Quality Policy

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Survey: show of hands …

- Who has one?
- Who knows what it says?
- Who knows … & is not in Quality Department?
- Does your CEO / Director know it?

- Write it down (for later)

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Outline:

- Why have one?
- Who sets it?
- What does it need to cover?
- What do you do with it?

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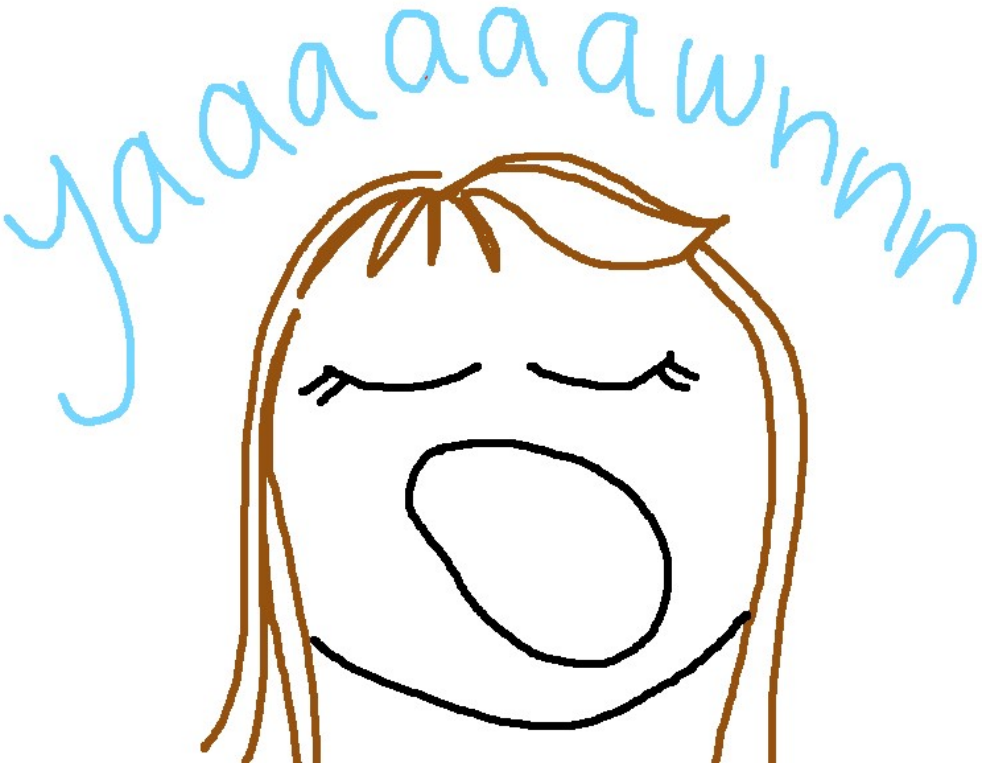
Why?

- More work for QA
- More paper
- Nobody will read it
- What is the point?



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Not a good attitude

Why?

- More work for QA
- More paper
- Nobody will read it
- What is the point?

Let's rather understand where this has come from …

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Let's rather understand where this has come from …

Why? Background.

- Who is ICH? http://www.ich.org/home.html
- ICH: International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use.
- Started 1992
- Harmonizing across US, EU and Japan, initially. Now far more global.
- Both Industry and Regulators participate, up-to-date thinking.
- Publishes Quality, Safety, Efficacy and Multidisciplinary guidelines.

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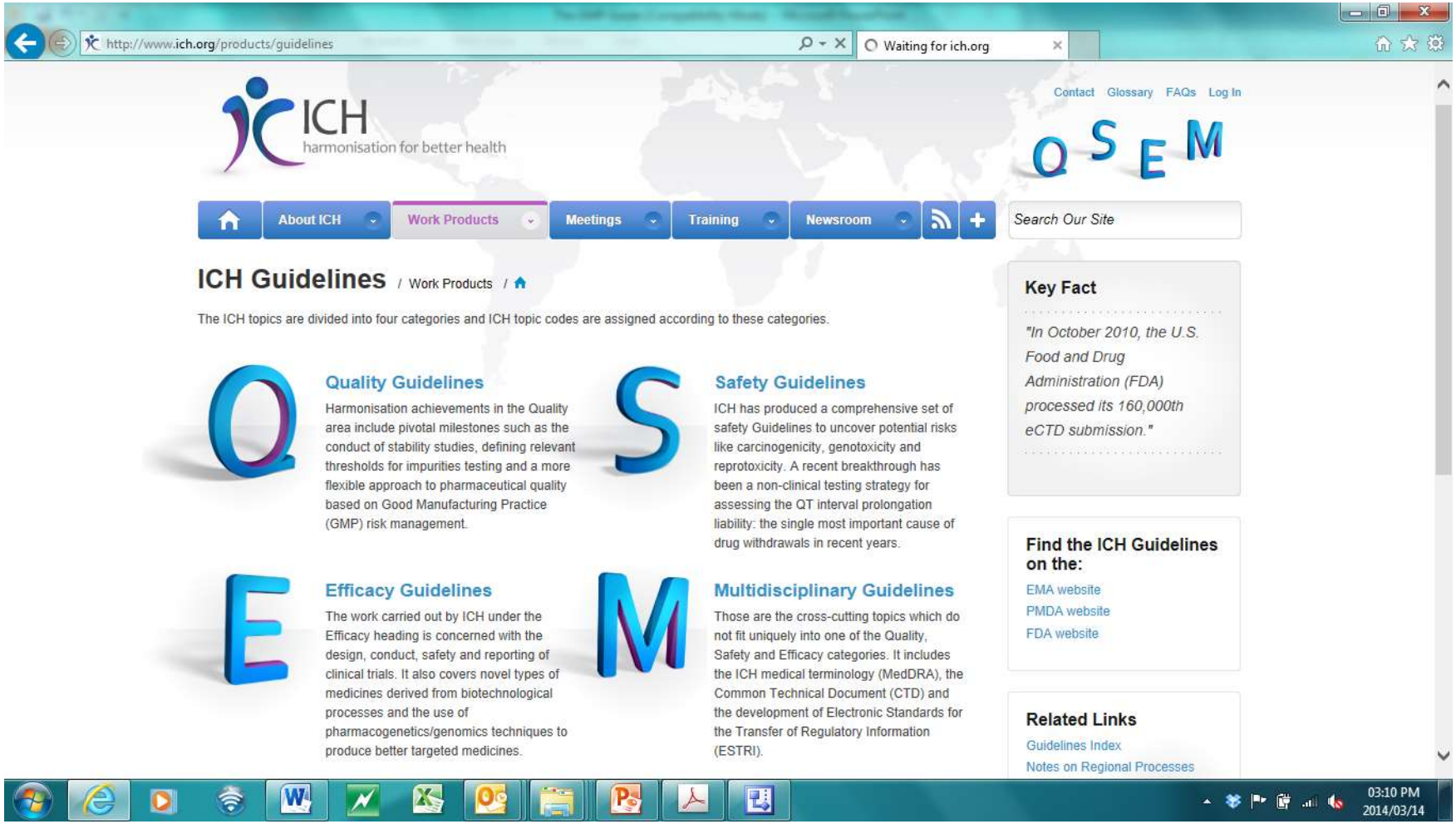

www.ich.org

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Why?

- ICH Q8, Q9, Q10 had a fundamental impact on the GMPs. (Webinar on this last year.)
- ICH Q10: Pharmaceutical Quality System (2008)
- Shift of responsibility for quality to the senior managers. Does not stop with the Quality managers.
- Incorporate into the GMPs many of the principles of ISO 9001: Quality Management Systems, applicable across manufacturing industries.
- E.g. CAPA, Management Review.
- Also Quality Policy, Quality Objectives and Quality Manual.
- Resulted in 7 of the 9 EU GMP Chapters being updated in the last in 2012-2014. Likely to cascade to other international GMPs.
- PIC/S GMP part 1 2017

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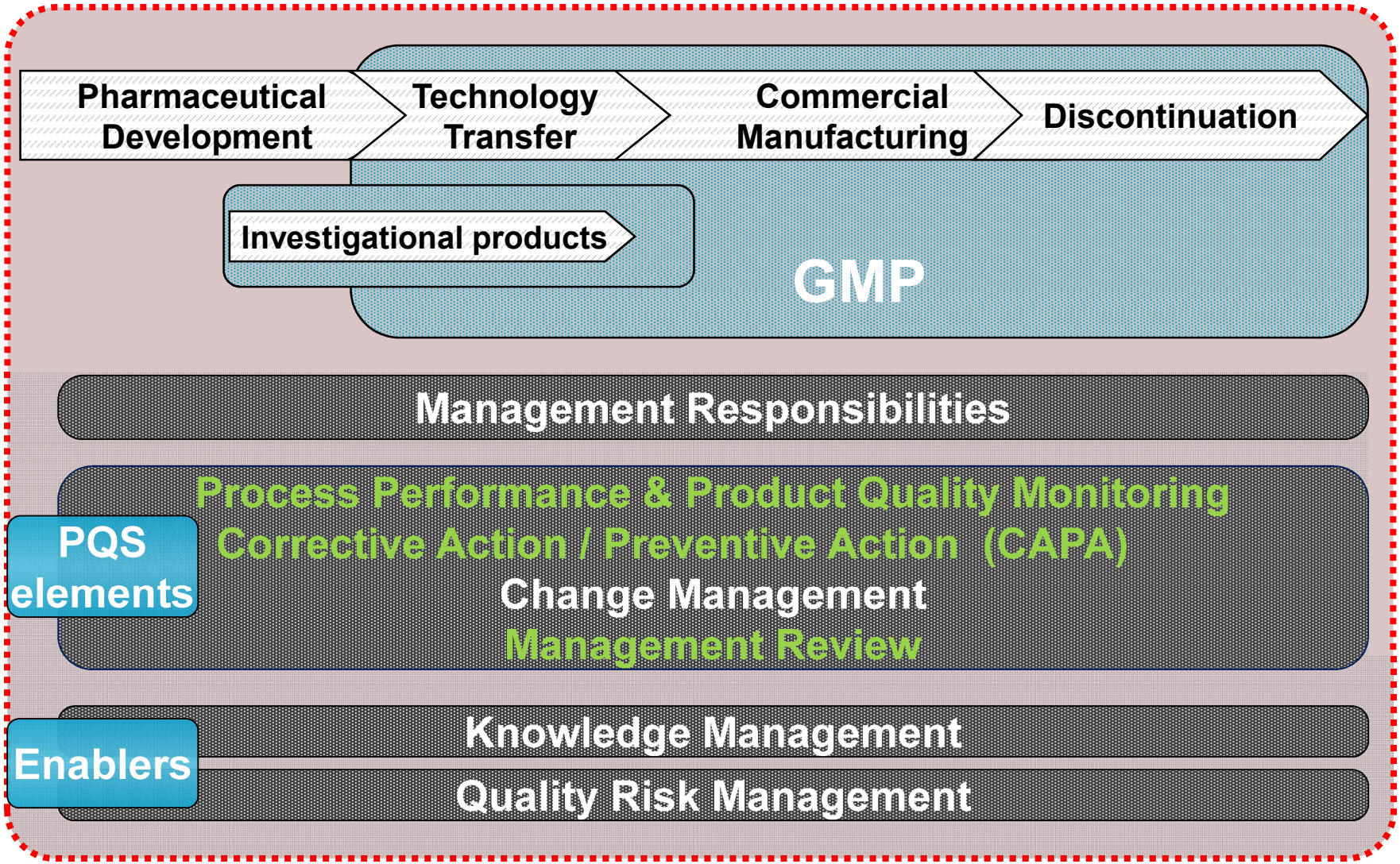
ICH Q10



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Why?

"Senior management should establish a quality policy that describes the overall intentions and direction of the company related to quality"

ICH Q10: Pharmaceutical Quality System (2008)

http://www.ich.org/products/guidelines/quality/article/quality-guidelines.html

2.2 Quality Policy

(a) Senior management should establish a quality policy that describes the overall intentions and direction of the company related to quality.

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Why?

- a strategic document
- directive of the top management with respect to quality
- values and framework
- to allow executive management to be consistent in the was it conducts business, especially in a crisis
- to share this with employees
- basis for setting quality objectives – & behaviours

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Why?

- Added in last EU GMP Chapter 2 Personnel update (2013) & PIC/S I Chapter 2 (Jan 2017)

"Senior management should establish a quality policy that describes the overall intentions and direction of the company related to quality."

organisation. Senior management should establish a quality policy that describes the overall intentions and direction of the company related to quality and should ensure continuing suitability and effectiveness of the quality management system and GMP compliance through participation in management review.

Eudralex: https://ec.europa.eu/health/documents/eudralex/vol-4_en
PIC/S: https://www.picscheme.org/en/publications?tri=gmp

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Summary of Quality Policy requirements:

- In place.
- …
- …
- …
- …

Your Quality Policy in place?

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Outline:

- Why have one?
- Who sets it?
- What does it need to cover?
- What do you do with it?

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Who?

"_____ should establish a quality policy that describes the overall intentions and direction of the company related to quality"

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Who?

"Senior management should establish a quality policy that describes the overall intentions and direction of the company related to quality"

ICH Q10: Pharmaceutical Quality System (2008)
AND
EU GMP Chapter 2 Personnel (2013)
AND
PIC/S I GMP Chapter 2 Personnel (2017)

Top management shall demonstrate leadership and commitment with respect to the quality management system by:
b) ensuring that the quality policy and quality objectives are established for the quality management system

ISO 9001 Quality Management Systems - Requirements (2015)

Who is senior (top) management?

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Summary of Quality Policy requirements:

- In place.
- Driven / Endorsed by management.
- …
- ...
- …

In place for your Quality Policy?

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Outline:

- Why have one?
- Who sets it?
- What does it need to cover?
- What do you do with it?

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What?

2.2 Quality Policy

(a) Senior management should establish a quality policy that describes the overall intentions and direction of the company related to quality.

(b) The quality policy should include an expectation to comply with applicable regulatory requirements and should facilitate continual improvement of the pharmaceutical quality system.

ICH Q10: Pharmaceutical Quality System (2008)

- Intentions and direction of company for Quality
- Intention to comply with regulations
- Commitment to Continual Improvement of PQS

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What?

- The quality manual, or equivalent documentation, should include a quality policy statement of management's commitment to an effective quality management system and to good professional practice.

- These policies should include a code of ethics and code of proper conduct to assure the reliability and completeness of data, including mechanisms for staff to report any quality and compliance questions or concerns to management.

WHO TRS 966 Annex 5 Guidance on good data and record management practices (2016)
http://www.who.int/medicines/areas/quality_safety/quality_assurance/guidelines/en/

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What?

5.2.1 Establishing the quality policy

Top management shall establish, implement and maintain a quality policy that:

a) is appropriate to the purpose and context of the organization and supports its strategic direction;

b) provides a framework for setting quality objectives;

c) includes a commitment to satisfy applicable requirements;

d) includes a commitment to continual improvement of the quality management system.

ISO 9001 Quality Management Systems - Requirements (2015)

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Summary of requirements:

- In place
- Driven / Endorsed by management.
- Describes Quality intentions, compliance to regulations, continuous improvement.
- Commitment to PQS, professional and ethical practice
- Provides the basis for Quality Objectives
- …

In place for your Quality Policy?

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Outline:

- Why have one?
- Who sets it?
- What does it need to cover?
- What do you do with it?

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Use?

(c) The quality policy should be communicated to and understood by personnel at all levels in the company.

(d) The quality policy should be reviewed periodically for continuing effectiveness.

ICH Q10: Pharmaceutical Quality System (2008)

intentions and direction of the company related to quality and should ensure continuing suitability and effectiveness of the quality management system and GMP compliance through participation in management review.

EU GMP Chapter 2 Personnel (2013)

5.2.2 Communicating the quality policy

The quality policy shall:

a) be available and be maintained as documented information;

b) be communicated, understood and applied within the organization;

c) be available to relevant interested parties, as appropriate.

ISO 9001 Quality Management Systems - Requirements (2015)

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Summary of Quality Policy requirements:

- In place Why?
- Driven / Endorsed by management. Who?
- Describes Quality intentions, compliance to regulations, continuous improvement. What?
- Commitment to PQS, professional and ethical practice What?
- Provides the basis for Quality Objectives What?
- Known and understood – CEO to floor, external stakeholders (often on website). Use?
- Reviewed periodically for continuing relevance (usually as part of management review). Use?

How many of these are in place for your Quality Policy?

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Example Quality Policy

Our company is committed to providing innovative high quality products and services that meet or exceed the expectations of our customers. This includes:

- Maintaining a shared quality vision and a focus on continuous improvement to our products, processes, and services (including delivery),
- Understanding the requirements and meeting the needs of our customers,
- Involving all employees in the delivery of quality products and services, and
- Meeting all current requirements for national and international regulations.

•Shows Commitment to quality
•Able to generate Quality Objectives
•Developed by Senior Management

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Some Examples

- Sanofi
- Pfizer
- Globe Pharmaceuticals

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Quality Policy Example

- The Quality mission is to assure that COMPANY X commercial and clinical products are manufactured, tested and released to meet the highest standards for quality, safety, identity, strength and purity, while facilitating innovation and improvement and adding value to COMPANY X.

- We are committed to successful collaboration with internal and external customers to ensure our customers are educated on COMPANY X Quality expectations, assuring GXP regulations are met or exceeded, best practices are incorporated and robust and efficient Quality processes are developed, followed and continuously improved.

Chris Masterson
A practical approach to implementing ICH Q10
Pharmaceutical Quality Systems