IPI Academy

MANAGEMENT forum

Presented by
Management Forum

Non-Conformance and Corrective Action for Medical Device Manufacturers

12 December 2024

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:
Live online

CPD:
3 hours for your records

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.

Programme

Non-Conformance and Corrective Action

- Regulatory requirements for non-conformance and corrective action
- Definitions and understanding CAPA
- Sources of non-conformance and writing an effective statement of non-compliance
- The non-conformance and corrective action cycle
- Assessment of the risk associated with non-compliance
- Root cause analysis tools and methodology
- Correction, containment and impact assessment

Non-conformance and Corrective Action (continued)

- Taking effective corrective action to address root causes
- Evaluation of the effectiveness of corrective action
- Use of electronic quality management systems for non-conformance management

Preventive Action

- Regulatory requirements for identification of preventive action
- Sources of preventive action and how to capture the details
- Root cause analysis
- Evaluation of the effectiveness of preventive action

Presenter

Annette Callaghan

A quality management professional, chartered biologist and member of the Royal Society of Biology, with over 35 years' experience in the medical device, pharmaceutical, biotechnology and food industries. Extensive knowledge of quality and environmental management systems, internal and third-party auditing and personnel training. Eligible to act as a Qualified Person as defined in Directive 2001/83/EC, as amended (previously 75/319 et al.) since 1993. A Qualified Notified Body Lead Auditor since 2002 (IRCA ref: 1182641).

Course date

12 December 2024

Live online
13:30-17:00 **UK (London)** (UTC+00)
Course code 14316

GBP **299** ~~349~~
EUR **429** ~~499~~
USD **501** ~~579~~
Until 07 Nov

How to book

Online:
ipi.academy/2696

Alternatively contact us to book, or if you have any queries:

Email:
info@ipi.academy

Phone:
+44 (0)20 7749 4749

Discounts

- Booking more than one delegate on any one date qualifies for a **15% discount** on the second and subsequent places.
- Most events qualify for an **early booking discount** prior to 6 weeks before the course date. Be sure to check on our website, where the latest discounts will be shown.

Further information

Fee
The fee includes all meals and refreshments for the duration of the course (for venue-based courses) and a complete set of course materials (provided electronically). If you have any particular requirements, please advise customer services when booking.

Please note
IPI Academy (and our training partners) reserve the right to change the content and timing of the programme, the speakers, the date and venue due to reasons beyond their control. In the unlikely event that the course is cancelled, we will refund the registration fee and disclaim any further liability.

Terms and conditions
The rest of the our terms, the event cancellation policy and the terms and conditions are on our website, please visit ipi.academy/content/terms-and-conditions

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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