The Concept of a Validated Process

Course description

"The Concept of a Validated Process" is a specialized course tailored for operators in the medical devices industry, providing a thorough understanding of process validation principles. This course covers the definition and significance of process validation, detailing the validation process itself. Participants will delve into crucial elements such as Equipment Qualification (EQ), Test Method Validation (TMV), and Operational Qualification (OQ). Emphasis is placed on comprehending control variables and recognizing their role in ensuring a validated process.

At the end of the course you will able to:

- Comprehend the concept and importance of process validation, recognizing its critical role in ensuring product quality, consistency, and compliance with regulatory standards.
- Be proficient in Equipment Qualification (EQ) and Test Method Validation (TMV), understanding how to qualify equipment and validate testing methods to maintain a validated process.
- Grasp the significance of control variables in maintaining a validated process, ensuring stability and reliability throughout manufacturing operations.
- Be aware of the potential consequences of poor practices in process validation, emphasizing the importance of precision and adherence to validation protocols for the integrity of medical device production.

Main topics

1 What is Process Validation?
2 The Validation Process
3 Equipment Qualification (EQ)
4 Test Method Validation (TMV)
5 Control Variables
6 Operational Qualification (OQ)
7 Consequences of poor practices

Contact

🌐 www.smdlearning.com

✉ info@smdlearning.com

🟢 +506 8544 7000

📍 Costa Rica

Course features

Instructor Led

Duration: 2 hours

Tools and templates

Simulated learning

Course certification