Batch Records

BTEC 101

Questions to answer

- What is the definition of a batch?
- What is a master batch record?
- What information is required on each page of the batch record?
- What information is required on each section of the batch record?
- What is a bill of materials?

What is a batch?

- A specific quantity of a product that has <u>uniform</u> (the same) character & quality, and is produced according to <u>one</u> manufacturing order made at the <u>same</u> time

- Like a batch of cookies

Master & Batch Production Records

- **Master production records** provide detailed step-by-step descriptions of the <u>production</u> process

- **Batch records** are exact copies of **master production records**
  - They are written upon to document **everything** that occurred during production of that one particular batch

Content of Batch Records -- General Document Requirements

- Each page typically contains (in the <u>header</u> section)
  - Company Name
  - Name of product being produced
  - Document Number
  - Revision Number
  - Page Number (X of Y)
  - Date

Content of Batch Records --
General Document Requirements

The first page of each section should contain approval signatures & dates of Production and QA

What do these signatures imply?

Data Recorded in Batch Records

- <u>Dates</u> that operations were performed

- Identity of operators & <u>verifiers</u>

- The <u>identity</u> of individual <u>equipment</u> used, via the unique equipment ID number.

- <u>Lot numbers</u> of each ingredient or in-process material used
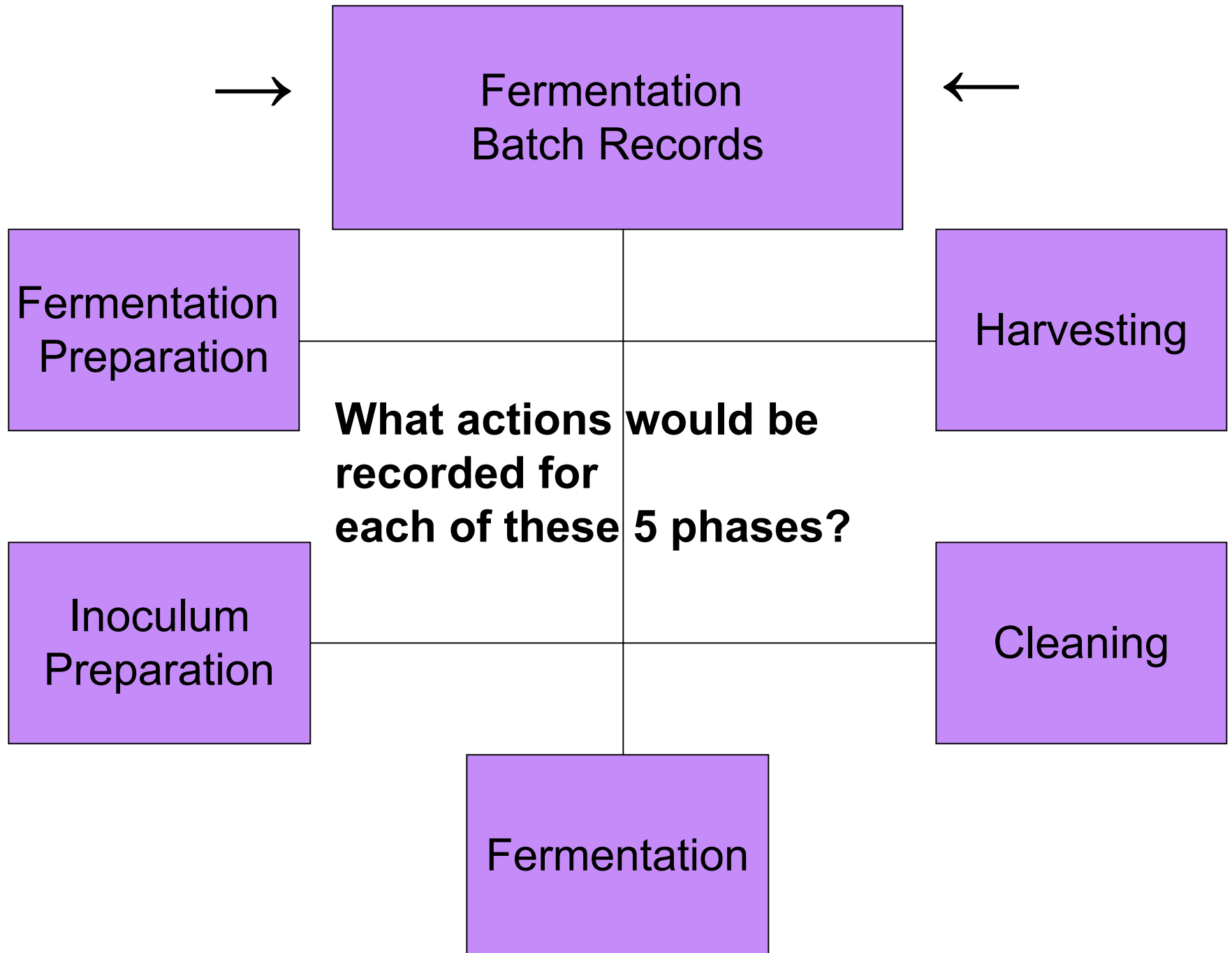
Data Recorded in Batch Records

- Results of all tests performed & investigations conducted

- Statements of yield at specific steps

- Copies or original of all key material labels used

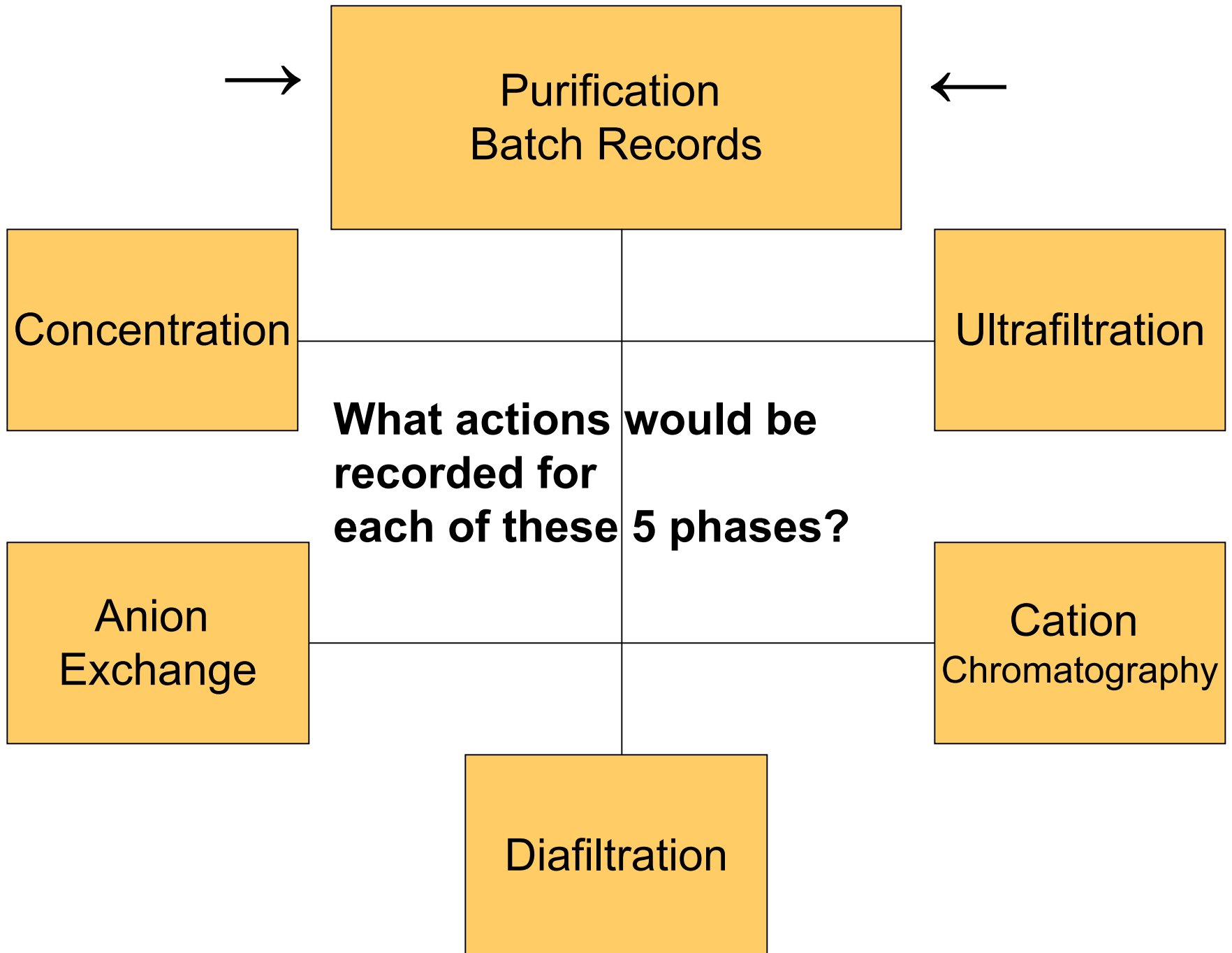- Weights & measures of all components used during the course of processing

Batch Records Organization

- Batch Records are typically divided into sections

- See following examples:
  - Fermentation Batch Records
  - Purification Batch Records

→ **Fermentation Batch Records** ←

Fermentation Preparation

Harvesting

What actions would be recorded for each of these 5 phases?

Inoculum Preparation

Cleaning

Fermentation

→ **Purification Batch Records** ←

Concentration

Ultrafiltration

What actions would be recorded for each of these 5 phases?

Anion Exchange

Cation Chromatography

Diafiltration

Content of Batch Records

- Each section begins with a Bill of Materials/Accountability sheet

- This lists the appropriate <u>amounts</u> of all raw materials & components <u>needed</u> to perform the operation described within that section

The BOM

- Records the actual amount <u>received</u>, the amount <u>used</u> in performing the operation, the amount <u>discarded</u> & the amount <u>returned</u> to storage

- 100% accountability is difficult to achieve, so "<u>percentage accounted for</u>" acceptance criteria for each operation is established

- Why track items so carefully?

Batch Records Provide:

- A <u>traceable</u> record describing <u>all</u> of the steps of the manufacturing process

- <u>Proof</u> that, while providing instructions to the operator, the process was conducted <u>following cGMPs</u>

Completing Batch Records

- Chronologically in the steps of the manufacturing process, filling blank spaces with data & signatures

- These spaces are filled in as each task is completed "Do/doc"

- So, in the review of a partially completed batch record, no spaces prior to the current activity should be empty

- **Typically the following Batch Record Practices must be adhered to:**

  - Write legibly
  - Use only blue or black indelible ink
  - Date each page of the batch record, how?
  - Enter hours & minutes, how?
  - Sign or initial all entries in a manner which is consistent with that used in the <u>signature log</u>

Correcting Batch Records

- Mistakes will happen! So, you must know how to correct them appropriately according to cGMP compliance

- To correct:
  - Cross out entry
  - Initial and date the change
  - Enter correct response above, below, or beside the incorrect entry

Correcting Batch Records

- **Mistakes cannot be corrected by:**
  - Erasing the entry
  - Writing over the entry
  - Using correction fluid to obliterate the entry
  - Destroying the document and starting a new sheet
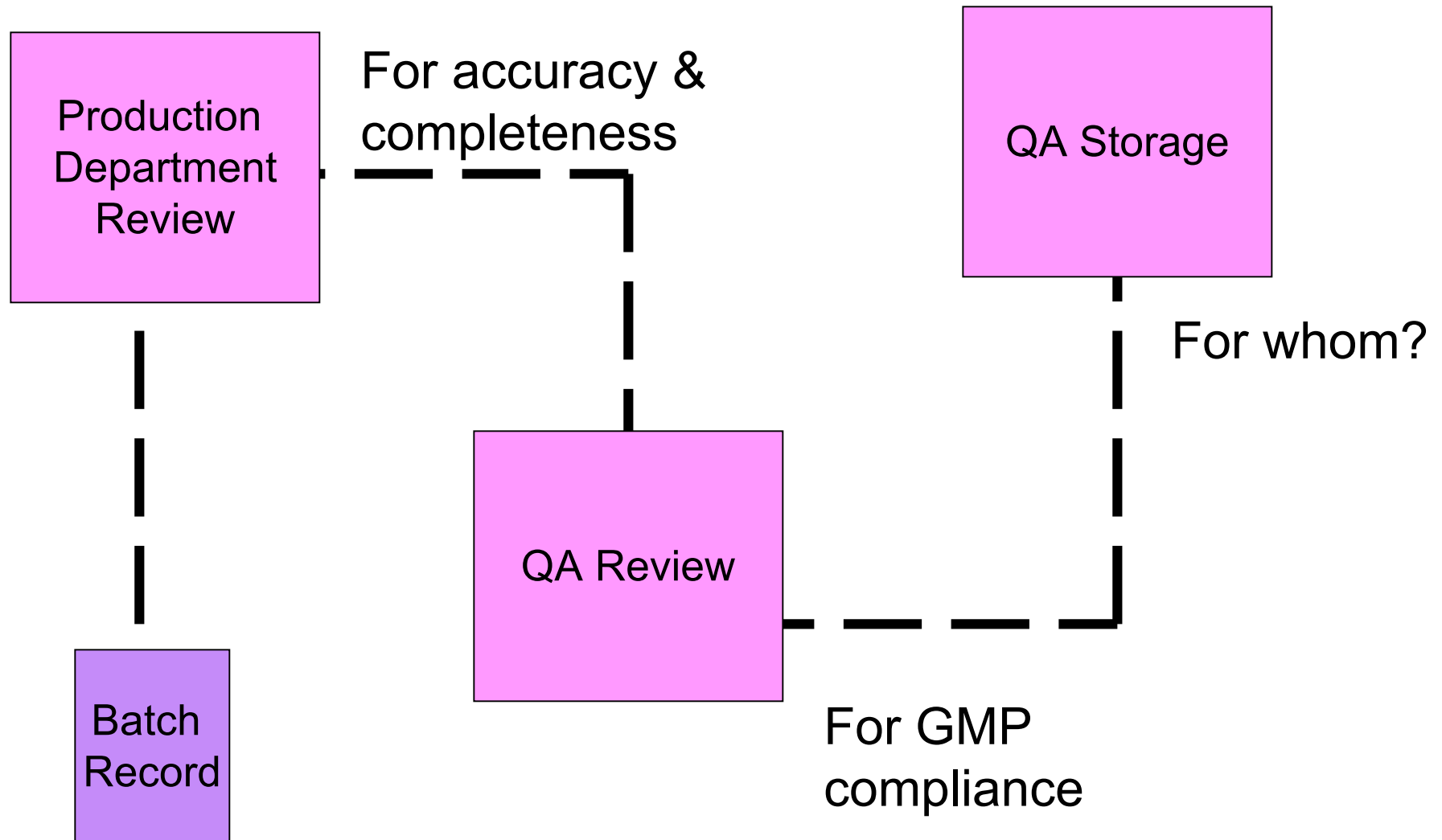
Do NOT write over!

Correcting Batch Records

- If a batch record contains a greater number of blanks then needed for a given entry, a diagonal line is typically drawn through the blanks and initialed, why?

Yeast extract	E336	G124	10 g	1.0 g

KB 083005

What happens to Batch Records Upon Completion of the Batch

Production Department Review

For accuracy & completeness

QA Storage

For whom?

Batch Record

QA Review

For GMP compliance

When is a Batch Completed and the Batch Record Approved?

A batch record should not be reviewed and approved until <u>all</u> processing and cleaning steps have been completed and the results of all QC testing are known

What Happens if the Batch is Lost Prior to Completion

- At some point, even the best manufacturing process may fail to perform properly. This failure may be due to contamination, equipment malfunction, or human error. At this point the batch and batch record are terminated

- Such partially completed documents must still be maintained and are often accompanied by a report detailing the reasons for the failure