مركز د. صالح عبدالله باوزير للإستشارات المهنية

Prof. Bawazir Pharma Consulting Center

26 OCTOBER, 2021 RIYADH

CTD Quality Module 3 for new chemical and Generic products

Chemistry, Manufacturing and Control (CMC) of Product quality requirement

Overview

The Pharmaceutical Development Module should describe the knowledge that establishes that the type of dosage form selected, and the formulation proposed are suitable for the intended use. This module should include sufficient information in each part to provide an understanding of the development of the drug product and its manufacturing process. CMC is an integral part of drug development, a regulatory submission and the on-going marketing and life cycle management of a medicinal product. As drug development of the dosage form moves from concept to commercialization, the breadth and depth of CMC documentation required in submissions increases in parallel.

Learning Objectives

- Define the different types of data requirements for type of product
- Describe the general CMC requirements for New Drug Application
- Distinguish CMC information required for special categories
- Understand the Substance part of the Module
- Identify the required information for product part of the module
- Understand how to respond to regulatory authority questions.

Key Topics

The CMC aspects of the regulatory submission will cover

- Characterization of the active substance
- • Raw materials used to manufacture the active substance and finished dosage form
- Description of the product and process development
- Description of the manufacturing processes
- Release and stability testing data for both the active substance and the dosage form
- Analytical methods and specifications used for testing and release of raw materials
- Container and closure systems

WHO SHOULD ATTEND

- Regulatory Affair staff
- Scientific office staff
- Production manager
- QA Manger
- QC Manager

08:45 – 09:00 REGESTRATION and COFFEE

SESSION 1 : 09:00 – 10:30

- **Principals of RA and CMC**
  - What is RA?
  - Role of Regulatory Affairs Pharmacist
  - Why is there CMC?
  - Overview on CTD Content
  - CMC Regulatory Affairs (CMC-RA)
  - CMC Modules of Regulatory Dossier

10:30 – 11:00 COFFEE BREAK

SESSION 2: 11:00 – 12:30

- **Chemistry - Drug Substance**
  - 3.2.S Drug Substance.
  - Drug Master File (DMF)
  - 3. Complete Information on the "3.2.S Drug Substance" Sections.
  - 3.2.S.2.2 Description of Process and Process Controls
  - 3.2.S.2.3 Control of Materials
  - 3.2. S.2.4 Control of Critical Steps and Intermediates
  - 3.2. S.2.5 Process Validation and/or Evaluation
  - 3.2.S.2.6 Manufacturing Process Development
  - 3.2.S.3 Characterization
  - 3.2.S.4 Control of Drug Substance

12:30 – 14:00 LUNCH BREAK

SESSION 3: 14:00 – 15:30

- **Manufacturing -1 Drug Product**
- 3.2.P Drug Product
- 3.2.P.1 Description and Composition of the Drug Product
- 3.2.P.2 Pharmaceutical Development
- 3.2.P.2.3 Manufacturing Process Development
- 3.2.P.2.4 Container Closure System
- 3.2.P.2.5 Microbiological Attributes
- 3.2.P.3 Manufacture
- 3.2.P.3.2 Batch Formula
- 3.2.P.3.3 Description of Manufacturing Process and Process Controls
- 3.2.P.3.4 Controls of Critical Steps and Intermediates
- 3.2.P.4 Control of Excipients
- 3.2.P.5 Control of Drug Product
- 3.2.P.6 Reference Standards or Materials
- 3.2.P.7 Container/Closure System 3.2.P.8 Stability

15:30 – 16:00: COFFEE BREAK

SESSION 4: 16:00 – 17:00

- **Manufacturing -2 Biological Product**
- Biotech Manufacturing Systems
- Things to Consider in Developing a Biotech Product
- CMC Considerations for Biologics
- Common CMC Issues for Therapeutics Proteins

Building Trust Between
Regulators and Industry

FOR REGESTRATION CLICK LINK BELOW

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Registration fees	2000.00
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Bank Account Details

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