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Fundamentals of Medical Device Awareness Single Audit Program (MDSAP) E-Learning

Course Description

To improve the safety and oversight of medical device manufacturing on a global scale, the Medical Device Single Audit Program (MDSAP) is developed to allow for a single regulatory audit of a Medical Device manufacturer by a MDSAP recognised auditing organisation, to satisfy the needs of multiple regulatory jurisdictions.

In this course, you will discover the fundamentals of MDSAP and gain an understanding of MDSAP Audit structure and core processes. In addition, you will discover how to apply and align MDSAP to the internal audit programme.

This e-learning course is especially designed for learners on the go. It provides you the convenience of self-paced learning allowing you to boost your competency and add value to your career.

Who will benefit

This course is specially designed for:

- Quality Assurance and Regulatory Affairs professionals
- Internal auditors, Quality engineers, Manufacturing engineers within medical device industry

Course Objective

Through this course, you will get an overview of MDSAP, including the objectives and requirements of the audit program, and the impacts of the model to your organisation. You will also learn about benefits of MDSAP such as the reduced time to gaining access to multiple markets with a single audit program that satisfies the needs of multiple regulatory authorities.

Course agenda

Topics to be covered in this course include:

- Overview and Objectives of MDSAP
- Benefits of MDSAP
- Roles and Responsibilities
- Uses of MDSAP
- Process Structure and Audit Tasks
- Nonconformity Grading System
- Impact of Audit Model to Organization
- Documentation and Reporting

Methodology

The course employs a variety of training tools such as content-embedded assessment, simulations, and other interactive exercises to enhance instructional delivery. Easily accessible via your preferred choice of device, the course allows you to log in and learn whenever, wherever.

The cumulative duration of the programme is 105 minutes, after which you will be required to pass a quiz to receive your internationally recognised e-certificate with a unique ID.

Sale Modes: Single License, Group License, SCORM Sale

Duration: 105 minutes

Number of Chapters: 8

Learning Mode: Self-Paced (LMS)

Number of Quizzes: 8

Interactivity Level (1-4): 3-complex

Language: English