Quality Agreements

A Practical Perspective

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Regulatory Expectation of Quality Agreements is Well Established

EU GMP Chapter 7: Requires a **Quality Agreement to define the responsibilities** of the contract giver and contract acceptor and states "Contract manufacture and analysis must be correctly defined, agreed and controlled"

FDA *DRAFT* Guidance for Industry: Parties involved in the contract manufacturing of drugs can utilize Quality Agreements to delineate their responsibilities and assure drug quality, safety, and efficacy.

Device 21 CFR 820.50 Purchasing Controls: Establish and maintain **procedures to ensure that all purchased or otherwise received product and services confo**

ICH 9: supplier and imp

ICH Q7: "There should be a **written and approved contract or formal agreement between a company and its contractors** that onsibilities, of each party"

What matters most is what is IN your Quality Agreement

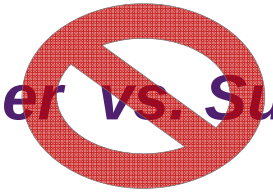
ICH Q10: "Th the management extends to the activities… **Responsibilities for quality-related activities of the contract giver and contract acceptor should be specified in a written agreement**." Control and review of any outsourced activities is ultimately the responsibility of the "pharmaceutical company" or Owner.

pter 1: When the tion holder is not ere should be a **t in place between the various parties that defines their respective responsibilities** in producing the quality review.

PIC/s Annex 20 Appendix: brief mention as Quality Risk Management as Part of Materials Management as an application for providing a comprehensive evaluation of suppliers and contract manufacturers (e.g. Auditing, **supplier quality agreements**). *This Annex is noted as voluntary.*

PIC/s Part 1, Chapter 7: Contract manufacture and analysis must be correctly defined, agreed and controlled in order to avoid misunderstandings which could result in a product or work or unsatisfactory quality. There must be a **written contract between the Contract Giver and Contract Acceptor which clearly establishes the duties of each party**.

Practicality of Quality Agreements is to Define the Working Relationship



Owner vs. Supplier **Partnership**

- **Manufacture**
- **Analytical Testing**
- **Release**
- **Product Lifecycle Maintenance**

- Whose Quality Systems are governing? Is terminology aligned?
- Is there an expectation of observing routine production or have a resident Person-in-Plant? What access is allowed?
- Are the boundaries of Quality audits defined?
- Which lab performs in-process and final release analysis? What if there is an out-of-specification result?
- How are deviations handled? Do all levels of deviations require the same notification, review and approval? Expected timelines?
- Which Quality Unit is responsible for final release of product? Stability testing?
- Both companies have responsibility for complaint investigation and response. How will the process be managed? Who maintains reserve/retain samples?
- What notification is required in the event of (and hopefully prior to) Field Alert Report issuance?
- How will the companies work together for regulatory inspection responses and commitments?
- What information should be shared during regulatory inspections?

Like other Quality Systems Elements, Effectiveness Checks are Useful

- As your business relationship evolves, so must the Quality Agreement
  - Contacts must be kept current; establish a review frequency
  - Key Performance Indicators and targets should be agreed upon, clearly defined and reviewed frequently at set intervals
  - Working team should monitor the sections that are not working well

- Quality Agreement Template is a good starting point
  - Pro: Creates consistency for organizations handling multiple customers or suppliers
  - Con: Over-generic; eliminate ambiguous language
  - Include unique details for each relationship
  - Keep it contemporary with changes in your systems

When Things Do Not Go As Planned

The Quality Agreement should define the escalation process for when issues advance beyond the standard scope or when the working team is not in alignment.

Conclusion: Quality Agreements

- Define terms of the relationship early and often
- Adhere to the terms of the agreement
- Escalate issues for resolution
- Understand the dynamic process NOT “One and Done”