

Quality Agreements/Control of Suppliers and Sub-contractors

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Agenda for Today

- 1 Quality Agreement: Process Overview
- 2 Quality Agreement: Why have it
- 3 Quality Agreement: Who's involved
- 4 Quality Agreement: Negotiating
- 5 Quality Agreement: Dealing with big industry suppliers
- 6 Case Studies: Quality Agreements with Big industries
- 7 Case Studies: Quality Agreements with a "mom & pop"

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Quality Agreements : Process Overview

Choose suppliers

Determine which suppliers to establish quality agreements with.

Should be key suppliers

Internal Resource

Get key individuals from QA, SCM, and Technical Experts (if needed)

Communication Plan

Determine who is to handle the communication

Set frequency of communication

Milestones & Gantt

Include checkpoints for draft reviews

Timing of final approval

Effective date of the agreement

Key Elements

Change Control

Audits

Document retention

Product traceability

Setting Expectations

How will the Quality Agreement be used

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Why have it?

- **Benefits for manufacturer and supplier**
 - have a common definition of "quality"
 - eliminates misunderstanding of quality expectations
 - agreed on key elements of the supplier's QMS
 - harmonize interpretation of regulations
 - gives guidance on handling quality related issues
 - secure that information provided from lot to lot are consistent

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Who's involved?

- **Key individuals with the company**
 - Quality Assurance
 - Supply Chain/Purchasing
 - Technical Experts (if applicable)
 - Legal
- **Lead communication should come from personnel in supply chain**

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Negotiating

- Will take some time
 - 5-6 back and forth discussions between both companies
- Be firm but collaborative
- Be prepared to have a good justification for imposing mandatory GMP requirements on suppliers who do not follow the same standards
- Be clear about what elements of the Quality Agreement are mandatory or optional

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Quality Agreements with Big industries

- Biggest challenge is to get them to see your needs
 - Suggestion is to explain the quality and safety of the product
 - Share with supplier who the real customers are, the patients
- Not as difficult as you might think
 - Your business may fit their “special” projects niche
 - They are just as interested to expand their product portfolio
- Build your case how and what benefits can be gain from the agreement
- Be flexible but firm

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Case Studies: Quality Agreements with Big industries

- Much more investment on time and resources
 - Has involved all levels of both the supplier and manufacturer's organization
- "Everything" is read
- Any standards and regulations quoted will be questioned and how they will be expected to live up to it
- Lots and lots of massaging of the language

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Case Studies: Quality Agreements with “mom & pop” shops

- Interest level is high
- Less discussions as compared with “Big” firms
- Less comprehension of how the quality agreement will impact their firm
- Requires some level of education and training
- Slim down version of the quality agreement, must capture key quality parameters

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Q & Answers

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