Quality Agreements: A Tool For Assuring Compliance at Contractors & Affiliates

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Why Create A Quality Agreement?

- Today's Pharmaceutical Business is Global.
- Large firms have operational sites all over the world.
- Small firms located at a single site will most likely market products globally.
- Manufacturing for a single local market is becoming a thing of the past.
- Components & Raw Materials are sourced globally.
- Intermediate Materials and testing can be sourced globally.

Why Create A Quality Agreement?

- How do we manage the quality of materials produced by a contractor or affiliate?
  - Traditional Audit
  - Person In The Plant
  - Reviewing Completed Documents
  - Certification Programs
  - Trust Your Affiliate or Contractor
- Get it in writing
  - Quality Agreements define relationships under a contractual framework

Why Create A Quality Agreement?

- There are specific roles played by both the contract giver and the contract acceptor.
- These roles may vary between different contractors or affiliates.
- Services provided may vary greatly.
- Defining roles and responsibilities up front creates a better working relationship and a more solid basis for business.

What Are the Regulatory Considerations?

- The EU has very defined requirements for the relationship between a service or material provider and the recipient of those services or materials.
- Contracts are to be put in place that clearly define the business relationship as it pertains to quality of materials or services.
- The roles and responsibilities of the contract giver and the contract acceptor are to be spelled out.
- Adherence to the contract must be monitored and enforced.

What Are the Regulatory Considerations?

- Original interpretation was a contract being put in place for non -related firms i.e. not affiliates
- Expectation now is that affiliates will also have a contract in place.
- In recent inspections FDA has inquired whether there are quality agreements in place for materials being provided by contractors and affiliates.
- Roche Nutley has had affiliate Quality Agreements since 1999.

Key Sections In A Quality Agreement

- General (License, self inspections, audits, inspections)
- Organization and Personnel (Qualification & Responsibilities)
- Buildings, Facilities and Equipment
- Handling of Materials and Packaging Materials
- Production and Process Controls
- Holding and Distribution
- Quality Control/Quality Assurance

Key Sections In A Quality Agreement

- Records, Reports and Documentation
- Reprocessing & Reworking
- Product Recall
- Special Requirements
  - Specific regulatory requirements unique to the site
  - Special requirements because of commitments to regulatory authorities
  - Special requirements unique to the firm (Company Policies or Directives)

Key Sections In A Quality Agreement

- Attachments
  - List of applicable SOPs
  - List of contacts
  - List of applicable specifications
  - List of applicable test procedures
  - List of approved subcontractors
  - List of approved suppliers
  - Required Forms (sampling forms, COA and COM)
  - List of authorized people and signatures
  - List of products covered by the Quality Agreement

Managing Quality Agreements

- Who should be included in Quality Agreements?
  - Contract Manufacturers (API, Intermediate Materials, Dosage Forms)
  - Contract Testing Labs
  - Contract Packagers
  - Contract Warehousing Operations
  - Sub contractors/Affiliates

Managing Quality Agreements

- Management of affiliates and contractors is largely based on the content of the Quality Agreement.
- Responsibilities for functions should be fully described.
- Any time limitations defined in local/global SOPs should be spelled out and agreed upon.
- Special needs should be detailed (i.e. content of APRs).
- Copies of documents listed in the attachments should be provided to the affiliate or contractor.
- If necessary training should be performed.

Managing Quality Agreements

Keeping the Agreement Current:

- Contact list is updated periodically to keep it current.
- Signature list updated periodically.
- Listings of procedures and specifications updated to keep current.
- New revisions of SOPs provided as needed.
- Quality Agreement reviewed annually for being current.
- Addenda added when necessary to make changes.

Making It All Work

Put the effort in up front:

- Create a template that can be used as a basis for Quality Agreements.
- Tailor the agreement to the contracted relationship.
- A contract test facility agreement will be extremely different then a contract manufacturing facility.
- Build a relationship with the contract acceptor.
- Work together as a team.
- Align the Quality Agreement with the Business Contract.

Making It All Work

Global contracts take a special effort:

- Putting different countries into the mix increases the challenge for establishing the agreement.
- The Quality Agreement needs to meet the regulatory requirements of each country.
- The more countries involved the more complex.
- The contract acceptor may have to agree to tighter time frames because of foreign regulatory requirements.

In Summation

- Quality Agreements serve as the foundation of a solid two way business relationship.
- Quality Agreements clearly define the roles and responsibilities of all parties.
- Quality Agreements include time frames and all special requirements for each contracted relationship.
- Allow oversight and management of quality for products being manufactured or tested by either contractors or affiliates.
- They are flexible and allow easy updating of requirements through its attachments.
- Govern the contracted relationship.

Ralph Napolitano, Head, Quality Management – Roche, EPPIC Panel Discussion, June 3, 2010 (Palo Alto)

QUESTIONS ?