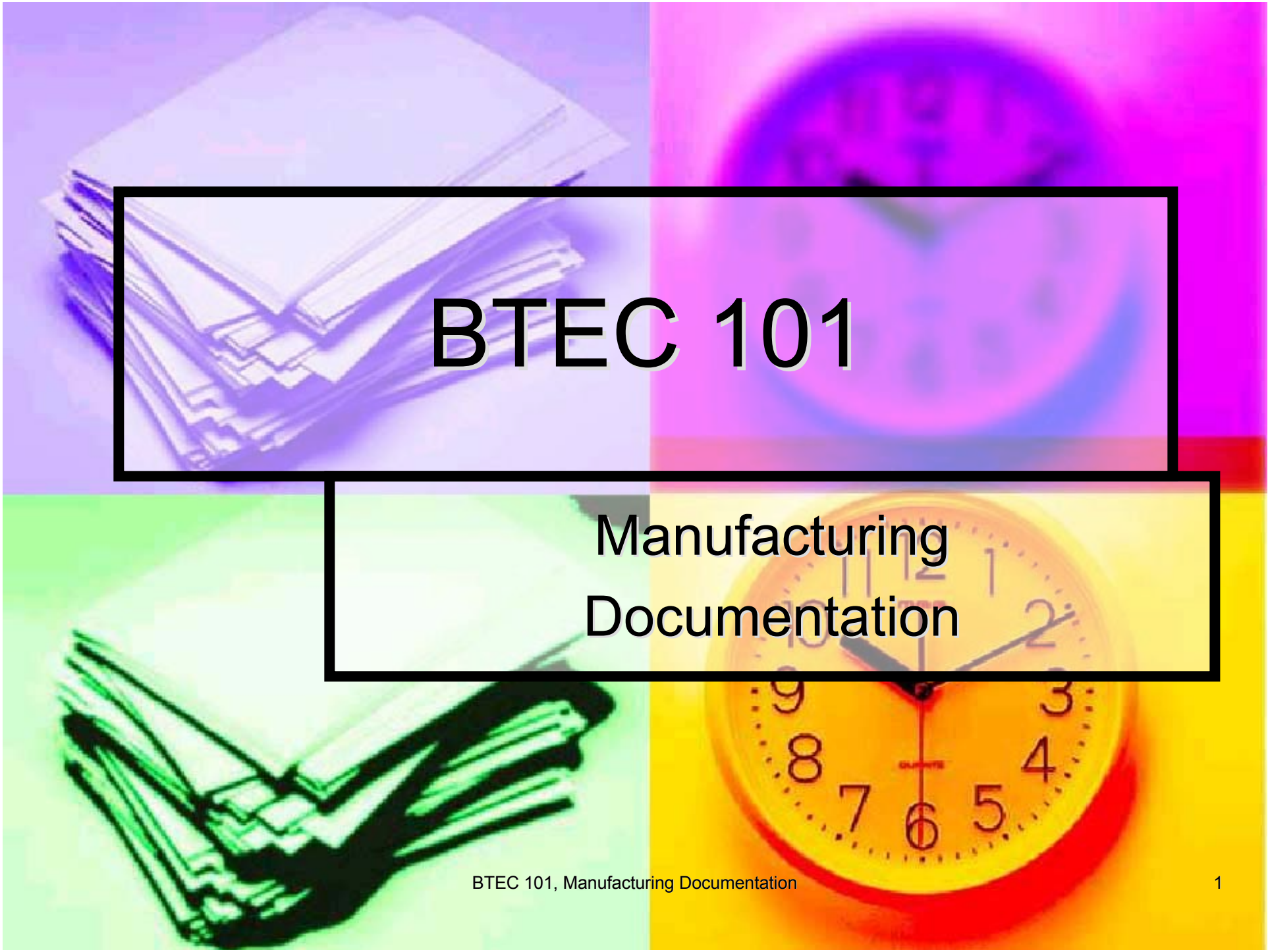


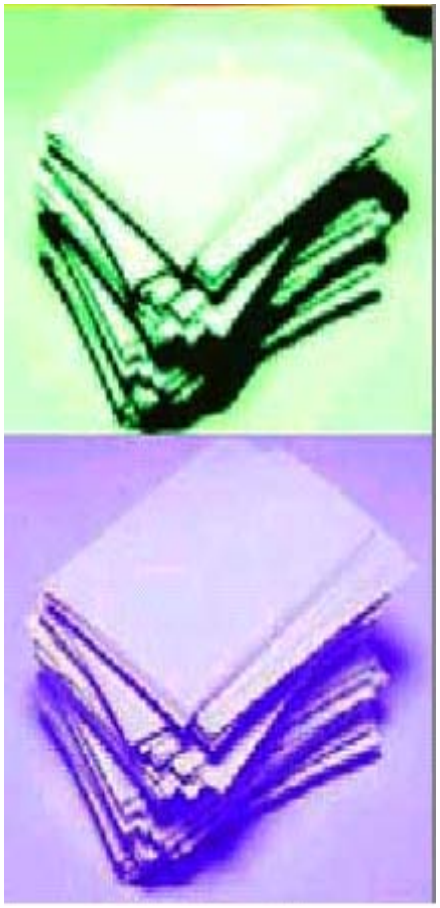
# BTEC 101

## Manufacturing Documentation

# Manufacturing Documentation Topics

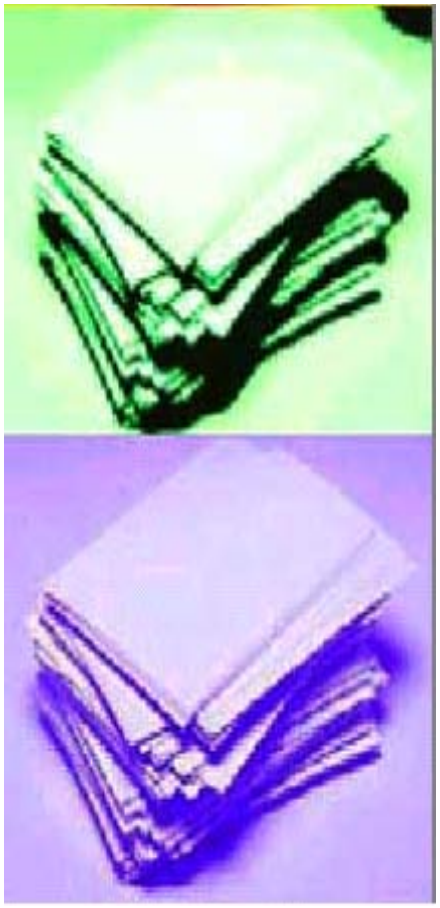
- Why must there be written records?
- Who must sign cGMP documents?
- Why is an auditable paper trail required?
- How does documentation assure personnel accountability?
- What information do all cGMP documents contain?
- From where are raw materials COAs obtained?
- What information is contained within an Equipment log?

# Documentation Compliance



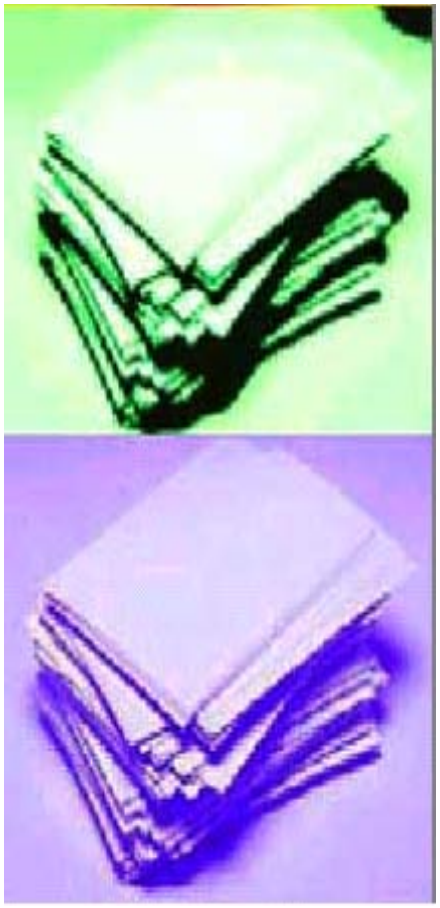
cGMP compliance requires that approved written procedures are _____ & documented for all steps in the production process

# Attributes of cGMP Documentation

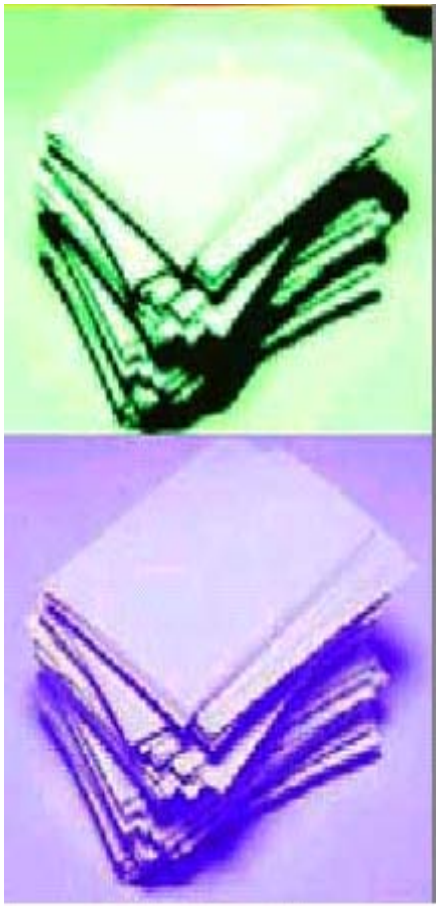


1. SOPs Present _____
2. Batch Records _____ information
3. _____ Reference other documents which relate to a specific step
4. Provide a complete discussion/record of all relevant information

# cGMP Documentation in Support of Product Manufacturing



- Raw Materials Specifications
- Standard Operating Procedures (SOPs)
- Master Production & Control Records
- Batch Production & Control Records
- Laboratory Records
- Equipment Cleaning and Use Logs

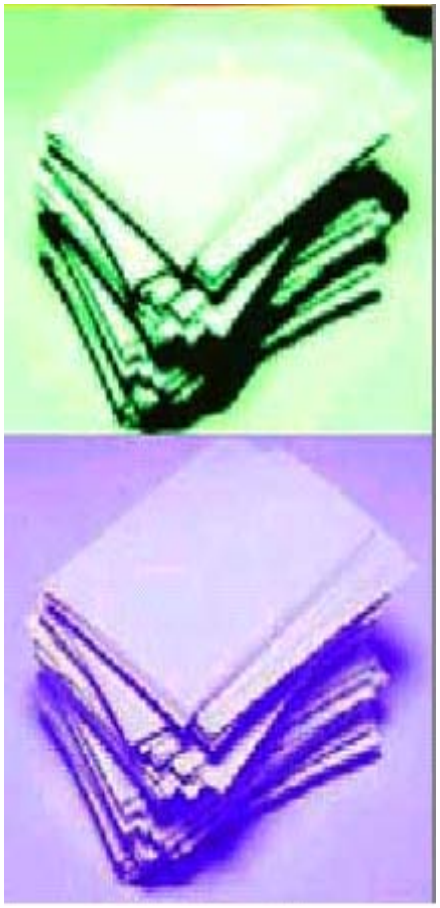


# Examples of Critical Operations

- Inoculating a Fermentor
- Weighing media components
- Adding chemicals to a fermentor

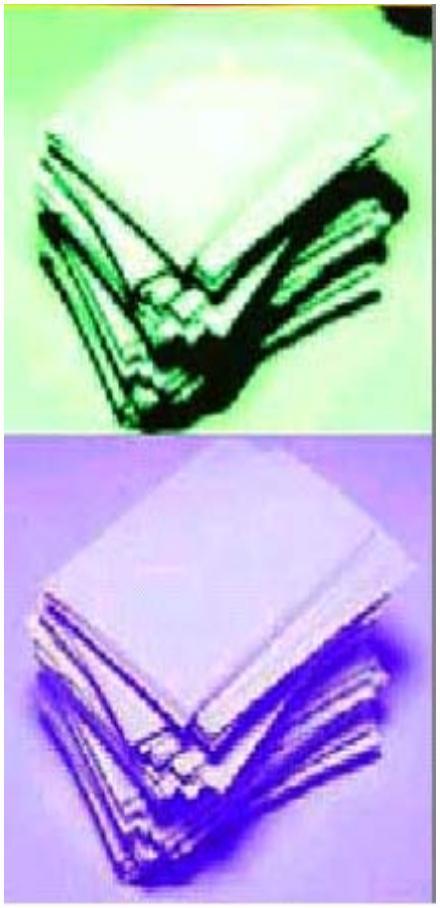
- Are these actions reversible, recoverable?

# Personal Responsibility



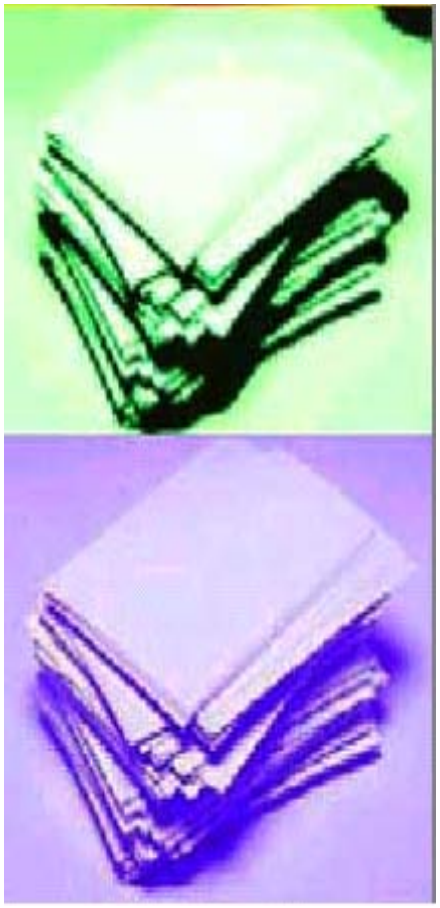
- Significant steps in the manufacture of a product must documented by whom?
- Signing _____ that the step was performed as directed
- _____ operations must be verified & require a second signature

# Raw Materials Specifications



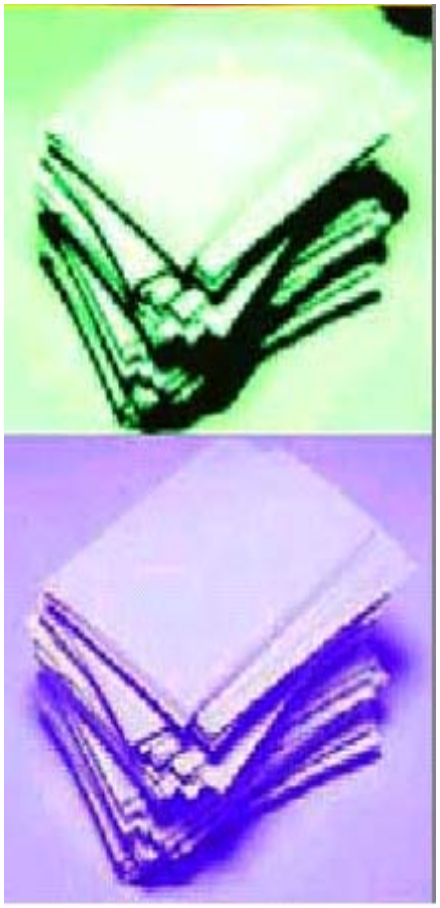
- Describe the quality _____ of critical raw materials used in manufacturing operations
- Usually accompanied by a Certificate of Analysis (COA) provided by manufacturer

# COAs



- COAs detail the component's
  - Identity
  - Purity
  - Performance Characteristics
- Contain signature of primary manufacturer's QC _____ to certify the _____ of the data they generated

# Standard Operating Procedures (SOPs)



- Provide _____ step by step instructions for performing a _____ operation

Standard Operating Procedure

# pH Adjustment

1. _____

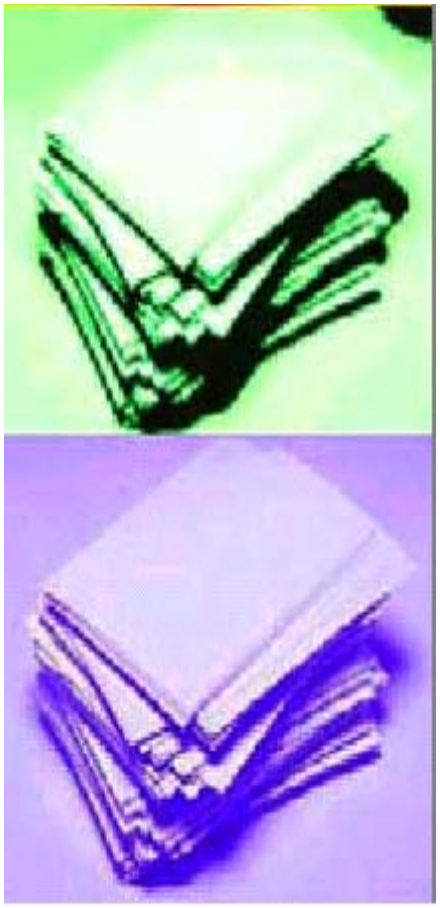
2. _____

3. _____

4. References

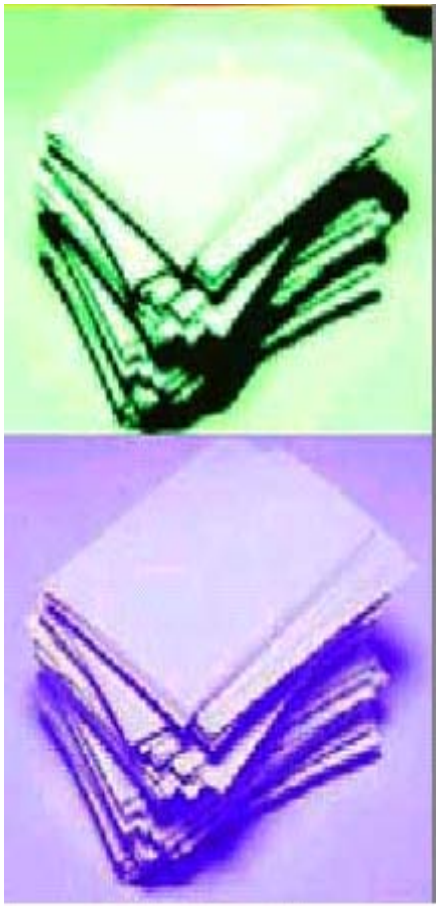
   SOP 50176 Operation of pH meter

# Master Production & Control Records



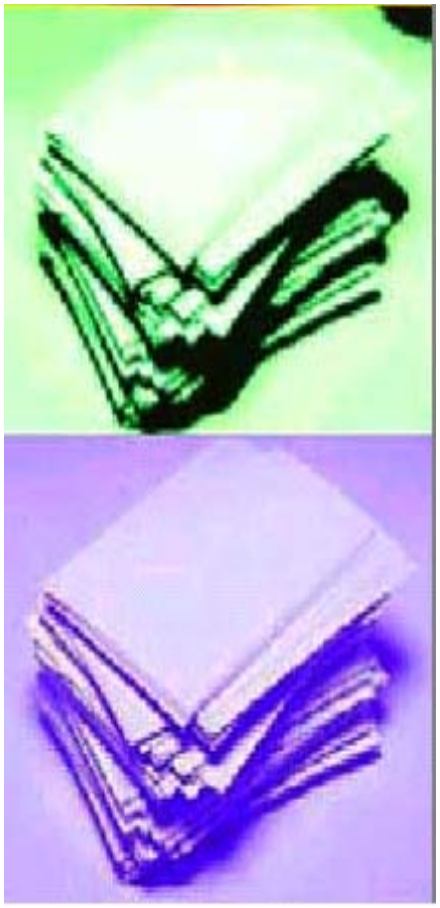
- Describe the product and its _____ manufacturing and control instructions, sampling & testing procedures and any special handling precautions
- Documented _____ of lot-to-lot consistency
- Assure uniformity between batches

# Batch Production & Control Records

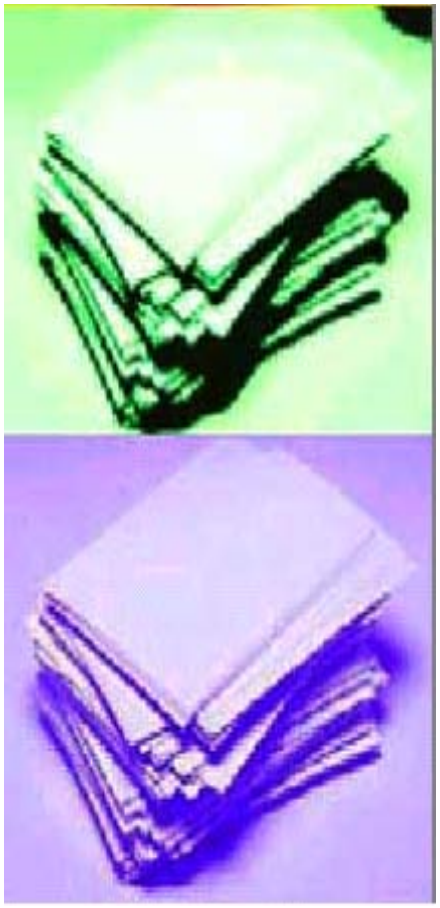


- _____ copies of Master Production Records
- Prepared for _____ batch of product manufactured
- Document each _____step in the manufacturing, processing, packing, or holding the batch
- Contains data, operator initials, _____ initials

# Traceability



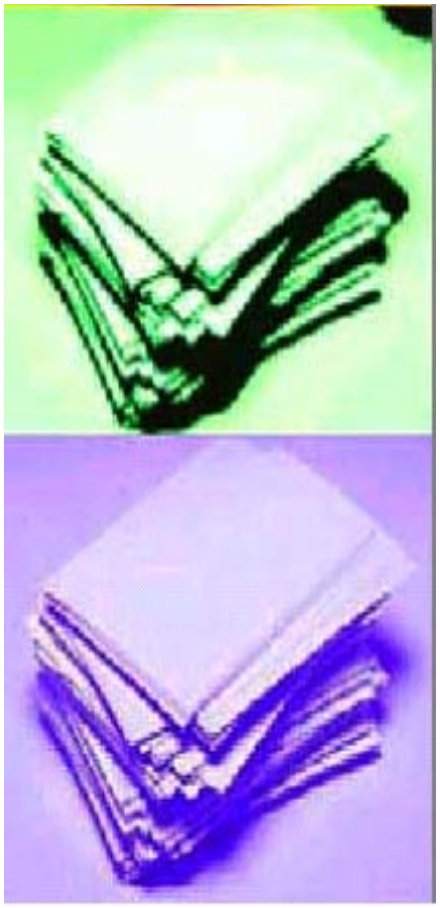
- All materials used in each production lot should be traceable to their _____ manufacturer
- Traceability is key to
  - Performing _____
  - _____ problems encountered during manufacture



# Laboratory Records (QC)

- Present complete _____derived from all tests conducted to demonstrate that the product _____ established specifications

# Equipment Cleaning and Use Logs



- Document use, _____ and cleaning of equipment used in manufacturing activities