

# Quality Policy

Dr Maureen Dennehy

[maureen@qast.co.za](mailto:maureen@qast.co.za)

<http://www.qast.co.za>





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)

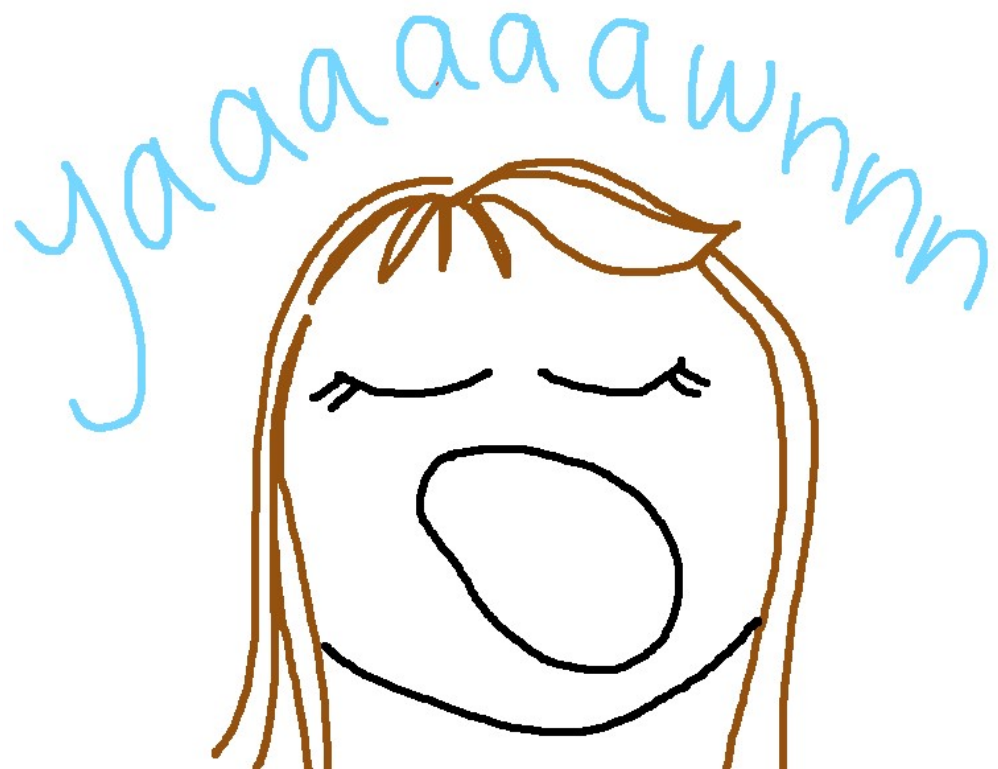


## Outline:

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

## Why?

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





**Why?**

Not a good attitude

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

yaaaaaawnnn



Let's rather understand  
where this has come from ...



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.



The screenshot shows the ICH (International Council for Harmonisation) website. The browser address bar displays <http://www.ich.org/products/guidelines>. The page features a navigation menu with links: Home, About ICH, Work Products, Meetings, Training, Newsroom, and a search bar labeled "Search Our Site".

The main content area is titled "ICH Guidelines" and includes a sub-header "Work Products". Below this, a paragraph states: "The ICH topics are divided into four categories and ICH topic codes are assigned according to these categories."

The four categories are presented in a 2x2 grid:

- Q Quality Guidelines**: Harmonisation achievements in the Quality area include pivotal milestones such as the conduct of stability studies, defining relevant thresholds for impurities testing and a more flexible approach to pharmaceutical quality based on Good Manufacturing Practice (GMP) risk management.
- S Safety Guidelines**: ICH has produced a comprehensive set of safety Guidelines to uncover potential risks like carcinogenicity, genotoxicity and reprotoxicity. A recent breakthrough has been a non-clinical testing strategy for assessing the QT interval prolongation liability: the single most important cause of drug withdrawals in recent years.
- E Efficacy Guidelines**: The work carried out by ICH under the Efficacy heading is concerned with the design, conduct, safety and reporting of clinical trials. It also covers novel types of medicines derived from biotechnological processes and the use of pharmacogenetics/genomics techniques to produce better targeted medicines.
- M Multidisciplinary Guidelines**: Those are the cross-cutting topics which do not fit uniquely into one of the Quality, Safety and Efficacy categories. It includes the ICH medical terminology (MedDRA), the Common Technical Document (CTD) and the development of Electronic Standards for the Transfer of Regulatory Information (ESTRI).

On the right side of the page, there is a "Key Fact" box with the text: "In October 2010, the U.S. Food and Drug Administration (FDA) processed its 160,000th eCTD submission." Below this is a section titled "Find the ICH Guidelines on the:" with links to the EMA website, PMDA website, and FDA website. At the bottom, a "Related Links" section includes links to the Guidelines Index and Notes on Regional Processes.

The Windows taskbar at the bottom shows the system clock as 03:10 PM on 2014/03/14.

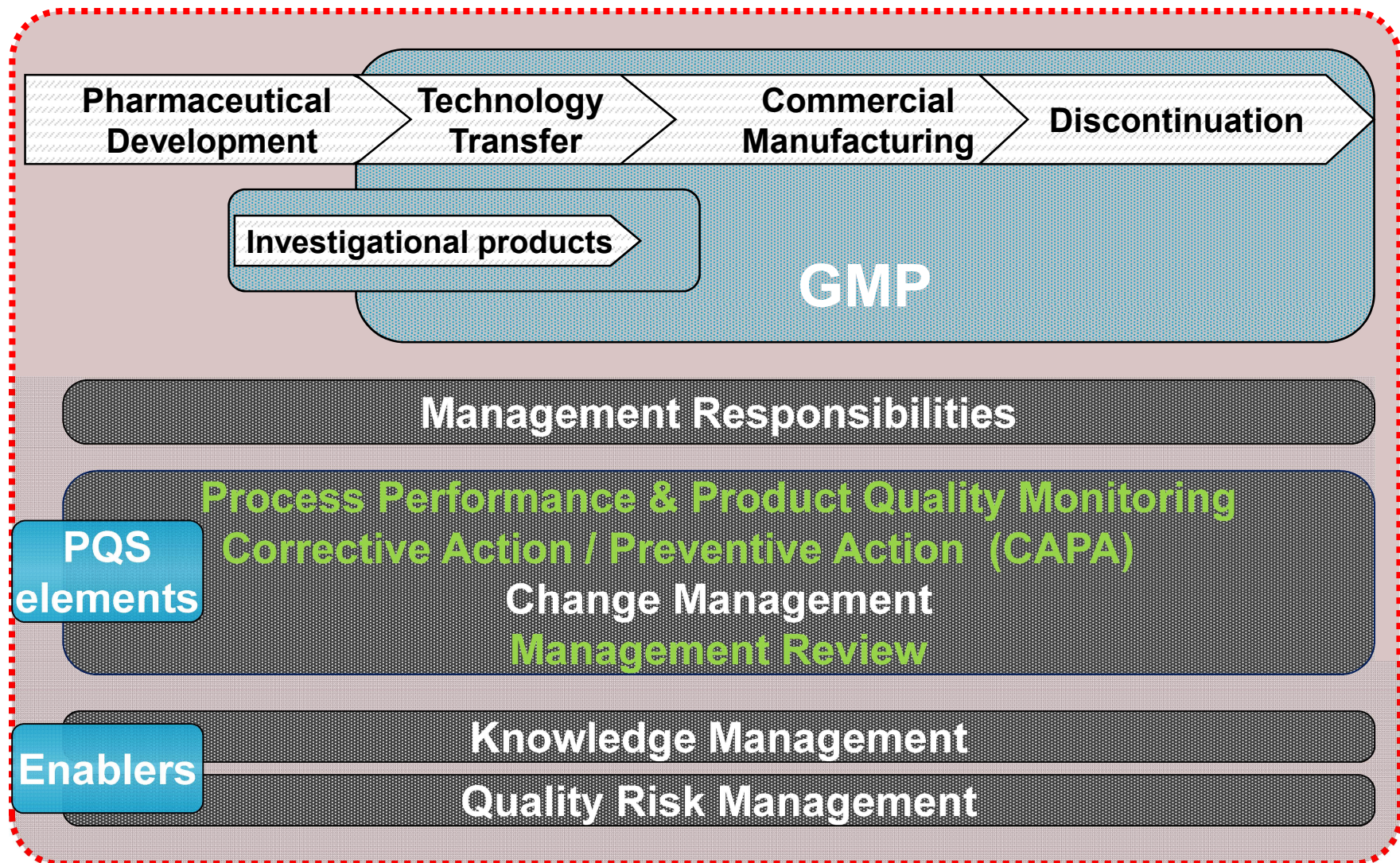




# Why?

- 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

## ICH Q10



# 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.



## 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 way it conducts business, especially in a crisis
- to share this with employees
- basis for setting quality objectives – & behaviours





## 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](https://ec.europa.eu/health/documents/eudralex/vol-4_en)  
PIC/S: <https://www.picscheme.org/en/publications?tri=gmp>



### Summary of Quality Policy requirements:

- In place.
- ...
- ...
- ...
- ...

Your Quality Policy in place?



## Outline:

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



## Who?

“\_\_\_\_\_ should establish a quality policy that describes the overall intentions and direction of the company related to quality”





# 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?



### Summary of Quality Policy requirements:

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

In place for your Quality Policy?



## Outline:

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

# 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

## 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/](http://www.who.int/medicines/areas/quality_safety/quality_assurance/guidelines/en/)

# 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)*



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?



## Outline:

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





## 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)*



### 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?



## 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**



## Some Examples

- Sanofi
- Pfizer
- Globe Pharmaceuticals



## 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