
# Good Manufacturing Practices in Component Lab

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# Good Manufacturing Practices GMP / cGMP

- WHO defines Good Manufacturing Practices (GMP) as “that part of quality assurance which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorization
- “cGMP” – where c = current, to reflect the dynamic nature of GMP
- Used interchangeably for current discussion
- *The guidelines stem from the law.*

WHO Expert Committee on Specifications for Pharmaceutical Preparations. Good Manufacturing Practices for Pharmaceutical Products. Technical Report Series No. 823 Annex 1, WHO Geneva, 1992

# Good Manufacturing Practices GMP / cGMP

- The basic tenet of cGMP is that quality is “built in” to a product, and not just tested in a finished product.
- To guarantee that not only the end product meets all the quality requirements as stipulated, but the entire manufacturing process has been standardized and repeated the same way for each and every product.

# GMP In Blood Center??

## The Drugs and Cosmetics Act (DCA) 1940 and Rules 1945

- **Schedule F, Part XII B , Section G :** Good Manufacturing Practices (GMPs) /Standard Operating Procedures (SOPs)
  - GMP in blood center must not only rely on robust standard operating procedures, GMP encompasses a comprehensive overview of the various elements of the manufacturing process.
- **Schedule M, Part I:** GMP (Good Manufacturing Practices) and Requirements of Premises, Plant and Equipment
  - Deals exclusively with GMP of pharmaceutical industry
  - We have observed cases where some issues have been raised by the drug inspectors in the Blood Bank Inspections citing the Schedule M. (Air curtains/ Steel tables, etc)
  - While debateable, knowledge of such GMP shall prove beneficial eventually

# What is GMP?

GMP is an umbrella term which encompasses a wide horizon of activities, checks, process controls which ultimately help to achieve a common goal – assurance of quality of the product.

# Quality Management

- GMP is a concept that derives its roots from industry
- It works on the prevention model (where manufacturing variations are avoided by rigidly controlling the manufacturing process) rather than detection model (where quality check and testing is used to discover deviations or defects).
- The quality assurance system comprises the GMP and Quality controls that eventually ensure that the final products shall be of quality that is required for their intended use.

# Standard Operating Procedures (SOP)

- Backbone of any successful quality assurance program and vital for the Good Manufacturing Practices compliance
- D&C Act categorically states the minimum requirement of SOPs required for the blood center
- They must describe specific tasks in a stepwise fashion, with clear mention of the person responsible for those tasks
- Should be detailed so that a qualified technical person even with minimal training should be able to follow them and manufacture products to meet the stipulated quality requirement.
- SOPs must be periodically reviewed and revised to reflect any change in process flow or equipment
- All the older version of the SOPs must be promptly removed, and only latest, in-use sops should be available to avoid any confusion

# Personnel

- Requires the most effort to standardise.
- Sufficient number of qualified personnel should be available
- There should be clear delineation of their duties and responsibilities.
- The staff should be educated in Good Manufacturing Practices by qualified trainers.
- Trained adequately regarding the tasks they are required to perform through initial and continued training
- Periodic examination to assess their continued competency, with an evaluation of their work done including record keeping and their specific tasks
- blood centres where blood components are manufactured must have a dedicated Technical Supervisor and technicians fulfilling the criteria as laid down in in Schedule F, Part XII B Sub heading C. Personnel, Clause(b) & (d).

# Documentation

- “Whatever is not documented is not done.”
- Most important line of defence in case of any medicolegal or regulatory requirement
- Records that are generated during the preparation of blood components
- Be indelible, accurate and legible
- Clear recording of the details of process that was followed including the temperature and speed of the centrifuge, the date and time at which the components were prepared, the signature of the person who made them
- Records must be authorized by technical supervisor and the Medical Officer/ Blood Transfusion Officer and preserved for 5 years

# Equipment

- Appropriate design, adequate size and suitable located in the component area
- At the level of blood center, all equipment must have qualification namely, Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ) specifying the critical test parameters, operating ranges, and acceptance criteria
- Calibrated periodically as per the Schedule F, Part XII B Sub heading E. Equipment
- Clear instructions regarding the procedure to use the machine and personnel who are authorized to use it
- Schedule for equipment maintenance and an alternative equipment should be available

# Equipment

- Software and the computers must also be validated for their use and should be protected from unauthorized use and access or alteration.
- Backup alternative available to ensure continuous operation in case of unavailability of computer data or access

# Manufacturing

- Ideal good manufacturing practice for the blood component starts from the initial donor registration and donor questionnaire
- The starting material, the blood bag must be stored or transported in specified temperature.
- The process must ensure that it is adequately filled with specified volume and must be accepted in the component area after meeting the set criteria.
- The traceability of the blood bag should be ensured, and the closed system should be maintained to ensure sterility at all times.
- The critical parameters of centrifugation rpm and temperature, the operator must be reflected in the documentation.

# Labeling

- Label is used to identify the product and also inform the user regarding the content of the container. In Blood center the label contains all the important information regarding the type of product, blood group, TTI status, date of collection and Expiry date. It serves as a final check regarding the suitability of the blood product for use. The labels should be colour coded as per the Schedule F, Part XII B Sub heading M. Labels

# Complaints And Recalls

- A system and process that handles the complaints regarding quality defect in the blood component. As per the hospital's protocol it may warrant a recall.
- These complaints could be limited to the quality of product, any adverse event associated with the product or even in response to information about the testing status of the donor.
- There should be a prompt decision to recall any other associated product or even initiate a look back for other components that might have been prepared earlier.
- All investigations, review must be completed in a time bound manner while making sure that the other product separation is not affected.

# Take Home Message

- The importance of Good Manufacturing Practices in blood component preparation cannot be over emphasized.
- It not only guarantees a high quality that is built in the product but also improves the standard of patient care to whom this product is transfused.