Course Title: FDA QSR & QSIT for Medical Devices: An Introductory Course

Course Duration: 2 Days (9.30 am - 4.30 pm)

Pricing: € 645.00 per person

Format: Live - virtual.

Queries: info@thelearningreservoir.com

Course Details	
Course Description	This introductory course provides a comprehensive overview of the US FDA Quality System Regulation (QSR) for medical devices. The course also covers the Quality System Inspection Technique (QSIT) approach to auditing, with a focus on management controls, design controls, production and process controls, corrective and preventive action, and other key quality system requirements. Participants will gain a solid understanding of the regulatory requirements and best practices for maintaining a compliant quality system for medical devices, as well as practical guidance for preparing for an FDA audit.
Delivery Method	Taught live by an expert tutor via Zoom. You can interact with other delegates and ask questions, just as you would in a traditional classroom.
Instructor	Dr. Fiona Masterson Fiona is a highly experienced quality management and operations management professional with over 25 years of experience in the industry. In addition to her work in fast-paced manufacturing environments, she also lectures part-time in universities. Fiona has a technical background and is highly skilled in delivering engaging training programs. She has worked extensively with the US FDA Quality System Regulation (QSR) for medical devices, serving as a lead quality auditor and subject matter expert for several subparts of 21 CFR Part 820. Fiona has also been audited by the FDA on 21 CFR Part 820 on numerous occasions. Fiona has worked on remediation projects for companies under corporate FDA warning letters and with form 483s observations. Fiona has impressive academic qualifications, including Bachelor and Master of Science degrees, and a Doctorate in Mechanical Engineering. Her research has been published in peer-reviewed journals, covering topics such as medical device and pharmaceutical regulatory affairs, on-the-job training, and innovative training technologies and strategies. With her extensive experience and knowledge, Fiona is an expert instructor for the course on "FDA QSR & QSIT for Medical Devices: An Introductory Course".

Learning Objectives	On completion of this training, participants will be able to: • Understand the purpose and scope of 21 CFR Part 820. • Identify the different subparts of the QSR, including General Provisions (Subpart A) , Quality System Requirements (Subpart B), Design Controls (Subpart C), Document Controls (Subpart D), Purchasing Controls (Subpart E), Identification and traceability (Subpart F) , Production and Process Controls (Subpart G), Acceptance activities (Subpart H), Non-conforming product (Subpart I), Corrective and Preventive actions (Subpart J), Labelling and Packaging Controls (Subpart K), Handling, Storage, Distribution and Installation (Subpart L), Records (Subpart M), Servicing (Subpart N) and , Statistical Techniques (Subpart O). • Understand the role of FDA guidance documents in medical device regulation and how to access and use them. • Learn about QSIT) and how it is used to evaluate compliance with the QSR. • Understand the different components of QSIT audits, including management controls, design controls, production and process controls, and. • Learn how to prepare for an FDA audit and what to expect during the audit process. • Understand the importance of medical device vigilance for manufacturers and how to comply with post-market surveillance requirements.
Who should take this course	Here are the target audience for the course described: • Individuals involved in the design, manufacture, testing, or distribution of medical devices. • Regulatory affairs professionals seeking to enhance their knowledge of FDA QSR and QSIT. • Quality assurance managers who want to ensure a compliant quality system for medical devices. • Engineers who want to gain a foundational understanding of FDA QSR and QSIT. • Anyone interested in learning the regulatory requirements and best practices for maintaining a compliant quality system for medical devices. • Individuals seeking practical guidance for preparing for an FDA audit.
Course Certificate	A certificate of completion will be issued on successful course completion.
Materials	Each participant will receive course materials in the days prior to the course starting. Please ensure you have access to these on the day.

Course Content Breakdown	
Day 1	• Introduction to FDA Quality System Regulation (QSR) for medical devices. • Identification and explanation of the different subparts of the QSR, including General Provisions (Subpart A), Quality System Requirements (Subpart B), Design Controls (Subpart C), Document Controls (Subpart D), Purchasing Controls (Subpart E), identification and traceability (Subpart F), Production and Process Controls (Subpart G), acceptance activities (Subpart H), nonconforming product (Subpart I), corrective and preventive actions (Subpart J), labeling and packaging controls (Subpart K), handling, storage, distribution and installation (Subpart L), records (Subpart M), servicing (Subpart N), and statistical techniques (Subpart O). • Review of past warning letters and Form 483s observations related to noncompliance with 21 CFR Part 820. • Understanding the role of FDA guidance documents in medical device regulation and how to access and use them. • Best practices for maintaining a compliant quality system for medical devices. Participants will engage in interactive exercises throughout the day.
Day 2	• Overview of QSIT and its role in evaluating compliance with the QSR • Understanding the different components of QSIT audits, including management controls, design controls, production and process controls, and corrective and preventive actions • Learning how to prepare for an FDA audit and what to expect during the audit process • Practical guidance for maintaining compliant quality systems and preparing for FDA audits • Understanding the importance of medical device vigilance for manufacturers and how to comply with post-market surveillance requirements. Participants will engage in interactive exercises throughout the day.