



## General Quality Provisions

1. **Process Control** – Seller shall utilize Control Plans and Statistical Process Control (“SPC”) techniques where appropriate within its manufacturing and testing environments. Control Plans define the normal operating ranges of the manufacturer’s critical process and inspection parameters. Seller is encouraged to use Failure Mode and Effect Analysis (FMEA) to identify these critical parameters and establish Control Plans. Seller shall manufacture to established statistical control limits and apply Statistical Quality Control (“SQC”) to final Product test results for Product properties listed in the Specifications as set forth in Exhibit A, unless otherwise agreed in writing by the parties. Seller shall promptly notify Grace when a specified Product property is out of control and detail the root cause and the defined plan for corrective action.
2. **Management and Notification of Change** – Seller shall develop and maintain a robust Management of Change process to ensure any change is sufficiently vetted to minimize potential impact to Product quality. Seller shall notify Grace of any significant change in materials, material manufacturers or manufacturing locations, processes, formulations, equipment, packaging, labeling, storage, handling, or test methods used by Seller or its contractors. Such notification shall be communicated in writing with as much time as possible, preferably at least six months in advance of such intended change, and shall include a complete description of the change along with the basis for such change. Grace may determine that further evaluation is necessary, either by Grace or Seller, prior to proceeding with implementation of said change. Upon request, Seller shall submit samples of Product produced under such new conditions for evaluation and approval by Grace. Seller shall not implement any change as referenced herein without Grace’s prior written consent.
3. **Supplier Qualification** – Seller shall only use qualified and approved suppliers for its Product materials. Qualified suppliers shall have demonstrated the capability of consistently meeting the technical and quality requirements of Seller.
4. **Measurement System** – Seller shall ensure that the measurement systems used in the manufacturing and testing of Product are properly maintained and calibrated. It is recommended by Grace that Seller conducts periodic experiments, commonly referred to as Measurement System Analysis (“MSA”), to determine the amount of variation due to its measurement system. Grace may conduct its own measurements to verify conformance to Specifications. Seller may be asked to participate in such studies to establish correlation between Grace’s and Seller’s measurements. If the parties disagree as to Product’s conformance to the Specifications, either party may deliver Product to a recognized, independent third-party laboratory, mutually acceptable to both parties, for testing to confirm Product’s conformance to Specifications.
5. **Traceability** – Seller shall maintain traceability records during all stages of material receipt and production and distribution of Product, including but not limited to (1) the tracking of Product lot/batch numbers, (2) material sources and lot/batch numbers, (3) operator names, (4) dates of processing and (5) inspection and testing activities. Seller shall, during the term of this Agreement plus two years, maintain such traceability records.
6. **Product Elimination Forecast** – Should Seller anticipate or contemplate the elimination of Product from its portfolio, Seller shall notify Grace in writing as far in advance as possible, preferably at least one year in advance of such elimination. As part of such communication, Seller shall provide its anticipated phase-out strategy for Product. Seller shall give consideration to providing Grace with sufficient supply of Product to last potentially up to two years at Grace’s then current demand.
7. **First-in, First-out (“FIFO”) and Product Shelf Life** – Seller shall manage its Product inventory on a FIFO basis and shall have a robust system for doing so. Seller shall not ship Product to Grace which is older than the most recent shipment of Product delivered to Grace, unless previously agreed in writing by Grace. Notwithstanding the foregoing, unless otherwise agreed, Product shall have no less than 50% of the remaining shelf life upon delivery to Grace.
8. **Product Storage** – Should Product require special storage conditions, Seller shall ensure that while in its possession, it is managed pursuant to the defined and documented requirements. If requested by Grace, Seller shall provide supporting data to demonstrate compliance with such conditions.
9. **Registration to ISO Standards** – Grace prefers that its suppliers including Seller are registered to the ISO 9001 standard and/or other such standards as may be appropriate. If requested by Grace, Seller shall provide Grace with a copy of its certificate(s) of registration. Should Seller not be registered to ISO 9001 or such other appropriate standards, Grace shall have the right to conduct a detailed audit of Seller’s quality and manufacturing systems and processes used to produce Product for the purpose of ensuring that Seller is capable of meeting Grace’s Product and service requirements. Notwithstanding the foregoing, Grace shall also have the right to conduct said audit even if Seller is appropriately registered.

10. **Business Continuity Plan (“BCP”)** – Seller shall maintain a Business Continuity Plan for the purpose of preventing and addressing disruptions to its Product supply chain in the event of a catastrophic failure or natural disaster. At Grace’s request, Seller shall provide Grace with a copy of its BCP.
11. **Responsiveness** – Seller shall respond to Product quality and delivery issues as quickly as possible. Within one business day of a reported issue, Seller shall provide written acknowledgement to Grace with an initial containment plan to address said quality or delivery issue. Notwithstanding the forgoing, Seller shall provide Grace with a written root-cause corrective action plan as soon as reasonably possible and until submitted, Seller shall provide regular updates to Grace.
12. **Pre-shipment Samples** – Upon written request from Grace, Seller shall provide pre-shipment samples pursuant to Grace’s instructions.
13. **Sustainability** - Grace partners with suppliers that are Responsible Care® compliant or similarly certified. Grace’s actions align with the highest of legal and ethical guidelines and the same is expected from Grace’s suppliers including Seller. Seller shall adopt reasonable social, environmental, health and safety standards and codes of conduct that minimize risk, support economic stability and promote responsible use of natural resources.
14. **Food and Pharmaceutical Applications** – Prior to entering a Supply Agreement, Grace shall notify Seller if Product is targeted for food and/or pharmaceutical applications. If so notified, Seller shall be required to meet the following provisions:
  - (a) **Current Good Manufacturing Practice (“cGMP”) and Equivalents** – Seller shall maintain and operate the facility used to manufacture Product in compliance with cGMP or an equivalent quality management guideline, such as ICH Q7, which ensures full traceability, cross-contamination prevention, and equipment calibration in accordance with cGMP.
  - (b) **Dedicated Equipment and Controlled Environment** – Seller shall use equipment dedicated to Product, as appropriate and applicable, and shall control any equipment dedicated to Product to prevent its use for other products. Where Grace agrees that dedicated equipment may not be necessary, Seller shall have established and documented cleaning programs to ensure prevention of cross-contamination. Seller shall maintain controlled access to the manufacturing facility for Product and shall monitor visitors for compliance with applicable Seller policies. Seller shall manufacture Product in a suitably controlled environment and monitor its critical process parameters such as temperature, air flow, particulates and microorganisms, as applicable and appropriate.
  - (c) **No Adulterants** – Seller shall not manufacture Product in a building, or using equipment, that contains non-process related toxic adulterants (including, but not limited to, ICH Q3 class I solvents, pesticides, and antibiotics such as penicillin and cephalosporin).
  - (d) **No Animal or Human-derived Materials** – Seller shall not use any materials, processing aids, packaging materials, or equipment-processing lubricants of any kind that contain or are derived from animal or human materials. Seller will provide Grace with a TSE/BSE certificate for all Product.