MEDICAL DEVICE AUDITING COURSES

INTERNAL AUDITOR TRAINING, BASED ON EU MDR AND MDSAP
3-5 days | Instructor-led / On-site

Students will gain valuable knowledge on how to prepare for the upcoming changes from the MDD to the MDR. Students will learn how to audit program management to include preparation of internal audit plans and how to address gaps during the audit. This course will also focus on understanding ISO 13485:2016 relative to the EU MDR and how companies can be prepared.

This class will helpful for experienced internal auditors seeking to expand their auditing knowledge to the EU MDR.

CQI/IRCA CERTIFIED LEAD AUDITOR COURSE – INCORPORATING ISO 13485:2016 AND MDSAP
5 days | Instructor-led / On-site

Students will plan, conduct, report and follow up on a QMS audit in accordance with ISO 13485:2016, MDSAP and EU MDR requirements. Throughout the course, students will learn how to apply MDSAP auditing strategies, adopted by Auditing Organizations in the MDSAP program, and learn to identify and grade nonconformities and prepare an audit report in accordance with MDSAP criteria. This course is currently certified to include ISO 13485:2016 and MDSAP requirements. Inclusion of EU MDR requirements in the accreditation is pending.

This class is helpful for all management and executive personnel with responsibility for medical device regulatory lifecycles, involvement with the design and implementation of quality management systems or involvement with product design and development.

MEDICAL DEVICE SINGLE AUDIT PROGRAM (MDSAP) REQUIREMENTS – PRACTICAL INSTRUCTION
1 day | Instructor-led / On-site

Students will understand the requirements of MDSAP and how Australia’s TGA, Brazil’s ANVISA, Canada’s HC, Japan’s PMDA and the United States’ FDA will implement the program moving from the pilot to the operational phase. Students will also understand the new regulatory QMS audit findings/nonconformance grading system and what grades trigger regulatory follow-up and comprehend the regulatory transitions for MDSAP and discuss strategies on how companies can optimize alignment.

This course is vital for any medical device quality professional including quality directors, managers, engineers and auditors responsible for implementing a quality management system in accordance with ISO 13485:2016 and planning to undergo an MDSAP audit.

MDSAP AND REGULATORY TRANSITIONS – THE BASICS: VIRTUAL TRAINING
2 hours | Online / On-demand (video-based course with exam)

Students will understand the new regulatory audit findings/nonconformance grading system and know what grades trigger regulatory follow-up within MDSAP. They will also learn to recognize the value of the MDSAP audit model, become familiar with the premise of the MDSAP audit time calculations and basic information to be included in the MDSAP audit report, and comprehend the MDSAP timeline and other upcoming regulatory changes.

This course is vital for any medical device quality professional including new hires, quality directors, managers, engineers and auditors responsible for implementing a quality management system in accordance with ISO 13485:2016 and planning to undergo an MDSAP audit.
PREMARKET REGULATORY COURSES

510(k) PREMARKET NOTIFICATION WORKSHOP – BRINGING MEDICAL DEVICES TO THE U.S. MARKET

2 days  |  Instructor-led / On-site

Students will understand 510(k) basics, including how to construct a complete 510(k) submission direct from the perspective of a former FDA reviewer. This workshop also provides insight on how to communicate effectively with FDA via the pre-submission process and takes you a step further on what to do when you have a cleared 510(k) device that needs modification, while considering risk management principles.

This course is vital for any medical device quality professional including quality directors, managers, engineers and auditors responsible for implementing a quality management system in accordance with ISO 13485:2016 and planning to undergo an MDSAP audit.

EU MEDICAL DEVICE REGULATION (EU MDR) – A COMPREHENSIVE OVERVIEW

2 hours  |  Online / Virtual
(Interactive computer-based course with exam)

In 2017, the Medical Device Regulation (EU MDR) 2017/745 was published, introducing major changes to the previous Medical Device Directive (MDD). Significant changes include device classification, requirements for technical documentation and clinical evidence. This Online computer-based learning course provides comprehensive instruction on the EU MDR. It walks students through every aspect of the regulation and identifies key topics and changes, including the new roles associated with EU MDR, standard requirements that must be met by all manufacturers regardless of class and the requirements for conformity assessments. By the end of this course, you will: (1) recognize the regulatory background in Europe, (2) identify the roles associated with the EU MDR, (3) discuss the manufacturing requirements of the EU MDR and (4) explain how to comply with premarket and postmarket requirements for conformity assessments.

This course is vital for any medical device quality professional including quality directors, managers, engineers and auditors looking to gain knowledge on the EU MDR.

FDA PRE-SUBMISSION PROGRAM (Q-SUB) EXPLAINED

1.5 hours  |  Online / Virtual
(Interactive computer-based course with exam)

Seeking feedback from the FDA is strongly encouraged by the Agency, but the process can be confusing and it’s important to be prepared for your FDA meeting. This course was developed by a recent FDA insider and provides an overview of the mechanisms available to request feedback from FDA regarding Investigational Device Exemption (IDE) applications or other premarket submissions, such as Premarket Approval (PMA) applications, Humanitarian Device Exemption (HDE) applications, Evaluation of Automatic Class III Designations (De Novo requests), and Premarket Notification (510(k)) submissions. The course covers logistics for submission, receipt, tracking and review of/response to these requests. The feedback mechanisms addressed include pre-submissions, informational meetings, study risk determinations, formal early collaboration meetings (i.e., agreement and determination meetings), submission issue meetings and PMA day 100 meetings.

This course is vital for any medical device quality professional including quality directors, managers and engineers.
QUALITY SYSTEM REGULATION COURSES

ISO 13485:2016 MEDICAL DEVICE QUALITY MANAGEMENT SYSTEM
1 day | Instructor-led / In-house
Students will understand the requirements of ISO 13485:2016, the design specifications for the 2016 version of ISO 13485 and the difference between ISO 13485:2003 and ISO 13485:2016. This course helps you to comprehend the intent and meaning of all clauses of ISO 13485:2016 and to recognize the interrelationship and linkages between the clauses and requirements.
This course is vital for any medical device quality professional including quality directors, managers, engineers and auditors responsible for implementing a quality management system in accordance with ISO 13485:2016.

U.S. QUALITY SYSTEMS REGULATION 21 CFR PART 820
7 hours | Online / On-demand (video-based course with exam)
This course includes six modules; the first five modules cover the U.S. Quality Systems Regulation (21 CFR 820) and the sixth module covers the Combination Products Regulation (21 CFR Part 4.) Each module includes a one-hour video instructional presentation by Kim Trautman, Executive Vice President, Medical Device International Services at NSF International, followed by an assessment on the information covered in the video.
This class is vital for any medical device R&D engineer, scientist and clinician as well as regulatory affairs and quality assurance professionals.

WHAT PEOPLE ARE SAYING

Content was perfect, instructors very knowledgeable and gave great examples.
Scott Gisler | Design Control Training Course

Very well organized and delivery was excellent!
Karla Palermo, Proctor and Gamble | ISO 13485, MDSAP and Regulatory Transitions Training Course

Great detail; Instructors all knowledgeable, approachable, engaging, funny.
John Clark | Lead Auditor Training Course

DESIGN AND DEVELOPMENT FOR MEDICAL DEVICES AND IVDS
2 days | Instructor-led / In-house
This course will provide you with an understanding of the actual risk management and design and development regulatory requirements relative to FDA’s 21 CFR 820, ISO 13485:2016 and the new EU regulations; as well as practical examples on how to minimize inefficient executions and documentation practices. The greatest benefit of this course is gained through open dialogue and sharing of current design and development processes to highlight how misperceptions of regulatory requirements have led to less than optimal practices. This course will provide you with knowledge to assist in all phases of your design and development projects, as well as retrospective gap analysis of design history files in preparation for the development of new technical files under the EU MDR and IVDR.
This class is vital for any medical device R&D engineer, scientist and clinician as well as regulatory affairs and quality assurance professionals.
**DESIGN AND DEVELOPMENT FOR MEDICAL DEVICES AND IVDS – AN OVERVIEW**

2 hours  |  Online / On-demand  
(video-based course with exam)

NSF International’s web-based virtual training course provides a basic understanding of design controls for medical devices and IVDs. Providing knowledge to comply with U.S. FDA’s Quality System Regulation, the quality management system international standard ISO 13485:2016 and the European Union Medical Device Regulation (EU MDR). Learn from global Quality Systems expert, Kim Trautman, a former U.S. FDA official. Kim also authored the current U.S. FDA quality system regulation and is a recognized leader of continued global regulatory harmonization efforts. By the end of this course, you should be able to: (1) identify design control requirements based on U.S. FDA quality system regulation, ISO 13485:2016 and EU MDR, (2) recognize how risk management ties into the design control process, (3) understand FDA’s auditing process and expectations of design controls and (4) identify appropriate application of design control requirements.

This course is important for medical device professionals, especially to those who conduct or participate in design phases of any project and/or quality systems activities specific to design control.

**CAPA DEVIATIONS AND WRITING NONCONFORMITIES**

2 days  |  Instructor-led / On-site

This highly interactive course provides students with the tools and skills needed to conduct root cause investigations using best practices. Students will be guided through the methodology to identify root causes and restore performance and on how to effectively write corrective action plans.

This course is important for medical device professionals, especially to those who conduct or participate in root cause investigations.

**RISK MANAGEMENT FOR MEDICAL DEVICES AND IVDS**

2 days  |  Instructor-led / On-site

This course provides the comprehensive understanding of risk management concepts within medical devices. Students will learn the product development process and regulation by building an optimum design and development process. Aspects of the design and development plan are thoroughly explained and students will understand product-specific performance standards. In addition, students will gain knowledge on design verification and validation methods, the design review process, the design history file construction, its management and control, building technical files and design dossiers, and risk management in the supply chain.

This course is vital for any medical device professional looking to expand their knowledge on comprehensive risk management processes and explain their interactions with the design and development activities of an organization.
**eLEARNING ONLINE COURSES**

**MDSAP AND REGULATORY TRANSITIONS – THE BASICS: VIRTUAL TRAINING**

2 hours | Online / On-demand (video-based course with exam)

Students will understand the new regulatory audit findings/nonconformance grading system and know what grades trigger regulatory follow-up within MDSAP. They will also learn to recognize the value of the MDSAP audit model, become familiar with the premise of the MDSAP audit time calculations and basic information to be included in the MDSAP audit report, and comprehend the MDSAP timeline and other upcoming regulatory changes.

This course is vital for any medical device quality professional including new hires, quality directors, managers, engineers and auditors responsible for implementing a quality management system in accordance with ISO 13485:2016 and planning to undergo an MDSAP audit.

**EU MEDICAL DEVICE REGULATION (EU MDR) – A COMPREHENSIVE OVERVIEW**

2 hours | Online / On-demand (computer-based training course – highly interactive with exam)

In 2017, the Medical Device Regulation (EU MDR) 2017/745 was published, introducing major changes to the previous Medical Device Directive (MDD). Significant changes include device classification, requirements for technical documentation and clinical evidence. This course provides comprehensive instruction on the EU MDR. It walks students through every aspect of the regulation and identifies key topics and changes, including the new roles associated with EU MDR, standard requirements that must be met by all manufacturers regardless of class and the requirements for conformity assessments. The module also provides premarket and postmarket requirements of conformity assessment. By the end of this course, you will: (1) recognize the regulatory background in Europe, (2) identify the roles associated with the EU MDR, (3) discuss the manufacturing requirements of the EU MDR and (4) explain how to comply with premarket and postmarket requirements for conformity assessments.

This course is vital for any medical device quality professional including quality directors, managers, engineers and auditors looking to gain knowledge on the EU MDR.

**FDA PRE-SUBMISSION PROGRAM (Q-SUB) EXPLAINED**

1.5 hours | Online / On-demand (interactive computer-based training course with exam)

Seeking feedback from the FDA is strongly encouraged by the Agency, but the process can be confusing and it’s important to be prepared for your FDA meeting. This course was developed by a recent FDA insider and provides an overview of the mechanisms available to request feedback from the Food and Drug Administration (FDA) regarding potential or planned medical device Investigational Device Exemption (IDE) applications or other premarket submissions, such as Premarket Approval (PMA) applications, Humanitarian Device Exemption (HDE) applications, Evaluation of Automatic Class III Designations (De Novo requests), Premarket Notification (510(k)) submissions, Clinical Laboratory Improvement Amendments (CLIA) Waiver by Application, and including certain Investigational New Drug Applications (INDs) and Biologics License Applications (BLAs). The course covers logistics for submission, receipt, tracking, and review of/response to these requests. The feedback mechanisms include pre-submissions, informational meetings, study risk determinations, formal early collaboration meetings (i.e., agreement and determination meetings), submission issue meetings, and PMA day 100 meetings.

This course is vital for any medical device quality professional including quality directors, managers and engineers.
U.S. QUALITY SYSTEMS REGULATION
21 CFR PART 820

7 hours | Online / On-demand
(video instruction with exam)

This course includes six modules, that cover the U.S. Quality Systems Regulation (21 CFR 820) and the Combination Products Regulation (21 CFR Part 4.) Each module includes an approximately one hour video instructional presentation by internationally recognized quality system expert, Kim Trautman.

This class is vital for any medical device R&D engineer, scientist, and clinician as well as Regulatory Affairs and Quality Assurance professionals.

DESIGN AND DEVELOPMENT FOR MEDICAL DEVICES AND IVDS – OVERVIEW

2 hours | Online / On-demand
(video-based course with exam)

This course provides a basic understanding of Design Controls for medical devices and IVDs. Providing knowledge to comply with FDA’s Quality System Regulation, the quality management system international standard ISO 13485:2016, and the European Union Medical Device Regulation (EU MDR). In addition, students will be able to identify design control requirements based on FDA quality system regulation, ISO 13485:2016, and EU MDR, recognize how risk management ties into the design control process, recognize the FDA’s auditing process and expectations of design controls, and identify appropriate application of design control requirements.

This course is vital for any medical device professional looking to bring products to market, or to manufacture or audit products in a particular country or in all MDSAP-participating countries. These courses are particularly helpful for employees responsible for regulatory compliance, including developing premarket submissions for entry into a particular country. Also, those interested in becoming a potential auditor under MDSAP should take these courses to demonstrate knowledge and competency in country-specific medical device requirements.

COUNTRY-SPECIFIC MEDICAL DEVICE REGULATION – AUSTRALIA, BRAZIL, CANADA, JAPAN AND UNITED STATES

2 hours / each country – or – total of 10 hours of instruction if purchased as a bundle | Online / On-demand

A comprehensive overview of each country’s medical device regulatory framework, including both premarket and postmarket requirements. These courses offer one-of-a-kind training that was developed by regulatory experts and former regulators from around the globe. The course content is highly interactive and designed with a visual learner in mind. Our global regulatory experts ensure that the content is up to date, providing English translation for some countries for which it is difficult to find this level of information. Learn what it takes to bring a product to market in each country and KEEP it there! You’ll also be introduced to the Medical Device Single Audit Program (MDSAP), and learn how each country is utilizing MDSAP. Includes competency assessments to provide documented evidence for the training requirements of ISO 13485:2016, the international quality management system standard.

This course is vital for any medical device professional looking to bring products to market, or to manufacture or audit products in a particular country or in all MDSAP-participating countries. These courses are particularly helpful for employees responsible for regulatory compliance, including developing premarket submissions for entry into a particular country. Also, those interested in becoming a potential auditor under MDSAP should take these courses to demonstrate knowledge and competency in country-specific medical device requirements.
REGISTER FOR OUR COURSES
To book your place in any course, or for further information, please contact medicaldevices@nsf.org, visit www.nsf.org or call +1 202 822 1850.

ON-SITE TRAINING
All our training can be brought On-site, tailored to your key concerns and delivered at a time that suits you. Contact us to discuss your requirements.

PHARMA BIOTECH eLEARNING
We also offer a wide range of pharmaceutical eLearning sessions. Study on the go, at home or at work at a time convenient to you. Visit www.nsf.org/info/pharma-e-learning.