

COGLS15

Improve product(s) and process quality within life sciences related work activities



Overview

This standard covers the competences you need to implement quality improvement of projects and processes within life sciences related work activities, in accordance with approved procedures and practices. You are required to take prompt and appropriate action to rectify any quality problems. You will also be required to present records and details of your work to the appropriate people.

During this work you must take account of the relevant worksite operational requirements, procedures and safe working practices AS THEY APPLY TO YOU.

The activity is likely to be undertaken by someone whose work role carries out life science related work activities. This could include individuals working in hospitals, scientific laboratories, schools and universities.

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Performance criteria

You must be able to:

- P1 evaluate the quality of product(s) and process within life sciences related work activity
- P2 report findings to the appropriate people with recommendations
- P3 discuss which recommendations will be carried out and prioritise
- P4 gain authorization to carry out recommendations in accordance with organizational policies and procedures
- P5 plan the introduction of improvements to the product(s) or processes
- P6 specify clearly the improvements that should be implemented
- P7 confirm that conditions are suitable to implement the improvements
- P8 ensure adequate resources are available to carry out the improvements within the allocated agreed time
- P9 provide clear and accurate instructions to all the relevant people control the use of resources to achieve the most effective results
- P10 ensure that the improvements are implemented according to the plan
- P11 record the implementation of the improvements
- P12 ensure any problems are resolved, recorded and the relevant people notified
- P13 assess and record the impact of the improvements on the quality of laboratory products or processes
- P14 notify relevant people of the impact of the improvements

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Knowledge and understanding

You need to know and understand:

- K1 why it's important to understand the latest technological developments in the life sciences industry and how to keep up-to-date with them
- K2 why it's important to analyse the impact of bringing in new life sciences technology or processes into the business
- K3 the health and safety requirements of the area in which the activities are being carried out
- K4 the importance of correct identification, and any unique organisational numbers
- K5 the organisational requirements for maintaining the security of the workplace
- K6 the lines of communication and responsibilities in your department, and their links with the rest of the organisation
- K7 the limits of your own authority and to whom you should report if you have problems that you cannot resolve
- K8 the quality criteria that could be used for different types of projects or processes within the life sciences related work activities
- K9 how to obtain and interpret records, charts, specifications, equipment manuals, history/technical support reports and other documents needed for the implementation of quality improvements
- K10 the laboratory processes and standard operating procedures in the area associated with the quality issues
- K11 the types and effects of quality improvements, and their impact
- K12 the factors that have to be taken into account when selecting the solution to a manufacturing quality problem
- K13 the techniques used to obtain information
- K14 methods and techniques involved in quality improvement implementation
- K15 methods and techniques involved in evaluating information
- K16 how to obtain and interpret legislative and regulatory documentation
- K17 organisational reporting procedures and documentation, and their application
- K18 whom to inform of actions taken, and by what means

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- K19 how to retrieve the necessary data from company information systems
- K20 the types of impact assessment systems/techniques available, and their application
- K21 how to record information
- K22 the resources required

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