Mannatech's Global Commitment to Quality Products

To develop innovative products, Mannatech's scientists seek unique technologies that anticipate the needs of today's sophisticated consumer. These products, of the highest quality and value, meet consumer, regulatory and industry standards. Bringing them to market requires a team of experienced professionals who contribute to the development, production, testing, storage, distribution, and post-market surveillance of our products.

Development

For many products, concepts are developed in our own state-of-the-art product prototyping laboratory. In this laboratory, our highly trained professionals produce and test product samples for palatability, preliminary stability and consumer acceptance. Mannatech strives to develop product formulations acceptable to international regulatory agencies. However, if this is not possible, country-specific formulation modifications may be necessary.

Production

Once a formulation has passed consumer and preliminary testing, Mannatech selects supply partners to manufacture, package, label, and test the product. Our Quality Assurance program complies with the U.S. Food and Drug Administration's (FDA) Good Manufacturing Practices (GMPs) for Dietary Supplements (*21CFR*111), which impact all aspects of product development, manufacture, evaluation, storage and distribution. Mannatech works diligently with Supply Partners to ensure GMP compliance. Many are certified by NSF International and/or the National Products Association (NPA), two organizations in the natural products industry committed to protecting public health and safety. International product formulations are produced in compliance with each country's specific regulatory agencies (e.g., Health Canada, the Australian Therapeutic Goods Administration, Japan Ministry of Health Labor and Welfare, Korea Food and Drug Administration, Taiwan Department of Health and the European Union and Member State Authorities).

Our supply partners must:

- Have up-to-date, well-maintained facilities that meet GMPs for Dietary Supplements and/or international requirements and have adequate space to minimize mix-ups and facilitate cleaning. Cleaning, sanitation, and pest control procedures are strictly enforced.
- Have technically suitable and well-maintained equipment that is properly identified, maintained, calibrated, and cleaned.
- Perform preventive equipment maintenance. Calibrations are performed using standards directly or indirectly traceable to the National Institute of Standards and Tests (NIST) or the American National Standards Institute (ANSI), or other international standards agencies.
- Follow manufacturing and packaging process controls described in pre-approved instructions.
- Purchase raw materials and components (including containers, labeling and packaging materials) from approved suppliers using predetermined specifications.
- Evaluate each lot of raw material and component for identity and purity.
- Provide Certificates of Analysis, which detail lot-to-lot compliance with quality requirements.
- Package and label products according to a rigorous control system to ensure that no mislabeling occurs. This is confirmed by random product sampling.
- Inspect each lot of finished product to ensure it meets established compositional, physical, chemical, and microbiological specifications.
- Agree to periodic audits by Mannatech personnel. If improvements are necessary, corrective actions are implemented to prevent recurrence of the deficiency and improve performance. Follow-up audits are performed to verify the effectiveness of previously implemented corrective actions.

Testing

Mannatech's Quality Assurance (QA) Program requires our manufacturing partners to use scientifically sound and appropriate specifications, sampling plans and testing procedures to ensure that materials, components and finished products conform to appropriate quality standards. We require that production, inspection, testing, labeling, packaging, holding and distribution activities are documented and that these documents are formally controlled as quality records. Mannatech maintains these records for a minimum of three years post product expiration. We take pride in our controls for individual lot traceability that ensure product genealogy. Our in-house QA programs require that Mannatech and/or our manufacturing partners:

- Test products to ensure they meet specifications.
- Test products to ensure they are stable under various storage conditions and are assigned appropriate expiration dates, modeled on International Committee on Harmonization (ICH) guidelines.
- Retain some raw materials and finished product samples for periodic examination during the retention period.
- Review lot records.
- Confirm that each product lot meets pre-determined specifications before distribution to consumers.

Storage and Distribution of Finished Products

Mannatech has procedures to ensure that products maintain integrity during handling, storage and distribution. These procedures are designed to prevent mix-ups, damage, deterioration, contamination or other possible adverse effects to finished products. Batch records are easily accessible, and accurate distribution records are maintained to facilitate a recall, in the unlikely event it is necessary. Our procedures require that products are:

- Quarantined until tested and approved.
- Stored under appropriate temperature, humidity and light conditions.
- Distributed on a first-in/first-expiry date basis.

Post-Market Surveillance

Mannatech reviews all product returns and complaints, identifies their cause, and implements corrective actions when appropriate. Complaints are taken very seriously by Mannatech and, as appropriate, customers are notified about the final outcome. Adverse events complaints are carefully evaluated, recorded and communicated to appropriate corporate personnel and external agencies, when required. Mannatech products have historically had a very low incidence of reactions or complaints.