

TRAINING COURSE OVERVIEW

Topic:

Animal Tissue and Derivatives Used in Medical Devices

Course Description:

This course is intended to introduce those working with animal tissue and animal tissue derivatives used in medical devices to applicable regulations, standards, and guidances.

Animal tissues and their derivatives are used in the design and manufacture of medical devices to provide performance characteristics that have been chosen for advantages over non-animal-based materials.

The range and quantities of materials of animal origin in medical devices vary. Animal tissue materials can comprise a major part of the device, can be a product coating or impregnation, or can be used in the device manufacturing process.

This course can be used to formally document training to the ISO 22442 International Standards for internal and external auditors.

Course Topics:

- Provide a brief history of the use of animal tissue in medicinal products
- Identify the types of animal tissues
- Discuss Microbiology as applied to animal tissues
- Discuss the ISO Standards for medical devices utilizing animal tissues and their derivatives Including:
 - ISO 22442-1 Application of risk management
 - ISO 22442-2 Controls on sourcing, collection and handling
 - ISO 22442-3 Validation of the elimination and/or inactivation of viruses and transmissible spongiform encephalopathy (TSE) agents
 - ISO/TR 22442-4 Principles for elimination and/or inactivation of TSE agents and validation assays for those processes
- Provide an overview of common Risk Management Techniques
- Discuss Production and Post-Production Monitoring Activities

Duration:

1 Day (8 hours)

Location:

TBD

Audience:

Internal Auditors
External Auditors
Directors
Managers
Supervisors
Engineers
Technicians
Inspectors

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Other:

Participants will be administered a pre-test proficiency assessment as well as a post-test knowledge assessment.

A certificate of completion will be issued for each course participant.

Contact:



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