Discover applications and advantages of cGMP raw materials
Learn how to streamline and secure dry repack operations
Get tips on managing materials quality and supply chain
cGMP Bioprocessing Solutions

cGMP refers to current Good Manufacturing Practice regulations enforced by the FDA—the sole decision maker of whether or not a pharmaceutical manufacturing facility complies with this particular set of rules that certifies the strength, quality, and purity of drug products. According to the FDA, each and every inspection follows a standard approach by highly trained FDA staff. When outsourcing operations or partnering with another company, it’s crucial to understand how they design, monitor, and control their manufacturing practices and facilities—before integrating them into your workflow. Ultimately, cGMP compliance removes the due diligence of investigating third parties and their offerings yourself—saving time, mitigating risk, and improving processes.

Quality is integral at every stage of bioprocessing. This guide was specifically designed for manufacturers sourcing raw materials, outsourcing dry repack operations, or both. What does cGMP mean for you? We’ll unpack that topic together.
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What We’ll Cover

cGMP raw materials include any ingredient or component manufactured, processed, packed, or held under cGMP regulations for pharmaceutical production. These minimum requirements safeguard the purity of materials, documenting crucial details—including changes, weights, measures, and batch numbers—and ensuring quality is built into every touchpoint. Raw materials might include:

- Buffer and cell culture media
- Pharmaceutical excipients
- Other salts, bases, carbohydrates, amino acids, etc.

Dry repacking is the process of packing dry or granular raw materials from original packaging into smaller, more manageable bags or containers. This method is often conducted under strict cGMP guidelines designed to reduce the risk of cross-contamination, poor facility maintenance, and human operator error—overall improving material handling and storage. Packaging might include:

- Glass bottles
- Plastic drums HDPE
- Stainless steel drums
- Single-use bioprocess bags
Modern Applications

In the pharmaceutical space, quality isn’t optional. Not only is it critical to company reputation, product uptake, and commercial success, but real humans are at the end of the supply chain. It’s your #1 priority to keep them safe, starting with cGMP raw materials and processes. Explore common applications in leading biopharmaceutical manufacturing facilities.

- **Biologic Production**
  Ensure products are safe, effective, and up to code.

- **Drug Formulation & Filling**
  Develop drugs, such as vaccines and therapeutics, in a controlled and compliant manner.

- **Protein Purification**
  Leverage chromatography techniques to purify proteins, such as monoclonal antibodies.

- **Cell Culture**
  Grow cells used to produce biologics, such as vaccines and therapeutics.

- **Dry Materials Storage**
  Foster a sterile environment to maintain material integrity and prevent contamination.

- **Quality Control & Assurance**
  Ensure products meet required safety standards for human use.
Advantages in Action

Adherence to cGMP regulations means facilities are in good working order, equipment is calibrated, processes are maintained, teams are qualified, and batches are successfully passing cGMP testing. Beyond building a solid foundation for the best manufacturing outcomes possible, the benefits of leveraging cGMP-compliant partners and processes are remarkable.

**Improved Efficiency**
Streamline the workflow with materials and procedures designed to optimize product flow and recovery rates.

**Reduced Costs**
Reduce the costs associated with cleaning, sterilizing, and maintaining reusable equipment with single-use, disposable packaging materials.

**Increased Safety**
Ensure the integrity of final products with materials manufactured in compliance with USP standards and tested for sterility, performance, and integrity.
Supply Chain Confidence

Who you choose to work with—from warehousing and logistics to sampling, repacking, and reactor charging—ultimately determines commercial effectiveness. ILC Dover is a trusted market leader and full-service provider of tubing, fluid transfer assemblies, bioprocess containers, and raw materials. We specialize in providing everything needed for bioprocessing, minimizing supplier management and maximizing profit.

We maintain an inventory of various cGMP raw materials that comply with multi-compendial grading and can make custom stocking agreements for specific quality or material requirements. We securely and efficiently integrate these materials into packaging solutions tailored to batch-specific container sizes and unique application requirements. Primary packaging options include:

**EZ BioPac® Packaging**
Prefilled, trust-weighted cGMP powders in single-use handling bags dispensed directly into vessels validated in customer processes for the safest, cleanest, and most efficient total solution.

**Regular Packaging**
Prepacked powder in competitively priced, industry-standard containers and versatile packaging solutions for an economical, flexible, and scalable solution.

**Powder Handling Solutions**

- **JetBreaker™**
  Reduces powder clumps to <10 mm in one fast, effective step

- **PAPR**
  Ensures the highest level of safety and productivity for operators

- **Powder Packing Services**
  1L–200L & cGMP Raw Materials
  Minimizes non-value-added work and maximizes production efficiency

- **EZ BioPac®**
  Maximizes efficiency of powder filling, transfer, and discharge
With product integrity on the line, there’s no room for error in biopharmaceutical manufacturing. That’s why cGMP regulations must be second nature to your facility, including every supplier with a stake in your workflow.

ILC Dover aims to deliver integrated products and packaging solutions that help biopharmaceutical manufacturers eliminate costly sourcing, warehousing, testing, filling, and cleaning processes while achieving maximum safety, compliance, and productivity. We take a consultative approach to every partnership, working to understand clients upfront and design solutions tailored to even the most complex packaging operations.

**Materials Sourcing**  
**Quality Assurance**  
**Supply Assurance**

**Materials Packaging**  
**Cost Saving**  
**Risk Avoidance**
B E Y O N D  B O U N D A R I E S®

ILC Dover is a world-leader in the innovative design and production of engineered flexible protective solutions for pharmaceutical and biopharmaceutical, flood protection, personal protection, bulk packaging, and aerospace industries. Our customers will attest to our relentless dedication to high value products, advanced technology, and responsive service, as our visionary flexible protective solutions have improved efficiency while safeguarding people, product, and infrastructure in hazardous conditions since 1947.

Seeking the right-fit total repack solution for your biomanufacturing operation? See what ILC Dover can do for you.