Quality Manual

Dr Maureen Dennehy

maureen@qast.co.za
http://www.qast.co.za

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Outline:

- From? (Guidance documents)
- What? (Contents)
- Who? (Audience)
    - Quality Manual vs Site Master File

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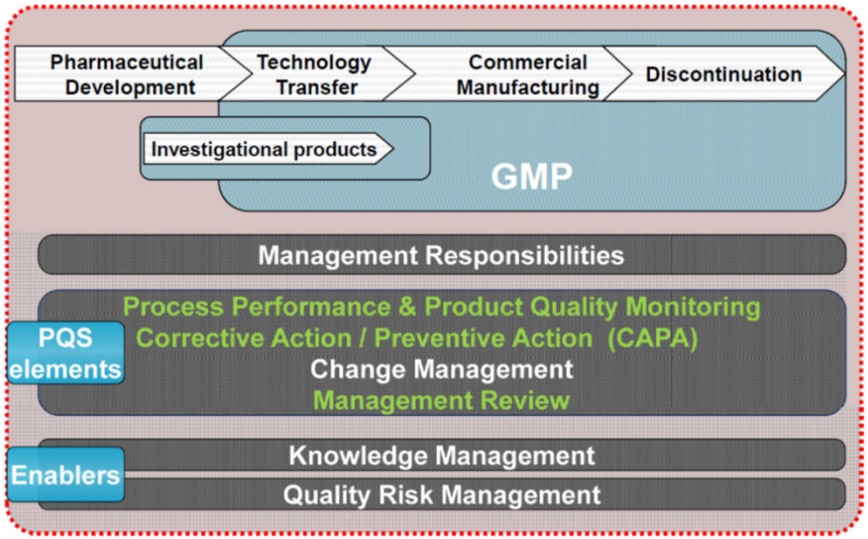
From?

ICH

1.8 Quality Manual

A *Quality Manual* or equivalent documentation approach should be established and should contain the description of the pharmaceutical quality system.

ICH Q10: Pharmaceutical Quality System (2008)
http://www.ich.org/products/guidelines/quality/article/quality-guidelines.html



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Brussels, 14 February 2008

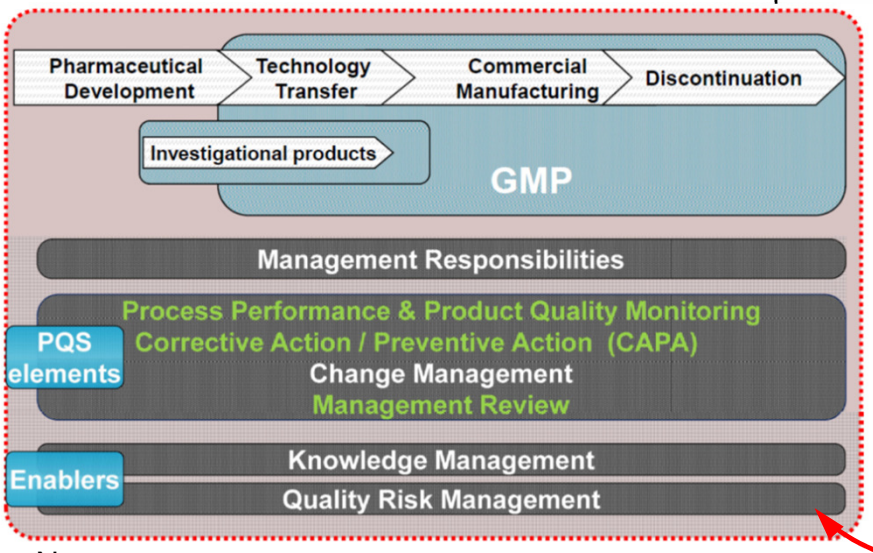
EudraLex
The Rules Governing Medicinal Products in the European Union

Volume 4
EU Guidelines to
Good Manufacturing Practice
Medicinal Products for Human and Veterinary Use

Part I
Chapter 1 Quality Management

2008

ICH Q10 Model of the PQS (2008)



EudraLex

The Rules Governing Medicinal Products in the European Union

Volume 4

EU Guidelines for

Good Manufacturing Practice for

Medicinal Products for Human and Veterinary Use

Chapter 1
Pharmaceutical Quality System

2012

New

1.7 The Pharmaceutical Quality System should be defined and documented. A Quality Manual or equivalent documentation should be established and should contain a description of the quality management system including management responsibilities.

EU GMP Chapter 1 Pharmaceutical Quality System (2012)
And PIC/S Chapter 1 (2017)

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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From?

What about WHO?

Added in update: Main Principles of GMP:

1.7 The PQS should be defined and documented. A quality manual or equivalent documentation should be established and should contain a description of the quality management system including management responsibilities.

WHO (2014). TRS 986, Annex 2
Good manufacturing practices for pharmaceutical products: main principles
http://www.who.int/medicines/areas/quality_safety/quality_assurance/TRS986annex2.pdf

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From?

More from WHO

- 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 (2016). TRS 996, Annex 5
Guidance on good data and record management practices
http://www.who.int/medicines/areas/quality_safety/quality_assurance/guidelines/en/

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From?

More from WHO – labs

quality manual

A handbook that describes the various elements of the quality management system for assuring the quality of the test results generated by a laboratory (see Part one, sections 2.1–2.2).

personnel. The elements of this system should be documented, e.g. in a quality manual, for the organization as a whole and/or for a laboratory within the organization.

Note: Quality control laboratories of a manufacturer may have this information in other documents than a quality manual.

WHO (2010). TRS 957, Annex 1
Good practices for pharmaceutical quality control laboratories.
file:///D:/Downloads/WHO_Doc_11_eng.pdf

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2.2 The quality manual should contain as a minimum:

(a) a quality policy statement, including at least the following:
  (i) a statement of the laboratory management's intentions with respect to the standard of service it will provide,
  (ii) a commitment to establishing, implementing and maintaining an effective quality management system,
  (iii) the laboratory management's commitment to good professional practice and quality of testing, calibration, validation and verification,
  (iv) the laboratory management's commitment to compliance with the content of these guidelines,
  (v) a requirement that all personnel concerned with testing and calibration activities within the laboratory familiarize themselves with the documentation concerning quality and the implementation of the policies and procedures in their work;
(b) the structure of the laboratory (organizational chart);
(c) the operational and functional activities pertaining to quality, so that the extent and the limits of the responsibilities are clearly defined;
(d) outline of the structure of documentation used in the laboratory quality management system;
(e) the general internal quality management procedures;
(f) references to specific procedures for each test;
(g) information on the appropriate qualifications, experience and competencies that personnel are required to possess;
(h) information on initial and in-service training of staff;
(i) a policy for internal and external audit;
(j) a policy for implementing and verifying corrective and preventive actions;
(k) a policy for dealing with complaints;
(l) a policy for performing management reviews of the quality management system;
(m) a policy for selecting, establishing and approving analytical procedures;
(n) a policy for handling of OOS results;
(o) a policy for the employment of appropriate reference substances and reference materials;
(p) a policy for participation in appropriate proficiency testing schemes and collaborative trials and the evaluation of the performance (applicable to national pharmaceutical quality control laboratories, but may be applied by other laboratories); and
(q) a policy to select service providers and suppliers.

WHO (2010). TRS 957, Annex 1 Good practices for pharmaceutical quality control laboratories.

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What?

1.8 Quality Manual

A *Quality Manual* or equivalent documentation approach should be established and should contain the description of the pharmaceutical quality system. The description should include:

(a) The *quality policy* (see Section 2);

(b) The scope of the pharmaceutical quality system;

(c) Identification of the pharmaceutical quality system processes, as well as their sequences, linkages and interdependencies. Process maps and flow charts can be useful tools to facilitate depicting pharmaceutical quality system processes in a visual manner;

(d) Management responsibilities within the pharmaceutical quality system (see Section 2).

ICH Q10: Pharmaceutical Quality System (2008)

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What?

- Quality Policy
- Scope of PQS
  - Include EHS? Corporate governance policies? HR policies? In other Manuals?
  - What standards are being followed? FDA, SFDA, WHO, EP
- PQS Processes
  - Suggests process maps, flow charts
  - VERY useful for training
- Management responsibilities

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What?

ICH Q10: Pharmaceutical Quality System (2008)

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ICH Q10 Snr Management Job Description (PQS)

- Ensure effective PQS
- Ensure resources for PQS
- Define roles, responsibilities, authorities
- Establish Quality Policy
- Set Quality Objectives
- Communication 2-way, top to bottom
- Govern (monitor and manage) PQS:
  - Set Quality Metrics
  - Set Quality Culture
  - Management Review of process performance, product quality

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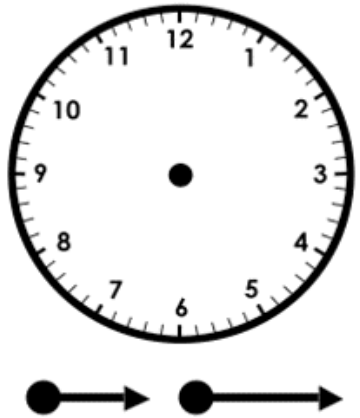
Who? (Audience)

When?



Site Master File and Quality Manual?
Do you really need both?

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Who?

- Internal company staff

When?

- Induction
- Routine training of Executives / staff in admin departments

Site Master File and Quality Manual?
Do you really need both?

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In Addition To SMF: There is overlap in some information

Regulation or Standard	Site Master File	Quality Manual
EU GMP	Yes (Chapter 4)	Yes (Chapter 1)
PIC/S GMP version 11 (2017)	Yes (Chapter 4)	Yes (Chapter 1)
WHO GDRP (2016)	No	Yes
EU and PIC/S SMF guidance document	Yes	No specific requirement
ISO 9001 (2015)	No	Yes (2013), No (2015) now more general
ICH Q10	No	Yes

Adapted from Tang, S. 2013. Site Master Files and Quality Manuals… Do manufacturer's really need both? *https://www.pharmout.net*

What are the main differences?

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SMF:

- For a site, not much information about GMP processes completed elsewhere
- Audience is the regulator, not internal