



Active Pharmaceutical Ingredient (API) Product Quality Agreement Template

The purpose of this document is to establish a Quality Agreement between Contracting Company Name and Contract Manufacturing Organization (CMO) Company Name regarding the manufacturing and supply of Drug Name Active Pharmaceutical Ingredient (API). This agreement outlines the responsibilities of Contracting Company Name and CMO Company with respect to the quality of the above drug substance, and the interface between the companies.

ARTICLE EXCERPT BEGINS

3.4 Person in the Plant

“...CMO Company Name shall permit Contracting Company Name to have manufacturing and/or quality representatives present during manufacturing and validation of critical process steps for Contracting Company Name product. Contracting Company Name will provide prior notification to CMO Company Name of their intention to witness product production. Contracting Company Name representatives at the facility will adhere to CMO Company Name quality and safety procedures. CMO Company Name shall provide a key contact person at their facility to communicate the production, product quality and safety-related requirements during production.

3.5 Resolution of Quality Issues

Representatives from both Contracting Company Name and CMO Company Name Quality Assurance departments will be involved in decision-making and resolution of quality issues as required (for example, resolution of the disposition of a product batch). All resolutions and action items will be documented in writing.

3.6 Adverse Drug Event (ADE) Reporting

In the event of an ADE being reported to CMO Company Name relating to the product, the CMO Company Name is required to notify Contracting Company Name within one (1) business day.

4. Controlled Documents

All documents used in the production of products, from receiving of raw material, to releasing of product, are maintained as per current CMO Company Name procedures. Controlled documents consist of the following, but are not limited to, receiving documents, test methods, SOPs, specifications, production records, batch records, product reports and protocols, and all product support documents, such as copies of change control investigations.

4.1 API Specifications

4.2 Raw Materials and Container/Component Specifications

4.3 Analytical Test Methods used for In-process and Release Testing of API

4.4 Master and Batch Production Records



4.5 Analytical Test Method, and/or Analytical Method Transfer and Validation Protocols and Reports

4.6 Stability Reports

4.7 Inventory Records for API

Product specific protocols and reports for analytical methods, technology transfer, stability studies, major equipment qualification, process and cleaning validation shall be reviewed and approved by CMO Company Name and Contracting Company Name.

CMO Company Name will provide Contracting Company Name with all necessary primary data, including, but not limited to, chromatograms, spectra, major equipment print outs, copies of laboratory records, with API release and stability test results, at the time the test results are officially reported to Contracting Company Name, but in no case to exceed thirty (30) business days..."

ARTICLE EXCERPT ENDS



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