Workshop

A practical approach: How to write, maintain and interpret master documents

Presenter:

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Introduction:

A quality management system (QMS) is a set of processes and procedures used to ensure that the products produced are of the highest quality and comply with all applicable regulations and guidelines, such as local and international Current Good Manufacturing Practices (cGMP), the International Conference on Harmonization (ICH) and the Pharmaceutical Inspection Convention Scheme (PICs) guidelines.
A QMS covers all aspects of the production process, including design, development, manufacturing, testing, and distribution.
It incorporates a range of quality control measures, including master documentation, document control, audits, and inspections, to ensure that all processes are consistent and repeatable, and that the applicant / manufacturer is in control of all processes at all times.
This is essential to ensure that products are safe, effective, and meet the needs of patients and also provides for a framework for continuous improvement, allowing companies to identify areas for improvement and implement corrective actions to prevent issues from recurring.

Who should take this course?

Quality Affairs pharmacists / scientists

Regulatory Affairs pharmacists / scientists

Responsible pharmacists in training

Course format:

Online on Microsoft Teams (2 half-days)

Course Content:

Day 1 – 23rd August 2023 (09:00 – 13:00)

1. Quality management systems (QMS)
2. Master documents

    a. Different types of master documents
        i. Applicant
        ii. Manufacturer / Packer / Analytical aboratory
3. Principles of good document practice

Day 2 – 24th August (09:00 – 13:00)

1. SOPs
    a. How to write, review, train, implement and manage a SOP
2. Site Master File (SMF)
    a. How to compile and manage a SMF
3. Batch manufacturing & packaging master documents
    a. Review of executed batch manufacturing & packaging documents vs. master documents
    b. Review of final product specifications and certificates of analysis
    c. Review of post-importation testing results

Course Outcomes:

At the end of this course the attendee will have a clear understanding of:

1. The components of a QMS
2. The management and control of master documents
3. The review executed batch documents against of master documents