GMED
LNE GROUP

2027 schedule

TRAINING - DEVELOPING SKILLS

In-person • Online • Blended

FOSTERING A CULTURE OF PARTNERSHIP TO ADVANCE GLOBAL HEALTHCARE

2027 ON-DEMAND TRAINING SESSIONS

In a regulatory landscape that continues to evolve across Europe and globally, manufacturers need more than theory; they need practical insight, strategic clarity, and direct access to experts who understand how requirements are applied in real life.

At GMED, training is not a side activity; it is an extension of our field experience as a Notified Body and certification partner. Our experts work daily with manufacturers, technical documentation, quality systems, and regulatory authorities. That real-world exposure translates into focused, practical, and actionable training sessions designed to help you anticipate expectations rather than just react to them.

Why Choose GMED Training?

- Led by field-experienced experts with hands-on regulatory and audit experience
- Interactive, small-group format (5–15 participants) to encourage discussion and peer exchange
- Real-life case studies based on actual regulatory scenarios
- Strategic and operational perspective; bridging compliance, quality, and market access
- Tailored content adaptable to your organization's maturity, product type, and target markets Flexible, On-Demand Format

All sessions are offered on demand and open once a minimum of 5 participants is reached.
Training can be delivered: virtually, hybrid or in-person.

This catalogue presents a selection of training topics that can be fully customized to your organization's specific objectives, product portfolio, and regulatory roadmap.

Whether you are preparing for CE marking, strengthening your Quality Management System, navigating IVDR/MDR transitions, or aligning with global regulatory frameworks, GMED provides structured, expert-driven learning designed to deliver measurable impact.

For further details, scheduling requests, or tailored proposals, please contact:
request@lne-gmed.com, your Business Development partner, or your Certification Project Manager.

We look forward to supporting your journey toward regulatory excellence in 2027.

GMED
LNE GROUP

Medical and health

Click on the title of each course for more information

Understand and implement European medical device regulations

1A. SA56 - In-person or Online - 2 days (14 hours)
European Medical Device Regulation (EU) 2017/745

1B. SA78 - In-person or Online (7 hours)
Understanding the requirements for importers and distributors under Regulations (EU) 2017/745 and 2017/746

2 SA58 - In-person or Online
Analyze the role of the PCVRR (Person Responsible for Ensuring Compliance with Regulatory Requirements)

3 SA57 - In-person or Online - 1.5 days (10.5 hours)
Technical Documentation per (EU) Medical Device Regulation 2017/745

4 SA65 - In-person or Online - 1 day (7 hours)
The Clinical Evaluation Report (CER) Requirements Under the EU MDR 2017/745

5 SA45 - In-person or Online - 1 day (7 hours)
Meeting regulatory requirements for post-market surveillance and vigilance

6 SA66 - In-person or Online- 1 day (7 hours)
Implementing the requirements relating to the UDI (Unique Device Identifier)

7 SA79 - In-person or Online (7 hours)
Advertising of medical devices

8 SA69 - In-person or Online - 2 days (14 hours)
Identify regulatory and legal responsibilities according to your role

9 SA82 - In-person or Online - 2 days (14 hours)
Auditing in accordance with the requirements of Regulation (EU) 2017/745

10 SA59 - In-person or Online - 1 day (7 hours)
Understand the requirements applicable to devices in Annex XVI of Regulation (EU) 2017/745

11 SA60 - In-person or Online - 1 day (7 hours)
Understand the requirements applicable to devices in Annex XVI of Regulation (EU) 2017/745

Go to first page

Medical and health

Click on the title of each course for more information

Understand and implement European regulations on DMDIVs

1A. SA50 - In-person or Online - 2 days (14 hours)
European in Vitro Diagnostic Device Regulation (EU) 2017/746

1B. SA78 - In-person or Online (7 hours)
Understanding the requirements for importers and distributors under Regulations (EU) 2017/745 and 2017/746

2 SA58 - In-person or Online - 1 day (7 hours)
Analyze the role of the PCVRR (Person Responsible for Ensuring Compliance with Regulatory Requirements)

3 SA71 - In-person or Online - 1 day (7 hours)
Technical Documentation per (EU) In Vitro Diagnostic Device Regulation 2017/746

4 SA72 -In-person or Online - 1.5 days (10.5 hours)
Perform a performance evaluation and clinical evidence assessment for in vitro diagnostic medical devices (IVDMDs)

5 SA45 - In-person or Online - 1 day (7 hours)
Post Market Surveillance and Vigilance

6 SA66 - In-person or Online - 1 day (7 hours)
Implementing the requirements relating to the UDI (Unique Device Identifier)

7 SA79 - In-person or Online - 1 day (7 hours)
Advertising of medical devices

8 SA69 - In-person or Online - 2 days (14 hours)
Identify regulatory and legal responsibilities according to your role

Go to first page

Medical and health

Click on the title of each course for more information

Understanding the requirements of clinical evaluation and adopting the right methodology

SA65 - In-person or online - 1 day (7 hours)

1 **Understanding the regulatory requirements of clinical evaluation in order to choose the right path**

SA09 - In-person or Online - 1 day (7 hours)

2A. **Systematic Literature Review for Medical Devices**

SA26 - In-person or Online - 1 day

Clinical Investigation of Medical Devices 2B.

Go to first page

Medical and health

Click on the title of each course for more information

Understand and implement international regulations

SA64 - In-person or Online - 2 days (14 hours)

1 **Medical Device Single Audit Program (MDSAP) for Manufacturers**

SA73 - In-person or Online - 2 days (14 hours)

2 **Know and implement the regulatory requirements of the MDSAP program countries**

SA14 - In-person or Online - 2 days (14 hours)

3 **Analyze US requirements (21 CFR-Part 820) to bring your quality system into compliance**

SA15 - In-person or Online - 2 days (14 hours)

4 **Prepare your application for the US market (510k, De NOVO, or PMA)**

Go to first page

Medical and health

Click on the title of each course for more information

Implement the requirements of the Quality Management System (QMS)

1. SA19 - In-person or Online - 2 days (14 hours)
   ISO 13485:2016 Requirements
2. SA74 -In-person or Online - 2 days (14 hours)
   Adapting your quality management system to the ISO 9001 standard
3. SA53 - In-person or Online - 1 day (7 hours)
   Design a medical device in accordance with the applicable requirements of ISO 13485
4. SA52 - In-person or Online - 1 day (7 hours)
   Managing subcontractors and suppliers in accordance with ISO 13485
5. SA67 - In-person or Online - 1 day (7 hours)
   Using statistical tools in the application of ISO 13485
6. SA68 - In-person or Online - 1 day (7 hours)
   Validate the software tools used in the quality management system
7. SA30A - In-person or Online - 2 days (14 hours)
   Mastering statistical process data (MSP)
8. SA30 - In-person or Online - 2 days (14 hours)
   Validate medical device manufacturing processes
9. SA24 - In-person or Online - 2 days (14 hours)
   Internal audit and supplier audit for medical device manufacturers
10. SA82 - In-person or Online - 2 days (14 hours)
    Technical Documentation per (EU) Medical Device Regulation 2017/745
11. SA45 - In-person or Online - 1 day (7 hours)
    Meeting regulatory requirements for post-market surveillance and vigilance

Go to first page

Medical and health

Click on the title of each course for more information

Managing Risks Associated with Medical Devices

SA02 - In-person or Online - 2 days (14 hours)

1 **Risk Management Applied to Medical Devices (ISO 14971:2019)**

SA03 - In-person or Online - 1.5 days (10.5 hrs)

2 **Implementation of the risk management process applied to medical devices in accordance with ISO 14971**

SA49 - In-person or Online - 2 days (14 hours)

3a. **Compiling a file on the engineering of the usability of medical devices**

SA36 - In-person or Online - 2 days (14 hours)

3b. **Medical Device Software Lifecycle per IEC 62304**

SA21A - In-person or Online - 2 days (14 hours)

3c. **Microbiology of medical devices and clean room working environment**

SA21B - In-person or Online - 2 days (14 hours)

3d. **Biocompatibility of Medical Devices**

SA76 - In-person or Online - 1 day (7 hours)

4 **Medical devices incorporating materials of animal origin (DMOA)**

SA77 - In-person or Online - 2 days (14 hours)

5 **Medical Device Electrical Safety**

Go to first page

Medical and health

Click on the title of each course for more information

Mastering Special Processes

SA30 - In-person or Online - 2 days (14 hours)

1 **Validate medical device manufacturing processes**

SA30A - In-person or Online - 2 days (14 hours)

2 **Mastering statistical process data (MSP)**

SA21A - In-person or Online - 2 days (14 hours)

3 **Microbiology of medical devices and clean room working environment**

SA41A - In-person or Online - 1 day (7 hours)

4 **Cleanliness of Newly Manufactured Medical Devices**

SA41B - In-person or Online - 1 day (7 hours)

5 **Reprocessing of reusable medical devices**

SA54 - In-person or Online - 2 days (14 hours)

6 **Packaging materials and systems for terminally sterilized medical devices**

SA35 - In-person or Online - 2 days (14 hours)

7a. **Moist heat sterilization: Process validation and control**

SA44 - In-person or Online - 1 day (7 hours)

7b. **Aseptic processing of healthcare products**

SA27A - In-person or Online - 2 days (14 hours)

7c. **Radiation Sterilization of Medical Devices**

SA27B - In-person - 2 days (14 hours)

7d. **Sterilization of medical devices using ethylene oxide**

SA70 - In-person - 2 days (14 hours)

7e. **Atypical sterilization of medical devices**

Go to first page

GNA-MA01 | Designing and facilitating engaging training

Objective

Design a structured training course with clear objectives and teaching methods adapted to adults. Facilitate an engaging training session by mobilizing participants and managing interactions.

Program

Day 1 — Designing an engaging training course (very practical) Goal for the day: leave with a training outline that is 80% complete- Engagement criteria - Key principles of andragogy - Guided workshops: - Formulate a teaching intention + objectives (simplified Bloom) - Build a progressive sequence using the 4C method - Choose appropriate active methods - Adapt materials and pace to profiles - Educational Design Sprint: creating an educational sequence - Enriched cross-feedback

Day 2 — Facilitate, adjust, engage (100% experimentation) Goal of the day: develop a solid and flexible approach - Establish a safe environment for facilitation - Manage pace, energy, and interaction - Approach difficult situations calmly - Facilitation lab on a mini-sequence - Structured group feedback - Immediate adjustments - Evaluation & transfer - Individual action plan

Prerequisites

No prerequisites

Duration (h) - 14.0

Go to first page

GNA-SA02 | Managing risks applied to medical devices according to ISO 14971

Click here to learn more and register to the scheduled public training.

Objective

Analyze the requirements of ISO 14971 Identify the requirements relating to risk management in Regulations 2017/745 and 2017/746 and the current ISO 13485 standard

Program

Day 1 Risk management applied to medical devices: NF EN ISO 14971:2019 standard - Context - Changes: NF EN ISO 14971:2012 VS NF EN ISO 14971:2019 - NF EN ISO 14971:2019- Definitions - General requirements - Different stages, methodology Quizzes - practical exercises - discussions
Day 2 NF EN ISO 14971:2019 standard (continued) - Annexes to the standard - Technical report ISO/TR 24971:2020 Risk management at the heart of medical device regulations Regulations 2017/745 and 2017/746 of the European Parliament and of the Council of April 5, 2017 on medical devices Standard NF EN ISO 13485:2016, medical devices, quality management system, requirements for regulatory purposesPractical exercises - discussionsCourse evaluation, summary and conclusions

Prerequisites

- A good knowledge of Directives 90/385/EEC or 93/42/EEC and Regulation 2017/745 is required.
- Knowledge of the ISO 13845 standard and the process approach is desirable.

Duration (h) - 14.0

Go to first page

GNA-SA03 | Implementation of the risk management process applied to medical devices in accordance with ISO 14971

Objective

Review the requirements of the ISO 14971 standard Learn how to build a risk management file in accordance with the ISO 14971 standard

Program

Day 1 Review of the requirements of the NF EN ISO 14971:2019 standard Case study_Practical exercises - discussions
Day 2 Case study_Practical exercises - discussions (continued) Course evaluation, summary, and conclusions

Prerequisites

Knowledge of the ISO 14971 standard is desirable

Duration (h) - 10.5

Go to first page

GNA-SA09 | Systematic Literature Review for Medical Devices

Click here to learn more and register to the scheduled public training.

Objective

Describe the regulatory context of clinical evaluation based on the literature relating to medical devices Describe the methodology and tools for implementing clinical evaluation based on the literature Determine the key factors and biases in the evaluation and relevance of bibliographic articles

Program

Presentation of regulatory requirements for clinical evaluation Methodology for clinical evaluation based on the literatureMethodology for evaluating the relevance of a publication Practical case study: evaluation of a bibliographic article Evaluation of the internship and conclusions

Prerequisites

- No prerequisites

Success factors

- Knowledge of the main principles of clinical evaluation
- Knowledge of the requirements of Regulation 2017/745/EU

Duration (h) - 7.0

Go to first page

GNA-SA14 | Analyze US requirements (21 CFR-Part 820) to bring your quality system into compliance

Objective

Identify the specific requirements of US regulations (FDA) relating to quality systems in the field of medical devices: 21 CFR-Part 820 (QSR) Identify the main differences between QSR and ISO 13485 Describe the steps involved in preparing for an FDA inspection

Program

Day 1 Presentation of the FDA: history, organization, and missionsMarketing procedures - Classification of medical devices - The main regulatory steps to be taken - The main product-related files: what is a 510(k)? What is a PMA? 21 CFR-Part 820: review of all requirements - Quality system requirements - Design control - Document control - Purchasing control
Day 2 21 CFR-Part 820: review of all requirements (continued) - Production and process control - Non-conforming product - Corrective and preventive action - Labeling and packaging control - Handling, storage, distribution, and installation - Records - Related services - Statistical techniques FDA inspection: preparation and procedure Comparison of QSR and ISO 13485 requirements Questions Course evaluation and conclusions

Prerequisites

No prerequisites required

Duration (h) - 14.0

Go to first page

GNA-SA15 | Prepare your application for the US market (510k, De NOVO, or PMA)

Objective

Analyze the regulatory process for obtaining marketing authorization according to the procedures in force in the US - 510(k), DENOVO, PMA Describe the regulatory classification system Identify the elements for building your 510(k) submission file Describe the evaluation steps and interactions with the FDA

Program

Day 1 - Regulatory environment and history of the FDA - Presentation of the FDA, marketing of medical devices in the US - Regulatory requirements (21 CFR) - Classification of medical devices - Registration, notification, application - The 510(k) process - Which type of device for which type of 510(k) - Review of the approach vs. PMA, DENOVO - Predicates and substantial equivalence (key points for determining equivalence - The pre-submission process - Applicable standards and guidance - Safety and performance testing - Clinical data
Day 2 The 510(k) dossier - Content - How to submit your dossier - Estimated timelines - Exchanges with the FDA (feedback and response letters) PMA process - Presentation of the process - Products subject to PreMarket Approval - The IDE: clinical evaluation and investigation - The PMA application - Content - Submission - Discussions with the FDA - Estimated timelines DENOVO process and other alternative processes Discussion, conclusion, and evaluation of the training

Prerequisites

Knowledge of 21 CFR 820 would be a plus, as would knowledge of the quality assurance design process.

Duration (h) - 14.0

Go to first page

GNA-SA16 | Analyze the Canadian requirements of the Medical Devices Regulations (SOR/98-282) to bring your quality system into compliance

Objective

Identify the specific requirements of US regulations (FDA) relating to quality systems in the field of medical devices: 21 CFR-Part 820 (QSR) Identify the main differences between QSR and ISO 13485 Describe the steps involved in preparing for an FDA inspection Medical Devices Regulations (SOR/98-282)

Program

Day 1 Presentation of the FDA: history, organization, and missions Marketing procedures - Classification of medical devices - The main regulatory steps to be taken - The main product-related files: what is a 510(k)? What is a PMA? 21 CFR-Part 820: review of all requirements - Quality system requirements - Design control - Document control - Purchasing control
Day 2 21 CFR-Part 820: review of all requirements (continued) - Production and process control - Non-conforming product - Corrective and preventive action - Labeling and packaging control - Handling, storage, distribution, and installation - Records - Related services - Statistical techniques FDA inspection: preparation and procedure Comparison of QSR and ISO 13485 requirements Questions Course evaluation and conclusions

Prerequisites

No prerequisites required

Duration (h) - 7.0

Go to first page

GNA-SA19 | ISO 13485:2016 Requirements

Click here to learn more and register to the scheduled public training.

Objective

Analyze the requirements of the ISO13485:2016 standard Identify the links between regulations and the ISO13485 standard
Program
Link with regulatory requirements Regulatory reminders Review of the requirements of the NF EN ISO 13485:2016 standard Process approach Review of the requirements of the NF EN ISO 13485:2016 standard (continued) Course evaluation, summary, and conclusions

Prerequisites

No prerequisites required

Duration (h) - 14.0

Go to first page

GNA-SA20 | Managing problems and non-conformities to improve performance

Objective

Identify and analyze the root causes of product, process, and/or quality system non-conformities in an effective manner Implement the appropriate methodology according to the context: QRQC, 8D, PDCA, DMAIC, etc. Use tools to structure the approach: QQOQCCP – Brainstorming – Ishikawa (7M) - The 5 Whys - The Pareto rule – The prioritization matrix - The A3 report, etc.Integrate ISO 13485 - ISO 9001-MDR-IVDR requirements at each stage of the resolution Lead a problem-solving approach in a continuous improvement process

Program

Day 1 Trainer introduction - Round table discussion Checking the level of learners (multiple-choice questionnaire) IntroductionTypes of non-compliance issues: product, process, quality management system Inventory of known standards in the relevant environment (operating procedures, risk analyses, monitoring plans, product specifications, process validation, control method validation, equipment calibration, etc.) Overview of methods: QRQC, 8D, PDCA, DMAIC – principles and differences Practical case study (real or fictional): Rapid resolution using QRQC:

Go to first page

Context and challenges of the problem or non-compliance using QQOQCCP, brainstorming, and 7M Ensure that immediate corrective actions are implemented to protect customers, employees, equipment, the environment, etc. Analysis of root causes: 5P, is or is not, FTA, etc. Identification and use of available data (records, products, standards, etc.) Identification and selection of actions to be implemented (prioritization matrix, decision grid, etc.) Communication of investigationsDay 2 Welcome – Confirmation of Day 1 learning Review of actions to be implemented and their impact on the organization's performance, objectives, indicators, etc. Deployment of action plans: Corrective, preventive Plan of experiment - GMP Roles and responsibilities (implementer, approver, consulted, informed) Planning - Milestones - Indicators Communication - A3 report Monitoring/validation of the effectiveness of actions and their impact on safety or performance Link with product/process/resource/installation risk analysis, etc. Documentation compliant with ISO 13485 / ISO 9001: resolution sheet, recording, traceability Final presentation of case studies - Taking on the role of problem-solving facilitator Assessment of learning Assessment of the internship, summary and conclusions

Prerequisites

- Basic knowledge of quality (ISO 13485, ISO 9001)
- Knowledge of company standards
- Basic knowledge of continuous improvement tools

Duration (h) - 14.0

Go to first page

GNA-SA21A | Microbiology of medical devices and clean room working environment

Objective

Understand and control the parameters that impact the microbiological safety of medical devices.Control the working environment.

Program

Day 1 Controlling environmental contamination - Design of clean areas. - Characterization of clean rooms and controlled areas. - Characteristics of microbiological safety cabinets (MSCs) - Equipment required for qualification, verification, and control. - Qualification of work areas - Particle qualification (viable and non-viable) - Control of physical parameters. - Certification of clean areas - Staff training and qualification - Routine controls and trend monitoring.Control of contamination in manufacturing processes. - Control of water quality - Control of raw materials and packaging items. - Control of manufacturing and assembly lines - Control of equipment
Day 2 Product contamination control - Validation of microbiological techniques applicable to medical devices - Control of microbiological contamination - Definition of bioburden limits and levels. - Microbial characterization of bioburden - Routine control and monitoring of bioburden - Bioburden peaks. - Data analysis - Endotoxin testing and control. Case study Course evaluation, summary, and conclusions

Prerequisites

General knowledge of standards and issues related to risk management and the safety of healthcare products.

Duration (h) - 14.0

Go to first page

GNA-SA21B | Biocompatibility of Medical Devices

Click here to learn more and register to the scheduled public training.

Objective

Identify the parameters that impact biocompatibility in order to better control them Understand the requirements for demonstrating the biocompatibility of medical devices Establish and understand the preclinical testing plan to be carried out for product and patient safety

Program

Day 1 Relationship between EN ISO 10993-1 and the requirements of Regulation 2017/745 EU Link with other standards essential to the application of ISO 10993-1 General principles of ISO 10993-1 Input data for the application of ISO 10993-1Approach and methodology according to ISO 10993-1 Factors to consider for relevance in device evaluation Definition of materials in the finished product for preclinical evaluation Classification of medical devices Biological evaluation process
Day 2 Biological evaluation tests/preclinical testsAnalytical methods and techniques - biological techniques Methods and techniques of analysis - chemical techniques Approach to the biological evaluation of medical devices in a risk management process Biocompatibility of materials/biocompatibility of processesPost-production information, feedback, material vigilance Review of scientific literature: methodology Scientific literature review: recommendations Scientific literature review: report writing Case study based on the ISO 10993-17 and ISO 10993-18 approachInternship evaluation, summary, and conclusions

Prerequisites

General knowledge of issues relating to the biocompatibility of healthcare products

Duration (h) - 14.0

Go to first page

GNA-SA24 | Internal audit and supplier audit for medical device manufacturers

Objective

Knowing how to develop and manage an audit program in accordance with ISO 19011 Knowing how to conduct an audit in the specific case of the NF EN ISO 13485 standard

Program

Purpose of internal and supplier audits ISO19011 approach Planning: Audit program and plan Managing the opening meeting Documents associated with the audit Writing up non-conformities Managing the closing meeting Audit and corrective action Role-playing Course evaluation, summary, and conclusions

Prerequisites

Knowledge of the requirements of the NF EN ISO 13485 standard

Duration (h) - 14.0

Go to first page

GNA-SA26 | Clinical Investigation of Medical Devices

Objective

Knowing how to develop and manage an audit program in accordance with ISO 19011 Knowing how to conduct an audit in the specific case of the NF EN ISO 13485 standard

Program

Purpose of internal and supplier audits ISO19011 approach Planning: Audit program and plan Managing the opening meeting Documents associated with the audit Writing up non-conformities Managing the closing meeting Audit and corrective action Role-playing Course evaluation, summary, and conclusions

Prerequisites

Knowledge of the requirements of the NF EN ISO 13485 standard

Duration (h) - 14.0

Go to first page

GNA-SA27A | Radiation Sterilization of Medical Devices

Click here to learn more and register to the scheduled public training.

Objective

Analyze applicable requirements Evaluate manufacturing conditions that impact the sterilization process Distinguish between the stages of sterilization process validation

Program

Day 1 Definitions and reference documents Control and mastery of the manufacturing process for the product to be sterilized Microbiological tests contributing to the validation of sterilization - Validation of the technique for recovering microorganisms from a medical device - Estimating the microorganism population - Controlling microbiological contamination Sterilization by irradiation - Principle, reference documents - Types of radiation/sterilizing agent - Installation file - Operational qualification - Product definition - Choice of sterilizing dose - Product-specific sterilizing dose
Day 2 Application of the 25kGy/15kGy VDmax method - Dose mapping - Validation: QO/QP - Dosimetry systems - Measurement uncertaintiesSafety and security checks for sterile products - Endotoxin and pyrogenicity tests - Biological tests Case study Course evaluation, summary, and conclusions

Prerequisites

Theoretical knowledge of ISO 11137-1 and ISO 11137-2 standards and/or initial experience in sterilization

Duration (h) - 14.0

Go to first page

GNA-SA27B | Sterilization of medical devices using ethylene oxide

Objective

Analyze applicable requirementsEvaluate manufacturing conditions that impact the sterilization process Distinguish between the stages of sterilization process validation

Program

Day 1 Definitions and reference documents Control and management of the sterilization manufacturing process Microbiological tests contributing to the validation of sterilization - Validation of the technique for recovering microorganisms from a medical device - Estimation of the microorganism population - Control of microbiological contamination Ethylene oxide sterilization - Principle, reference documents - Different phases of the cycle - Steam quality control - IQ/OQ validation - Establishment of the validation load - Concept of product families and criteria for including new or modified products - Qualification of microbiological performance - Qualification of physical performance
Day 2 Ethylene oxide sterilization (continued) - Qualification of performance (continued) - Metrology of physical quantities - Preparation of the validation report - Biological indicators, PDEs, inoculated products - Adoption of routine cycle parameters - Product release BI validation Requalification ISO 11135 version 2014 - main changes Residue controls Safety control - Endotoxin and pyrogenicity testing - Biological testing - Risk assessment conceptCase study Course evaluation, summary, and conclusions

Prerequisites

Theoretical knowledge of ISO 11135 standards and/or initial experience in sterilization

Duration (h) - 14.0

Go to first page

GNA-SA30 | Validate medical device manufacturing processes

Objective

Implement process validation according to the QI, QO, QP method Describe the factors and organize process control Develop an MSP sampling plan

Program

Day 1 - Introduction - Approach - Approach and methodology - Responsibility and scope of qualification - Qualification process - The qualification master plan, policy, and program - Specifications - The qualification plan, equipment and software validation - Design qualification - Preliminary risk analysis
Day 2 - Functional analysis - Detailed and residual risk analysis - Protocol template, test sheet, and report - Installation qualification - Operational qualification - Performance qualification - Final report and qualification certificate - Maintaining qualified status - Process validation - Raw data - Qualification examples - Course evaluation and conclusions

Prerequisites

Basic knowledge of European regulations relating to medical devices

Duration (h) - 14.0

Go to first page

GNA-SA30A | Mastering statistical process data (MSP)

Objective

Review the fundamental concepts of statistical process control. Master the statistics of control charts associated with the variation of a measurement during a process observation period. Implement control charts to ensure control of variability in your critical processes.

Program

Day 1 - General introduction - Statistical reminders - Prerequisite (1) for Statistical Process Control (SPC): the robust engineering approach - Prerequisite (2) for Statistical Process Control (SPC): the normative approach - Prerequisite (2) for Statistical Process Control (SPC): process validation - Prerequisite (3) for Statistical Process Control (SPC): capability/stability of resources - Metrology concepts (measurement system analysis) - Introduction to uncertainty studies (gage R&R) - Process capability
Day 2 - Control charts - Control chart principles - Constructing a control chart: sampling mode and calculation of control limits based on a reference period - Differences between control limits and specification limits - Western Electric rules for determining whether a process is out of control - Different types of control charts - Simple individual charts - Shewhart charts (mean/dispersion) for detecting rapid disturbances: Xbar/R, Xbar/S - CUSUM and EWMA charts (moving averages) for detecting slow disturbances - Attribute charts such as P charts or C charts - Multivariate charts (Hotelling's T2) - Response in the event of out-of-control - Statistical Process Control in the Enterprise: DMAICS - Sampling - Control plan, sampling according to standard 2859-1Course evaluation and conclusions

Prerequisites

No prerequisites

Duration (h) - 14.0

Go to first page

GNA-SA35 | Moist heat sterilization: Process validation and control

Objective

Acquire the methodological basics and technical and documentary tools for the implementation, validation, control, and audit of the moist heat sterilization process. Know how to apply the process to atypical cycles.

Program

IntroductionBibliographic references and standardsMoist heat sterilization - Characterization of the sterilizing agent and its effectiveness - Qualification of the installation, operation, and performance - Instrumentation, indicators, and recording system - Calibration and metrology of indicators - Heat distribution test - Heat penetration test - Routine monitoring and control Validation approach - Microbiological bases contributing to validation - Development of the sterilization cycle - Use of Fo, Fbio, Z, and D - Biological indicators - Validation of formulas/calculations - Maintaining process effectiveness Sterilization cycles/atypical cycles Course evaluation and conclusions

Prerequisites

Theoretical knowledge of standards EN 554, EN ISO 17665 European Pharmacopoeia and/or initial experience in sterilization

Duration (h) - 14.0

Go to first page

GNA-SA36 | Medical Device Software Lifecycle per IEC 62304

Click here to learn more and register to the scheduled public training.

Objective

Identify European and US regulatory requirements related to software development and validationIdentify normative documents or guidelines useful for declaring compliance with regulatory requirementsImplement quality management principles for the development of medical device software

Program

Day 1 Regulations: regulatory provisions relating to software development and validation Presentation of US and European requirementsPresentation of standards and guidelines available to manufacturers to meet regulatory requirements Software development planning Definition of requirements (system input data)Software design and construction
Day 2 Implementation of a risk management process applied to softwareSoftware testing Configuration and cybersecurity management Software maintenance and troubleshooting: how to apply a corrective and preventive action process Course evaluation, summary, and conclusions

Prerequisites

Knowledge of the principles of quality management and risk management processes (EN 14971) will facilitate participation in the course.

Duration (h) - 14.0

Go to first page

GNA-SA41a | Cleanliness of Newly Manufactured Medical Devices

Click here to learn more and register to the scheduled public training.

Objective

Acquire the methodological basics and technical and documentary tools for the implementation, validation, control, and audit of the cleaning process for single-use medical devices.

Program

Day 1 Introduction Normative and regulatory context DefinitionsEnvironment: production, processing, transfer, and packaging areas Identification and qualification of equipment - Qualification of facilities - Operational qualification - Performance qualification Validation- Prospective validation - Retrospective validation Requalification Establishment of specifications - Description and identification of medical devices - Identification of pollutants, contaminants, and their origin - Determination of acceptable pollutant levels - Compatibility of the cleaning and decontamination process with medical devices - Cleaning process selected - Implant family Cleaning process - Preparation of devices for cleaning - Manual cleaning - Automatic cleaning - Cleaning products, solvents, active ingredients - Water quality Analysis methods and techniques - Physicochemical techniques - Biological and microbiological techniques - Quality controls Additional information: ISO 15883-1/ISO 17664 Change and modification control Risk management, safety control Course evaluation and conclusions

Prerequisites

- Basic knowledge of medical device regulations
- Basic knowledge of CE marking requirements

Duration (h) - 7.0

Go to first page

GNA-SA41b | Reprocessing of reusable medical devices

Objective

Acquire the methodological foundations and technical and documentary tools necessary for the implementation, validation, control, and audit of the cleaning process for reusable medical devices.

Program

Introduction o Terms and definitions o Normative and regulatory context o EN ISO 17664, ISO 17664-2, ISO 15883-1, ISO 15883-5 o AAMI TIR30, ASTM F3293-18, AAMI ST98, o Performance requirements o Decontamination o Disinfection o Sterilization o Considerations relating to test soiling o Considerations relating to load o Cleaning effectiveness test criteriao Compliance testing o Validation of cleaning test method o Requirements for washer-disinfectors o Immersion test apparatus o Manual cleaning o Cleaning type testing o Cleaning performance qualification testing o Process residues o Immersion test procedure o Standard test specimen elution procedure o Residual contaminant determination o Process compatibility o Cleaning process effectiveness o Cleaning process qualification criteria o Cleaning process selection criteria o Cleaning process validation criteria o Cleaning process verification criteria o Cleaning process control criteria o Cleaning process monitoring criteria o Cleaning process documentation criteria o Cleaning process record-keeping criteriao Cleaning process traceability criteria o Cleaning process traceability documentation criteria o Cleaning process traceability record-keeping criteriao Cleaning process traceability documentation requirements

Go to first page

GNA-SA44 | Aseptic processing of healthcare products

Objective

Apply the methodological principles and technical and documentary tools necessary for the implementation, validation, control, and auditing of the process Apply the process and work in a ZTA environment

Program

Introduction - Terms and definitions - Normative references, quality system elements, GMP Qualification of equipment, facilities, and process validation - Operational qualification, periodic requalification, and revalidation - Filter qualification - Media fill: process simulation Premises and manufacturing environment - Facilities and equipment - Vacuum, gas, and clean steam installations - Use of isolatorsPersonnel - Training for ZTA qualification - Clothing, sanitary conditions - Flow of people and materials Product manufacturing - Raw materials and packaging items - Liquid filtration, aseptic filling - Assembly, use of filling equipment and utensils Quality control and testing of the finished product - Bioburden, endotoxins, sterility testing, pyrogen testing, etc.Product release Environmental monitoring and controls - Particulate and microbiological monitoring programEquipment maintenance - Cleaning, disinfection, and sterilization of equipment and the ARA on site - Monitoring of cleaning and disinfection effectivenessManagement of risks associated with aseptic distribution Internship evaluation and conclusions

Prerequisites

- Basic knowledge of medical device regulations
- General knowledge of European standards and pharmacopoeia relating to aseptic distribution processes
- Initial experience of working in an aseptic processing area (APA) is a plus

Duration (h) - 7.0

Go to first page

GNA-SA45 | Post Market Surveillance and Vigilance

Click here to learn more and register to the scheduled public training.

Objective

Analyze the requirements for post-market surveillance and vigilance in regulations Identify the tools to use, the methods to implement, and the forms to fill out Apply the new provisions of Regulations (EU) 2017/745 and (EU) 2017/746

Program

Regulatory requirements for post-market surveillance (PMS) and vigilance Analysis of new applicable requirements EUDAMED database (vigilance module) Transitional provisions relating to PMS and vigilance - The expectations of the notified body Implementation of requirements: PMS plan, PSUR, SCAC, etc. (tools, methods, forms) Key operational role of the notified body - New activities Course evaluation and conclusions

Prerequisites

General knowledge of EU regulations 2017/745 and EU 2017/746

Duration (h) - 7.0

Go to first page

GNA-SA46 | Vigilance in Europe and internationally: Identification, incident management, and audit preparation

Objective

Understanding the vigilance requirements of Regulations (EU) 2017/745 and (EU) 2017/746 (MDR, RDIV)Identifying the responsibilities of the various players involved in vigilance in Europe Identifying, assessing, and reporting vigilance incidents and implementing the necessary corrective actions Knowing how to establish and deploy an effective vigilance activity within your PMS system Extending vigilance management to an international context (MDSAP, FDA, etc.)Preparing your quality system for vigilance audits and inspections

Program

Day 1 – Mastering the European framework – the regulatory basis for vigilance - Entry quiz: Assessment of initial knowledge - Introduction and mapping of the European regulatory framework (MDR/IVDR) - Key definitions: incident, serious incident, FSCA, FSN, trend report - Vigilance stakeholders: roles and responsibilities (manufacturer, PRRC, NB, competent authority) - Incident management process: notification, deadlines, investigation, and reporting in the MIR - FSCA processing: triggering, FSN, coordination with CA - Post-market surveillance activities and deliverables (PMS report, PSUR, trend report) - Case study No. 1: Analysis of different types of complaints and detection of incidents - Case study No. 2: Identification of a serious incident and completion of an MIR form - Case study No. 3: Preparation of a trend report after detecting a significant increase in the frequency/severity of non-serious incidents

Go to first page

Day 2 – Extending skills to the international level – global vigilance - Introduction: from Europe to the international arena (MDSAP program countries - Regulatory comparison: EU vs. FDA vs. Health Canada vs. TGA vs. ANVISA - Reporting tools: Eudamed, MedWatch, etc. - Audit and inspection requirements (GMED, FDA, MDSAP) - Organization of a global vigilance system: harmonization, centralization, global monitoring - Case studies: non-serious incident/serious incident, product recall, multi-country FSCA - Collaborative workshop: building an international vigilance flowchart - Exit quiz – assessment of learning outcomes - Course evaluation, summary, and conclusions

Prerequisites

General knowledge of MD regulations

Duration (h) - 14.0

Go to first page

GNA-SA49 | Compiling a file on the engineering of the usability of medical devices

Objective

Analyze the requirements of standards EN 62366-1 and EN 60601-1-6 Describe the usability engineering process in relation to the design, risk management, and post-market surveillance processes Describe the steps involved in implementing the process: identification of contexts of use, description of usability specifications, validation of solutions

Program

Day 1 Introduction to usability engineering Presentation of regulatory and normative requirementsDescription of the usability engineering process, integration and interaction with the design, risk management, and post-market surveillance Process data
Day 2 Process implementation - User-centered design - Context of use - Usability specifications - Design solutions - Solution evaluation Course evaluation and conclusions

Prerequisites

- Basic concepts of risk management
- EN ISO 14971 standard
- Knowledge of process management principles
- Reading of EN 62366 and/or EN 60601-1-6 standards

Duration (h) - 14.0

Go to first page

GNA-SA50 | European in Vitro Diagnostic Device Regulation (EU) 2017/746

Click here to learn more and register to the scheduled public training.

Objective

Examine the structure of European Regulation (EU) 2017/746 on in vitro diagnostic medical devicesAnalyze the requirements of European Regulation (EU) 2017/746 on in vitro diagnostic medical devices

Program

Timetable/transitional provisions Responsibility and role: manufacturer/authorized representative/importer/distributor Changes to covered products and definitions Classification General safety and performance requirements Common specifications Identification and traceability Content of technical documentation and declaration of conformity Methods of proof Post-market surveillance, vigilance Course evaluation and conclusions

Prerequisites

No prerequisites

Duration (h) - 14.0

Go to first page

GNA-SA52 | Managing subcontractors and suppliers in accordance with ISO 13485

Objective

Define the identity card for the purchasing and subcontracting process Identify the criteria for selecting and evaluating a subcontractorDraw up subcontracting specificationsChoose the re-evaluation method

Program

Identify the characteristics of the purchasing process Position and interface the process within the company's process mapping Analyze and understand the requirements of the standard Identify the minimum requirements for specifications Course evaluation and conclusions

Prerequisites

No prerequisites required

Duration (h) - 7.0

Go to first page

GNA-SA53 | Design a medical device in accordance with the applicable requirements of ISO 13485

Objective

Define the design process identity card Analyze the requirements applicable to the design of medical and in vitro devicesDeploy the method on a practical case

Program

Identify the characteristics of the design process Position and interface the process within the company's process mapping Analyze and understand the requirements of the standard Plan the design and development stages Identify the input and output data for design and development Understand the activities involved in reviewing, verifying, validation, and transfer activities for design and developmentManage and control design and development changes Course evaluation and conclusions

Prerequisites

No prerequisites required.

Duration (h) - 7.0

Go to first page

GNA-SA54 | Packaging materials and systems for terminally sterilized medical devices

Objective

Identify the input data required for the design of a Packaging System Explain the steps involved in validating a Packaging System Identify all aspects to be taken into account when defining monitoring and revalidation procedures

Program

Packaging for terminally sterilized medical devices - Normative references - Medical packaging guidelines - Terms and definitions - Information to be provided - Sterile barrier materials and systems - Design and development of packaging systems Performance testing and demonstration of compliance - Test methods - Sampling - Microbial barrier properties - Compatibility with the sterilization process - Compatibility with the labeling system - Stability testing Validation of packaging processes (forming, sealing, and assembly)- Facility qualification - Operational qualification - Performance qualification - Process control and monitoring - Process modifications and revalidation - Packaging system assemblyCourse evaluation and conclusions

Prerequisites

Basic knowledge of medical device regulations

Duration (h) - 7.0

Go to first page

GNA-SA56 | European Medical Device Regulation (EU) 2017/745

Click here to learn more and register to the scheduled public training.

Objective

Examine the structure of European Regulation 2017/745 on medical devices Analyze the requirements of European Regulation 2017/745 on medical devices

Program

Day 1 Scope and definitions Systems and kits Roles and responsibilities - Manufacturer - Authorized representative - Importer - Distributor - Person responsible for ensuring compliance with the regulations - Cases where the manufacturer's obligations apply to others Classification Content of technical documentation General safety and performance requirements
Day 2 Clinical evaluation Methods of proof Post-market surveillance Requirements relating to the vigilance system European database on medical devices Timetable/transitional provisions Course evaluation and conclusions

Prerequisites

No prerequisites required.

Duration (h) - 7.0

Go to first page

GNA-SA57 | Technical Documentation per (EU) Medical Device Regulation 2017/745

Click here to learn more and register to the scheduled public training.

Objective

Identify the components of technical documentation for establishing the conformity of medical devices (MD) with regulatory requirements Identify best practices for structuring technical documentation, taking into account the expectations of notified bodies and competent authorities responsible for MDs and market surveillance

Program

Day 1 Overview of regulations, guides, and recommendationsIdentification of applicable requirements - Evidence to establish/demonstrate compliance - Identification of actors who can intervene/contribute to the constitution of the TD - Review of general safety and performance requirements (EGSP) - Group workshop: identification of new/revised requirements Content of the technical documentation (TD): structured approach - Identification of constituent elements Day 2 Content of the technical documentation (TD): structured approach (continued) - Group workshop: identification of new/revised requirements - Link between EGSP and TD content TD update requirements Technical documentation management: responsibilities and update proceduresEC Declaration of Conformity: technical documentation output data - Responsibilities - Content and update procedures Course evaluation and conclusions

Prerequisites

- A general knowledge of the regulatory framework for medical devices is desirable.
- Basic understanding of CE marking requirements for technical documentation.

Duration (h) - 10.5

Go to first page

GNA-SA58 | Analyze the role of the PCVRR (Person Responsible for Ensuring Compliance with Regulatory Requirements)

Objective

Identify the requirements and responsibilities applicable to the role of the PCVRR Identify and analyze the provisions to be implemented within the Quality Management System Analyze the role of the PCVRR in the company

Program

Presentation of the objectives, reference framework, and profiles concerned Introduction to the Regulations and Article 15 Qualifications of the PCVRR - who must appoint the PCVRR The responsibilities and missions of the PCVRR - MDCG Guide 2019-7 Exceptions and cases of external PCVRR The role of the PCVRR within the company Integrating the role of the PCVRR into a Quality Management System The PCVRR at the manufacturer and the authorized representative Sanctions Exercises, role-playing and feedback on real-life cases: MD compliance before market launch Post-market surveillance - various exercises to prepare for this role Course evaluation and conclusions

Prerequisites

- Basic knowledge of European regulations on medical devices (Regulation (EU) 2017/745)

Duration (h) - 7.0

Go to first page

GNA-SA59 | Understand the requirements applicable to devices in Annex XVI of Regulation (EU) 2017/745

Objective

Gain an overview of the regulatory framework governing these products Be able to identify these products, classify them, and determine the conformity assessment procedures Understand the common specifications Be familiar with the transitional provisions applicable to these devices

Program

Introduction and assessment of trainees Regulatory framework for medical devices Devices covered and classification Common specifications Transitional provisions Course assessment, summary, and conclusions

Prerequisites

No prerequisites

Duration (h) - 7.0

Go to first page

GNA-SA60 | Understanding the requirements applicable to combination products under Article 117 of EU Regulation 2017/745

Objective

Know how to position combination products among health products Understand the definition of a combination product Medical Device - Medicinal Product Know the regulatory environment for medicinal products used in combination with a medical device Know the requirements for a marketing authorization application for a medicinal product used in combination with a medical device

Program

Introduction Healthcare products Combined products Medical device - Medicinal product The regulatory environment Registration of a combined product Typical composition of a submission dossier Course evaluation, summary, and conclusions

Prerequisites

No prerequisites

Duration (h) - 7.0

Go to first page

GNA-SA64 | Medical Device Single Audit Program (MDSAP) for Manufacturers

Click here to learn more and register to the scheduled public training.

Objective

Identify the requirements and develop the skills needed to prepare for and conduct an MDSAP audit.Understand the structure, audit approach, and content of the MDSAP program, the links to ISO 13485 and additional regulatory requirements, the qualification of nonconformities, and the management of audit reports in order to prepare for the MDSAP audit.

Program

Day 1 Introduction to the MDSAP program - Purpose of the program - Fundamentals - Principles and program flow - Regulatory requirements covered by the program The flow of an MDSAP audit, the audit sequence. Review of the 7 MDSAP processes - Purpose and objective - Audit tasks and links to other processes - Additional country-specific requirements - Conformity assessment
Day 2 Review of the 7 MDSAP processes (continued) The audit request and its process - Initial certification audit (the different phases) and audit cycle - MDSAP audit: Audit plan (selection of tasks, definition of the scope of the audit), management of non-conformities, audit report - Post-audit activities. Course evaluation and conclusions

Prerequisites

- Knowledge of the basic principles of quality management
- Knowledge of the medical device sector
- Understanding of ISO 13485: 2016

Duration (h) - 14.0

Go to first page

GNA-SA65 | The Clinical Evaluation Report (CER) Requirements Under the EU MDR 2017/745

Click here to learn more and register to the scheduled public training.

Objective

Identify the different possible paths for demonstrating clinical evidence Distinguish the issues involved in each of the possible paths for conducting clinical evaluation Choose the appropriate path for the clinical evaluation of your medical deviceEstablish post-market clinical follow-up appropriate for your medical device

Program

What is a clinical evaluation?Regulatory requirements for clinical evaluation Identify the different pathways for demonstrating clinical evidence Analyze the different pathways for demonstratingclinical evidence Choosing the most appropriate route for your situation Regulatory requirements for post-market clinical follow-up Building a PMCF in line with the output data from the clinical evaluation and risk management Course evaluation and conclusions

Prerequisites

Knowledge of the requirements of Regulation 2017/745

Duration (h) - 7.0

Go to first page

GNA-SA66 | Implementing the requirements relating to the UDI (Unique Device Identifier)

Objective

Analyze and understand European regulatory requirements related to the UDI Identify the main differences with the UDI already applicable for the US market Implement a UDI implementation plan

Program

Identify applicable European regulatory requirements / Comparison with US requirementsIdentify designated assigning entities for the European market Implement an action plan: illustrations with examples of medical devices Questions and evaluation of the course

Prerequisites

Knowledge of the requirements of Regulations (EU) 2017/745 and (EU) 2017/476

Duration (h) - 7.0

Go to first page

GNA-SA67 | Using statistical tools in the application of ISO 13485

Objective

Review the normative and regulatory context for the use of statistical techniques Learn about the methodologies and tools needed to meet the requirements of the NF EN ISO 13485 standard
Analyze and know how to question statistical methods when evaluating your QMS
Program
Regulatory and normative context Concept of statistics Statistical techniques and change management Statistical techniques and sampling Statistical techniques and capability Statistical techniques and PMS Internal audit: How to audit statistical techniques Course evaluation, summary, and conclusions

Prerequisites

No prerequisites

Success factor: Knowledge of the NF EN ISO 13485 standard

Duration (h) - 7.0

Go to first page

GNA-SA68 | Validate the software tools used in the quality management system

Objective

Identify applicable requirements Organize the evaluation of QMS software tools Implement a software tool validation strategy

Program

Analysis of applicable requirements Description of the evaluation methodology Description of the different validation methods Example of a validation protocol Change management Course evaluation, summary, and conclusions

Prerequisites

Knowledge of the basic principles of quality management

Duration (h) - 7.0

Go to first page

GNA-SA69 | Identify regulatory and legal responsibilities according to your role

Objective

Know how to identify your role(s): manufacturer, distributor, importer, authorized representative, assemblerKnow how to identify your regulatory obligations according to your role(s) (including with regard to the purchaser, user, patient, administration) Know how to identify the responsibilities of the person in charge of regulatory compliance (Art. 15) Be able to contractually agree on requirements with distributors/importers and authorized representatives Understand liability regimes (contractual, tortious, defective products) and risks of penalties (e.g., violations of Regulations (EU) 2017/745 and 2017/746)

Program

Presentation of the regulatory context Description of the roles and obligations of economic operators Identify the responsibilities of the person in charge of regulatory compliance (Art. 15) Contractualization of regulatory requirements (subcontractor, distributor, agent, and importer) Description of liability regimes and penalties incurred Course evaluation and conclusions

Prerequisites

Overview of the European regulatory framework: Regulations (EU) 2017/745 and (EU) 2017/746

Duration (h) - 14.0

Go to first page

GNA-SA70 | Atypical sterilization of medical devices

Objective

Acquire the methodological basics and technical and documentary tools necessary for the implementation, validation, control, and audit of the sterilization process using hydrogen peroxide or other atypical agents applicable to the sterilization of healthcare products.

Program

Day 1 Welcome and introduction Introduction Bibliographic references and standards Characterization of the sterilizing agent - Sterilizing agent - Microbicidal efficacy - Approach based on biological load - Combined biological load/biological indicator approach - Determination of inactivation kinetics - Neutralization method Characterization of the process and equipment Safety, quality, and performance requirements
Day 2 Product definition / Process definition - Microbiological quality - Product safety and performance - Biocompatibility - Effects on materials - Safety and environmentDevelopment of the sterilization cycleValidation: IQ, OQ, and PQReview and approval of validationRelease of the product after sterilization Routine monitoring and control Process control - Data to be monitored - Maintaining process effectiveness - Equipment maintenance - Requalification - Evaluation of modifications Internship evaluation, summary, and conclusions

Prerequisites

General knowledge of microbiology

Duration (h) - 14.0

Go to first page

GNA-SA71 | Technical Documentation per (EU) In Vitro Diagnostic Device Regulation 2017/746

Click here to learn more and register to the scheduled public training.

Objective

Identifying the components of technical documentation for establishing the conformity of in vitro diagnostic medical devices (IVDMDs) with the requirements of Regulation (EU) 2017/746
Identifying best practices for structuring technical documentation, taking into account the expectations of notified bodies and competent authorities responsible for MDs and market surveillance

Program

Overview of regulations, guides, and recommendations Identification of applicable requirements - Evidence to establish/demonstrate compliance - Identification of actors who can intervene/contribute to the constitution of the TD - Review of general safety and performance requirements (EGSP) - Group workshop: identification of new/revised requirements Content of the technical documentation (TD): structured approach - Identification of constituent elementsContent of the technical documentation (TD): structured approach (continued) - Group workshop: identification of new/revised requirements - Link between the EGSP and the content of a TD Requirements for updating the TD Management of technical documentation: responsibilities and updating procedures EC Declaration of Conformity: output data from technical documentation - Responsibilities - Content and updating procedures Course evaluation and conclusions

Prerequisites

- A general knowledge of the regulatory framework for in vitro medical devices is desirable
- Understanding of CE marking requirements for technical documentation

Duration (h) - 7.0

Go to first page

GNA-SA72 | Perform a performance evaluation and clinical evidence assessment for in vitro diagnostic medical devices (IVDMDs)

Objective

Identify the definitions of performance evaluation related to clinical studies according to the IVDMD Regulation Identify the required analytical performance studies Understand the nature of clinical performance studies, as well as legal and regulatory requirements

Program

Day 1 Introduction Regulatory requirements for performance evaluation and safety (Annex I)Presentation of the three pillars of clinical evidence (Annex XIII) Approaches for presenting different data: RVS, RPA, and RPC Different clinical performance pathways (ISO 20916)
Day 2 Regulatory requirements for post-market clinical performance follow-up Course evaluation and conclusions

Prerequisites

Knowledge of the requirements of Regulation 2017/746

Duration (h) - 10.5

Go to first page

GNA-SA73 | Know and implement the regulatory requirements of the MDSAP program countries

Objective

Analyze the regulatory requirements of the MDSAP program countries Identify the regulatory requirements that require adaptation of your quality management system Ensure support for an MDSAP audit

Program

Day 1 Presentation of the main processes reviewed during the audit, including: - Periodic reporting activities - Notification of changes - Reporting to authorities - Design requirements - Audit and certification rules
Day 2 Country regulations - Australia, Brazil, Canada, Japan, and the US Including product classification and registration in each country Course evaluation and conclusions

Prerequisites

Read the document "MDSAP AU P0002.006 Audit Approach" and the ISO13485:2016 standard.

Duration (h) - 14.0

Go to first page

GNA-SA74 | Adapting your quality management system to the ISO 9001 standard

Objective

Analyze the requirements of the ISO9001: 2015 standard Translate the requirements into actions and/or deliverables Identify the key elements for continuous improvement of your quality management system

Program

Day 1 Origin of the standard Common misconceptions – fact and fiction Usefulness of ISO 9001 Link with other standards or management systems The seven basic principles The concept of processes The context of the organization Management responsibility Management system planning Day 2Support activities Carrying out operational activities Performance evaluation Continuous improvement QuizCourse evaluation and conclusions

Prerequisites

No prerequisites

Duration (h) - 14.0

Go to first page

GNA-SA76 | Medical devices incorporating materials of animal origin (DMOA)

Objective

Understanding the current regulatory approval process Explaining the key steps in the consultation process under 722/2012 Identify requirements for demonstrating control of suppliers of materials of animal origin Notified body expectations regarding submission documentationIdentify common pitfalls and potential questions from the notified body and/or competent authority Identify requirements for post-production information gathering

Program

Context Regulations Application of risk management Controls on sourcing, collection, and handling Inactivation/elimination of viruses and/or pathogens Notified body expectations for dossier content The case of tallow Post-production requirements Impact of PMS

Prerequisites

Knowledge of medical device regulations

Duration (h) - 7.0

Go to first page

GNA-SA77 | Medical Device Electrical Safety

Objective

Determine the applicable medical equipment requirements to design products for compliance Define insulation parameters and requirements Determine creepage, clearance, insulation thickness and dielectric strength requirements Identify appropriate grounding / earthing, fire protection and mechanical requirements Create accurate and concise design and purchase specifications for critical components to achieve safety compliance goals Identify performance testing, marking, documentation requirements

Program

Equip medical device manufacturers with the right strategy to ensure their Medical Device Electrical Safety processes can withstand heightened scrutiny from NBs. The course covers the general details of the standard and features numerous built-in knowledge checks that allow learners to apply and reinforce the new concepts throughout the training. Designed to build a solid foundation, the course explores key aspects of the standard including its general philosophy, scope, structure, evolution, adaptation for use as national standards, the use of risk management, and the requirements for markings and accompanying documents.

Prerequisites

Knowledge of medical device regulations

Duration (h) - 14.0

Go to first page

GNA-SA78 | Understanding the requirements for importers and distributors under Regulations (EU) 2017/745 and 2017/746

Objective

Identify the new responsibilities of distributors and importers of medical devices Analyze the new responsibilities of distributors and importers of medical devices Establish an action plan to meet these requirements

Program

Presentation of objectives, reference framework, and relevant profiles Presentation of context Main changes Scope of application Obligations of importers and distributors How to meet obligations Focus on post-market surveillance Exercise: Develop an action plan Course evaluation and conclusions

Prerequisites

General knowledge of EU Regulation 2017/745 or EU 2017/746

Duration (h) - 7.0

Go to first page

GNA-SA79 | Advertising of medical devices

Objective

Know and understand the regulations relating to the advertising of medical devices in order to design compliant advertising materials Know and understand the regulations relating to the advertising of medical devices in order to ensure compliant digital communication Recognize promotional material from non-promotional material

Program

Presentation of the day's program Legal framework for advertising medical devices General rules and requirements Controls and sanctions Presentation of clinical study results Internet and e-media What is advertising? Review process for promotional materials Course evaluation and conclusions

Prerequisites

No prerequisites required

Duration (h) - 7.0

Go to first page

GNA-SA82 | Technical Documentation per (EU) Medical Device Regulation 2017/745

Objective

Linking the requirements of EN ISO 13485 to those of Regulation (EU) 2017/745 Knowing how to audit the requirements of Regulation (EU) 2017/745

Program

Introduction Reminder of the QMS requirements of Regulation (EU) 2017/745 Review of the requirements of EN ISO 13485 in relation to those of the Regulation- 4. Quality system - 5. Management review - 6. Resource management - 7. Product realization - 8. Measurement, analysis, and improvement Course evaluation, summary, and conclusions

Prerequisites

Understand the requirements of ISO 13485, Regulation (EU) 217/745, and auditing techniques according to ISO 19011

Duration (h) - 14.0

Go to first page

GNA-SA92 | Responding to the recommendations of the FDA's pre-market cyber guides

Objective

Understanding the FDA's cybersecurity considerations for medical devices Analyzing recommendations for the design of medical devices and in vitro diagnostic devices Analyzing the deliverables expected by the FDA

Program

Define key terms related to the FDA's Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions guidance Present the important chapters of the Cybersecurity in Medical Devices guidance: Quality System Considerations and Content of Premarket SubmissionsAnalyze and understand the security control recommendations Analyze and understand the recommendations relating to architecture diagramsAnalyze and understand the deliverables expected in a submission Analyze and understand the documentation to be submitted for IDE ((Investigational Device Exemption) Analyze and understand the requirements of the Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions guidanceIdentify input and output data during a submission Internship evaluation and conclusions

Prerequisites

Basic concepts of the FDA medical device approval process

Duration (h) - 7.0

Go to first page

FOSTERING A CULTURE OF PARTNERSHIP TO ADVANCE GLOBAL HEALTHCARE

GMED

@LNE-GMED

request@lne-gmed.com ▪ +1 (301) 495 0477 ▪ lne-gmed.com