

# Ensuring Quality From Start to Finish



## A high-level overview of Letco by Fagron's quality process.

At Letco by Fagron, quality is built into every stage of the product lifecycle—not added at the end. Cross-functional controls, documented procedures, trained personnel, and independent Quality Assurance oversight help ensure that materials and products meet defined requirements before they move forward. The process extends from supplier selection and receipt through testing, repackaging, release, distribution, and ongoing performance monitoring.

### 1 Supplier and Service Provider Qualification

Quality begins before material is purchased. Suppliers, manufacturers, packaging-component providers, and cGMP service providers are evaluated through questionnaires, quality agreements, document review, regulatory verification and performance history. We perform onsite audits of our manufacturers facilities. Quality Assurance approves or rejects each source and maintains its qualification status.

### 2 Purchasing, Receipt, and Quarantine

Materials are purchased from approved sources and checked upon arrival for shipment condition, quantity, identity, labeling, and required documentation. Incoming materials are placed in quarantine and remain unavailable for use or distribution until the required inspection, sampling, testing, documentation review, and formal Quality Assurance disposition are complete.

### 3 Sampling, Testing, and Inspection

Quality Assurance reviews the manufacturer's Certificate of Analysis and determines the applicable testing and inspection requirements. Every delivery of every chemical batch undergoes identification testing with periodic verification of the full manufacturers certificate of analysis (COA). Direct-to-stock materials are inspected using risk-based sampling, while packaging components are evaluated against defined specifications and applicable container-closure requirements. Any discrepancy is documented, investigated, and escalated as appropriate.

### 4 Controlled Repackaging and Labeling

Approved materials enter controlled repackaging and labeling operations performed by trained personnel using documented instructions. Controls address personnel practices, line clearance, equipment readiness, material identity, reconciliation, labeling accuracy, packaging integrity, and good documentation practices. Deviations or nonconformances are segregated and evaluated before processing continues.

### 5 Final Inspection, Documentation Review, and Release

Before release, Quality Assurance performs a final review of the finished units and the associated batch record or work order. This review confirms that required steps were completed, results met specifications, documentation is accurate and complete, and any deviations were appropriately resolved. Repackaged or relabeled finished units receive final inspection, and the applicable Letco by Fagron Certificate of Analysis is generated and reviewed. Quality Assurance retains final authority to release, reject, return, or otherwise disposition the lot.

### 6 Storage and Distribution

Released products are stored under defined conditions that protect identity, strength, quality, and integrity. Inventory controls support traceability and appropriate stock rotation. Distribution activities preserve required storage and transport conditions and ensure that customers receive the correct product, approved labeling, Certificate of Analysis, Safety Data Sheet, and other applicable documentation.

### 7 Complaints, Investigations, and Continuous Improvement

Quality oversight continues after distribution. Product quality complaints are documented, evaluated, investigated, and trended. Investigations may include record review, examination or testing of complaint and retain samples, supplier involvement, root-cause analysis, and corrective and preventive action. Internal audits, supplier performance monitoring, management review, change control, and CAPA activities help identify risk, verify effectiveness, and strengthen the quality system over time.



**Decatur, Alabama** — Home of our Letco by Fagron warehouse and distribution operations.

**Together, we create the future of personalizing medicine.**

For pharmacy compounding use by licensed professionals. Compounded preparations are not FDA-approved.