Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

Good Documentation Practice
Session 2

Good Documentation Practice
A refresher
EU GMP Chapter 4: Documentation

Required GMP documentation:

- Site Master File
- Instructions:
  - Specifications
  - Manufacturing Formulae, processing, Packaging and testing instructions
  - Procedures
  - Protocols
  - Technical agreements
- Records/Report type:
  - Records
  - Certificate of Analysis
  - Reports

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Principle

Good documentation constitutes **an essential part** of the quality assurance system and is key to operating in compliance with GMP requirements. The various types of documents and media used should be fully defined in the **manufacturer's Quality Management System (Chapter 1)**. Documentation may exist in a variety of forms, including **paper-based, electronic or photographic media**. The main objective of the system of documentation utilized **must be** to establish, control, monitor and record all activities which directly or indirectly impact on all aspects of the quality of medicinal products. The Quality Management System should include sufficient instructional detail to facilitate a common understanding of the requirements, in addition to providing for sufficient recording of the various processes and evaluation of any observations, so that ongoing application of the requirements may be demonstrated.

There are **two primary types of documentation** used to manage and record GMP compliance: **instructions** (directions, requirements) and **records/reports**. Appropriate **good documentation practice** should be applied with respect to the type of document.

Suitable controls should be implemented to ensure the **accuracy, integrity, availability and legibility** of documents. Instruction documents should be free from errors and available in writing. The term ‘written’ means recorded, or documented on media from which data may be rendered in a human readable form.

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Generation and Control of Documentation, 4.1 – 4.6

4.1 ….. should be defined and adhered to… Complex systems need to be understood…… may exist in hybrid forms…… controls should be in place to ensure the integrity

4.2 ……designed, prepared, reviewed, and distributed with care……. not allow any error to be introduced through the reproduction process

4.3 ……approved, signed and dated by appropriate and authorised persons

4.4 …. instructions should be laid out in an orderly fashion and be easy to check

4.5 …. regularly reviewed and kept up-to-date

4.6 …. should not be hand-written; although, where documents require the entry of data, sufficient space should be provided for such entries

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Good Documentation Practices, 4.7 – 4.9

4.7 Handwritten entries should be made in clear, legible, indelible way.

4.8 Records should be made or completed at the time each action is taken……. significant activities …are traceable

4.9 Any alteration …..should be signed and dated; ……should permit the reading of the original information. …….the reason for the alteration should be recorded

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Retention of Documents, 4.10 – 4.12

4.10 …..clearly defined which record is related to each manufacturing activity and where this record is located……ensure the integrity of the record.

4.11 ….. one year after expiry of the batch to which it relates or at least five years after certification of the batch by the Qualified Person, whichever is the longer

4.12 …. retention period will depend on the business activity

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Specifications, 4.13 – 4.16

4.13 …. should be appropriately authorised and dated specifications for starting and packaging materials, and finished products.

4.14 Specifications for starting and packaging materials

4.15 Specifications for intermediate and bulk products

4.16 Specifications for finished products

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Manufacturing Formula and Processing Instructions, 4.17 – 4.21

Approved, written Manufacturing Formula and Processing Instructions should exist for each product and batch size to be manufactured.

4.17 Manufacturing Formula

4.18 Processing Instructions

4.19 Packaging Instructions

4.20 Batch Processing Record

4.21 Batch Packaging Record

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Procedures and records, 4.22 – 4.32

There should be written procedures and records……

4.22 – 4.24 Receipt

4.25 Sampling

4.26 Testing

4.27 – 4.29 Other

4.30 Clear operating procedures should be available for major items of manufacturing and test equipment.

4.31 Logbooks should be kept……

4.32 ……. inventory of documents within the Quality Management System should be maintained

Good Documentation Practice

KNOWLEDGE IS IN THE ROOM

Workshop activity:

Discuss until break

In groups

- What practical steps do you take to ensure Good Documentation Practice?
  - Decide on top 5 for group
- What is the biggest hurdle to ensuring Good Documentation Practice?

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