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Document Development

Developing documents is a pre-requisite to GMP manufacturing. While the document formatting is not critical, the included information is. Below are essential sections of any production record that are mandated by the regulatory bodies.

Scope

Define the scope of the document by listing the intended product type, product name, responsible division, and any limitations.

Equipment

Include a list of equipment needed for the process and a space to document the identification and status of each equipment.

"Records provide evidence of various actions taken to demonstrate compliance with instructions"

Material

Include a list of required material and a space to document their quantities, identification number, and expiry dates.

Personnel

Provide a space to document the information of the personnel who will perform significant steps, or verify them.

Procedure

- Provide detailed and clear instructions for personnel to follow.
- Provide testing/calculating instructions, as appropriate, and provide a proper documentation space/method.
- Ensure all information are recorded concurrently, and provide a method for the information to be verified by a second person.

"Good documentation constitutes an essential part of the quality assurance system and is key to operating in compliance with GMP requirements"

Review

- Dedicate a section for management review; production document should be reviewed/signed by management.
- Dedicate a section for quality assurance (QA) review; completed production document should be reviewed by QA personnel.