Pharmaceutical Consultancy Services

Quality Management MODULE 2
in Drug Development

27 to 29 September 2023

This three-day training provides insight into the regulatory requirements for drug development from both the viewpoint of regulatory authorities as well as inspection bodies.

TARGET AUDIENCE

Professionals in pharmaceutical and biotechnological industries, Professionals in institutions and Contract Research Organisations (CRO's), Hospital pharmacists and Postgraduate students.

LEARNING GOALS

- Understand the basic concepts of quality, nonclinical- and clinical drug development.
- Find, interpret, and understand relevant GxP guidelines and identify the key regulatory requirements for products in development.
- Identify the location of quality, nonclinical- and clinical data in the Common Technical Document (CTD).

RESULTS

- Awareness of the difference between the GxPs and regulatory expectations.
- Understanding of your role in the drug product development.
- Knowledge on how to identify gaps in the data package to be submitted for regulatory approval.

CONTENTS

- API – Profile of lead compound: R&D steps and R&D data
- Medicinal chemistry - Quality in lead finding and optimization
- Pharmaceutical formulations (incl. development, quality management and GMP)
- Drug development in Dutch hospital pharmacies
- Regulatory requirements - quality, clinical and nonclinical (incl. CTD, Clinical Trial Applications)
- GLP and nonclinical development program
- Execution of a GLP compliant study
- GMP during nonclinical and clinical development
- Clinical development and GCP
- Clinical phase I, II and III
- Real-life case studies

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Go to the training overview on our website to register:

www.pcs-nl.com

GROUP DISCOUNTS APPLY, INQUIRE WHEN REGISTERING!

Quality Management MODULE 2

MODULE LEADER

The Module Leader will be announced later.

GENERAL INFORMATION

Educational Form Seminar
Date 27 to 29 September 2023
Location Area of Utrecht, the Netherlands

RELATED COURSES

Quality Management –
the Role of the Qualified Person
This five-day training provides insight into an integrated approach on quality management as a good business practice.

Quality Management in Sterile Manufacturing
Three days of training on sterility assurance challenges in the pharmaceutical industry and hospital pharmacies.

Quality Management in Manufacturing of Biopharmaceuticals
Three days on manufacturing biopharmaceuticals & quality aspects

What makes a PCS training so special?

343

More than 343 participants so far!

32

This is the 32nd edition of this training.

87%

87% of participants would recommend this training to others.

7,4

The average rating for this module is 7,4 out of 10.