BRC Training Course

Medical Device Single Audit Program (MDSAP) Fundamentals

Course Description

The Medical Device Single Audit Program (MDSAP) is an international initiative to implement a program through which a single audit of a medical device manufacturer that will be accepted by multiple regulators to address QMS/GMP requirements. Participating regulatory authorities include Australia, Brazil, Canada, Japan and the USA.

This 1-day course is relevant for any size organization selling medical devices into the participating regions. It will help you to determine if your own Quality Management System processes are consistent with the requirements of the MDSAP audit model and assist in preparing you to host an MDSAP audit.

Who Should Take It

- Individuals with responsibility for management, operation, implementation or maintenance of an ISO 13485:2016 Quality Management System.
- Individuals responsible for Quality Assurance or Regulatory Affairs.
- Senior Management
- Quality Managers, Members of the Quality Team and/or Internal Audit Team

Learning Objectives

- Understand the fundamentals, structure and scope of the MDSAP program.
    - MDSAP audit processes and their interrelationships.
    - MDSAP and organizational regulatory compliance.
    - MDSAP reporting and nonconformity grading.
- Differentiate between MDSAP audits and other types of QMS audits.
- Review the different MDSAP documents.
- Review the MDSAP audit sequence.
- Understand the 7 MDSAP processes and what auditors will be looking for when addressing each.

Prerequisites

None. This is an introductory course. (Previous experience working within an ISO 13485 quality management system and/or a medical device quality environment is helpful, but not required.)

Location

On-Site

Duration

1 Day