Managing Quality Assurance Expectations

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Establishing Expectations the Players

- Contractee: The entity/establishment holding an agreement for services with a *Contractor*
- Contractor: The entity/establishment providing a product and/or services related to the manufacture process
- Subcontractor: An entity/establishment the *Contractor* utilizes to perform product analytics or manufacturing functions.

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Pre Contract and Agreement Expectations

Perform Due Diligence Assessment to Establish Expectations of Both Parties

- Initiate formal “capabilities”/versus “needs” discussion
- Perform audit with a general (open) exchange related to current capabilities
  - Contractor should be forthcoming related to current and future capabilities

Managing Expectations versus Capabilties

- Determine gaps between contractee’s expectations and contractor’s capabilities
  - Openly discuss options for “closing the gaps”, assuming that is the path both entities choose to continue to pursue
  - Discuss options for compromise, for example:
    1) Issue: Contractor does not have capability to store retains
    2) Issue: Contractor has limited material storage capacity
    3) Issue: Schedule of Contractor annual facility shutdown
    4) Issue: Contractee required manufacture start date

Generate a Mutually Agreed Upon Quality Agreement

Quality Agreement Purpose

- Defines specific quality and regulatory parameters (requirements)
- Assigns responsibility to each quality/regulatory parameter
- Should be separate from an overall contract
- Should be in place prior to initiating activity

Quality Agreement Contents

Preamble
Purpose
Scope
Policy Statements
Definitions
Term of Quality Agreement
Survival Clause
*Responsibilities
Approved Subcontractors
Contractor and Contractee Communication Contacts

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*Responsibilities

Regulatory Authorization
Equipment, Facilities, Personnel
Documentation
Receipt and Storage of Materials
Product Related Manufacture
Testing and Analysis
Storage and Shipment

*Responsibilities Continued

Product Disposition
Records
Change Control
Deviations, Investigations and CAPA
Complaints
Retrieval of Product
Contractor and Contractee Site Audits
Regulatory Agency Inspections

Quality Agreement Approach

1) Generate a basic QA agreement template (version controlled)
2) Determine contractor and contractee expectations up-front
3) Modify your template per the specific agreed upon contractee/contractor approach (version controlled)
4) Amend the QA Agreement, as needed.

	RESPONSIBILITIES	Contractee ABC	Contractor Univ of Z	N/A (not applicable)
8.0	**REGULATORY AUTHORIZATION**			
8.1	Maintains facility registrations, licenses and authorizations required by applicable laws to operate a cGMP facilities.		✓	
8.2	Prepares, maintains and updates the IND. Submits to the FDA.	✓		
8.3	Maintains an independent quality unit who establishes and maintains an effective Quality System.		✓	
9.0	**EQUIPMENT, FACILITIES, AND PERSONNEL**			
9.1	Provides equipment used in the manufacture and analytics related to the Product.	✓	✓	
9.2	Performs equipment maintenance and calibration.		✓	
9.3	Performs equipment qualification.		✓	
9.4	Performs general facility maintenance and sanitization.		✓	
9.5	Provides a qualified facilities to perform the manufacture of Product in accordance with *ABCs* instructions, and in compliance with FDA and local regulations.		✓	
9.6	Ensures that the staff engaged in the manufacture of Product has the education, training, and experience necessary to perform their assigned functions.		✓	
10.0	**DOCUMENTATION**			
10.1	Maintains a controlled document management system to initiate, review, revise, obsolete, and archive all		✓	

Alternate Approach with Consilidation:

	9.0 EQUIPMENT, FACILITIES, AND PERSONNEL		
9.1	Provides equipment used in the manufacture and analytics related to the Product.	✓	✓
9.2	Performs equipment maintenance, calibration and qualification.		✓
9.3	Performs general facility maintenance and sanitization.		✓

	RESPONSIBILITIES	Contractee ABC	Contractor Univ of Z	N/A (not applicable)
13.0	**TESTING AND ANALYSIS**			
13.1	Develop test methods and method for verification/validation as appropriate.	✓		
13.2	Responsible for the management of in-process and final testing of the Product.		✓	
13.3	Manages analytical method transfer for those methods to be performed by a third party.			✓
13.4	Performs in-process and final testing of the Product.		✓	
14.0	**STORAGE AND SHIPMENT**			
14.1	Provides segregation of released and quarantined material.		✓	
14.2	Stores Product in accordance with storage specifications utilizing a continuous storage condition monitoring system.		✓	
14.3	Ships product to approved consignee.		✓	
14.4	Documents unfulfilled specifications in the case of Product shipment to another manufacturing facility prior to final release. Document with an approved "Ship at Risk of Production Material for Further Manufacturing Movement Assessment"			✓
14.5	Performs final product release.		✓	

Rather than Modifying Each QA Agreement Utilize "Not Applicable"

Successful Quality Agreement

1) Do you home work upfront related to capabilities
2) Contractor and Contractee must partner to ensure success
3) Compromise (when appropriate) related to QA Agreement content

WORKING TOGETHER TO ACHIEVE SUCCESS

By Frits Ahlefeldt