

Process Validation At a Glance

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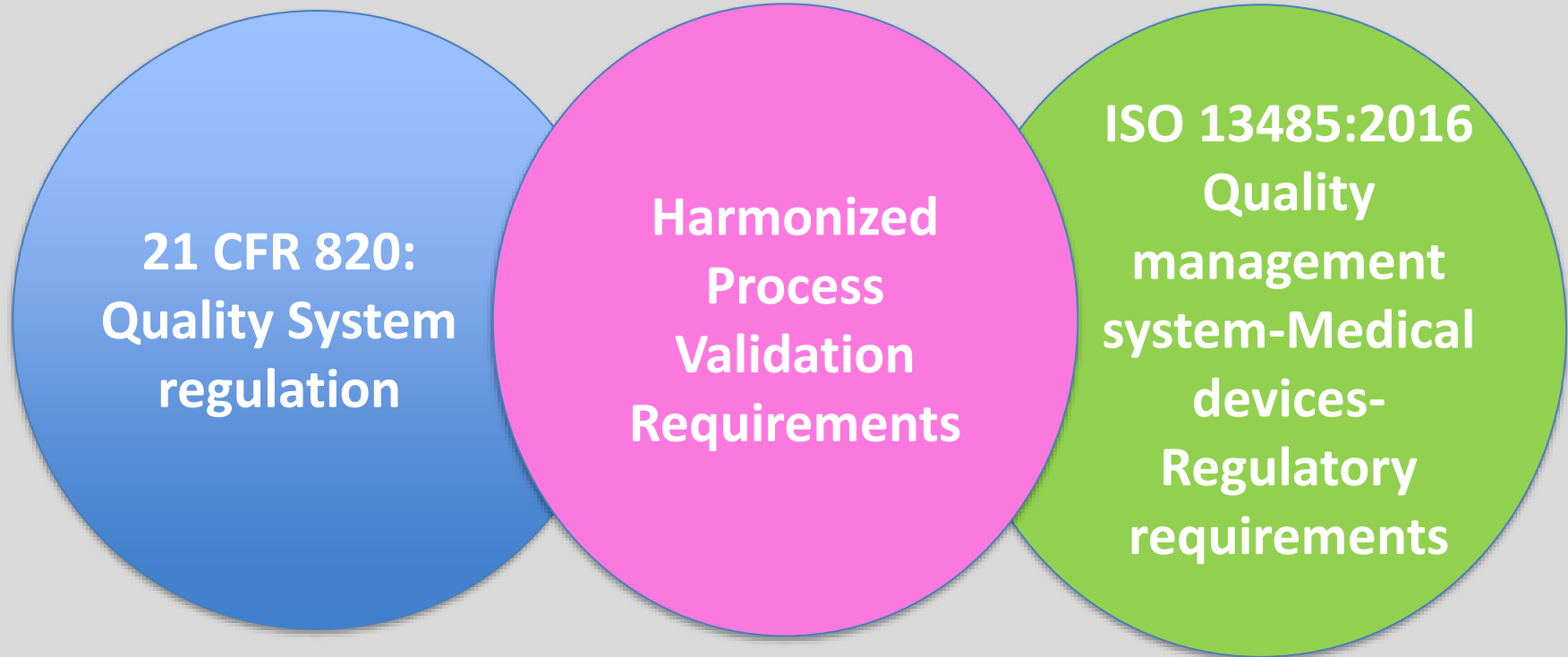
**How do you ensure
your processes
consistently make
product that meet
specifications?**





**VALIDATED
PROCESS**

Process Validation



Learning Objectives

- Review basic Process Validation information
- State the QS regulation and ISO 13485: 2016 requirements for Process Validation
- Identify the similarities and differences in QS regulation and ISO 13485: 2016 requirements for Process Validation
- Review a Process Validation example

Process Validation

Process Validation

- Objective evidence that a process produces a result or product meeting its specifications
 - Defined in 21 CFR 820.3(z)(1)
- Part of the production and process controls subsystem of a quality system
- A series of qualifications based on established protocols
- Completed prior to finished device release

Process Validation

- Required if destructive testing is necessary to show the process produced desired result
- Required if routine end-product testing
 - Does not examine all quality attributes
 - Cannot verify the desired safety and efficacy of the finished product

Process Validation Requirements

- **Title 21 Code of Federal Regulations, Part 820: Quality System Regulation (21 CFR 820)**
 - 21 CFR 820.75 (Process Validation)
- **ANSI/AAMI/ISO 13485:2016: Medical devices-Quality management systems- Requirements for regulatory purposes (ISO 13485:2016)**
 - Clause 7.5.6 (Validation of processes for production and service provision)
 - Clause 7.5.7 (Particular requirements for validation of processes for sterilization and sterile barrier systems)

List of Processes Requiring Validation

- Sterilization
- Aseptic processing
- Injection molding
- Welding

Benefits of Process Validation

- More consistent quality and increased output
- Reduced inspection and testing
- Fewer complaints
- Less scrap/rework
- Predictable planning/scheduling
- Fewer recalls

QS regulation and ISO 13485: 2016 Process Validation Requirements

Process Validation Requirements

21 CFR 820.75

- Process shall be validated when results cannot be fully verified
- Process shall be approved according to established procedures
- The validation activities and results shall be documented
 - The date
 - Signature of individual approving validation
 - Major equipment validated

Process Validation Requirements

21 CFR 820.75

- Monitor and control process parameters for validated process
- Ensure specified requirements continue to be met
- Ensure validated processes are performed by qualified individual
- Document validated processes
 - monitor and control methods and data
 - date performed
 - individual performing the process

Process Validation Requirements

21 CFR 820.75

- When changes or process deviations occur
 - Review and evaluate the process
 - Perform revalidation where appropriate
 - Document review, evaluation, and revalidation

Process Validation Requirements

ISO 13485: 2016, Clause 7.5.6

- Process shall be validated where results cannot be verified or is not verified
- Validation demonstrate the process ability to achieve planned results
- Document procedures for validation of processes including:
 - defined criteria for review and approval of processes
 - qualification of equipment and personnel

Process Validation Requirements

ISO 13485: 2016, Clause 7.5.6

- Document procedures for validation of processes including:
 - use of specific methods, procedures and acceptance criteria
 - statistical techniques with rationale for sample sizes
 - requirements for records
 - revalidation and criteria for revalidation
 - approval of changes to the processes
- Maintain records of results, conclusions, and necessary action

Process Validation Requirements

ISO 13485: 2016, Clause 7.5.7

- Validation of sterilization and sterile barrier systems
 - Document procedures
 - Validated prior to implementation and following changes
 - Maintain records of the results, conclusions and necessary actions

Knowledge Check

What are the benefits of validating processes?

- A. Fewer recalls
- B. More consistent quality
- C. A & B
- D. More scrap/rework

Similarities and Differences of Process Validation Requirements

QS regulation and ISO 13485: 2016

Process Validation Requirements

Similarities

- Require validation of processes where results cannot be fully verified
- Require approval of process to be included in the procedure
- Require validation results and activities to be documented/maintained

QS regulation and ISO 13485: 2016

Process Validation Requirements

Similarities

- Require changes to the process to be addressed
- Require revalidation where appropriate

QS regulation and ISO 13485: 2016

Process Validation Requirements

Differences

21 CFR 820.75

- Explicit requirements for monitoring, controlling, and documenting validated processes
- Ensure specified requirements are met
- Explicit requirement to have qualified operators perform validated processes

ISO 13485:2016 Clause 7.5.6

- Lists specific items that shall be contained within validation procedures

QS regulation and ISO 13485: 2016

Process Validation Requirements

Differences

21 CFR 820.75

- Not specific requirement

ISO 13485:2016 Clause 7.5.7

- Requires procedures for the validation of sterilization and sterile barrier systems
 - Validated prior to use
 - Validated following product or process changes
 - Records of validation results, conclusions, and any actions

Knowledge Check

What is one example of a similar process validation requirement of the QS regulation and ISO 13485 standard?

- A. List specific requirements to be included in the validation process procedures
- B. Require validation of a process where results cannot be fully verified
- C. A & B

Process Validation Example

Filling Process



Company A manufactures blood culture bottles



The blood culture bottles are filled with a liquid



Company A has a validation procedure in place for using this filling process



The validation procedure is in accordance with ISO 13485: 2016

Filling Process

To comply with the Quality System regulation, 820.75:

- Conduct gap analysis of validation procedure

- Revise procedures to include the following requirements:

- The date and signature of individual approving the validation
- To monitor, and control the filling process parameters for the validated process

Filling Process

Revise procedures to include the following requirements:

- Qualification requirements for the individual performing validation

- The monitoring and control method and data for the validated filling process

- Requirements to include the date validation was performed

Filling Process

Revise procedures to include the following requirements:

- Requirements to include the individual performing the validation or major equipment used
- Requirement to document all of the validation activities

Resources

Slide Number	Cited Resource	URL
2	Medical Devices; Current Good Manufacturing Practice (CGMP) Final Rule: Quality System Regulation (<i>contains Preamble</i>)	www.federalregister.gov/documents/1996/10/07/96-25720/medical-devices-current-good-manufacturing-practice-cgmp-final-rule-quality-system-regulation
2,5,6,8,10,12,15,16	Quality System regulation	www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-820?toc=1
5,6,12,15,16	ISO 13485:2016, Medical devices- Quality management systems- Requirements for regulatory purposes	
	AAMI Quality Systems White Paper Comparison of 21 CFR 820 to ISO 13485:2016	www.aami.org/docs/default-source/uploadedfiles/filedownloads/whitepaper/qs-white-paper-21cfr820-13485.pdf

Resources



Slide Number	Cited Resource	URL
9,10	GHTF Quality Management System- Process Validation Guidance	www.imdrf.org/sites/default/files/docs/ghtf/final/sg3/technical-docs/ghtf-sg3-n99-10-2004-qms-process-guidance-04010.pdf
	Federal Register Notice of the Proposed Rule to the Quality System Regulation Amendment	www.federalregister.gov/documents/2022/02/23/2022-03227/medical-devices-quality-system-regulation-amendments

Summary

- Process validation establishes evidence that the process will produce desired product or results.
- There are several benefits to process validation including having fewer recalls.
- Process validation requirements of the QS regulation and ISO 13485:2016 standard are harmonized.

Questions

