FDA's Quality Agreements Guidance

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“Supplier Compliance”

- It is the responsibility of a **manufacturer to assure** that all **its suppliers are compliant** with FDA’s current GMP requirements applicable to their operations.

- **Supplier management** starts with appropriate qualification, contracts, and quality agreements, and requires continuing quality assurance (QA) practices including sampling and testing, and supplier audits.

Common FDA Inspection Findings

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- Vendor qualification inadequate
- Poor access control to incoming material
- Inadequate testing and release criteria
- Use of “Out of Specification” material
- Vendor changes without appropriate process
- Poor risk management leading to high risk events
- Poor management of risk events
- Poor documentation practices

FDA Guidance on Quality Agreements

26-Jan 2017

- FDA issue a detailed document on the expected contents of Quality Agreements with contract manufacturers and test laboratories.

"Contract Manufacturing Arrangements for Drugs: Quality Agreements,"

https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM353925.pdf

- While the document states that **these are not enforceable requirements**, they are the **agency's current expectations**.

non-binding recommendations

- The document is **consistent with** the EU requirements as detailed on **Chapter 7** of the Eudralex.

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- It covers the following **commercial manufactured drug categories** :

  human drugs APIs veterinary drugs biological products

  drug substances combination products finished products

  biotechnology products

- It does not cover:

  human cells medical devices tissues

  cellular or tissue-based products dietary supplements

The FDA suggests that “from a cGMP perspective, manufacturing activities are the **most important element** in a quality agreement” and “the **most critical pieces** are quality control and change control.”

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There is no statutory or regulatory requirement for a quality agreement between owners and contract facilities!

- **FDA recommends** that owners and contract manufacturers implement written quality agreements to define each party's manufacturing activities/roles **to ensure compliance with cGMP**.

- In drafting the quality agreement, the **parties may rely on quality management principles** and engage in "defining, establishing, and documenting their activities in drug manufacturing operations, including processing, packing, holding, labeling operations, testing, and quality control operations."

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- The **quality agreement cannot be used** as a means **to delegate/assign responsibility to comply with cGMP.**

For instance, even when the owner uses a contract manufacturing facility, the owner's quality control unit is responsible for approving and rejecting drug products manufactured by the contract facility, including the final release of the drug product.

- From the agency's guidance, it is apparent that **FDA considers c**ontract facilities to be an extension **of the owner's facility** and recommends both the owner and contract facility to work together to establish and maintain quality oversight of contract manufacturing operations and materials produced under the contracted manufacturing agreements.

Contents of the Quality Agreement

- A quality agreement defines **the owner's and the contract facility's** roles **and manufacturing** activities under cGMP.

- The FDA recommends including, at least, the **following sections** in the quality agreement:
  (1) purpose/scope – to cover the nature of the contract manufacturing services to be provided;
  (2) definitions – to ensure that the parties agree on precise meaning of terms;
  (3) a resolution of disagreements section describing how the parties will resolve disagreements regarding issues, such as quality;
  (4) manufacturing activities – to document quality unit and other activities associated with manufacturing processes, as well as control of changes to manufacturing processes; and
  (5) life cycles of, and revisions to, the quality agreement..

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- The agency added that the quality agreements may be reviewed during inspections, and they **should not cover general business terms** and conditions.

- Preferably, the quality agreement **should be separate** or at least severable **from other business documents**.

Fragen

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