Quality Risk Management ICH Q9

Executive summary

for competent authorities and industry

Disclaimer: *This presentation includes the author's views on quality risk management theory and practice. The presentation does not represent official guidance or policy of authorities or industry.*

Executive summary

The situation today

The situation today for both regulators and industry

> Increasing external requirements

> Increasing efforts and costs

> Growing complexity and scope of risks

Empowerment & Flexibility is needed

> Master complexity and streamline decision making

> Proactive disclosure build trust and understanding

> Improve communication through sharing best practice and science based knowledge

> Convert data into knowledge

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New Regulatory Paradigm

- **ICH Regulators:**
  - > **FDA: New paradigm with the 21st Century GMP initiative**
  - > **EMEA: Revised EU directives**
  - > **MHLW: Revised Japanese law (rPAL)**
- **EU & Japan became involved at ICH GMP Workshop in July 2003: 5 year vision agreed:**

  "Develop a harmonised pharmaceutical quality system applicable across the life cycle of the product emphasizing an integrated approach to quality risk management and science"
- **Consequent ICH Expert Working Groups (EWG):**
  - > **ICH Q8, on Pharmaceutical Development, doc. approved 2005**
  - > **ICH Q9, on Quality Risk Management, doc. approved 2005**
  - > **ICH Q10, on Quality Systems, topic accepted 2005**

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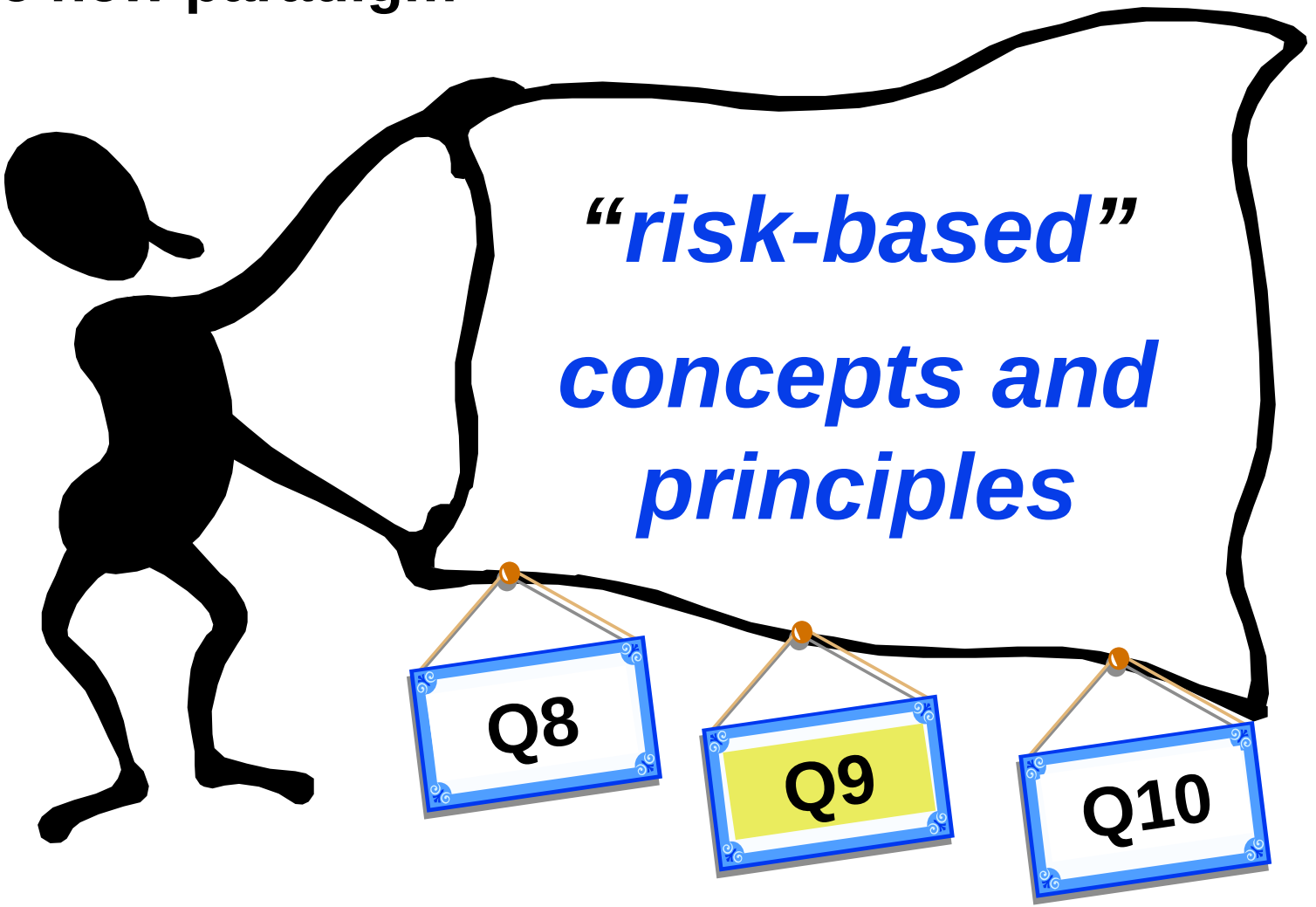
The new paradigm



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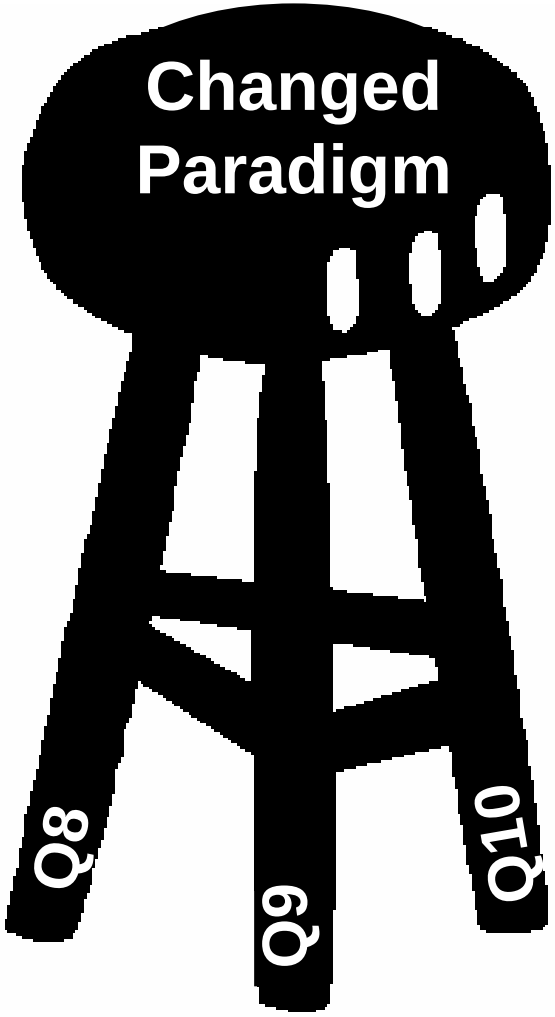
Incremental steps



Pharmaceutical Development (Q8)

Past: Data transfer / Variable output

Present: Knowledge transfer / Science based / Consistent output

Quality Risk Management (Q9)

Past: Used, however poorly defined

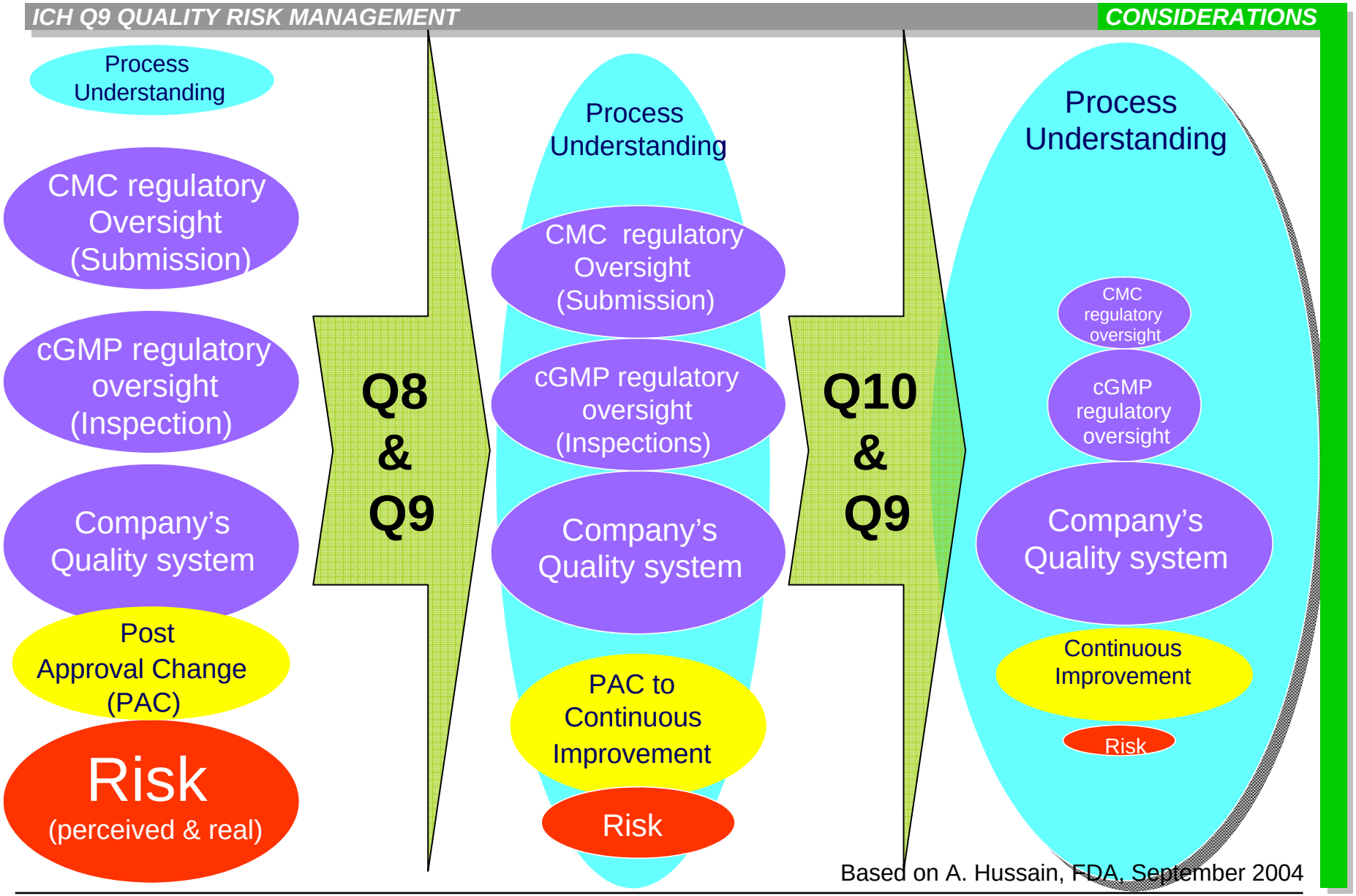
Present: Opportunity to use structured process thinking

Pharmaceutical Quality Systems (Q10)

Past: GMP checklist

Future: Quality Systems across product life cycle

Executive summary



Executive summary

The Desired State driven by ICH Q9

- **Manage risk to patient, based on science:**
  - > **Product, process and facility**
  - > **Robustness of Quality System**
  - > **Relevant controls to assess & mitigate risk**
- **Level of oversight required commensurate with the level of risk to patient for:**
  - > **Marketing authorisation applications**
  - > **Post-approval change review**
  - > **GMP inspections**

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The Desired State

- **Barriers to continuous improvement reduced or removed**
  - > Improved manufacturing efficiency
  - > Sustained or improved product quality
- **Specifications based on parameters that truly impact product quality**
- **Common understanding and language on risk**
- **Both, industry and competent authorities focus on areas of greatest risk and understanding of residual risks**

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Pharmaceutical industry and quality risk management

- **Pharmaceuticals have lagged behind related industries in adopting structured risk management in the quality area; e.g.**
  - > Medical devices have ISO 14971
  - > Food industry uses HACCP

- **We are using quality risk management but**
  - > Implementation is patchy
  - > It is often not fully integrated with rest of the Quality System

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Advantages of quality risk management as technique

- **Improves decision making**
  - > **Identifies what gives most benefit to the patient**
- **Is scientific & data-driven**
  - > **Reduces subjectivity**
- **Ranks risk - allows prioritization**
  - > **Better use of resources**
- **Means of building in Quality**
- **Improves transparency - inside organisation and builds trust with competent authorities**
  - > Enables regulatory flexibility
- **Benefits apply throughout product lifecycle**

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Why did we need ICH Q9?

- **To ensure a common understanding of Quality Risk Management (QRM) among industry and competent authorities**
- **To facilitate moving to the "Desired State"**
  - > **To facilitate communication and transparency**
  - > **To move from 'fire fighting' to management of risk**
- **ICH Q9 explains**
  - > **A common language and process**
  - > **Potential methodologies for QRM**
  - > **Where QRM can add value**

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Quality Risk Management is NOT

- **Hiding risks**
- **Justifying poor quality of product and / or processes**
- **Excusing industry's obligation to comply with regulatory requirements**

HOWEVER

- **It might bring about the revision or withdrawal of some non risk base guidance**

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What does Senior Management need to do?

- **Ensure organisation is aware of ICH Q9 and the opportunity it affords**
  - > **Appropriate education and training**
- **Encourage open, risk aware culture**
  - > **Establish & support "QRM leaders" across organisations**
- **Encourage integration of Quality Risk Management with existing Quality systems**
  - > **Do NOT set up as a separate department**
  - > **Coordinate implementation and resource allocation**
  - > **Prioritise; start small, learn as you go**

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Conclusions

- **ICH Q9, together with "Pharmaceutical development" (ICH Q8) and "Quality systems" (ICH Q10), provides opportunity for a revised, optimised and, less restrictive regulatory paradigm**
  - > **Based on scientific knowledge**
  - > **Enable continuous improvement**
  - > **Greater transparency and efficiency**
  - > **Focusing on things that add value for patients**
  - > **Improved relationship between industry and competent authorities based on trust**
- **We must seize this opportunity**

Executive summary

Keep always in mind the

Principles of Quality Risk Management

The evaluation of the risk to quality should be based on scientific knowledge and ultimately link to the protection of the patient

The level of effort, formality and documentation of the quality risk management process should be commensurate with the level of risk

ICH Q9


Focus resources
where they matter most to protect the patient