Implementation of ICH Q8, Q9, Q10

Q-IWG
Status and Update

International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use

ICH Q8, Q9 & Q10 A real opportunity

- Benefit of a New Paradigm
  - Process Understanding
  - Process Capability and Robustness
  - Continuous improvement changes
  - A life cycle approach: A focus investment during the development with the benefit at the manufacturing
  - Increased flexibility to implement
  - QbD, a reality: Already 14 centralised approved product application in EU including elements of a QbD approach
  - Quality by design : A cultural change
  - Annex 1 of ICH Q10

Q-IWG: Status and Update

Scenario	Potential Opportunity
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: ○ increase 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: ○ facilitate science based pharmaceutical quality assessment; ○ enable innovative approaches to process validation; ○ establish real-time release mechanisms.
4. Demonstrate effective pharmaceutical quality system and product and process understanding, including the use of quality risk management principles (e.g., ICH Q8, ICH Q9 and ICH Q10).	Opportunity to: ○ increase use of risk based approaches for regulatory inspections; ○ facilitate science based pharmaceutical quality assessment; ○ optimise science and risk based post-approval change processes to maximise benefits from innovation and continual improvement; ○ enable innovative approaches to process validation; ○ establish real-time release mechanisms.

A step by step: A cultural change

- Learning by doing
- Support of the implementation is required
  - From the theory to the practical aspect
  - Clarifying in Q&A
  - Training / workshop
- Role and value of Quality-Implementation Working Group (Q-IWG)

ICH Q-IWG: Goals and Achievements

- Q&A 46 already done & complementary to come
- Cooperation outside the 3 ICH Regions facilitated by the Global Cooperation Group (GCG) in ICH
- Collaboration with other not-for-profit organisation e.g. PIC/S, PDA (PCMO), ISPE (PQLI),…
- Consider possible gap/barrier on existing ICH Q guidelines with the new paradigm: Review & proposed actions
- Training & Workshop

Q-IWG Goals and Achievements: Q&A

- **This Questions and Answers document (Q&A) are there to support the harmonised implementation the guidelines of ICH Q8, Q9 and Q10**
  - Brussels Oct 08 First Q&A ICH SC approval: April 2009
  - Yokohama June 09 New Q&A ICH SC approval: June 2009
  - St Louis Oct 09 New Q&A ICH SC approval: October 2009
- **Outcome from Tallinn / Washington D.C. / Tokyo**
  - An opportunity to clarify and to complete existing Q&A

Q-IWG: Q&A Status

	currently	open
For general clarification	**3**	
Quality by Design (QbD) topics	**1**	**+ 3**
- Design Space	8	**+ 3**
- Real Time Release Testing	12	**+ 8**
- Control Strategy	5	
Pharmaceutical Quality System	**8**	**+ 1**
GMP Inspection practice	**3**	
Knowledge Management	**5**	
Software solution	**1**	
Total	**46**	**+15**

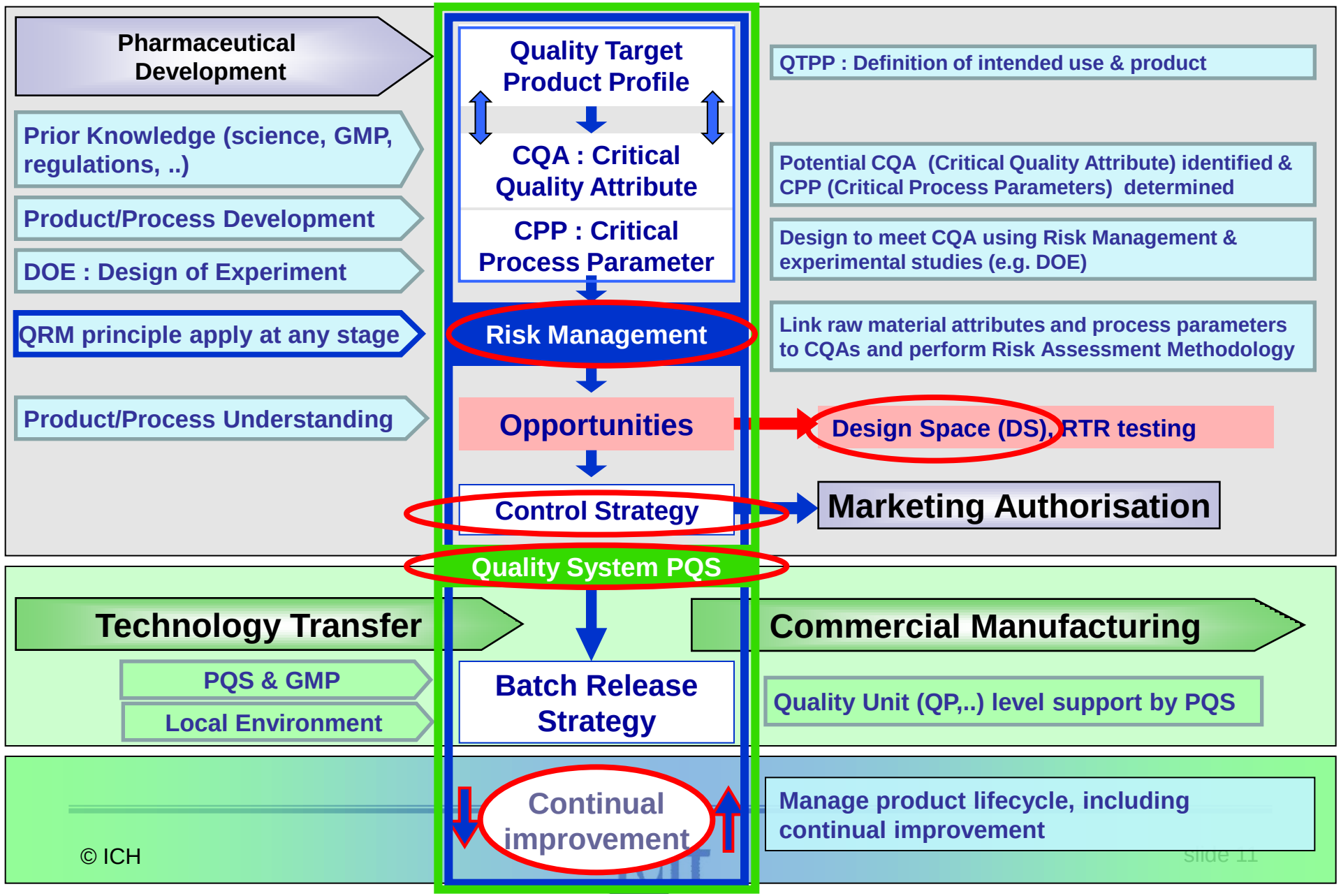
Q-IWG Goals and Achievements: External Collaboration

- Explore possibility of collaborations with non-profit scientific organisations by soliciting input on technical issues as appropriate
- Evaluate relevant papers, etc. and consider referencing in response to questions
- Facilitate training and communication to ensure globally consistent implementation of ICH Q8, Q9, Q10

This ICH Q-IWG Training / Workshop: What is the difference?

- Only 3 workshops endorsed and operated by the ICH Q-IWG
- A story based on a case study, on the life cycle aspect. Development assessment manufacturing and inspection
- The same workshop will be offered by the same faculty in each of the three ICH regions.
- All attendees to participate in the breakouts on each life
- Report back for future Q-IWG Q&A development
- Workshop materials will be published by ICH and can be used for internal training by authorities (assessors and inspectors) and industry
- The idea behind: to illustrate the concept of enhanced approach, which can be apply from simple to complex molecule
- Complexity of the scheme …

Key Steps for a product under Quality by Design (QbD)



Q-IWG Goals and Achievements : Outcome of the Tallinn training

- **Key messages: clear or not**
  - Critical / Non Critical
- **Practical concerns of implementation**
  - DS : Design Space supports life cycle management
  - CS : Relationship between RTRt and specification
  - QRM : Outline relative risk and how to present it
  - PQS : Flexibility to allow Continual Improvement
- **Clarification required**
  - CTD : How and where to present QbD,…..

Q-IWG: Status and Update

THANK YOU