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# The QP in the year 2015

C Brading  
7th November 2006

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# First a warning on future prediction...



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## 2015 in context

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### 2015 is only 9 years away

- Only 2 more world cup football competitions
- 3 years after the London Olympics

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### But look at changes in the last 9 years (since 1997)

- Enlarged EU
- Revise EU Directive on Medicinal Products
- Advancement of ICH Quality topics (Q7a, Q8, Q9, Q10)
- Introduction of CTD
- Advancement of technology
- etc...



# What will the 2015 look like...?

Pharmaceutical Industry

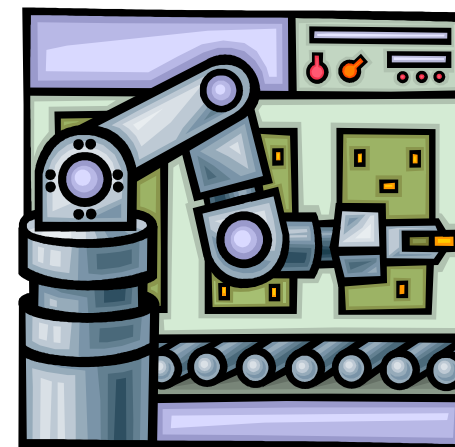
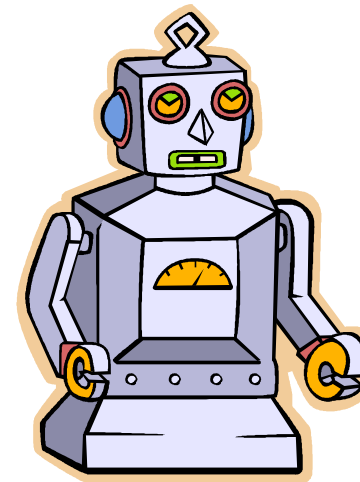
Products

Processes

Regulatory Requirements

Quality Systems

The QP role



# Pharmaceutical Industry



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# Pharmaceutical Industry

## Evolution of “major” markets

- Not just USA, EU and Japan

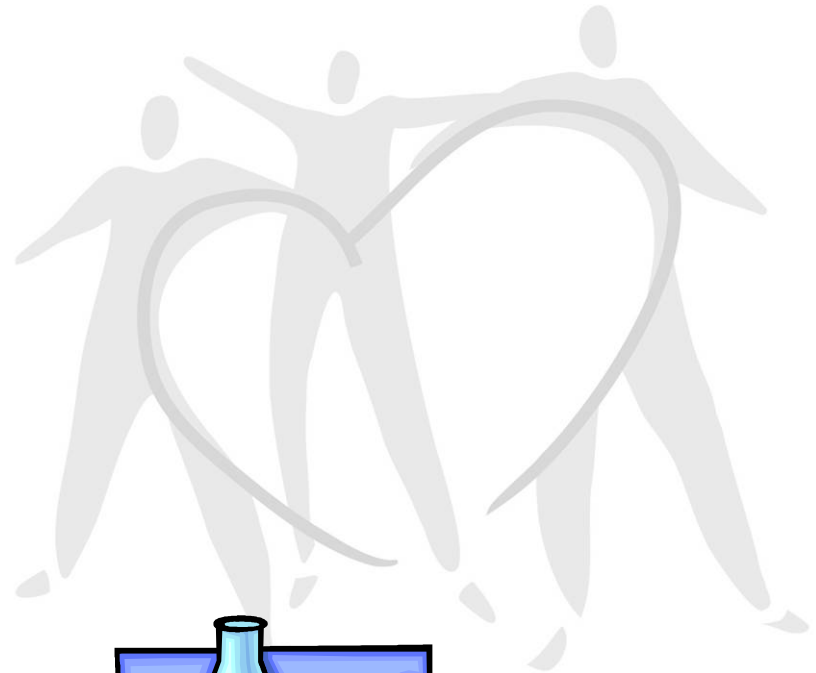
## Further consolidation of the research based industry

- Smaller number of larger companies with increased market share
- More global manufacturing sites

## Pressure on costs

- Further generic competition
- Drive on lean manufacturing
- Search for low cost suppliers

# Products



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# Products

## New products providing more targeted treatment for major diseases

- Pressure to increase efficacy whilst reducing side effects
- Impact of understanding of role of specific genes
- Increased role of biotechnology

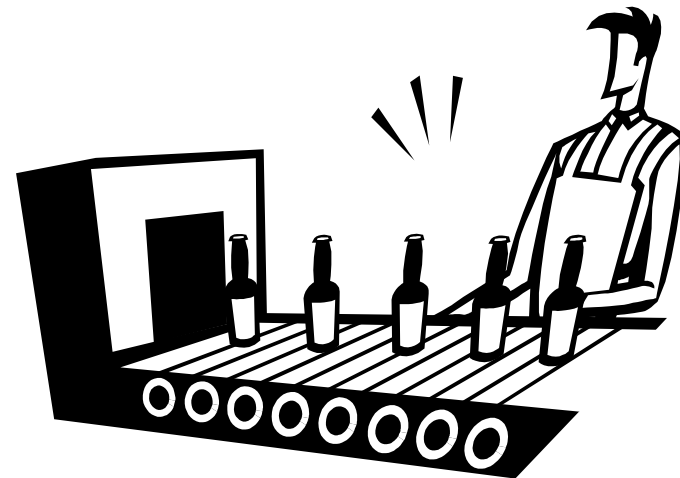
## More use of delivery technologies

- Inhalation / Nasal
- Skin patch
- Auto-injection

## Increase combination of drugs

- Multi-active products

# Processes



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# Processes - Production

## Better understanding of process critical parameters

- Concept of design space (ICH Q8)

## Further automation

- Increased use of process auto-regulation
- Links to on-line and in-line controls
- Electronic batch records

## Increasing complexity of processes

- Linked to delivery systems
- Use of biological / biotechnology process steps



# Processes – Product Analysis

## Increased technology

- On-line and in-line analysis in real time
- Chip base microanalysis methods

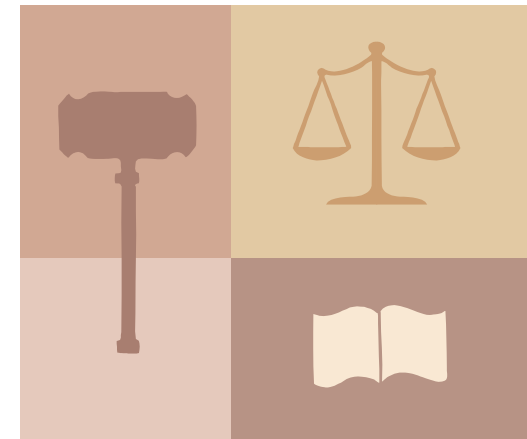
## Change in control strategies

- Monitoring of parameters that have proven correlation with end product quality

## Challenge to the concept of end product testing specification

- How to handle more data captured during production
- Move to parametric release

# Regulatory Requirements





# Regulatory Requirements - GMP

## Implementation of ICH Q8, Q9 and Q10

- Systematic approach
- Risk assessment

## Proliferation of site inspections by foreign inspectorates

- Result of increased regulation in market outside ICH / mutual recognition countries

## Proliferation of detailed GMP requirements

- As above

## Increased EU GMP requirements

- GMP for excipients
- GMP for packaging suppliers

## Increased notifications of product quality issues



# Regulatory Requirements - Dossier

## Electronic dossiers

- e-CTD format

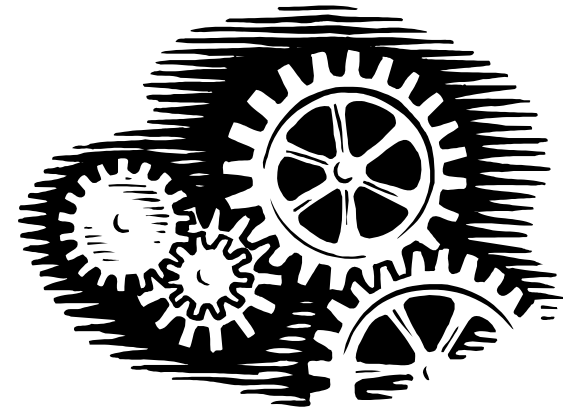
## Regulatory dossier maintenance

- Need to maintain all products with 'state of art' dossiers

## Revised manner for handling post-approval changes

- "Regulatory Agreements"
- Annual reporting

# Quality Systems



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# Quality Systems

Increased use of trend analysis systems to identify product quality issues

- Role of the product quality reviews

Use of risk management tools

- Implementation of ICH Q9

Increased use of management reviews to monitor effectiveness of overall quality systems

- Implementation of ICH Q10
- Link to financial control requirements

# The QP Role



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# ...so what for the QP role?

## Situation 1 – Best Case

Role concentrates primarily on Quality System in place

- To assure overall product quality
- To ensure compliance to “regulatory agreement”

Clear product / process design space available

- To enable a rapid analysis of impact of process deviations
- To be able to introduce post approval process improvement without waiting for regulatory changes

Ability to effectively use information technology

- Easy extraction of data from electronic batch record systems, LIMS etc.
- Use of statistical tools for trend analysis

Delegation of activities to other professional quality professionals



## ...so what for the QP role? Situation 2 – Worst Case

— The current batch-by-batch focus is retained...

- Detailed review of batch documentation

— ...to which is added all the additional tasks...

- Management reviews
- Product Quality reviews
- QP declarations on APIs, excipients, packaging items etc.

— ...and all of this drowning in a sea of data (but no information)...

- Automated processes
- Automated analysis (real time)

— ...with changes very difficult to make and control...

— ...and no delegation except to other QPs

**Thank you...**



**...and any questions??**



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