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Contract Manufacturing Arrangements for Drugs: Quality Agreements

Guidance no. UCM 353925

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Introduction *(1/2)*

- FDA's Current Thinking
  - Both the owner and the parties involved in contract manufacturing activities *(Commercial Manufacturing)* to ensure compliance with cGMP.
- Why FDA issued this guidance?
  - To help both parties understand the importance of quality agreement.
  - Recommendations, to be considered for contract manufacturing arrangements.
- What is Commercial manufacturing?
  - Manufacturing processes *(processing, packing, holding, labeling operations, testing, and quality unit operations)* that result in drugs intended to be marketed, distributed, or sold.
  - Does not include research and development activities, manufacturing of material for investigational new drug studies (e.g., clinical trials, expanded access), or manufacturing of material for veterinary investigational drugs.

Many of the principles described in the guidance could be applied in pre-commercial stages of the pharmaceutical life cycle

Introduction *(2/2)*

- Categories of drugs covered in the guidance-
  - Human drugs, veterinary drugs, certain combination products, biological and biotechnology products, finished products, APIs, drug substances, in-process materials, and drug constituents of combination drug/device products.
- Type of drugs not covered in the guidance-
  - Type A medicated articles and medicated feed, medical devices, dietary supplements, or human cells, tissues, or cellular or tissue-based products.

What is a Quality Agreement?

- Relationship between owners and contract facilities
  - Owners-
    - Manufacturers of APIs, drug substances, in-process materials, finished drug products, including biological products, and combination products.
  - Contract Facility-
    - Parties that perform one or more manufacturing operations on behalf of an owner or owners. *(A contract facility may also be an owner depending on its role, e.g Sub-contracting)*
- A quality agreement is a comprehensive written agreement between parties involved in contract manufacturing which shall describe their respective cGMP related roles, responsibilities and activities in drug manufacturing and each of them understand and agree to the same. However, they cannot be used to delegate statutory or regulatory or statutory responsibilities to comply with cGMP.
- The owners should adopt a quality risk management approach *(ICH Q7, Q9 and Q10 guidances)* and ensure processes are in place to assure control of outsourced activities.

Elements of a Quality Agreement

Manufacturing activities	-	Clearly document and list all of the specific activities that need to ensure compliance to cGMP along with the key responsible party for each activity.
Quality unit activities	-	❑ For product release, in addition to the contract facilities who are responsible for approving or rejecting the product or results of their manufacturing operations including final release. ❑ The agreement should document the process to understand when, how and what information, the two parties shall communicate with each other, verbally and in writing. ❑ This shall include scenarios in case of any objectionable conditions observed during audits and inspections of the facility, also covering communicational suggestions/ findings etc. ❑ This shall include the responsibility of approving failure investigation reports.
Facilities and equipments	-	Agreement shall include the list of contract facility sites including address and specific services provided at each site. It should also document the party responsible for validating processes and qualifying and maintaining equipments/instruments.

Elements of a Quality Agreement

Material management	-	The quality agreement should include procedures to prevent mix-ups and cross contamination, identify individual party's responsibility on component specification, establishing processes for auditing, qualifying and monitoring component suppliers, inventory management.
Product specific considerations	-	This section will document process or procedures specific to the product namely specifications, batch numbering, lot disposition, process validation, product knowledge transfer to be followed by the owner and contract party.
Laboratory controls	-	The quality agreement will document the need to access the laboratory facilities by both the party through defining roles and responsibilities.
Documentation	-	This section shall define the review and approval process that needs to be followed by the owner and the contract party. It should also document the change control process to address the changes to SOP, Manufacturing records, specifications, etc.

The End

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