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Ensuring Good Manufacturing Practice in supply chain processes

What is GMP?

Good Manufacturing Practice (GMP) comprises a set of regulations ensuring that products are consistently produced and controlled according to quality standards.

In the context of cell culture media, the EXCiPACT™ GMP standard for Excipients/Pharmaceutical Auxiliary Materials (PAMs) ensures that the cell culture media are:

Of **reliable quality**

Safe for use

Suitable for their **intended** purpose

Able to support the growth and maintenance of cells in a laboratory or production setting

Why is a qualified supply chain essential for GMP cell culture products?

Ensures product quality and consistency
Prevents contamination and errors

Regulatory compliance
Ensures that all materials meet regulatory standards

→ Organizations like the International Pharmaceutical Excipients Council – Federation (IPEC Federation) bring producers, distributors and users of pharmaceutical excipients together.

Risk mitigation
Reduces risks of recalls, legal issues, and reputational damage

Traceability and documentation
Enables a quick response to deviations or investigations

Supply continuity
Includes contingency planning, multiple suppliers, and inventory management

Recommended GMP requirements in supply chain

Supplier qualification and management

- Conduct regular audits to ensure supplier compliance
- Establish clear agreements outlining GMP responsibilities
- Monitor supplier performance continuously

Raw material and component sourcing

- Test incoming materials for identity, purity and quality
- Maintain detailed records for material traceability
- Store materials under controlled conditions to prevent degradation

Packaging and labeling

- Ensure accurate labeling with batch numbers and expiry dates
- Use tamper-evident packaging to protect product integrity
- Implement serialization for product traceability

Manufacturing process control

- Validate processes to ensure consistent product quality
- Identify and mitigate risks to prevent contamination
- Regularly maintain and calibrate equipment

Storage and transportation

- Continuous monitoring of storage conditions like temperature
- Maintain clean, pest-free and organized facilities
- Manage cold chain logistics for temperature-sensitive products

Distribution and supply chain integrity

- Maintain comprehensive records of product movement
- Conduct audits of logistics partners
- Establish contingency plans for emergencies

Essential documentation practices to maintain traceability throughout the supply chain

Comprehensive batch records

Document every step of production and packaging

Include raw material lot numbers, equipment used, personnel involved and process parameters

Inventory and warehouse logs

Use inventory management systems to track material movement, storage conditions and expiry dates

Document quarantine, release, and rejection status of materials

Deviations and CAPA

Record all deviations, non-conformances, and Corrective and Preventive Actions (CAPA)

Ensure root cause analysis and follow-up actions are documented

Material traceability documentation

Maintain material specifications, Certificates of Analysis (CoA) and Certificates of Compliance (CoC)

Record supplier information, lot numbers and receipt dates

Change control records

Document any changes to processes, suppliers, or materials with a formal Change Control procedure

Include risk assessments and approvals

Supplier qualification and audits

Maintain records of supplier audits, qualification status and quality agreements

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