




Quality Agreements: Technical & Quality Aspects


IPAC-RS Training
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Maidenhead (UK), 28 May 2008



Agenda



- Introduction**
- Quality Agreement**
- Topics based on IPAC-RS Guideline**
- Summary**
- Backup**
 - Topics based on ISO 9001**
 - Topics based on GMP/QSR**

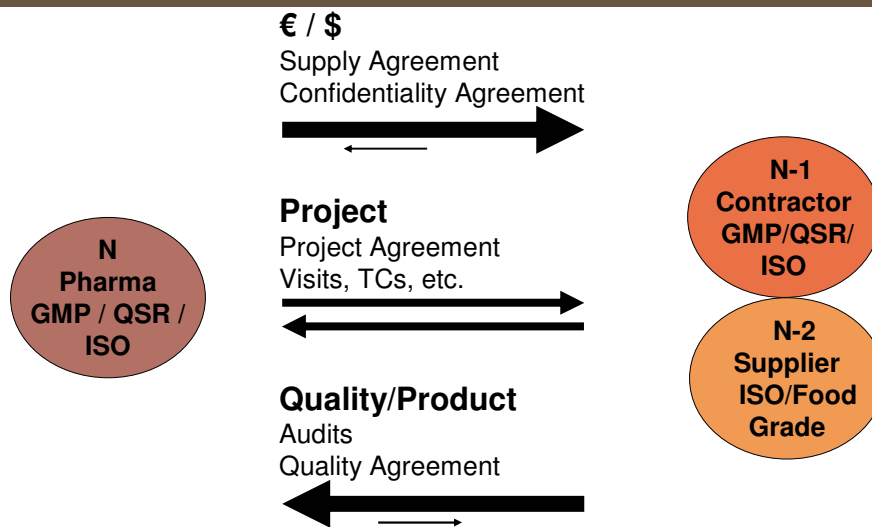


Introduction QA

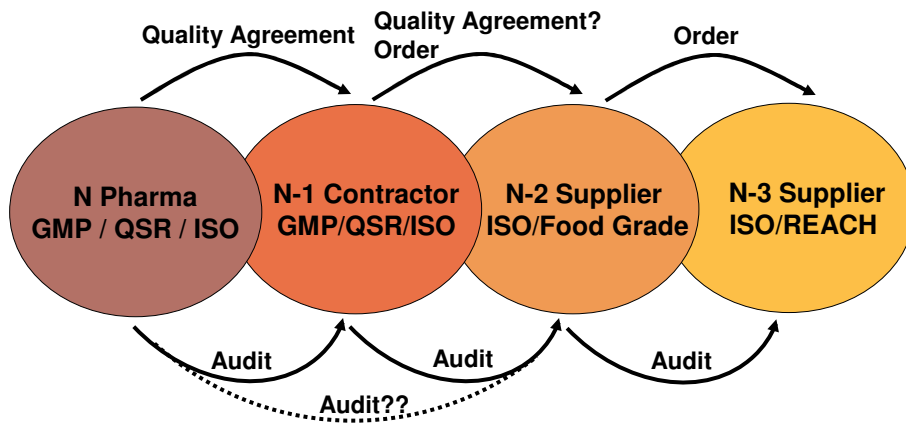
**„Every System is
perfectly designed
to achieve the
results that it gets. „**

David Beckwith

Levels of Relation



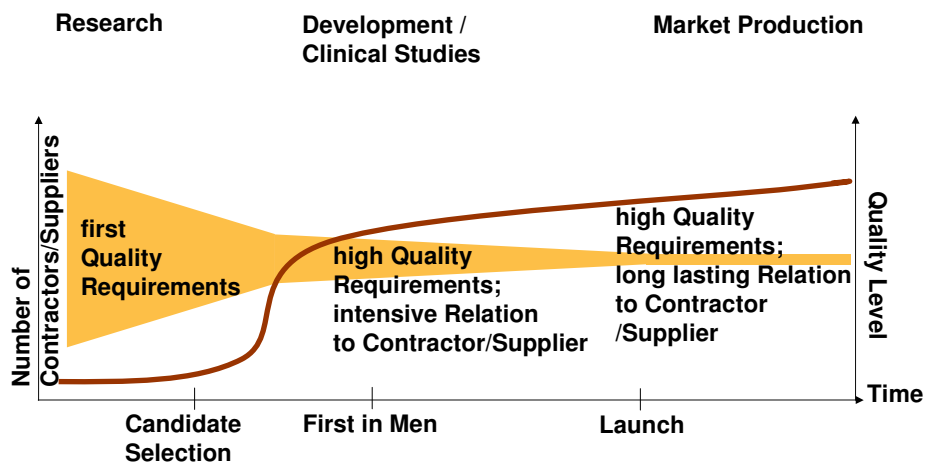
Supply Chain



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Quality & Device Contractors / Suppliers



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Types of Quality Agreements

- Type I:
Quality agreements contain technical aspects and serve the function of both a quality agreement and technical agreement
- Type II
Quality agreement at very high level, covering general GMP issues, and supplemented by a separate, more detailed technical agreement

When do I need a Quality Agreement?

Supplier:

- provides commercially available products



Supply Agreement

Contractor:

- provides products / service according to company's standards or specifications



Supply + Quality Agreement

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Quality Agreement (1)

EU GMP 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 of unsatisfactory quality. There must be a written contract between the Contract Giver and the Contract Acceptor which clearly establishes the duties of each party. The contract must clearly state the way in which the Qualified Person releasing each batch of product for sale exercises his full responsibility.

Note: This Chapter deals with the responsibilities of manufacturers towards the Competent Authorities of the Member States with respect to the granting of marketing and manufacturing authorisations. It is not intended in any way to affect the respective liability of contract acceptors and contract givers to consumers; this is governed by other provisions of Community and national law.

<http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/vol-4/pdfs-en/cap7en.pdf>

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Quality Agreement (2)

US QSR – 21CFR820.200

Where servicing is a specified requirement, each manufacturer shall establish and maintain instructions and procedures for performing and verifying that the servicing meets the specified requirements.

<http://frwebgate.access.gpo.gov/cgi-bin/get-cfr.cgi?TITLE=21&PART=820&SECTION=200&YEAR=2000&TYPE=TEXT>

Quality Agreement (3)

- SOP how to manage a quality agreement
- Normal life cycle management (create, review, approve, periodic review, withdraw)
- Link the quality agreement to a supply agreement
- Ranking: supply agreement > quality agreement
- Use a template
- Include the severability clause (depending on the supply agreement)
- 3-Way agreements possible

Quality Agreement (4)

- Involve experts (line unit, purchasing, QA, out-sourcing management, law, etc.)
- Define the responsibilities for you and the contractor/supplier in detail
- Give access of the signed agreement to the experts

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Quality Agreement (1)

IPAC-RS General Documents

- **References** (see 2)
- **Definitions** (see 3 definitions and terms & 1.1 examples of components)
- **Batch records** (see 7.2.2 requirements related to the product & 7.5.3 component batch documentation)
- **Change control and notification** (see 7.2.3.1 for documents, material, specifications, processes, facility, equipment & 7.3.7 design and development changes)
- **Complaints** (see 7.2.3 customer communication & 8.2.1.1)
- **Document retention** (see 4.2 documentation requirements)

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Quality Agreement (2)

IPAC-RS Testing

- **Requirements for raw material and subcomponents** (see 7.2.3.3 specifications & 7.3.1.1 design and development planning & 7.4.3 verification of product)
- **Component testing** (see 7.3.1.1 design and development planning & 8.2.4 monitoring and measurement of product)
- **Retained samples** (see 7.5.4 customer property)
- **Lot approval & product release** (see 7.2.3.3 specifications & 8.3 nonconforming product)

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Quality Agreement (3)

IPAC-RS Production (1)

- **Material suppliers** (see 7.3.1.2 use-by/requalification dating & 7.4.1 purchasing process)
- **Manufacturing environment** (see 6.3 infrastructure & 6.4 work environment)
- **Cleanliness and hygiene** (see 6.4 work environment & 9.1.4 cleaning, 9.2 component cleaning, 9.3 foreign particles)
- **Process validation** (see 7.1 product realization & 7.3 design and development & 7.3.6 design and development validation & 7.5.2 validation of process & 9.1.4 .1 cleaning validation)

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Quality Agreement (4)

IPAC-RS Production (2)

- **Equipment qualification & validation** (see 4.2.3 control of electronic documents & 6.3 infrastructure & 7.3 design and development & 7.5.1 control of production & 7.5.2 validation of process & 7.6 measuring and monitoring devices & 9.1.3 equipment and maintenance)
- **Rework & reprocess** (see 7.1 product realization & 8.3 nonconforming products)

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Quality Agreement (5)

IPAC-RS General Quality (1)

- **Customer audits** (see 7.4.1.3 supplier qualification & 7.4.3 data verification & 7.4.4 re-qualification)
- **Regulatory contacts and audits** (see 7.3.1 design and development planning & 7.3.2 design and development input)
- **Regulatory compliance** (see 8.2.2 internal audits)
- **Subcontractor management** (see 7.4.1 subcontracting & control of supply chain & 8.4 analysis of data)
- **Supply agreement** (see 7.2.3.2)

Quality Agreement (6)

IPAC-RS General Quality (2)

- **Recalls** (see 8.3 nonconforming products & 8.5.2 corrective actions)
- **Resolution of quality issues** (see 8.4 analysis of data & 8.5.2 corrective actions & 8.5.3 preventive actions)
- **Responsibility matrix** (see 4.1 quality unit & 5.1, 5.2, 5.5 management & 6.2.2 competence and training)

Elements to Consider in an Agreement

by Louis Leger, Valois

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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

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Quality Agreement (1)

ISO 9001

- **Scope of the agreement** (contract or co-development, analytic only, clinical batch, etc.)
- **ISO certification**
- **Normative references and Company quality requirements / definitions**
- **Special requirements** (see e.g. audit results)
- **Quality management system** (general requirements, documentation, electronic data)
- **Management responsibility** (planning, communication)

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Quality Agreement (2)

ISO 9001

- **Resource management** (provision, infrastructure, equipment, environment)
- **Product realization** (planning, change control, specifications, design and development, purchasing, production, control of measurement & monitoring devices)
- **Measurement, analysis and improvement** (monitoring & measurement, control of nonconforming product, analysis, improvement)

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Quality Agreement (3)

PS 9000

- **Contamination control**
- **Printed materials**
- **Origination/Artworks**
- **Print media & conversion**

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General Topics of a Quality Agreement (1)

GMP/QSR

- **Scope of the agreement** (contract or co-development, analytic only, clinical batch, etc.)
- **GMP / ISO certification**
- **General GMP/QSR conditions (guidelines) and Company quality requirements**
- **Special requirements** (see e.g. audit results)

Topics in addition to IPAC-RS are underlined

General Topics of a Quality Agreement (2)

GMP/QSR

- **Starting/Raw materials responsibility** (e.g. for procurement/testing/ storage/ retention samples)
- **Measures to avoid cross contamination** (e.g. highly active compounds)
- **Requirements for further sub-contracting**
- **Testing materials responsibility** (e.g. procurement/ quality/ preparation/release)
- **Equipment responsibility** (e.g. qualification, validation, calibration, cleaning)
- **Requirements of documentation review & approval and archiving & handover**

General Topics of a Quality Agreement (3)

GMP/QSR

- **Storage and transport of product / retention samples**
- **Responsibility for product release**
- **Responsibility for failure investigations / deviations**
- **OOS result investigations**
- **Change Control**
- **Inspection rights**
- **Development report**
- **Handling of waste materials**

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General Topics of a Quality Agreement (4)

GMP/QSR

- **List of contact persons** (supply of documents, material etc.)
- **Responsibility for CMC and regulatory documentation**
- **TSE requirements**
- **Responsibility for reference standards**

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Product Specific Topics of a Quality Agreement (1)

Examples to be covered in addition

- **Product Specifications** (incl. storage conditions)
- **Product specific responsibility list and contact details**
- **Master manufacturing/packaging instructions** (incl. IPC testing)
- **List of raw/starting materials** (specifications, storage conditions, responsibility for procurement and testing/ test method validation and required supplier)
- **Responsibility for testing of product**
- **Amount of retention / reference samples**

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Product Specific Topics of a Quality Agreement (2)

Examples to be covered in addition

- **Complete testing instructions**, (e.g. for raw/starting materials, finished product)
- **Responsibility for validation of product test methods**
- **Material safety information**
- **Shipping instructions**
- **List of packaging materials** (examples of printed components, etc.)

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