



SeerPharma[®]
CONFIDENCE IN COMPLIANCE

Online GMP Training

GMP5 | Documentation and Records

This module looks at the role of GMP documentation in providing a history of manufacturing from supplier to customer, including the requirements of master instructions, Standard Operating Procedures (SOPs), batch records, quality control records and how to complete GMP records.

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

ASIA-PACIFIC'S LEADER IN QUALITY AND GMP SOLUTIONS

CONSULTING • TRAINING • QMS SOFTWARE • CONTRACTING

www.seerpharma.com



GMP5 | Documentation and Records

CONTENT

Introduction

- Objectives
- Reviews and assessment

Requirements

- What do you think?
- What do the GMP rules state?
- Regulatory requirements
- GMP compliance
- Documentation and records
- Document features
- Document control
- Select true or false for each statement
- What is required as part of GMP batch documentation? Select all that apply.

GMP documentation

- What do you think?
- What do the GMP rules state?
- Types of documentation
- Specifications
- Inward goods
- Manufacturing formula, instructions and batch records
- Other production documentation
- Quality control (QC)
- Fill in the blanks
- How must batch records be completed? Select all that apply.

Record keeping

- What do you think?
- What do the GMP rules state?
- Importance of record keeping
- Completing records
- Which correction is correct?
- Select true or false for each statement

Case study

- What do you think?
- What do the GMP rules state?
- Introduction
- Identify some documentation issues
- Tell the QA Director what you think

Conclusion

- Summary