product received from outside the organization's QMS.*

7. Product Realization

7.5 Production and service provision

- **Control of production and service** requires *controlled conditions* and includes many aspects:

    - infrastructure (see 6.3)

    - documentation and records (procedures, specifications, work instructions, test results result's, etc.)

    - defined by *impact on quality & regulatory requirements* as well

        Records are key!

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7. Product Realization

7.5 Production and service provision

- **Validation of processes for production & service** is required where the resulting output cannot be verified!
  - defined criteria for review and approval of processes
  - approval of equipment and *personnel qualification*
  - use of specific methods and procedures
  - criteria for revalidation
  - software used in automated processes **MUST** be validated

7. Product Realization

7.5 Production and service provision

- **Identification** is required throughout the product realization process. It includes:
  - raw materials
  - components
  - finished medical devices

  This facilitates fault diagnosis in the event of quality problems is a pre-requisites for traceability!

- Provisions for identifying & segregating returned medical device from conforming product must also be established!

7. Product Realization

7.5 Production and service provision

- **Traceability** means the ability to trace the history or location of a product or activity by recorded identification:
  - forward to customers (also known as "tracking") device tracking
  - backward to raw materials, components, processes used in manufacturing, calibration, etc.

Example: trace a nonconformity back to it's s source and determine location of the remainder of the affected batch/series.

Particular requirements are defined for implantable devices!

7. Product Realization

7.5 Production and service provision

- **Customer property** within the context of the standard is defined as property or assets owned by the customer and under control of the organization.

- Examples of such property are:

  - raw materials or components supplied for inclusion in product (including packaging materials),

  - product supplied for repair, maintenance or upgrading,

  - product supplied for further processing (e.g., packaging, sterilization or testing),

  - customer intellectual property

These must be properly identified, safeguarded, maintained, etc.

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7. Product Realization

7.5 Production and service provision

- **Preservation of product** applies throughout the product realization processes and includes storage, handling, transportation and delivery (may include installation).
    - gloves, static-dissipative measure, gowning,
    - temperature, humidity, dust (particle count),
    - packaging
    - method of transportation (air, sea, ground, environmentally controlled, etc.)

    To avoid damage, deterioration or contamination during handling, storage, distribution.

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7. Product Realization

7.6 Control of monitoring and measuring devices

- The standard explicitly refers to monitoring and measuring devices, **including software** . To ensure valid results, instruments shall be:
  - calibrated or verified at specified intervals (traceable to standard!)
  - uniquely identified (traceability to products!)
  - protected from damage/deterioration or inadvertent adjustment during storage and use

Software used in the monitoring or measurement process must be validated!

Exempt from calibration may be: instruments used for indication only (not quantitative!), volumetric measurement glassware, etc.

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8. Measurement, Analysis, and Improvement

8.1 General

- Monitoring and measurement processes are required to:
    - ensure product conformance
    - ensure conformance of the QMS
    - maintain effectiveness of the QMS

8.2 Monitoring and Measurement

- **Feedback** as key performance indicators of the QMS include:
    - customer related information, post-market surveillance, etc.)
    - internal & external audit results
    - monitoring and measurement of processes (not limited to production processes but also QMS processes!)
    - monitoring and measurement of product (may extend to point of installation!)

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8. Measurement, Analysis, and Improvement

8.3 Control of nonconforming product

- This includes nonconforming product occurring in the organization's own facilities as well as to nonconforming product **received** or **delivered** by the organization.
  - determine product(s) affected
  - identify the nonconforming product (at supplier, in house, in transit, at customer)
  - document the existence and root cause of the nonconformity
  - evaluate the nature of the nonconformity
  - determine and record disposition to be made,
  - control (e.g. by physical segregation) the subsequent processing of the nonconforming product consistent with the disposition decision
  - notify others as appropriate (regulatory authorities, customer, supplier, alternate manufacturing facilities, etc.)
  - define and implement **corrective** and **preventive** actions
  - assess the effectiveness of corrective and preventive actions

8. Measurement, Analysis, and Improvement

8.4 Analysis of data

- This includes determination, collection, and analysis of appropriate data to demonstrate the
  - ❑ suitability and effectiveness of the QMS and
  - ❑ to evaluate if improvement of the QMS effectiveness can be made.

- This encompasses supplier performance, product conformance, trends of processes & products, feedback, etc.

- The results of these activities should feed into management reviews as well considered for risk management activities.

- They also serve to identify opportunities for preventive actions.

8. Measurement, Analysis, and Improvement

8.5 Improvement

- **Corrective action** is intended to eliminate nonconformities with the intent to prevent recurrence
- **Preventive action** is initiated to address potential nonconformities
- **Nonconformities may be identified:**
  - in the QMS
  - on the product
  - in manufacturing processes
  - in metrology
  - with training
  - environmental conditions
  - control of equipment
  - with suppliers, etc.

Conclusion

- As quality system standards are updated, you must ensure that your QMS keeps up with those updates in order to remain in compliance.

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ISO 13485 Benefits

- Access to markets that recognize or require the certification including Canada and Europe.

- Implementing a Quality Management System, in general, helps to motivate staff and provide a better definition of roles and key responsibilities.

- Reduce operational costs by highlighting process deficiencies and improving efficiency

- Increase customer satisfaction by consistently delivering quality products and systematically addressing complaints

- Proven commitment to quality through an internationally recognized standard

- Adds transparency to the way complaints, surveillance or product recalls are handled

Required Procedures (Clause)

- Procedures for validation of the application of software used in QMS (4.1.6)
- Procedures required by the standard (4.2.1.c)
- Procedure for control of documents (4.2.4)
- Procedure for control of records (4.2.5)
- Procedures for management review, including documented planned intervals (5.6.1)
- Procedures to monitor and control the work environment (6.4.1)
- Procedures for design and development (7.3.1)
- Procedures for transfer of design and development outputs to manufacturing (7.3.8)
- Procedures to control design and development changes (7.3.9)
- Procedures for purchasing process (7.4.1)
- Procedures and methods for control of production (7.5.1.a)

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Required Procedures (Clause)

- Procedures for servicing, including reference materials and measurements (7.5.4)

- Procedures for validation of processes for production and service provision (7.5.6)

- Procedures for validation of application of SW used in production and servicing (7.5.6)

- Procedures for validation of processes for sterilization and sterile barrier systems (7.5.7)

- Procedures for product identification (7.5.8)

Required Documents (Clause)

- Roles undertaken by organization under applicable regulatory requirements (4.1.1)
- Statement of quality policy (4.2.1.a) See 5.3.
- Statement of quality objectives (4.2.1.a) See 5.4.1.
- Quality manual (4.2.1.b) See 4.2.2.
- Documents necessary for effective planning, operation, and control of processes (4.2.1.d)
- Documents specified by applicable regulatory documents (4.2.1.e)
- Quality manual: scope, exclusions, procedure references, process interactions (4.2.2.a-c)
- Outline in quality manual of documentation structure used in QMS (4.2.2)
- Medical device file with documents demonstrating conformity and compliance (4.2.3)
- Documents of external origin necessary for planning and operation of the QMS (4.2.4.f)

Required Documents (Clause)

- Responsibilities and authorities (5.5.1)
- Interrelation of personnel who manage, perform, or verify work affecting quality (5.5.1)
- Processes for establishing competence, giving training, and ensuring awareness (6.2)
- Requirements for infrastructure: conformity, avoiding mix-ups, orderly handling (6.3)
- Requirements for maintenance activities, including maintenance intervals (6.3)
- Requirements for work environment needed to achieve product conformity (6.4.1)
- Requirements for health, cleanliness, and clothing of personnel (6.4.1.a)
- Arrangements to prevent contamination: work environment, personnel, product (6.4.2)

Required Documents (Clause)

- Requirements for control of contamination for sterile medical devices (6.4.2)

- Processes for risk management in product realization (7.1)

- Output of planning for product realization (7.1)

- Product requirements (7.2.2.a)

- Arrangements for communicating with customers (7.2.3)

- Design and development planning (7.3.2) See 7.3.2 a through 7.3.2.f.

- Arrangements for design and development reviews (7.3.5)

- Arrangements for design and development verification(7.3.6)

- Verification plans for design and development: methods, criteria, techniques (7.3.6)

- Arrangements for design and development validation (7.3.7)

- Validation plans for design and development: methods, criteria, techniques (7.3.7)

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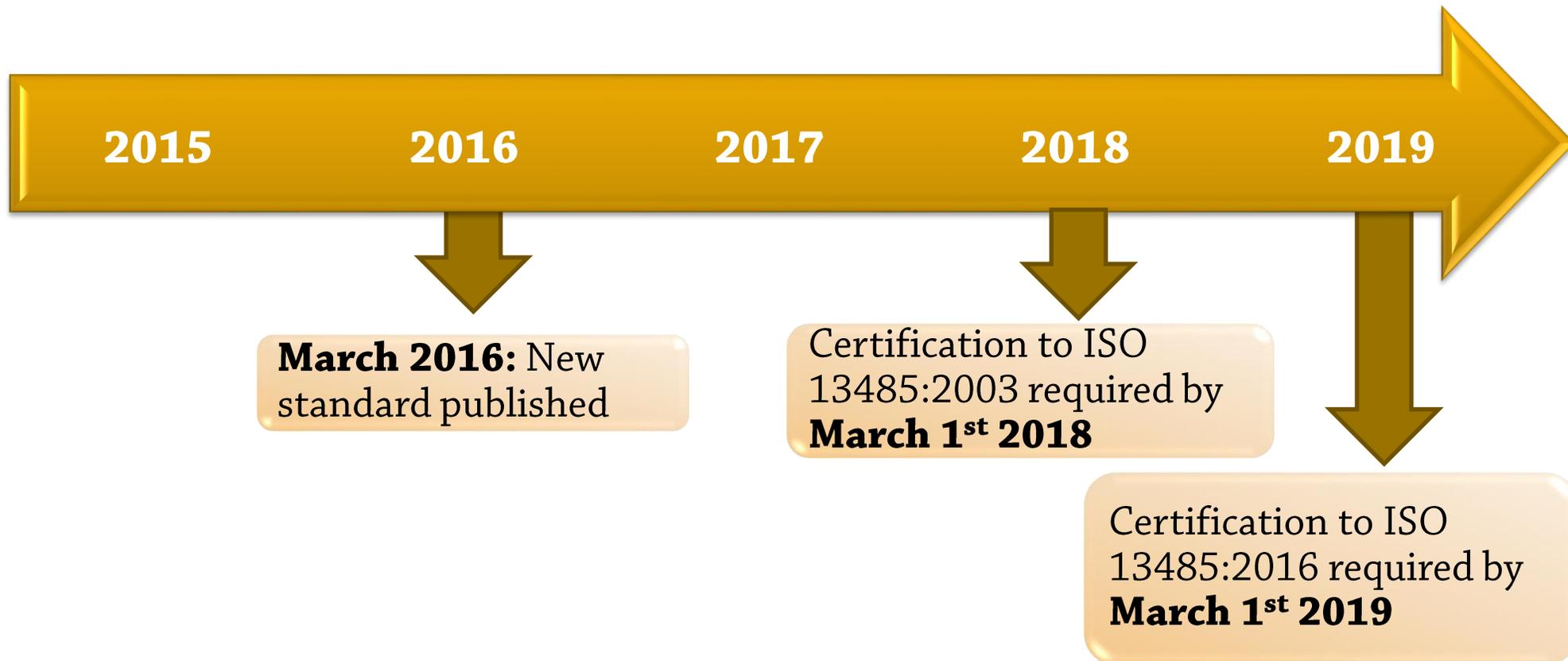MANUFACTURING EXTENSION
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Required Documents (Clause)

- Purchasing information for traceability (7.4.2)
- Requirements for cleanliness of product or contamination control of product (7.5.2)
- Requirements for medical device installation and acceptance criteria (7.5.3)
- System to assign unique device identification to the medical device (7.5.8)
- Requirements for special conditions needed if packaging alone cannot preserve (7.5.11.b)
- Methods for obtaining and using customer feedback on meeting requirements (8.2.1)
- Justification for any compliant not investigated (8.2.2)
- Any correction or corrective action resulting from complaint handling process (8.2.2)
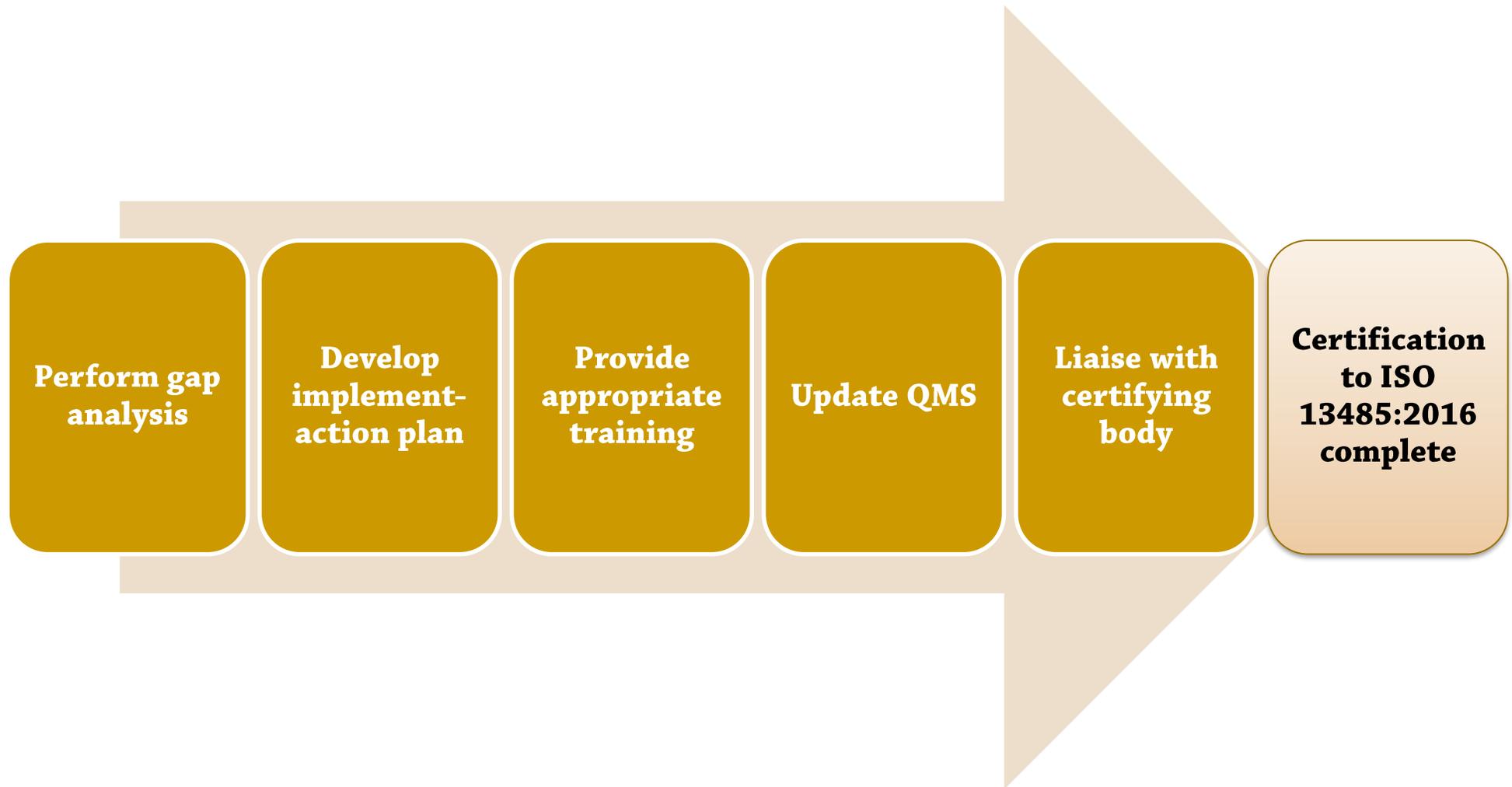- Arrangements for product verification (8.2.6)

Implementation

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ISO 13485:2003 Overview
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ISO 13485 Transition Timeline

2015   2016   2017   2018   2019

March 2016: New standard published

Certification to ISO 13485:2003 required by **March 1st 2018**

Certification to ISO 13485:2016 required by **March 1st 2019**

Transition Plan

Perform gap analysis → Develop implement-action plan → Provide appropriate training → Update QMS → Liaise with certifying body → Certification to ISO 13485:2016 complete

How Purdue MEP Can Help

■ Implementation/Consulting:

- New ISO 13485 implementations
- Conduct gap analysis for transition from ISO 13485:2003 to 2016
- Assist with the updating of QMS from 13485:2003 to 2016
- Conducting internal audits to ISO 13485

❑ Training:

- Problem solving (8D, 5 Why, 7 Step)
- Core Tools Training (FMEA, MSA, APQP, PPAP, and SPC)
- Quality Technician

■ Training:

- ISO 13485 overview training (management overview version also available)
- ISO 9001:13485 internal auditor training
- Risk-based thinking training
- Training for other management system standards (ISO 14001, TS 16949, ISO 13485, AS 9100, and ISO 50001)

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