

Elements to consider in a Quality Agreement

Overview

- [Introduction \(Section 8.2.4.1\)](#)
- A QA is needed to agree on Component characteristics (performance, packaging, etc...) that will ensure an OINDP Component is supplied to the agreed, required standard
- Applies to Fully developed/customized or off-the-shelve Components*
- Cross-referencing between TA / QA (and SA).

**Custom or new developments should be designed around a Development Agreement that should include elements of this guidance.*

Elements to consider



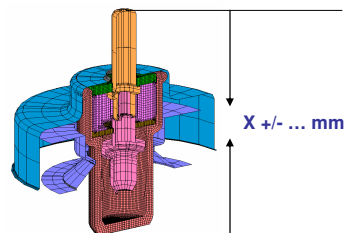
- **Batch Records**
- **Change Control**
 - Strategy for changes (risk-based approach)
 - Categorization/Notification plan
 - To be covered in ensuing session
 - Validation standards (SOP) – may not be restricted to CC
- **Complaints/Claim management/Dispute**
 - Procedure for documenting complaints.
 - Response timing table.
 - Responsibilities
 - Agree on action plan for technical Dispute / resolution of quality issue (i.e. 3rd party testing,...)



Elements to consider



- **Component Testing/Specifications**
 - Product identification codes (Required by FDA)
 - Aspect (Visual)
 - Drawings/Materials/Suppliers
 - Performance specifications
 - Physico-Chemical specifications
 - Defects classification (by AQL, Sigma Level etc)
 - Sampling plan
 - Product Cleanliness (FP sec. 9.2/3)
 - Microbial levels
 - Line clearance
 - Certification (CofC, CoA,...)
 - Confirmatory testing

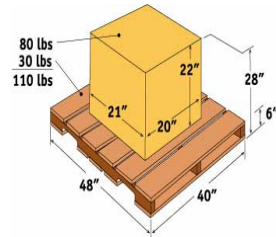


Elements to consider



- **Component Specifications (cont'd)**

- Packaging/Shipping details (Labels, pallets,...)
 - Protective packaging, Sealed/Double bag minimum
 - Carton/Pallet specs/diagram
 - Labeling (information, adhesives,...)
- Shelf life certification (Recommended storage conditions,...)



**Note: Parties should consult with each other to discuss any change to specifications and initiate a change control.*

Elements to consider



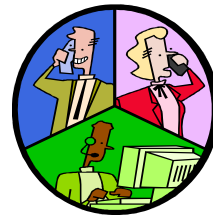
- **Customer/Internal Audit plan**

- Agree on auditing schedule
- Self inspection procedures

- **Definitions**

- **Documentation / Batch Release**

- Batch Records content
- Document retention schedule
- Sampling plan/retains



Elements to consider



- **Manufacturing environment**

- Identify Site(s)
- Facility Design
- Environment/Ventilation control (Min. I S 9000 9.2.1), ISO 14644-1?
- Cleaning procedure/schedule
- Microbial controls (Product contact part manufacturing)
- Ancillary/Process additives/material (agree on need and safety, control)
- Warehouse (Handling of materials/pallets, storage, ...)
- General Hygiene (Procedures, Clothing,...)
- Equipment maintenance
- Insect/Pest control

Elements to consider



- **Materials Control***

- Raw Material/Components
- Physical characteristics
 - Identification/Grade
 - Mechanical properties
 - Certification, Compendial testing
 - Storage
- Chemical requirements (extractables, residues)
- (N-2) Supply/Quality agreements

* *Controlled extraction studies should be performed during the development of a product. Many Component suppliers routinely control extractables on components . Non-contact parts typically can be controlled by tests which are relevant to the performance of the Component not requiring extractable controls.*

Elements to consider



- **Outsourcing (3rd party supply) – Sec. 7.4.1**
 - Supplier is responsible for assuring quality of purchased components.
 - Control of Raw materials
 - Inspection/Audit of suppliers
 - Validation of tooling at Suppliers
 - Periodic review/confirmation of certificates.
- **Process/Cleaning validation (sec 9.1.4)**
 - “Supplier shall have a Validation Plan that will result in the ability to provide documented evidence that manufacturing processes will consistently deliver Component meeting pre-determined quality specifications.”
 - Examples of procedures/systems:
 - Cross Contamination (Line clearance, Waste Mgmt, Ancillary mat’ls)
 - Pre- or Post manufacture cleaning as applicable
 - Define what must be approved by Customer
 - Control of documents

Elements to consider



- **Regulatory (Compliance, Contacts, audits)**
 - OINDP Manufacturer and Supplier should work together to assure Component regulatory compliance.
 - Specify applicable regulations (ex. IPAC-RS guidelines, ISO, FDA, EU,...)
- **Rework/Rejections/Deviations/Waste**
 - Define what must be approved by Customer.
 - Have a plan to investigate any issues.
 - Documentation strategy (i.e. Certificates)

Elements to consider



• Responsibility Matrix

DIVISION OF RESPONSIBILITIES		
Requirement	COMPANY	SUPPLIER
A. Regulatory Compliance		
1 Maintain valid manufacturing license	N/A	X
2 Adhere to approved New Drug Application/ Market Authorization	X	N/A
3 Provide access to history of and actions resulting from government inspections	N/A	X
4 Maintain documentation of personnel training	N/A	X
5 Perform calibration of instruments and equipment at suitable intervals	N/A	X
6 Provide site access and liaison for facilities audits and inspections	N/A	X
B. Raw Materials and Components		
1 Provide Specification	X	N/A
2 Provide Sampling Plans	N/A	X
3 Provide Test procedure	X	X
4 Test methods validation/verification	N/A	X
5 Vendor qualification and monitoring	N/A	X
6 Performance of quality control	N/A	X
7 Release for processing	N/A	X
8 Retention of quality control test record	N/A	X
9 Retention of reference samples	N/A	X

Responsibility Matrix (Cont'd)



Requirement	COMPANY	SUPPLIER
C. Sub-assemblies and Finished Component		
1 Provide Specification	X	X
2 Provide Sampling Plans	N/A	X
3 Provide Test procedure	X	X
4 Provide manufacturing instructions	N/A	X
5 Prepare batch history record	N/A	X
6 Perform In process testing	N/A	X
7 Provide reference standards	N/A	X
8 Assignment of lot number	N/A	X
9 Packaging record	N/A	X
10 Pallet pattern instructions	N/A	X
11 Master of shipping label	N/A	X
12 Bill of materials	N/A	X
13 Retention of packaging record	N/A	X
14 Retention of retained samples	N/A	X
15 Retention of production and control test records	N/A	X
16 Transportation under required conditions	N/A	X
D. Component Release		
1 Qualified Person responsible for release to COMPANY	N/A	X
2 Provide Certificate of Conformance	N/A	X
3 Provide investigation report for deviations	N/A	N/A
4 Qualified Person responsible for final release	N/A	X
E. Packaging Materials and Shipping		
1 Provide Specification	X	X
2 Provide Sampling Plans	N/A	X
3 Provide Test procedures	X	X
4 Supply/Procurement materials	N/A	X
5 Performance of Quality Control	N/A	X
6 Receipt of COC for materials	N/A	X
7 Retention of quality control test records	N/A	X
8 Pallet pattern	N/A	X
9 Supply Carton/Shipper label format/information	N/A	X

Responsibility Matrix (Cont'd)



Requirement		COMPANY	SUPPLIER
H. Finished Product Recall			
1	Decision to initiate recall related to finished product	X	N/A
2	Notification to authorities	X	N/A
3	Notification to customer/ consumer	X	N/A
4	Investigations related to Component manufacturing and control	X	X
I. Disposal of Waste/Rejects			
1	Sub-components, sub-assemblies or finished Component	N/A	X
2	Packaging waste	N/A	X
3	Provide certificate of destruction destroyed at COMPANY's request	N/A	X
J. Reprocessing			
1	Responsible for final decision for non routine reprocessing	X	X
2	Qualification of reprocessing method	X	X
3	Acceptance criteria	X	X
4	Release of Component	N/A	X

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Summary

Quality Agreement:

- to agree with a contractor on mutual quality standards
- based on IPAC-RS requirements
- in the context of a supply agreement / confidentiality agreement / technical agreement / audit / order
- SOP and templates are prerequisites to manage the document life cycle
- => **Insure supplier is providing a component with consistent high quality**

