

Altech® QUALITY SYSTEM

Ensuring and exceeding customer requirements of biotechnology, quality and service

LEADING CERTIFICATIONS



AFIA SF/SF ISO 9001:2000 FCI RUPP
GLP GMP HACCP



Delivering Product Quality and Traceability: 8 Key Checkpoints

1. Receiving

- QA approved raw material specifications
- RUPP certified vendors
- Inspections
 - Delivery documents
 - Trailer seal
 - Trailer condition
 - Cross-contamination
 - Insect infestation
 - Raw material condition weigh/label
- First-In, first-out stock control system



2. Raw Material Storage

- Placed in QA hold area
- Sample assayed by QA lab to accept/reject
- QA Inspection Release Form for release/hold
- Retention sample storage
- Proper storage to eliminate cross-contamination



3. Formulations & Batching

- Unique product name and code
- Strict control maintained by QA/QC department
- Macola database system



4. Production Process

- Batch card
 - Ensures compliance with product specifications
 - Identifies raw material and usage during processing stages
- Validation of processes
 - Monitoring and measuring devices
 - Calibration of scales
 - Sieve screen/magnet inspections
 - Internal audits of product color, flow, weight and smell
 - Carry-over and homogeneity testing
- Raw material identification and traceability



5. Packaging

- Labeling
 - Product identification
 - Unique batch number
 - Expiration date
- Internal audit
 - Label information
 - Package seals
 - Pallet appearance
 - Pallet tag
 - Total weigh\units



6. Quality Assurance

- Sample analysis of finished goods performed by QA lab
- Storage of retention samples
- Equipment monitoring and measuring
 - Calibration
 - Temperature
 - Preventive maintenance
 - Monitoring programs



7. Finished Goods Storage

- Storage and handling according to specification sheet
- Traceability from finished product to point of first customer
- Product on hold in ERP system pending QA inspection release
- Physical hold on product pending QC release approval



8. Shipping

- Shipping Audit
 - Trailer condition
 - Product pallets and quantities
 - Cross-reference documentation

