IPI Academy

MANAGEMENT forum



Presented by
Management Forum

Non-Conformance and Corrective Action for Medical Device Manufacturers

The identification of non-conformances and ensuring that they are dealt with in a timely and appropriate manner is a key part of any medical device Quality Management System (QMS). This course provides an introduction to the regulatory requirements as they relate to the identification and handling of non-conformances and how manufacturers may demonstrate compliance.

Format:
Bespoke training

CPD:
3 hours for your records (depending on your requirements)

Certificate of completion

Course Overview

The identification of non-conformances and ensuring that they are dealt with in a timely and appropriate manner is a key part of any medical device Quality Management System (QMS). Regulations for medical device quality management systems include particular requirements for non-conformance, correction, corrective and preventative actions. These requirements relate to non-conformances identified through internal audits, external audits, routine processes, customer complaints vigilance and many other activities. Evidence of a QMS which deals with non-conformance and prevents recurrence is important and expected when demonstrating conformity with the regulations.

These requirements are defined in ISO 13485, the international standard for medical device quality management systems, as well as in 21 CFR 820 and other global regulations.

This course provides an introduction to these regulatory requirements as they relate to the identification and handling of non-conformances and how manufacturers may demonstrate compliance.

Benefits of Attending

- **Understand** the sources of non-conformance within a medical device QMS
- **Learn** techniques to establish the root cause of a non-conformance
- **Understand** the difference between containment, correction, corrective action, and preventative action
- **Gain** an awareness of the ways in which an effective Corrective and Preventative Action (CAPA) system can lead to improved performance and regulatory compliance

Who Should Attend

- Managers and supervisors working within a regulated Quality Management System (QMS)
- Regulatory Compliance specialists
- Quality Management System (QMS) specialists
- Internal Auditors
- Regulatory and Quality professionals

Please note that access to a copy of ISO 13485 would be beneficial to delegates attending this training. If you do not already have access to this through your organisation, please see below the ways to acquire it:

ISO 13485 -
https://www.iso.org/standard/59752.html

This standard is also available from national standards organisations such as BSI, DIN, AFNOR, AAMI, NSAI, etc.

Reviews

★★★★☆

[My goal was to gain] a comprehensive view of the nonconformities management process and facing it from different perspectives. It was accomplished by this course. [Speaker] was exhaustive in the topic; interactive; she enriched the webinar with a lot of useful examples.

Annalisa Scopelliti
Junior Quality Assurance Specialist
SENTINEL CH. SpA
Dec 12 2024

Run this programme in-house for your whole team

Coming to IPI Academy for your in-house training provides an all-inclusive service which gives you access to a wide variety of content, learning platforms and delivery mechanisms as well as your own personal training adviser who will work with you from the initial enquiry through to feedback and follow-up after the programme.

With over 600 trainers, all practitioners and experts across a huge range of fields, we can provide the training you need, where you need it, when you need it, and at a price which suits your budget. Our approach to tailored learning and development consists of designing and delivering the appropriate solution for each client.

For your FREE consultation and to find out more about how we can work with you to solve your training needs, please contact our training advisers:



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IPI Academy

IPI Academy is a training initiative of Falconbury and Management Forum; leading providers of industry training for over 30 years, based in the UK.

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