



ICH Q10 Pharmaceutical Quality Systems: An Industry Perspective

**APEC LSIF Quality Guidelines Seminar
Seoul, September 2007**

**The GSK Quality Management System for the
manufacture and supply of products**

Quality Management System

- *The introduction of the Quality Management System (QMS) for the manufacture and supply of products is a significant milestone for GSK. The quality of our products cannot be compromised: quality is vital for our patients and customers, our regulators and our shareholders. The QMS is critical in ensuring that quality is at the heart of everything we do, through product development, manufacture, supply and sale.*

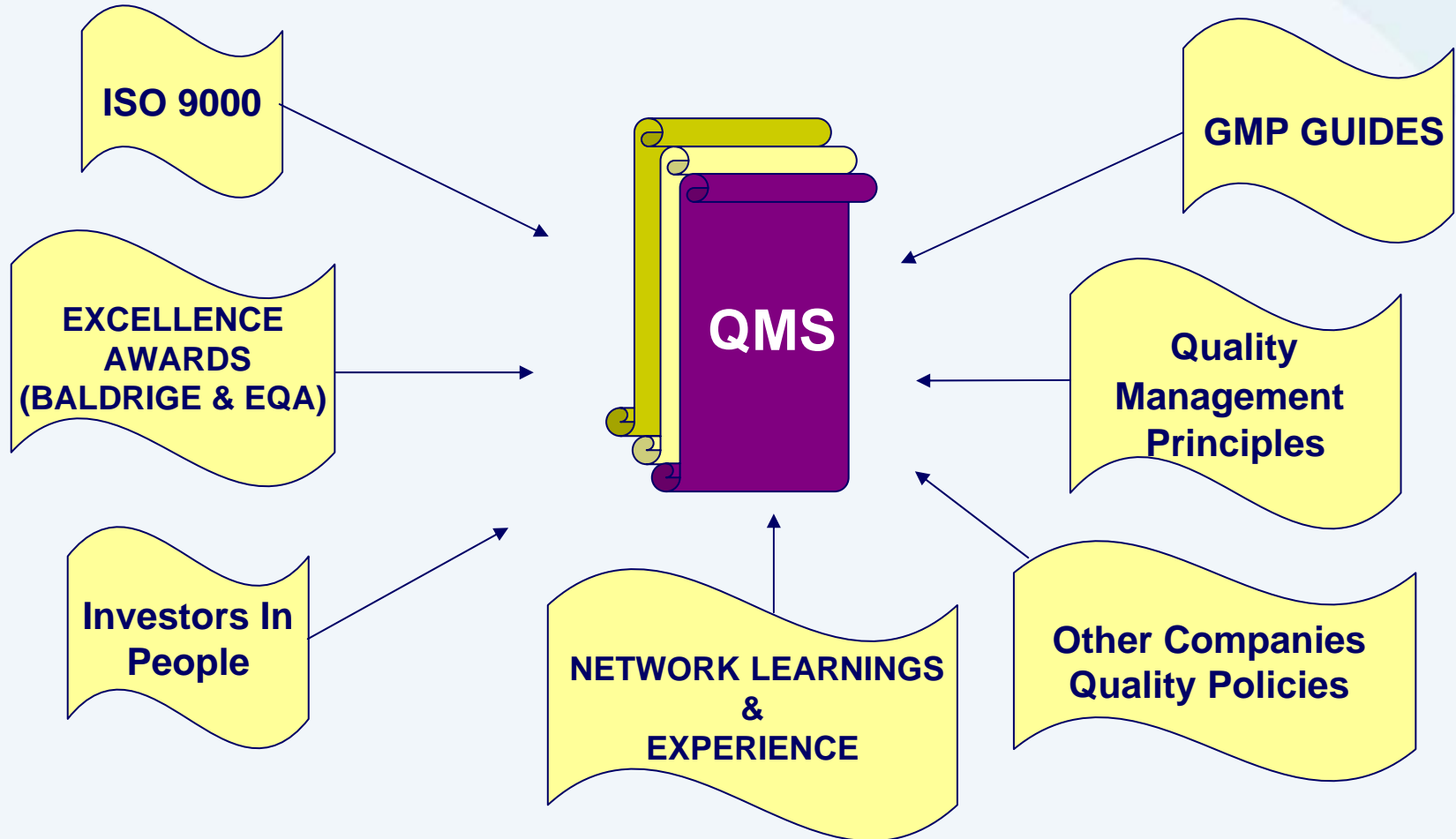
QMS objective

- To demonstrate world class leadership in quality, compliance and improvement.
- Recognises that one of the biggest risks to shareholder value is a loss of reputation with the regulators.
- Once a company runs into problems with the regulators it not only affects their ability to manufacture and supply existing products, but, as history shows, also severely impacts their ability to gain approval for new products.
- GSK shares the same goal as the regulators: to provide safe and effective products for our patients and customers.
- Building trust with the regulators so that they see us as a model, not as a target, plays a key role in meeting the expectations of the other groups.
- When implemented properly the QMS provides a framework and mechanism for us to meet these increasing compliance expectations across all our operations.

What is the QMS

- ... a leadership 'tool' that enables us to drive the business proactively towards our global quest to improve human life by enabling people to do more, feel better and live longer.
-an efficient system designed to ensure the quality of the product, meeting regulatory requirements and continuous business improvement. Setting minimum standards for GSK around the world.

QMS is a comprehensive system



Policies, processes and guidelines are aligned to international regulatory requirements, performance standards and benchmarking activities

The Evolving Pharmaceutical Environment – A Vision



From

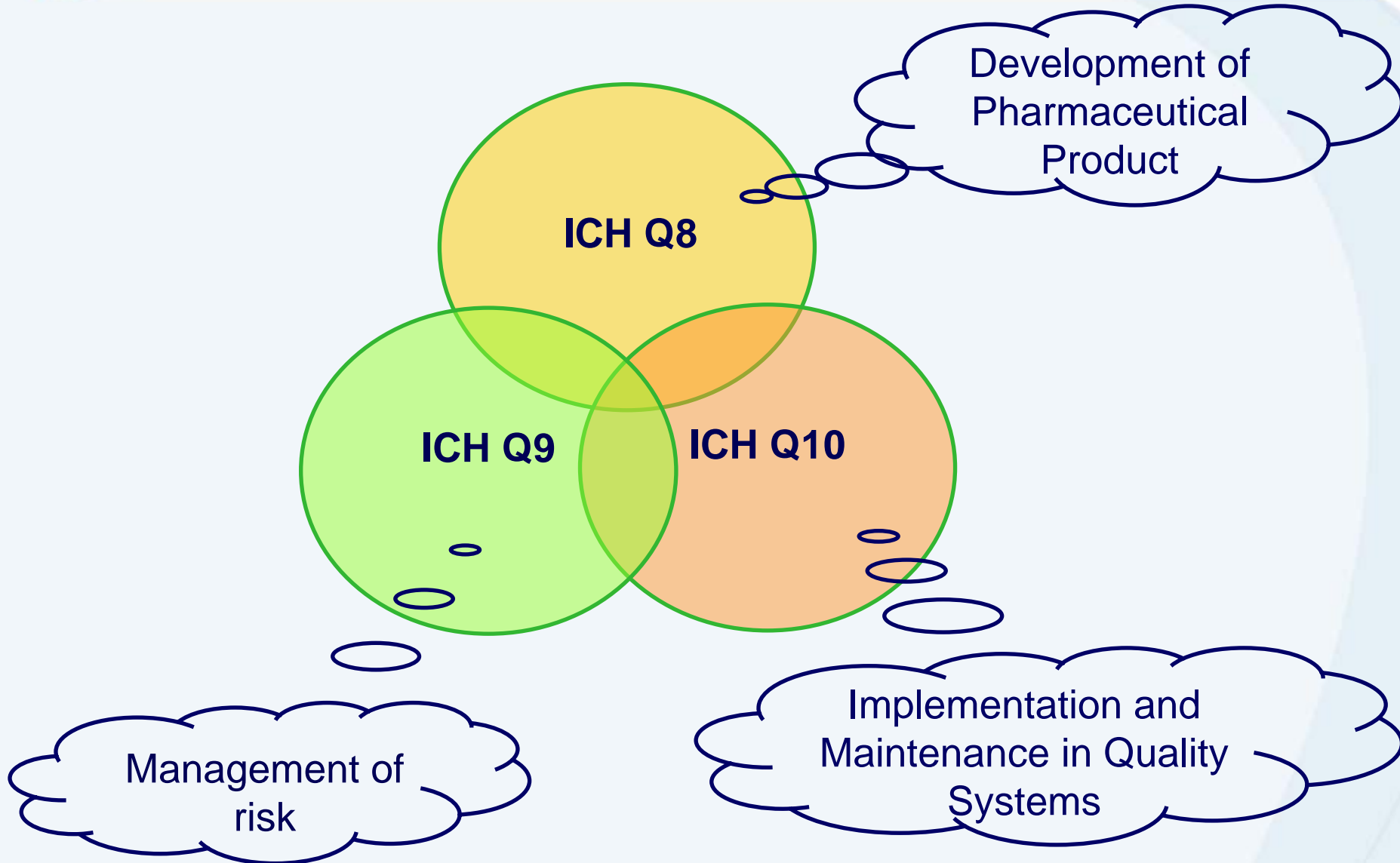
- Specifications based on process history
- End product testing
- Validation through three consecutive batches pre launch
- Focus on reproducibility, ignoring variation
- Processes locked down, changes require review. Less flexibility in lifecycle management
- Quality control



To

- Control strategy developed from process understanding and control
- Real time assurance of quality
- Ongoing validation through routine manufacture
- Focus on robustness, controlling variation
- Flexible process allowing continuous improvement
- Quality assurance

ICH Q8/Q9/Q10 – A Quality Strategy



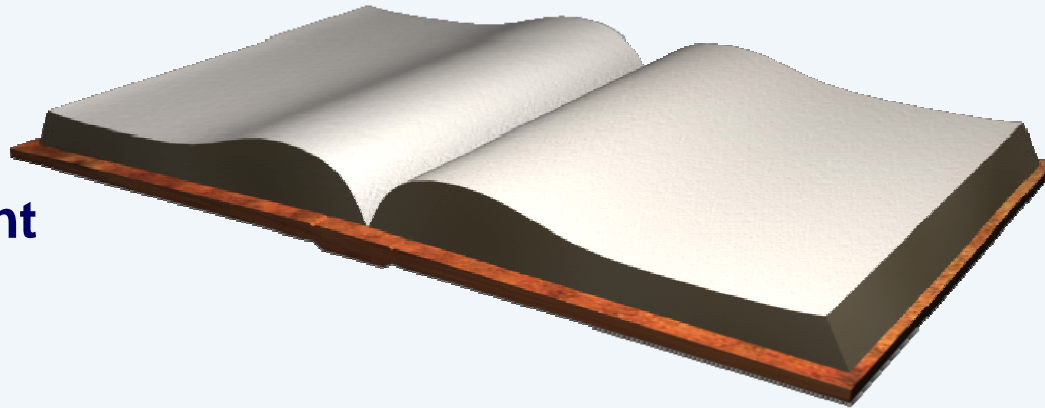
ICH Q10 – A Comprehensive Quality Strategy

- ICH Q10 (With ICH Q8 and ICH Q9) provides an opportunity for industry to make a step change in applying the concepts of Quality by Design (**Q8**) and Science-based Risk Assessment (**Q9**) within a modern Quality System (**Q10**)
 - Q8/Q9/Q10 are strategic guidance
- Q10 is seen as fully complementary to Q8 and Q9 but is clearly optional - however if a company chooses to adopt Q10 the guideline should be applied in full and not just in parts
- Maximum benefit to companies will be achieved through comprehensive adoption of all 3 ICH guidelines together
 - Highlighted in Q10
 - Provides a clear framework for companies and authorities to discuss how risk assessment is applied and how this fits with the quality system and science based approaches to developing and manufacturing pharmaceuticals.

ICH Q10 - Objectives

Achieve Product Realisation

**Facilitate
Continual
Improvement**



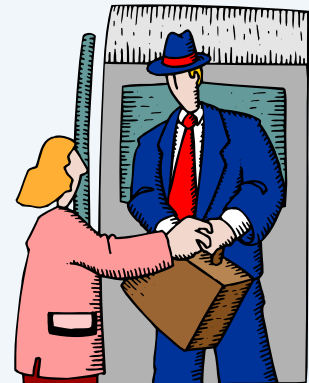
Establish and Maintain a State of Control

ICH Q10 - Scope

- ICH Q10 is a model for a pharmaceutical quality system that can be implemented throughout the different stages of a product lifecycle
 - *applies to pharmaceutical drug substances and drug products, including biotechnology and biological products, throughout the product lifecycle*
 - *It is intended that the elements of Q10 should be applied in a manner that is appropriate and proportionate to each of the product lifecycle stages, recognising the differences among them and the different goals at each stage*



Greater Independence
Different life stages



ICH Q10 - Key Elements

- This slides highlights some of the key elements of Q10 and hence of a Pharmaceutical Quality System
- **Management** including defined senior management responsibility; highlights the importance of leadership, governance, role definition, monitoring, communication, resource
- **Monitoring & review** systematic monitoring and review to ensure a state of control is maintained
- **Continual Improvement** foster excellence and continual improvement in products and systems
- **Knowledge management** effective and comprehensive capture and transfer of knowledge through the product lifecycle
- **Change Control** highlights the importance of change management systems including management of changes within the defined design space even though as outlined in Q8 they may not requiring regulatory action

ICH Q10 - Key Advantages for Industry

- Q10 allows a harmonized concept of a Pharmaceutical Quality System between the three ICH regions which should be helpful to industry
 - Extension and acceptance of these concepts to other regions will reflect the truly global pharmaceutical industry
 - How to manage with differing global requirements?
- Application of Q10 will help to demonstrate industry and regulatory commitment to robust quality systems and technical innovation and enhance consistent global availability of medicines
- It will also encourage reduction of variability leading to more consistent product quality, improved process robustness and efficiency
- Reinforce the bridge between development and manufacturing including importance of knowledge management throughout the product lifecycle
- Benefits outlined in Annex 1 of ICH Q10 recognise the potential benefits for industry and regulators

ICH Q10 – Annex 1 – Potential Opportunities to Enhance Science and Risk Based Regulatory Approaches

But may make compliance with evolving GMP requirements easier

Allows limited regulatory resource to be applied where it will have greatest impact

<u>Scenario</u>	<u>Potential Opportunity</u>
1. Comply with GMPs	Compliance – status quo
2. Demonstrate effective pharmaceutical quality system, including effective use of quality risk management principles (e.g., ICH Q9 and ICH Q10).	Opportunity to: <ul style="list-style-type: none">• increased use of risk-based approaches for regulatory inspections
3. Demonstrate product and process understanding, including effective use of quality risk management principles (e.g., ICH Q8 and ICH Q9).	Opportunity to: <ul style="list-style-type: none">• facilitate science-based pharmaceutical quality assessment;• enable innovative approaches to process validation;• establish real-time release mechanisms.

Move the pharmaceutical industry into the 21st Century

ICH Q10 – Annex 1 – Potential Opportunities to Enhance Science and Risk Based Regulatory Approaches

Decrease
reliance on
inspections

<p>4. Demonstrate effective pharmaceutical quality system and product and process understanding, including the use of quality risk management principles (ICH Q8, ICH Q9 and ICH Q10).</p>	<p>Opportunity to:</p> <ul style="list-style-type: none">• increased use of risk-based approaches for regulatory inspections;• facilitate science-based pharmaceutical quality assessment;• optimize science and risk-based post-approval change processes to maximize benefits from innovation and continual improvement;• enable innovative approaches to process validation;• establish real-time release mechanisms.
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Facilitate
regulatory
flexibility

ICH Q10 – Interaction with cGMP

- “Q10 is not intended to create any new expectations beyond the current regulatory requirement” is but intended to **complement** current GMPs through an increased emphasis on 3 specific areas, hence the content that is **in addition to cGMP’s is clearly optional**:



Management responsibility and oversight



Ongoing improvement and innovation throughout the product lifecycle



Use of risk based decision making for quality decisions

ICH Q10 – The challenge for Industry

- To deliver cohesive and comprehensive implementation of concepts and elements of QbD (Q8/Q9/Q10) across the product lifecycle
- To develop/reinforce integrated or complementary systems across the product lifecycle to facilitate a comprehensive Quality Strategy between development and manufacturing
- To capture, transfer and manage knowledge throughout the product lifecycle to facilitate continual improvement

ICH Q10 - Current Status

- Step 3 reached (regulatory consultation) May 2007



- Comments from Industry by November 2007

ICH Q10 Pharmaceutical Quality Systems

- cGMP is already mandatory
- Quality Systems are already in place, this is not new!
- ICH Q10 is not mandatory
 - but maximum benefits envisaged when concepts in Q8/Q9/Q10 are embraced
- The pharmaceutical industry operates globally, global acceptance of concepts maximises benefits for all
- Successful implementation will increase trust between Regulators and Industry and will facilitate more effective oversight by Regulatory authorities, allow greater flexibility in manufacturing for Industry and will ensure the quality of drug products for patients



THANK YOU