



How to write a batch record

A *batch record* is the digital or paper documentation of a manufacturing process. The batch record contains the raw materials list, equipment or tools list, material manipulations, calculations, and simultaneous quality review information necessary to make and release a final product.

Outline

The outline becomes the requirement document or document plan for the batch record. This information informs the template design and assists the author in populating the content.

1. Outline the process from start to finish.
2. If the process happens over more than one day, consider breaking the outline into manufacturing days.
3. Within each day include the sections appropriate for your product type and manufacturing environment:
 - a. Overview of the day (time-saving tips/possible workflow challenges)
 - b. Pre-Line clearance (equipment, software, and materials)
 - c. QA pre-checks
 - d. Pre-Process procedures
 - e. Procedures organized in chunks that promote efficiency and accuracy
 - f. Post-Process procedures
 - g. Post-Line clearance
 - h. Comments
 - i. Review and Department Signoffs
4. Within the sections include steps, task tables, or forms:
 - a. For manual calculations and verification of those calculations.
 - b. For movement between departments, labs, and storage containers.
 - c. For making decisions based on volume or other results, which can result in continuing, changing to another process, or aborting a process.
 - d. For recording:
 - i. Who performed and who verified critical steps.
 - ii. Start and stop times for critical items.

Templates

Templates are the structures that help authors create new batch records efficiently and consistently. They help manufacturing personnel because they provide a consistent look and feel so personnel can focus on the words and not on why the document was formatted differently for another time.

1. For new processes, complete a review to make sure that all documentation needs are met before designing a derivative template for authoring.
2. Design pages that guide the eye to follow the steps.
Note: For paper batch records, include enough white space for comments.
3. Design formats for different work environments to assist the operator and verifier.
Example: controlled environment versus an open workbench

Content

Language is important in a batch record

1. For efficiency and consistency use templates for information that repeats.
2. Include enough information in the batch record so that the least trained operator can successfully complete the process.
3. Make sure that all language in the steps has only one meaning and that the language is familiar to the operators.
4. Supplement the language with graphics for ease of use.
5. Include necessary safety messaging.

Review

Everyone in the cross-functional team must agree that this is the way the process is completed.

1. Complete a round of review and incorporate all feedback that is necessary for completeness, efficiency and safety.
2. Complete a second round of approvals after the incorporation of comments.

Storage

Keep the batch record in the quality document management system of record.