Medical Device Single Audit Program (MDSAP): Fundamentals and Readiness

International Training

Number of days 2

Key information about the course

Gain the knowledge and skills required to successfully host a MDSAP audit within your organization.
Obtain in depth knowledge about this new type of audit and how your organization is best prepared to support the completing of requirements within the allotted time.

Discover how this program differs from the traditional ISO 13485 through its regulatory audit approach, the grading of nonconformities, and handling of the audit report. This course will prepare you to host a MDSAP audit and allow you to determine if your own internal QMS processes are consistent with the requirements of the MDSAP audit mode for the jurisdictions where your products are marketed.

Upon completion of this training, delegates will be able to support their organization to maintain compliance to ISO 13485 and jurisdiction requirements in the countries engaged in the MDSAP program.

International training - Medical Device Single Audit Program (MDSAP): Fundamentals and Readiness

Agenda

Day 1

- Benefits to you, welcome and introductions
- Course aim, learning objectives and course structure
- Fundamentals of MDSAP
  - Origin and objectives
  - Key terms and definitions
  - Manufacturer benefits
  - Structure, requirements and outputs
- Structure and scope of the MDSAP audit program
  - Process, sequence and duration
  - Regulatory audit approach and requirements
  - Stage 1 and Stage 2 audits
  - Nonconformity grading
  - Considerations for MDSAP participation
  - Relationship with other QMS standards
- MDSAP and other QMS audits
  - MDSAP and auditing in the medical device industry
  - Differences between ISO 13485 and ISO 14971
- MDSAP documents
- Management process
  - Purpose and outcomes of process
  - Top management focus in MDSAP
  - QMS requirements and planning
  - Development of audit scope
  - Jurisdictional additions (to ISO 13485)
  - Distribution controls
- Measurement, analysis and improvement process
  - Purpose and outcomes of process
  - Analysis of data
  - Control of nonconforming product
  - Internal audits
  - Jurisdictional additions (to ISO 13485)

International training - Medical Device Single Audit Program (MDSAP): Fundamentals and Readiness

Agenda

Day 2

- Refresh quiz
- Design and development process
  - Purpose and outcomes of process
  - Design control and device classification
  - Risk management focus
  - Jurisdictional additions (to ISO 13485)
- Production and service controls process
  - Purpose and outcomes of process
  - Jurisdictional additions (to ISO 13485)
  - Control interactions
- Purchasing process
  - Purpose and outcomes of process
  - Purchasing control considerations
  - Jurisdictional additions (to ISO 13485)
- Device marketing authorization and facility registration process
  - Purpose and outcomes of process
  - Jurisdiction specific definitions
  - Device market authorization
  - Facility registration
  - Change Notification considerations
- Medical device adverse events and advisory notices process
  - Purpose and outcomes of process
  - Jurisdictional additions (to ISO 13485)
- Course review and final questions
- End of the course

Once you have completed the training, you will receive a BSI training certificate.

International training - Medical Device Single Audit Program (MDSAP): Fundamentals and Readiness

Pedagogical objectives

- Improve auditing skills focused on regulatory auditing
- Improve competence for MDSAP internal auditors and the support needed to host a MDSAP audit
- Assess your own audit models and suggest improvement
- Be prepared to support an efficient MDSAP audit by your selected Auditing Organization

Skills to be acquired

Upon completion of this training, you will have the:

Knowledge to:

- Demonstrate awareness of MDSAP fundamentals
- Explain the structure and scope of the MDSAP audit program:
- MDSAP audit processes and their interrelationships
- MDSAP and organizational regulatory compliance
- MDSAP reporting and nonconformity grading
- Explain the differences between MDSAP and other QMS audits
- MDSAP and auditing in the medical device industry
- ISO 13485 and ISO 14971
- Identify MDSAP documentation

Skills to:

- Prepare to host a successful MDSAP audit
- MDSAP 7 auditing process requirements
- Plan audit scopes
- Analyze data sources required during process audits
- Analyze control interactions
- Use correct jurisdictional terminology

Targeted audience

Quality Assurance and Regulatory Affairs professionals within medical device organizations currently active in participating territories and organizations expanding their market reach to jurisdictions participating in MDSAP.

Pedagogical, technical and framing means

Course materials including:

- Introduction to the training, detailed program and security assignments
- Course presentation, theory and activities/ role plays
- Answers to the activities
- Videos
- Additional documents, distributed during the sessions, to use for the activities
- Attendance sheet to be signed

Assessment specifics

- Questionnaire to assess the knowledge at the end of the training
- Customer survey

What is included ?

- Course materials, provided electronically
- Letter of attestation
- Official certificate

bsi.

International training - Medical Device Single Audit Program (MDSAP): Fundamentals and Readiness

Prerequisites: Delegates will benefit from reviewing the MDSAP Companion Document and ISO 13485:2016 standard before attending this course.

These training modules are eligible to the subsidizing by the public institutions in France (OPCO);

Each delegate receives a training convention after the enrollment.

Please note that for the public sessions, you have until 48h before the start of the course to confirm your enrollment. For the in-house sessions, the deadline would be of two weeks prior to the start of the course.

Should you be in a disabled situation, please contact us and indicate what details should be taken into account.

You can contact us on **training.france@bsigroup.com** or **01 89 79 00 40**

Contact us:

Phone: **+33 (0)1 89 79 00 40**

Email : **training.france@bsigroup.com**

Website : **bsigroup.fr/nos-services-formation**