

Introduction

Overview

Learning objectives

Who should take this course?

Module overview

Module 1: The Starting Line

Overview

What is GMP?

What is cGMP?

World Health Organization (WHO)

Why GMP?

Module 2: Cases From History

Overview

Cases from history

1930 – Lubeck – BCG Vaccine

1938 – Sulphanilamide

1940 – Contaminated Caps – Lambert

1955 – Polio Vaccine

1962 – Thalidomide

Why GMP is so Important?

Module 3: GMP Regulations

Overview

GMP Regulations & Guidelines

GMP's in Different Countries

WHO

ICH

EMA

MHRA

USFDA

GMP concept

What aspects of manufacturing does cGMP cover?

Review activity

Module 4: Quality Management System (QMS)

Overview

What is Quality Management?

Standard Operating Procedures (SOP)

Quality Objective

GMP as a part of Quality Assurance

Requirements for an effective QA program

ICH Q10

Life Cycle Phases of GMP

Module 5: Premises

Overview

Premises

Production Areas

Changing Rooms

Storage Areas

Quality Control Areas

Module 6: Personnel

Overview

Personnel

General Principles

Staff Product Contact Requirements

Grades A,B,C & D

Personal Hygiene

General considerations for manufacturing areas

Review activity

Module 7: Changes to Equipment

Overview

Equipment

Balances

Utilities

Documentation

Change control

Module 8: Qualification & Validation

Overview

Definitions

Qualification Vs Validation

Risk Assessment

Types of Validation Documentation

Module 9: Complaints and Product Recalls

Overview

Complaints and product recalls

Classification of defects – critical

Classification of defects – major

Classification of defects – minor

Product recall procedures

Module 10: Self-Inspection

Overview

Self-inspection

Frequency

Self inspection team

Self Inspection approach – systems

Self inspection approach – areas

Review activity

Module 11: Production Practices

Overview

Good Practices in Production

Prevention of Cross Contamination

Module 12: Quality Control

Overview

Quality Control

Sampling

Documentation

Stability Programme

Quality Testing

Moving forward