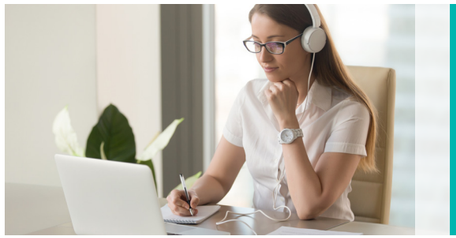
MEDICAL DEVICE TRAINING & EDUCATION COURSES

COURSES

4 AUDITING COURSES

5 PREMARKET REGULATORY COURSES

6 QUALITY SYSTEM REGULATION COURSES



8 eLEARNING COURSE LIST

AUDITING COURSES

EU MDR - Internal Auditor Training

3 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 ISO 13485:2016 relative to the EU MDR and how companies can be prepared.

This class will be 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 learn about 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 discuss and review the new regulatory QMS audit findings/nonconformance grading system and what grades trigger regulatory follow-up. Finally the regulatory transitions for MDSAP and 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 learn about 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 learn about 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 workshop 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 eLearning 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 learn about 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 will help you to recognize 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, 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.

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.

WHAT PEOPLE ARE SAYING

Content was perfect, instructors very knowledgeable and gave great examples.

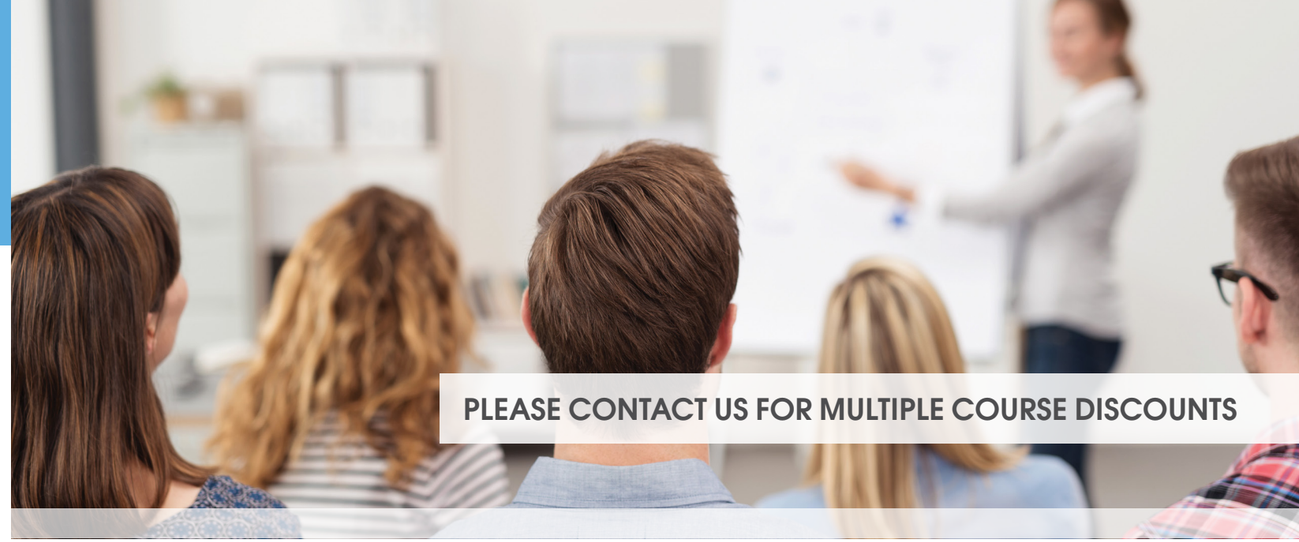
Scott Gisler | Design Control Training Course

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



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Design and Development for Medical Devices and IVDs – an Overview

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

This eLearning course provides a basic overview 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) recognize 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 a comprehensive overview of risk management concepts within medical devices. Students will learn about 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 learn how to identify 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 COURSE LIST

EU MEDICAL DEVICE AND IN VITRO DIAGNOSTIC REGULATION (EU MDR & IVDR)

European Union Medical Device Regulation – EU MDR

This course provides comprehensive instruction on the EU MDR. It covers every aspect of the regulation and identifies key topics and changes, including economic operators and new roles associated with EU MDR, standard requirements that must be met by all manufacturers regardless of class, and the pre- and post-market requirements of conformity assessment.

Post-Market Surveillance and Vigilance Requirements for Manufacturers (EU 2017/745)

Post-market surveillance for manufacturers is covered in Articles 83-86. Articles 87-89 cover post-market vigilance requirements. This course reviews the requirements set forth in these articles in detail, with expert advice provided throughout the course.

European Union In Vitro Diagnostic Device Regulation – EU IVDR

This course provides comprehensive instruction on the EU IVDR. It covers all aspects of the regulation and identifies key topics and changes, including the economic operators and new roles associated with EU IVDR, standard requirements that must be met by all IVD manufacturers, and pre- and post-market requirements of conformity assessment.

Design Controls for Medical Devices and IVDs (video-based)

This video-based training course provides a basic understanding of design controls for medical devices and IVDs. It covers how to comply with the U.S. FDA's Quality System Regulation, 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.

U.S. FDA REGULATIONS

U.S. FDA Medical Device Reporting Requirements

The U.S. Medical Device Reporting regulation (21 CFR Part 803) contains mandatory requirements for manufacturers, importers and device user facilities to report certain device-related adverse events and product problems to the FDA. This course provides critical information to ensure mandatory reporters maintain compliance with the regulation.

U.S. Quality Systems & Combination Products – Practical Application (video-based)

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 Regulation of Combination Products (21 CFR Part 4). Each module includes an approximately one-hour video instructional presentation by Kim Trautman, Executive Vice President, at NSF International, followed by an assessment on the information covered in the video.

U.S. FDA Medical Device Complaint Handling and Servicing – Plus ISO 13485:2016 Requirements

Maintaining proper complaint files is an essential element of the medical device quality management system. This course examines the importance of a properly functioning complaint handling system and the relationship between complaints, service reports, U.S. medical device reporting and CAPA. It provides a side-by-side comparison of complaint handling requirements in the U.S. versus those in the ISO 13485:2016 standard.

U.S. FDA Pre-Submission (Q-Sub) Program – Requesting FDA Feedback

The pre-submission or Q-Sub program is a voluntary mechanism to get FDA's feedback on specific questions necessary to guide product development and/or application preparation. This course provides instruction critical to prepare for a successful meeting with the FDA.

Design Controls for Medical Devices and IVDs (video-based)

This video-based training course provides a basic understanding of design controls for medical devices and IVDs. It covers how to comply with the 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.

Deciding When to Submit a new 510(k) for Existing Devices

The FDA is aware of some confusion surrounding the guidance, Deciding When to Submit a New 510(k) for a Change to an Existing Device. As such, FDA has worked diligently over the past few years to enhance predictability, consistency and transparency while maintaining a "least burdensome approach." The new updated guidance provides greater detail of the regulatory framework, policies and practices underlying FDA's decision-making process and provides much needed clarity for industry on FDA's expectations. In this course we walk through these changes and discuss how to determine when to submit.

INTERNATIONAL STANDARDS AND PROGRAMS

ISO 13485:2016 – International Medical Device Quality Management System (QMS) Standard

This course provides in-depth instruction and expert clarification of ISO 13485:2016, the standard that serves as a basis for many medical device QMS regulations around the globe. This course covers the goals of the standard and detailed information regarding Clause 4-QMS, Clause 5-Management Responsibility, Clause 6-Resource Management, Clause 7-Product Realization and Clause 8-Measurement Analysis and Improvement.

ISO 14971:2019 – Application of Risk Management to Medical Devices

ISO 14971 states that manufacturers shall establish, document and maintain a risk management process to identify hazards, estimate and evaluate the risks of these hazards, control risks and monitor the effectiveness of the controls. An effective risk management program applies to all stages of the medical device lifecycle and is considered an integral part of a manufacturer's QMS. This course presents the key foundations of the risk management process as defined in ISO 14971 and provides expert tips on how to navigate the process.

U.S. FDA Medical Device Complaint Handling and Servicing – Plus ISO 13485:2016 Requirements

Maintaining proper complaint files is an essential element of the medical device quality management system. This course examines the importance of a properly functioning complaint handling system and the relationship between complaints, service reports, U.S. medical device reporting and CAPA. It provides a side-by-side comparison of complaint handling requirements in the U.S. versus those in the ISO 13485:2016 standard.

Data Integrity: Overview and Documentation Completion, Review and Approval

Problems with data integrity continue to lead to vigorous regulatory actions. Such issues can be prevented with a thorough knowledge and understanding of the regulators' requirements. This course is aimed at anyone working in the pharmaceutical industry and provides an overview of what is meant by data integrity; what needs to be considered during documentation completion, review and approval; and how to keep your data complete, consistent and accurate throughout the data lifecycle.

Design Controls for Medical Devices and IVDs (video-based)

This video-based training course provides a basic understanding of design controls for medical devices and IVDs. It covers how to comply with the 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.

MDSAP

MDSAP and Regulatory Transitions – The Basics Training

This video-based course provides the basic knowledge to prepare for the Medical Device Single Audit Program (MDSAP). It helps key personnel realize the urgency regarding MDSAP readiness and offers answers to vital questions direct from global quality systems expert, Kim Trautman. Learn about the MDSAP audit model, grading nonconformances and regulatory transition timelines, to name just a few highlights.

Global Medical Device Regulatory Requirements (five-course MDSAP countries bundle)

This course bundle provides comprehensive medical device regulatory requirements for all five countries currently utilizing MDSAP audits in their regulatory framework: Australia, Brazil, Canada, Japan and the United States. These five separate courses can also be taken individually.

COUNTRY-SPECIFIC MEDICAL DEVICE REGULATIONS

Australia

Comprehensive regulatory requirements including the regulatory framework, pre- and post-market requirements, and instruction on the way Australia is utilizing MDSAP.

Brazil

Comprehensive regulatory requirements including the regulatory framework, pre- and post-market requirements, and instruction on the way Brazil is utilizing MDSAP.

Canada

Comprehensive regulatory requirements including the regulatory framework, pre- and post-market requirements, and instruction on the way Canada is utilizing MDSAP.

Japan

Comprehensive regulatory requirements including the regulatory framework, pre and post market requirements, and instruction on the way Japan is utilizing MDSAP.

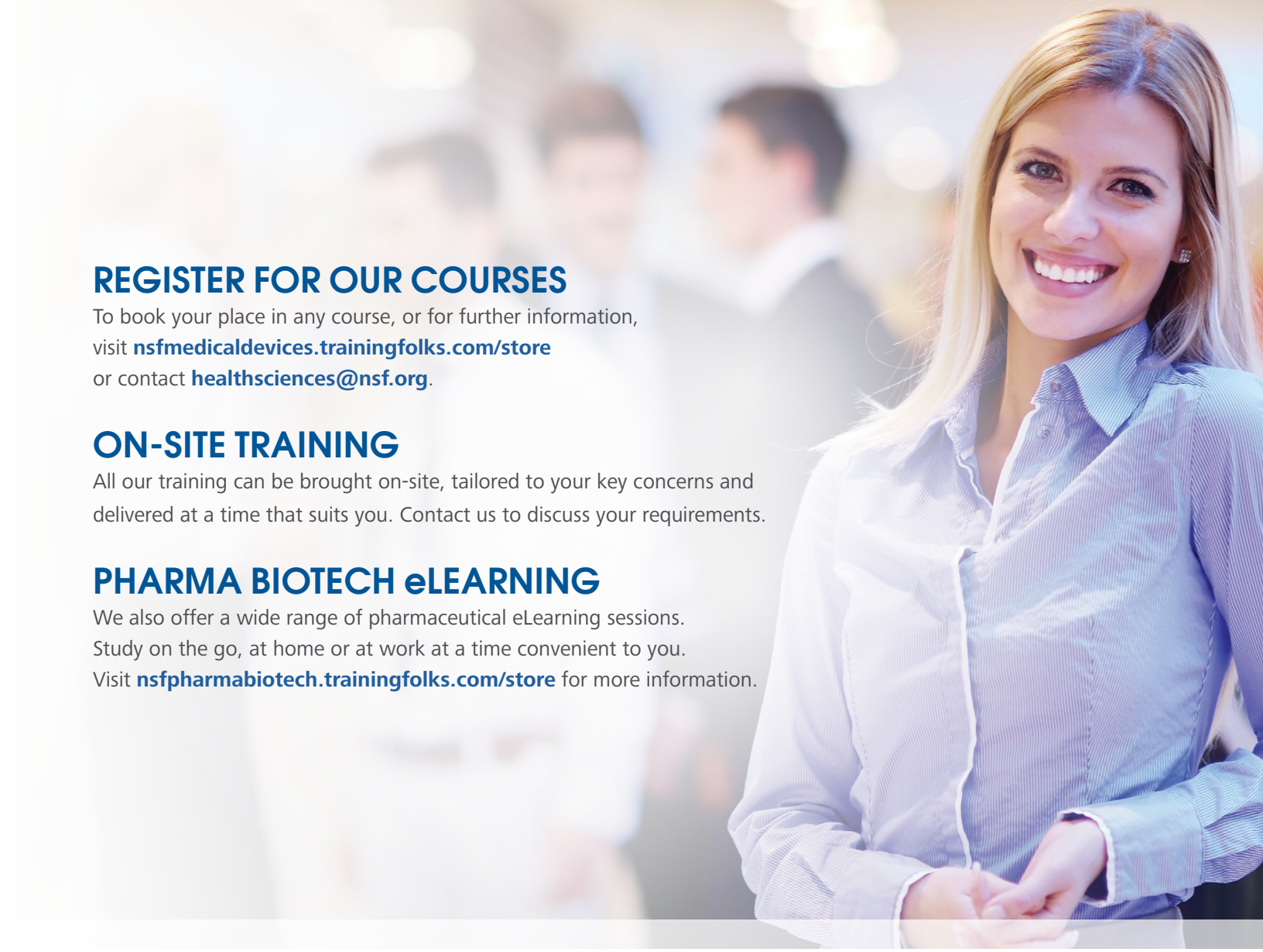
United States

Comprehensive regulatory requirements including the regulatory framework, pre and post market requirements, and instruction on the way the U.S. is utilizing MDSAP.

China

This course provides a comprehensive overview of China's medical device regulatory framework, including both pre-market and post-market requirements. China's medical device regulation program has evolved rapidly over the past two decades. This two-hour overview covers the changes and key aspects of the regulations as they pertain to both domestic and overseas manufacturers.

All courses include a competency assessment and a Certificate of Successful Completion for your training files.



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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 **nsfpharmabiotech.trainingfolks.com/store** for more information.

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