



# Preparing for Your First Clinical Batch

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# Entering Drug Development!

## Building your drug development organization

- Getting **development expertise** on board
- Developing a **regulatory strategy** for the candidate medicinal product
- Developing a **pharmaceutical quality system**

## Completing the drug discovery phase

- Successful **proof of principle study**
- Securing **intellectual property**
- Full **documentation** of materials, methods, studies, data, ...

# The Drug Development Team

- Project leader
- CMC leader
- Nonclinical leader
- Clinical leader
- Regulatory leader



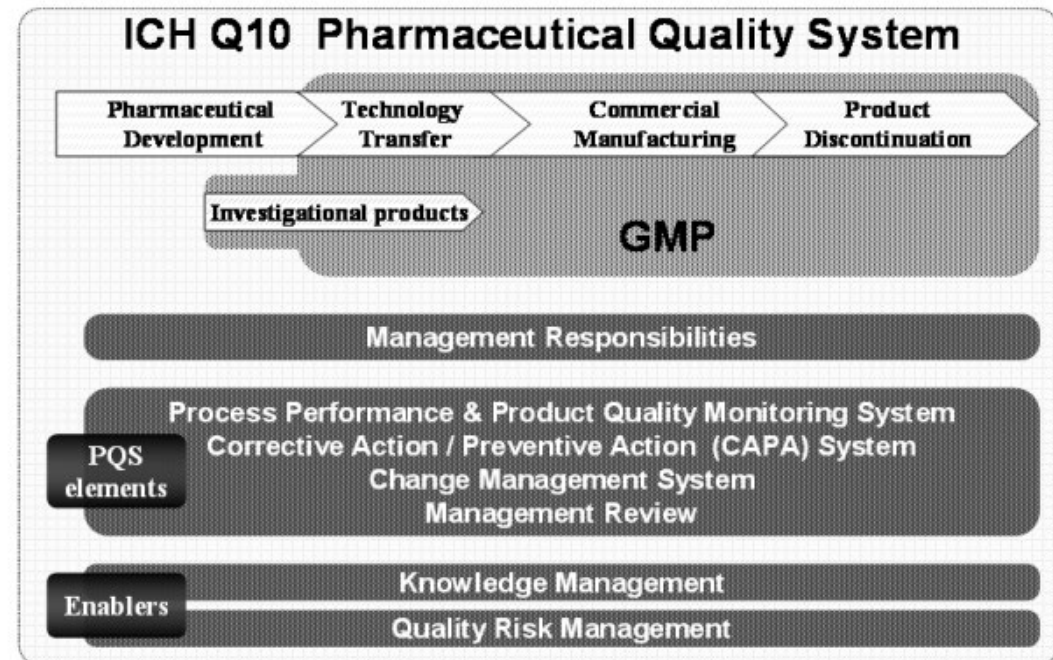
# Entering an Heavily Regulated Environment!

Laws and regulations e.g.:

- Good Manufacturing Practices
- Pharmaceutical Quality System
- EU and US Pharmacopoeia
- ICH, EMA, FDA Guidelines

## Annex 2

Diagram of the ICH Q10 pharmaceutical quality system model



# Options for Production of Clinical Materials

## Outsourcing

- Possible for platform products e.g. Mabs, gene therapy products

## Renting clean rooms

- E.g. transition of R&D team into GMP production

## In house production

- Building your own clean rooms



# In Case of Outsourcing or Renting of Clean Rooms

## Quality Agreement (or Technical Agreement) required

- GMP requirement
- Product safety and quality
- Focus: clear definition of roles and responsibilities

## Different from the commercial agreement

- Focus: scope, planning, cost, warranties, confidentiality
- Reference made to Quality Agreement

# In Case of in House Production

## Building your clinical manufacturing organisation

- Manufacturing
- Process Development
- Engineering, Maintenance, Validation
- Analytical Development
- Quality Control
- Quality Assurance

# Summary

## Planning for your first clinical batch is:

- Entering drug development
- Entering a heavily regulated environment
- Creating your own drug development team
- Develop your regulatory strategy
- Start building your pharmaceutical quality system
- Deciding on your production strategy



# Thank you

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