



# Empirical Bioscience Incorporated

## SUPPLIER QUALITY AGREEMENT

This document contains general conditions to which a supplier must comply to be an approved vendor for Empirical Bioscience. These conditions are necessary, in part, to meet the requirements of our quality system and those of the ISO 13485 standard to which we conform.

This Agreement is made this day, by and between Empirical Bioscience Approved Vendors and Empirical Bioscience Incorporated, whose address and place of business is 2007 Eastcastle DR SE Grand Rapids MI 49508.

***It is preferred that supplier shall have, and maintain, either ISO 9001 or ISO 13485 Certification or maintain a quality system that meets the requirements of Empirical Bioscience Incorporated.***

- 1) Prior to issuance of purchase orders by Empirical Bioscience all vendors be pre-qualified as Approved Vendors and shall complete and submit a Vendor Questionnaire prior to such qualification.
- 2) The supplier agrees to provide appropriate documentation assuring that any product supplied conforms to the specified requirements.
- 3) The supplier will notify Empirical Bioscience Incorporated of any changes made to the products or process that may affect product quality or performance.
- 4) The supplier will notify Empirical Bioscience Incorporated in writing of any manufacturing mishaps, deviations, nonconformities, processes missed or changed which could affect products shipped to, or on behalf of, Empirical Bioscience Incorporated. Notification includes changes made to the product that could affect its quality.
- 5) The supplier agrees to become part of any failure investigation process that may result from a product failure or incident which generates a Complaint, Corrective or Preventative Action -- The supplier further commits to completing the investigation and implementing changes resulting from the investigation in a reasonable and timely manner consistent with the requirements of Empirical Bioscience Incorporated.
- 6) The supplier agrees to immediately inform Empirical Bioscience Incorporated of any regulatory audit relating to Empirical Bioscience Incorporated products including processes or procedures used in their manufacture. The



supplier further agrees to provide Empirical Bioscience Incorporated with copies of documentation relating Empirical Bioscience product sand copies of related Corrective Actions taken to resolve audit findings. Copies may be edited to protect proprietary of confidential material not related to Empirical Bioscience Incorporated products.

- 7) The supplier agrees to use only approved sub-contractors in the manufacture of Empirical Bioscience Incorporated products and further agrees to Empirical Bioscience Incorporated auditing said sub-suppliers should that prove necessary.
- 8) Supplier agrees to permit Empirical Bioscience Incorporated personnel, or a third party designated by Empirical Bioscience Incorporated to visit the Supplier's facilities during normal business hours, but not more frequently than once per year unless required by quality issues, to conduct quality audits, at Empirical Bioscience Incorporated's expense, including the right to review records maintained by the Supplier related to Empirical Bioscience Incorporated's products.
- 9) Supplier agrees to maintain both a document control and record control system sufficient to meet the obligations under this Agreement. All product changes should be reflected in the document control systems and maintained in accordance with applicable archival requirements.