COGSQP-10

Report and Document Quality System Practices

Overview

This standard covers the use of good reporting and documentation practice that should be applied in accordance to the quality management system (QMS) and the competences you need to certify products for release or non-release under Marketing Authority License into the supply chain.

You will be required to demonstrate that the reporting and documentation processes are followed and completed accurately and on time. You will be required to monitor and review the systems and be expected to recommend improvements or develop new methods of reporting and documentation within the requirements of the Marketing Authority (MA), GMP and manufacturing site licenses

The Qualified Person is responsible for the reporting and documentation system, to establish, control, monitor and record all activities which directly or indirectly impact on all aspects of the quality of medicinal product.

Performance criteria

You must be able to:

P1 ensure the use and application of all reporting and relevant documents described in the organisations QMS and in accordance to good manufacturing practice.
P2 ensure system data problems, issues and incidents are reported and acted upon in accordance to procedures and timelines.
P3 report to the appropriate authority as laid down by the company and the marketing authority.
P4 follow reporting procedures as prescribed by the company.
P5 identify documentation to be completed relating to the qualified persons role.
P6 record details accurately in appropriate format in a clear, legible and indelible way.
P7 complete all documentation according to company procedures to ensure medicinal products are fully traceable.
P8 ensure that the final document meets regulatory and compliance requirements, confirming any changes are signed and dated, with reason for change.
P9 make sure documents are available to all appropriate authorities to inspect.

P10 respond to requests for information in an appropriate manner whilst following organisational procedures.
P11 inform the appropriate authority of requests for information received.

Knowledge and understanding

You need to know and understand:

K1 the requirements of key regulation documents concerning qualified persons, including principles and guidelines of current Good Manufacturing Practices (GMP) for pharmaceutical products.
K2 the requirements for current Good Clinical Practices (GCP) for human and veterinary medicines.
K3 the current Manufacturing Importation Articles.
K4 the organisation's compliance policies and procedures.
K5 the documentation used in your organisation.
K6 the different methods of recording and maintaining information used in the organisation
K7 reporting incidents where standard operating procedures are not followed.
K8 the importance of complete and accurate documentation.
K9 the production workflow sequences and materials demand.
K10 the escalation matrix for reporting identified issues, hazards and breakage.
K11 the method of obtaining and interpreting records, charts, specifications, equipment manuals, history and technical support reports and other documents.

Glossary

**Glossary of Reports and Documentation Types*
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Site Master File

A document describing the GMP related activities of the manufacturer.
Instructions
Directions or requirements

Specifications

Describe in detail the requirements with which the products or materials used or obtained during manufacture have to conform.
Manufacturing Formulae, Processing, Packaging and Testing Instructions
Provide detail all the starting materials, equipment and computerised systems (if any)to be used and specify all processing, packaging, sampling and testing instructions.
Procedures
Otherwise known as Standard Operating Procedures, or SOPs), give directions for performing certain operations including sampling, testing

Protocols

Give instructions for performing and recording certain discreet operations.

Technical Agreements

Are agreed between contract givers and acceptors for out sourced activities.

Batch Processing Record

Record kept for each batch processed. It should be based on the relevant parts of the currently approved Manufacturing Formula and Processing Instructions.

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