

# GMP



## Documentation and Records

This module discusses the role of documentation in providing a history of manufacturing from supplier to customer, including the requirements of Standard Operating Procedures (SOPs), Batch Processing Records, Quality Control Records and Logs.

### Objectives:

- Recognise the importance of procedures
- Recognise the importance of record keeping
- Identify the possible consequences of not completing and certifying GMP documents
- Identify how to complete batch records and associated supporting documents

# Course Outline

## INTRODUCTION

- o Welcome
- o Outcomes
- o Reviews and assessments

## NEED FOR DOCUMENTATION

- o What do you think?
- o GMP solution
- o Need for documentation
- o GMP compliant documents
- o Documentation & records
- o Document control
- o GMP rules for control
- o Introducing a standard procedure
- o Review

## GMP DOCUMENTATION

- o What do you think?
- o GMP solution
- o Specification
- o Inward goods
- o Production
- o Packaging
- o Quality Control

## RECORD KEEPING

- o What do you think?
- o GMP solution
- o Importance of record keeping
- o Completing records
- o Changes to records
- o Review

## THE FIXITKWIK CASE STUDY

- o What do you think?
- o GMP solution
- o Introduction
- o Investigation
- o What is your conclusion?
- o Review

## SUMMARY

- o Summary