# SVQ in Quality Operations in the Science Industries at SCQF level 6

***Qualification Reference Number GV4J 46***

**Candidate Personal Competence Summary**

| Name | Company/Centre |
|---|---|
| Job Title | GQA Registration Number |

| Unit Number | Title | Level | Credit Value | Assessor Signature | Date |
|---|---|---|---|---|---|
| **Mandatory Units** | | | | | |
| COGLS301 | Maintain Health and Safety Procedures in Life Sciences and Related Industries | 6 | 9 | | |
| COGLS202 | Maintain Effective and Efficient Working Relationships in Life Sciences and Related Industries | 6 | 3 | | |
| COGLS327 | Applying Basic Statistics in Life Sciences and Related Industries | 8 | 16 | | |
| COGLS203 | Use Information Recording Systems in Life Sciences and Related Industries | 6 | 6 | | |
| | **Optional Units - Candidates must take 4 Units-at least 3 of these must be from Optional Units Group A** | | | | |
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**RELIABLE EVIDENCE: The forms of evidence available include**

| | | | |
|---|---|---|---|
| Observation in the workplace | | Simulation(s) | |
| Oral assessment of knowledge | | Work records | |
| Written work/assignment | | Photographs/Video | |
| Witness statement(s) | | Audio | |
| Testimonial(s) | | Products | |
| Other (please state) | | | |

| | Name and Signatures | Date |
|---|---|---|
| Candidate | | |
| Lead Assessor | | |
| Internal Verifier | | |
| EQA | | |

Candidate ID Photograph

**Introduction to the Qualification – Assessor Section**

## Who is this Qualification for?

This qualification is aimed at those who carry out activities in the science and associated technical working environments.

It is not expected that all individuals in this sector carry out the same activities: the qualification is structured to endure that there is a high degree of flexibility in the qualification. The standard covers the most important aspects of the job. This qualification is at SCQF level 6 and should be taken by those who are fully trained to deal with routine assignments. Candidates should require minimum supervision in undertaking the job.
Candidates for this qualification will primarily be:

Working in roles associated with scientific and technical related occupations, this could include activities related to a wide range of specific activities, the optional units have suitable units and combination of units to make them as widely accessible as possible.

## What is required from candidates?

Candidates should achieve all the mandatory units listed below, plus the required number of units from the 2 groups of optional units
Candidates should prove that they can achieve all the statements listed from each element. Guidance on the evidence that will be acceptable is contained in the introduction to each unit.

| Unit Number | Mandatory Units | Level | Credit Value |
|---|---|---|---|
| COGLS301 | Maintain Health and Safety Procedures in Life Sciences and Related Industries | 6 | 9 |
| COGLS202 | Maintain Effective and Efficient Working Relationships in Life Sciences and Related Industries | 6 | 3 |
| COGLS327 | Applying Basic Statistics in Life Sciences and Related Industries | 8 | 16 |
| COGLS203 | Use Information Recording Systems in Life Sciences and Related Industries | 6 | 6 |
| **In addition to the qualification mandatory units, candidates must also achieve 4 optional units, at least 3 of these must come from Optional Units Group A** | | | |
| **Optional Units Group A - Pick 3 or 4 Units** | | | |
| COGLS216 | Operating in a Clean Room or Aseptic Facility in Life Sciences and Related Industries | 6 | 9 |
| COGSQO-03 | Assure Quality Methods and Procedures in a Science or Technology Environment | 6 | 5 |
| COGSQO-05 | Inspect Quality of Raw Material and Products within in a Science or Technology Manufacturing, Storage and Distribution Environment | 6 | 3 |
| COGSQO-13 | Conduct Scientific or Technical Sampling and Testing Operations | 5 | 6 |
| COGSQO-02 | Analyse and Interpret Data in Science or Technology Related Industries | 7 | 9 |
| COGLATA3-09 | Carry out scientific or technical Investigations | 7 | 9 |
| COGLS11 | Solve problems in life sciences related work activities | 6 | 7 |
| COGLATA4-05 | Plan and run scientific or technical projects for workplace activities | 7 | 5 |

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|---|---|---|---|
| COGLATA3-11 | Diagnose faults, repair and maintain scientific or technical equipment for workplace activities | 7 | 8 |
| **Optional Units Group B - Pick up to 1 Unit** | | | |
| COGSQP-09 | Maintain License Requirements and Good Manufacturing Practice (GMP) to Ensure Compliance | 7 | 8 |
| COGSQO-09 | Maintain and improve quality documentation and processes for science or technology-based industries | 8 | 4 |
| COGLS9 | Make presentations for life sciences related work activities | 8 | 8 |
| COGREG-02 | Analyse audits and inspections to ensure compliance to regulations in a Life Science Environment | 8 | 6 |
| COGREG-05 | Gather, collate and provide information & guidance to meet organisational compliance | 8 | 7 |
| COGREG-06 | Ensure compliance and respond to issues or deviation from standards or best practice in a Life Science Environment | 8 | 8 |

### Assessment Guidance

Evidence should show that the candidate can cover the scope of performance outlined for each relevant unit consistently over an appropriate period.

### Types of evidence:

Evidence of performance and knowledge is required. Evidence of performance should be demonstrated by activities and outcomes, and should be generated in the workplace only, unless indicated under potential sources of evidence (see below). Evidence of knowledge can be demonstrated through performance or by responding to questions.

### Potential sources of evidence:

The main source of evidence for each unit will be observation of performance. This can be supplemented by the following types of physical or documentary evidence:

- Accident book
- Correspondence/discussion with customer
- Customer feedback
- Damage and defect reports
- Delivery records
- Equipment used
- Inspection reports
- Notes and memos
- Audio/photographic/video
- Safety records
- Telephone logs
- Installation activity
- Witness testimony
- Simulation of accident or emergency
- Organisational reporting systems

**Please Note that photocopied or downloaded documents such as manufacturers or industry guidance, H&S policies, Risk Assessments etc., are not normally acceptable evidence for GQA qualifications unless accompanied by a record of a professional discussion or assessor statement confirming candidate knowledge of the subject. If you are in any doubt about the validity of evidence, please contact your GQA EQA.**

# GQA Qualification Implementation Requirements covering Centre Approval, Candidate Assessment and ongoing Quality Assurance

This document indicates the requirements of approved centres delivering GQA qualifications and/or units of credit. This document complements the appropriate SSC Assessment Strategy linked to this qualification.

**1. Equality of Opportunity**

Equality of access to fair and valid assessment is necessary for all candidates undergoing assessment. This may mean making reasonable adjustments to normal assessment methods for candidates with particular or special assessment requirements. Candidates work patterns should not become a barrier to assessment, the organisation of which may have to be flexible. In the same way, reasonable adjustment arrangements may be necessary for candidates with a disability. For example, a candidate who is unable, through disability, to produce oral or written evidence, may be allowed to use the method they normally use as a substitute for the required form of communication. Reasonable adjustments need to be approved by GQA.

**2. Recognised/Approved Assessment Centres**

2.1 Individual centres must be approved by GQA to offer specific qualifications and / or units of credit. A centre may be a single organisation or a partnership of two or more organisations. It may operate at a single location or have satellites. For further details see the GQA booklet "Guide to Centre Approval". The Centre Approval process is carried out by a GQA approved EQA. Each Centre must maintain a centre file. It is important to be clear what the steps in the assessment process are:

- plan evidence collection and opportunities for assessment
- collect evidence
- judge evidence
- determine whether sufficient evidence has been presented
- make an assessment decision and give feedback to the candidate

**NB Any deviation from the norm must be approved by a GQA EQA**

**2.2 Assessors and Verifiers**

All Assessors of candidate performance must be competent, to make qualitative judgements, both in the skills they are assessing and in the assessment of candidates and hold the appropriate Assessor national award. Assessor occupational knowledge related to the qualifications being assessed is essential and must be illustrated to GQA prior to approval.

Internal Verifiers are responsible for the quality assurance of the assessment process within a centre. They should have a relevant occupational background, be competent in internal verification and hold the Internal Verifier national award. It is recommended that Internal Verifiers work towards national recognition of assessor competence.

EQAs are responsible for ensuring accurate and consistent standards of assessment across centres, qualifications, units of credit and over time. They should have a relevant occupational background, be competent in External Quality Assurance and hold the EQA national award
GQA will approve and licence all individuals involved in the assessment and verification of its approved qualifications and / or units of credit. Individuals who are working towards the Assessor or Internal Verifier national awards can only be provisionally licensed. The judgement of provisional licence holders will need to be agreed/authorised by a fully qualified and GQA licensed individual who cannot carry out a dual role in relation to a specific candidate.

All GQA Assessors and Verifiers must undertake a minimum of 2 significant CPD activities in both occupational areas and assessment and verification. Reflective CPD records must be maintained and made available to GQA EQAs for review.

**2.3 Centre Approval, Monitoring Reviews and Quality Assurance**

The centre recognition/approval process is the start of a significant part of the awarding body's quality assurance system. The Approval process will begin with an EQA review of centre procedures to ascertain the potential centre's ability to deliver GQA qualifications and / or units of credit. Centres will be expected to meet the relevant regulatory authority criteria for delivery of qualifications prior to initial approval; continued compliance with the criteria will be monitored through regular EQA visits. It is recommended that centre reviews are conducted at minimum every six months by a GQA EQA.
New or multi-site centres may be required to undertake quarterly or more frequent EV reviews to ensure that different locations can be seen to satisfy the national requirements.

GQA will ensure that unacceptable barriers relating to the assessment and internal verification of candidates in small companies do not deny recognition of competence to competent young workers. In such circumstances, GQA will demonstrate that its quality assurance procedures remain sufficient and rigorous to ensure that the competence outcomes have standing and credibility in the occupational area.

- Enhanced quality procedures to ensure consistency of assessment and verification will be necessary and will include:
- a high level of sampling of assessment decisions N.B. In some instances, the EQA may visit each assessment location and qualification / unit of credit candidate (e.g., single candidates dispersed throughout different small companies on government funded programmes)
- an in-depth scrutiny of assessment plans, materials and records
- specific centre guidance aimed at the successful implementation of qualifications and / or units of credit in SMEs via approved centre partnerships. This can include guidance on the quantity and quality of valid, authentic, and transferable evidence expected to be attributed to individual candidates
- ensuring centres are following the requirements prescribed in any appropriate assessment strategies and applicable codes of practice
- the identification and publication of good practice in centres

As part of the Quality Assurance process Proskills require an Enhanced External Quality Assurance process. This will be in the form of 1 significant underpinning knowledge question answered by the candidate for each unit of the qualification. The questions will be decided by GQA, and guideline answers must be submitted for approval and once approved kept in the Centre File to allow independent assessment

**3. Qualification/Unit of Credit Candidates**

All candidates must register with a GQA recognised/approved centre. The centre must maintain appropriate candidate personal details for external audit purposes etc.

The centre will provide candidates with advice and guidance on how to prepare for assessment and allocate an Assessor who will assess candidate ability to meet the requirements of the relevant qualifications / unit of credit.

It is the candidate's responsibility to demonstrate competence and to do this they must:

- prove they can consistently meet all the qualification and / or unit of credit criteria
- provide evidence from work, that they can perform competently in all the contexts specified in the qualification / unit of credit requirements
- prove that they have the knowledge and understanding required to perform competently, even where they have not provided evidence from the workplace

It is therefore critical that quality evidence is provided in a format to allow the Assessor to decide and for the Internal Verifier to audit/verify his/her decision.

**4. Evidence**

A qualification and / or credit is awarded when a person has achieved the necessary outcomes of the qualification and / or unit of credit.

The specific combination of units necessary to achieve a qualification is detailed in the qualification structure. Certificates of Unit Credit can be awarded when candidates achieve anyone, or more, units from the qualification. The evidence the candidate brings forward is primarily evidence of performance of what he/she can do, not just what he/she knows. The assessment criteria / qualification requirements are described within the qualification and / or unit of credit itself and can incorporate practical skills and knowledge.

The assessor's role is to judge each relevant item of evidence. Each must be judged against the qualification and / or unit of credit requirements. It is not sensible to collect evidence against individual criteria. Nor is it effective. If items of evidence were collected for each of the criteria, the candidate may have to produce many items of evidence, well above the number required. GQA recommend holistic assessment.

When judging each item of evidence, the assessor is deciding whether the evidence:

- is authentic – i.e., produced by the candidate
- meets the criteria
- relates as appropriate to a context defined within the qualification and / or unit of credit
- confirms that the candidate has the required underpinning knowledge

When the assessor decides about the candidate's competence, he or she examines all the evidence available to determine:

- if the evidence covers all the evidence of achievement
- whether the evidence indicates consistency in competent performance
- whether there is enough evidence on which to base an inference of competence

The answer can only be:

- yes (the candidate is competent)
- no (the candidate is not yet competent)
- there is insufficient evidence to decide

Consistency means that the individual is likely to achieve the standard in their work role, in the different activities defined

**5. Performance Evidence**

Performance evidence can be what the individual produces, or the way the individual achieves the standard.

One is called product evidence and the other process evidence.

Product evidence is tangible – you can look at it and feel it. Products can be inspected and the candidate can be asked questions about them.

To make a fair and objective assessment, the assessor must be able to answer the question: Is there sufficient evidence that the candidate can consistently meet the requirements of the qualification and / or unit of credit? Process evidence describes the way the candidate has achieved an outcome – how they went about it. This may be, for example, the way the quality of products is checked, or the way customer complaints are handled. This usually means observing the candidate in action.

Performance evidence may cover several outcomes. It makes sense to plan evidence collection so that what the candidate does, in the normal course of their job, can be related to different outcomes and units. The activities that clearly link to the qualification and / or unit of credit requirements are the things to concentrate on when planning evidence collection and assessment and when monitoring the candidate's progress. Look for opportunities in the candidate's job when evidence can be collected against several units at the same time.

Performance evidence can be:

- Naturally occurring – evidence produced in the normal course of work. Evidence of this sort is usually of high quality and reliable. It is also cost effective to collect naturally occurring evidence
- Taken from previous achievements – the candidate may be able to bring forward evidence from previous work experience to show that they are still competent to the standard
- Evidence of prior achievement can be used when it can be shown to support a judgment that the candidate can still achieve the standard. So, the assessor must be satisfied that the evidence of prior achievement is sufficiently reliable to justify saying that the candidate is currently competent
- Simulated – from circumstances specially designed to enable the candidate's performance to be assessed. Simulation is generally not acceptable

The exceptions this are:

- Dealing with emergencies
- Dealing with accidents
- Certain pre-approved real time simulators
- Limited other procedures that cannot be practically performed in the workplace, and for which sufficient evidence can be collected through other means

**NB: It is not always possible or feasible to collect naturally occurring evidence. It is likely that some simulation may be needed, when it may take too long to wait for the evidence to arise e.g., it may be an aspect of performance which occurs infrequently. An example of this may be evidence of how to deal with emergencies i.e., it makes sense to look for evidence from sources other than naturally occurring ones, rather than for, say, waiting for the building to burn down. Centres must obtain GQA EV approval prior to the use of simulation.**

**Knowledge evidence**

Being able to achieve a standard requires the ability to put knowledge to work. The qualification and / or unit of credit indicates the knowledge each person should use if they are to perform competently.

It should not be necessary to test all the candidate's knowledge separately; however, any exception to this would be detailed in the relevant Assessment Strategy. Performance evidence could show that the candidate knows what he or she is doing. When this is not the case, or if the assessor is not convinced from the performance evidence, it may be necessary to check the individual's knowledge separately.

Oral or written assessments must clearly provide a suitable means of checking the breadth and depth of an individual's knowledge. Assessors will need to judge the best mix of knowledge evidence according to individual circumstances. Knowledge evidence is useful when deciding the quality of performance evidence but must not be used in isolation to judge competence or as an alternative to performance evidence. Care must be taken that candidate evidence is auditable and verifiable.

**NB: These Qualification implementation guidelines are generic across the full range of GQA qualifications. Further guidance on acceptable evidence on each qualification will be found in the Introduction to the Qualification section of the candidate booklet.**

**SVQ Candidate Declaration**

Candidate Name……...

Centre/Company Name……..

Assessor(s) Name(s) …….

I acknowledge receipt of this copy of the GQA qualification booklet. The unit structure provides information on which units must be achieved to be awarded the NVQ/SVQ. The individual units detail the necessary requirements etc. that I must achieve. I understand that I will have an important role in preparing for and planning assessments and with guidance from the assessor I will collect and record relevant evidence.

I understand that all evidence should be produced by me or be directly attributable to me.

I have been informed of the appeals system and have been issued with a copy of the appeals procedure, should I want to appeal against any part of the assessment process.

I understand the assessments will be carried out in line with the company/centre Equal Opportunities Policy.

Candidate Signature ……

Date ……..

| COGLS301 | **Maintain Health and Safety in Life Sciences and Related Industries** *(Level 6, 9 Credits)* |
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**Overview**

This standard covers the skills you need to maintain health and safety in a workplace where scientific and similar activities are performed. You must observe all legal, statutory and organisational requirements, be able to identify any hazards and potential risks and follow workplace standard operating and emergency procedures to ensure the safety of yourself, colleagues and others.

You will be expected to initiate and complete scientific or similar tasks and procedures, including, where relevant, responsibility for supervising or guiding others. You will be expected to exercise autonomy and judgement within limited parameters, taking personal responsibility for your own actions and for the quality and accuracy of the work that you carry out. You will be expected to work to instructions, with minimum supervision, either on your own or as part of a team. You will also be aware of different perspectives or approaches used within the workplace.

Your underpinning knowledge will provide you with an understanding of your work to interpret and evaluate relevant workplace information and ideas. It will provide you with an understanding of the scientific or similar processes used.

You will understand the equipment, materials and consumables in adequate depth to provide a sound background for carrying out the activities to the required specification.

| ***Performance Criteria*** *You must be able to:* | **Evidence 1** | **Evidence 2** | **Evidence 3** |
|---|---|---|---|
| **P1** ensure that your work is carried out in accordance with workplace procedures to protect yourself and others | | | |
| **P2** accurately assess health and safety in relation to your work and the workplace and recognise hazardous materials | | | |
| **P3** use safe practices and the appropriate personal protective clothing (PPE) and equipment for the work | | | |
| **P4** identify any breaches to health and safety procedures and report them to the appropriate person as soon as possible | | | |
| **P5** maintain and keep tidy your work area to a standard of health and safety which is consistent with local policies and legal requirements | | | |
| **P6** dispose of hazardous materials, waste and waste containers safely and correctly | | | |
| **P7** follow the correct procedure when an emergency arises or is suspected | | | |
| **P8** identify and recommend health and safety improvements to your work area and/or environment | | | |
| **P9** communicate the required information about the work done, to authorised people, in accordance with departmental and organisational procedures | | | |

| ***Knowledge and Understanding Criteria*** *You need to know and understand:* | **Evidence 1** | **Evidence 2** | **Evidence 3** |
|---|---|---|---|
| **K1** the health and safety requirements of the area in which you are carrying out the activities | | | |
| **K2** the implications of not taking account of legislation, regulations, standards and guidelines when conducting the activities | | | |

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|---|---|---|---|
| **K3** the standard operating procedures (SOP) and manufacturers' instructions, as set down in local operating manuals and schemes of work | | | |
| **K4** the importance of selecting and using the relevant personal protective equipment (PPE), including protective clothing, gloves and eye protection when handling hazardous materials | | | |
| **K5** the specific safety precautions to be taken when working with scientific and related equipment and computer-based systems (to include such things as safety guidance relating to the use of visual display unit (VDU) equipment and workstation environment (such as lighting, seating, positioning of equipment), and repetitive strain injury (RSI) | | | |
| **K6** the location and correct use of fire alarm call points and emergency equipment | | | |
| **K7** the lines of communication and responsibilities in your department, and their links with health and safety representatives and the rest of the organisation | | | |
| **K8** the correct storage and disposal procedures for hazardous materials | | | |
| **K9** why risks in the workplace should be assessed and the correct action to be taken | | | |
| **K10** local procedures for emergency evacuation (including escape routes and assembly points) | | | |
| **K11** the location of spillage kits and the procedures to follow in the event of spillages of chemicals and/or biological fluids and materials | | | |
| **K12** how to identify and recommend health and safety improvements to our work area and/or environment | | | |
| **K13** the control of substances hazardous to health (COSHH) regulations, and their application in the workplace (such as chemicals, radioactive substances and/or biological materials) | | | |
| **K14** the range of signs and symbols used for the warning of workplace hazards and prohibited practices | | | |
| **K15** the types of hazards, dangerous occurrences and hazardous malfunctions which may be present in the workplace, why these must be reported and how these can be minimised | | | |
| **K16** the correct procedures for the segregation, storage, transport and disposal of hazardous materials and waste | | | |

| **Assessor Comments/Feedback** |
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| COGLS202 | **Maintain effective and efficient working relationships in life sciences and related industries** *(Level 6, 3 Credits)* |
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**Overview**

This standard is about the need to maintain effective and efficient working relationships in a workplace where scientific or technical activities are performed. It involves taking responsibility for your own actions and behaviours and communicating effectively with others. It will require knowledge and adherence to organisational procedures whilst maintaining good working relationships with colleagues.

Good working relationships are essential to the effective operation of any workplace. Time spent resolving disagreements is time away from what is the main purpose of any organisation.

While you are expected to be familiar with your own responsibilities regarding relevant organisational procedures, you are not expected to be a specialist in health and safety or any other aspect of organisational development.

For the purposes of this standard, 'colleagues' means any internal or external person you have contact with.

| ***Performance Criteria*** *You must be able to:* | **Evidence 1** | **Evidence 2** | **Evidence 3** |
|---|---|---|---|
| **P1** ensure that your work is carried out in accordance with workplace procedures | | | |
| **P2** meet workplace standards for timekeeping, appearance and behaviour | | | |
| **P3** communicate effectively to ensure that all relevant information is passed to the appropriate people | | | |
| **P4** recognise the extent of your role within the organisation, seeking assistance when required | | | |
| **P5** recognise your own limitations and seek advice and help when required | | | |
| **P6** participate in reviewing your own performance with the appropriate people | | | |
| **P7** deal with disagreements in an amicable and constructive way, so that good relationships are maintained | | | |

| ***Knowledge and Understanding Criteria*** *You need to know and understand:* | **Evidence 1** | **Evidence 2** | **Evidence 3** |
|---|---|---|---|
| **K1** the organisational structure and lines of accountability within the company | | | |
| **K2** the formal lines of communication open to you | | | |
| **K3** the health and safety requirements of the area in which you are carrying out the activities | | | |
| **K4** the legal and regulatory frameworks within which you are working and the implications of failing to comply with either | | | |
| **K5** the correct procedures for the work you are carrying out | | | |
| **K6** the interactions which take place between your speciality and others where the same speciality is used | | | |

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|---|---|---|---|
| **K7** how your work activities may affect others within the department and the workplace | | | |
| **K8** the lines of communication and responsibilities in your department, and their links with the rest of the organisation | | | |
| **K9** the limits of your own authority and to whom you should report if you have problems that you cannot resolve | | | |
| **K10** the reasons why good working relationships are important | | | |
| **K11** how to create and maintain good working relationships and the methods of working effectively with others | | | |
| **K12** the problems that can affect relationships in the workplace and the procedures for dealing with disagreements within the workplace | | | |
| **K13** the departmental performance review process, and your role in this process | | | |
| **K14** the reasons why effective communication is important, and the methods used for communicating effectively | | | |

| **Assessor Comments/Feedback** |
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| COGLS327 | **Applying Basic Statistics in Life Sciences and Related Industries** *(Level 8, 16 Credits)* |
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**Overview**

This standard is about applying basic statistics within life sciences and related industries. You will be expected to use statistics to both plan/design the study and to handle the data from the activity.

The activity will include a sampling plan, collection and analysis of the data followed by a report which includes a statistical analysis of the results.

Reliable data is essential in any organisation. Simply collecting the data is not enough, applying a statistical approach will ensure that results can be reported with a higher degree of confidence in their reliability.

You will be expected to determine the scope/parameters of the work and to carry it out within them, recording all results. You will then be expected to use the data gathered to produce a statistical analysis, which is likely to include, mean, standard deviation, standard error and confidence intervals (or similar measurements). The results will be presented in a graphical form. Any improvements or actions necessary will be reported ready for implementation.

Your responsibilities will require you to comply with organisational policy and procedures for the statistical activities undertaken and to report any problems you cannot personally resolve. You will be expected to work with minimum supervision, taking personal responsibility for your own actions and for the quality and accuracy of the work that you and your team carry out.

Your underpinning knowledge will provide a good understanding of design of experiments/activities and enable you to adopt an informed approach to applying basic statistics. You will understand data analysis and its application.

| ***Performance Criteria*** *You must be able to:* | **Evidence 1** | **Evidence 2** | **Evidence 3** |
|---|---|---|---|
| **P1** ensure that the work is carried out in accordance with workplace procedures to protect yourself and others | | | |
| **P2** select the experiment/process that is to be the subject of statistical study | | | |
| **P3** determine the scope/parameters of the study | | | |
| **P4** estimate the resources and the expected benefits for the stud | | | |
| **P5** carry out a pilot study and ensure good experimental management | | | |
| **P6** implement any improvements suggested from the pilot study, before carrying out the full study | | | |
| **P7** record the results in the appropriate format | | | |
| **P8** analyse the data gathered using the appropriate statistical method | | | |
| **P9** produce the results of the statistical analysis in the appropriate format interpret the statistical data collected and produce a report of the results | | | |
| **P10** communicate the required information about the work done, to authorised people, in accordance with departmental and organisational procedures | | | |

| ***Knowledge and Understanding Criteria*** *You need to know and understand:* | **Evidence 1** | **Evidence 2** | **Evidence 3** |
|---|---|---|---|
| **K1** the health and safety requirements of the area in which the activities are being carried out | | | |
| **K2** the legal and regulatory frameworks within which you are working and the implications of failure to comply | | | |
| **K3** the lines of communication and responsibilities in your department, and their links with the rest of the organisation | | | |
| **K4** the limits of your own authority and to whom you should report to if you have problems that you cannot resolve | | | |
| **K5** how to determine the scope of an experiment | | | |
| **K6** the advantages of good experimental design | | | |
| **K7** how to use a sampling plan and experimental method to reduce systematic errors | | | |
| **K8** the advantages of using basic statistics in data analysis | | | |
| **K9** the meaning of and how to use basic statistical terms such as 'population' and 'sample' | | | |
| **K10** the types of distribution curves and their properties | | | |
| **K11** how to calculate mean, median, mode, standard deviation, range, inter-quartile range and variance | | | |
| **K12** how to create and use tables, charts and graphs e.g., histograms, box plots, time series charts, pareto diagrams, stem and leaf diagrams etc | | | |
| **K13** how to construct confidence intervals | | | |
| **K14** how to assess the significance of the results of a study | | | |
| **K15** how to present the data in a suitable form in a report | | | |

| **Assessor Comments/Feedback** |
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| COGLS203 | **Use Information Recording Systems in Life Sciences and Related Industries** *(Level 6, 6 Credits)* |
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**Overview**

This standard covers the skills you need to use information recording systems for scientific or similar activities, in accordance with approved procedures and practices. You will be expected to select and use relevant knowledge, ideas, skills and procedures to complete well-defined tasks and address straightforward problems. This includes accessing, registering and inputting batch/sample or patient data in a Laboratory Information Management System (LIMS) or other information recording system.

You will be expected to show you have identified, gathered and used relevant information and understand the importance of preparation and tidying before and after work and confidentiality issues. You will work under supervision, whilst taking responsibility for the quality and accuracy of the work that you carry out.

Your underpinning knowledge will provide a good understanding of scientific or technical facts, procedures and ideas to complete well-defined tasks and address straightforward problems in the workplace.

| ***Performance Criteria*** *You must be able to:* | **Evidence 1** | **Evidence 2** | **Evidence 3** |
|---|---|---|---|
| **P1** ensure that your work is carried out in accordance with workplace procedures, health and safety, environmental and other relevant regulations and guidelines | | | |
| **P2** keep information systems up to date and store the information correctly, accurately, securely and confidentially | | | |
| **P3** use correct passwords to access the relevant laboratory databases, and maintain the security and integrity of information | | | |
| **P4** use correct search procedures to confirm that batch/patient demographic data on samples received are correct | | | |
| **P5** follow correct protocols for registering new batch/sample/patient data | | | |
| **P6** select correct laboratory data/patient files, and accurately input batch/patient and clinical details with the requested tests for each sample/specimen | | | |
| **P7** complete required back-up procedures regularly | | | |
| **P8** retrieve required information and distribute to the relevant people according to deadlines and workplace procedures | | | |
| **P9** communicate the required information about the work done to authorised people | | | |

| ***Knowledge and Understanding Criteria*** *You need to know and understand:* | **Evidence 1** | **Evidence 2** | **Evidence 3** |
|---|---|---|---|
| **K1** the health and safety requirements of the area in which you are carrying out the activities | | | |
| **K2** the scientific or similar techniques and processes that you must use correctly in the workplace | | | |
| **K3** the limits of your own authority and to whom you should report if you have problems that you cannot resolve | | | |
| **K4** the importance of correct documentation, identification, and any unique workplace coding system | | | |

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|---|---|---|---|
| **K5** the skills and procedures needed to do the routine tasks and work activities allocated | | | |
| **K6** the importance of completing tasks and procedures to the required time deadlines and organisational standard | | | |
| **K7** the different types of information systems that can be used, including recording, filing, retrieval of information and distribution systems | | | |
| **K8** how to use backup systems and why they are important | | | |
| **K9** how to always ensure the confidentiality and security of information and why this is important | | | |
| **K10** how to identify problems, and what is the appropriate action to take within the limits of your responsibility | | | |

**Assessor Comments/Feedback**

| COGLS216 | **Operating in a clean room or aseptic facility in life sciences and related industries**<br>*(Level 6, 9 Credits)* |
|---|---|

**Overview**

This standard covers the skills you need to follow health and safety procedures in a workplace where activities are performed. You must observe all legal, statutory and organisational requirements, be able to identify any hazards and potential risks and follow workplace standard operating and emergency procedures to ensure the safety of yourself, colleagues and others.

You must be able to recognise the limitations of your own work and ask for appropriate help and advice when needed. You will work under a high level of supervision, whilst taking responsibility for your own actions, the quality and accuracy of the work that you carry out and the necessary safeguards to protect yourself and others in the workplace.

Your underpinning knowledge will provide an understanding of your work, to safely apply the appropriate scientific and related principles and practices in the safe use of the materials, equipment, consumables and instruments used to perform your work activities.

| ***Performance Criteria*** *You must be able to:* | **Evidence 1** | **Evidence 2** | **Evidence 3** |
|---|---|---|---|
| **P1** ensure that your work is carried out in accordance with workplace procedures to protect yourself and others | | | |
| **P2** carry out visual quality checks on your personal protection equipment (PPE) prior to entering the working environment | | | |
| **P3** follow the correct procedures for entering, working in and exiting the clean room or clean work area | | | |
| **P4** remove personal protection equipment (PPE) on completion of clean room or clean work area activities, and dispose/store in line with the correct procedure | | | |
| **P5** communicate the required information about the work done, to authorised people, in accordance with departmental and organisational procedures | | | |

| ***Knowledge and Understanding Criteria*** *You need to know and understand:* | **Evidence 1** | **Evidence 2** | **Evidence 3** |
|---|---|---|---|
| **K1** the health and safety requirements of the area in which you are carrying out the activities | | | |
| **K2** the implications of not taking account of legislation, regulations, standards and guidelines when conducting the activities | | | |
| **K3** the correct procedures for the work you are carrying out | | | |
| **K4** the limits of your own authority and to whom you should report if you have problems, you cannot resolve | | | |
| **K5** the organisational requirements for maintaining the security of the workplace | | | |
| **K6** the importance of wearing protective clothing when handling materials such as biochemical substances, pathogens and antigens | | | |
| **K7** the range of equipment used to contain and handle biochemical substances, pathogens and antigens | | | |
| **K8** the correct fitting and use of clothing and personal protective equipment (PPE) that must be worn in a clean room or clean work area (such as for body, hands, eyes, ears, feet, mouth and face) | | | |

| | | | |
|---|---|---|---|
| **K9** the specific safety precautions to be taken when working in a clean room or clean work area environment | | | |
| **K10** the procedures for entering and exiting the clean room or clean work area, and the authority needed to do so | | | |
| **K11** the classification of the relevant clean room or clean work area, and how these impacts on you | | | |
| **K12** the procedures and methods for storing and maintaining issued clothing and personal protective equipment (PPE) | | | |
| **K13** how to apply procedures for dealing with damaged or dirty clothing and personal protective equipment (PPE) | | | |
| **K14** the policy and procedures relating to personal items (such as body lotions, make-up, jewellery, contact lenses, footwear, own clothing) | | | |

| **Assessor Comments/Feedback** |
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| COGSQO-03 | **Assure Quality Methods and Procedures in a Science or Technology Environment**<br>*(Level 6, 5 Credits)* |
|---|---|

**Overview**

This standard covers the competences you need to assure quality methods and procedures in a science or technology environment.

You will be required to demonstrate that you can identify suitable quality assurance methods and procedures and ensure that the specified quality assurance methods and procedures are implemented correctly in accordance with authorised procedures.

| ***Performance Criteria*** *You must be able to:* | **Evidence 1** | **Evidence 2** | **Evidence 3** |
|---|---|---|---|
| **P1** ensure that your work is carried out in accordance with standard operating procedures (SOPs), regulatory or license requirements and Good Manufacturing Practices (GMP) | | | |
| **P2** always work safely, complying with health and safety and other relevant regulations and guidelines | | | |
| **P3** establish clear and precise criteria for assuring the quality of science manufacturing processes and systems | | | |
| **P4** identify suitable quality assurance methods and procedures | | | |
| **P5** ensure that the specified quality assurance methods and procedures are implemented correctly | | | |
| **P6** obtain accurate information from valid sources on the science manufacturing projects or processes being quality assured | | | |
| **P7** clearly specify the required quality of science manufacturing processes | | | |
| **P8** assess accurately and realistically the quality of the science manufacturing processes | | | |
| **P9** ensure that information on quality is provided to the appropriate people | | | |
| **P10** recommend improvements to quality to the appropriate people | | | |

| ***Knowledge and Understanding Criteria*** *You need to know and understand:* | **Evidence 1** | **Evidence 2** | **Evidence 3** |
|---|---|---|---|
| **K1** the health and safety requirements of the area in which you are carrying out the science activities | | | |
| **K2** the implications of not taking account of legislation, regulations, standards and guidelines when conducting science activities | | | |
| **K3** the standard operating procedures, as set down in local science operating instruction documents or manuals (including computer-based systems) | | | |
| **K4** the importance of following equipment manufacturers' operating instructions | | | |
| **K5** the principles of Good Manufacturing Practice (GMP) applied in the workplace (if applicable) | | | |
| **K6** the importance of wearing protective clothing, gloves and eye protection when handling materials including chemical, biochemical substances, and the equipment used to contain and process them | | | |

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|---|---|---|---|
| **K7** the science product and batch process tracking and records system | | | |
| **K8** the types of handling and sorting system, and the procedures used for science products undergoing processing in the science facilities. | | | |
| **K9** the importance of correct identification, and any unique organisational or scientific numbers | | | |
| **K10** the organisational requirements for maintaining the security of the workplace | | | |
| **K11** the lines of communication and responsibilities in your department, and their links with the rest of the organisation | | | |
| **K12** the limits of your own authority and to whom you should report if you have problems that you cannot resolve | | | |
| **K13** the quality criteria that could be used for different types of scientific processes | | | |
| **K14** the quality assurance methods that are available | | | |
| **K15** statistical methods for recording and analysing scientific processes | | | |
| **K16** other non-statistical methods that could be used for obtaining information on scientific processes | | | |
| **K17** the relevant sources of valid information on scientific processes | | | |
| **K18** who should be involved in the scientific quality assurance process | | | |
| **K19** the type of impact that scientific quality assurance could have on the organisation | | | |
| **K20** who requires information on scientific quality assurance, and the procedures for informing them | | | |
| **K21** how to obtain quality information on resources used by the scientific environment | | | |
| **K22** how to determine the resources that are necessary to ensure that quality methods and procedures are applied | | | |
| **K23** how to determine the availability and suitability of resources | | | |
| **K24** the regulations and guidelines relevant to your area of responsibility | | | |
| **K25** how to obtain and interpret information on regulations and guidelines | | | |
| **K26** the types of recommendations that could emerge from the quality assurance process | | | |
| **K27** methods of presenting scientific quality assurance recommendations | | | |

**Scope/Range**

**1.** Carry out all the following activities:

**1.1** establish clear criteria as the basis of the quality assurance process
**1.2** obtain accurate information from appropriate sources for consideration in the process
**1.3** assess and specify the quality requirements for the scientific projects or processes
**1.4** identify suitable quality assurance methods, techniques and procedures
**1.5** assess the implications of implementing the quality assurance procedures
**1.6** present recommendations for improvements to the quality assurance process to the appropriate people
**2.** Develop quality assurance procedures that cover two of the following:

**2.1** new project/process
**2.2** revisions to existing project/process
**2.3** legal/legislative requirement
**2.4** international/national standards
**2.5** company standard operating procedures

**3.** Obtain accurate information from five of the following sources:

**3.1** quality assurance department
**3.2** equipment manuals/specifications
**3.3** FDA/EMEA/MHRA regulations (and any other relevant industry regulator)
**3.4** project output specifications
**3.5** other regulations and guidelines
**3.6** international/national standards
**3.7** legal/patented information
**3.8** company standard operating procedures
**3.9** customer specifications

**4.** Identify suitable quality assurance methods and procedures for four of the following:

**4.1** manufacturing output specification
**4.2** material specifications
**4.3** patents
**4.4** product quality checks
**4.5** batch inspection
**4.6** manufacturing methods
**4.7** process parameters
**4.8** technical support procedures
**4.9** schedule checking
**4.10** legal requirements
**4.11** use of international/national standards
**4.12** company standards operating procedures
**4.13** other (please specify)

**5.** Ensure that the quality assurance methods and procedures comply with four of the following:

**5.1** organisational standard operating procedures (SOP)
**5.2** equipment operation specification
**5.3** health, safety and environmental requirements
**5.4** manufacturing record keeping
**5.5** recognised compliance agency/body's standards
**5.6** customer standards and requirements

**5.7** aseptic/sterilisation requirements
**5.8** relevant standards for example, BS and/or ISO standards

**6.** Record details of work done, and communicate the details to the appropriate people, using:

**6.1** verbal report Plus one method from the following:
**6.2** written or typed report
**6.3** specific company documentation
**6.4** computer-based record
**6.5** electronic mail

| **Assessor Comments/Feedback** |
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| COGSQO-05 | **Inspect Quality of Raw Material and Products within a Science or Technology Manufacturing, Storage and Distribution Environment** *(Level 6, 3 Credits)* |
|---|---|

**Overview**

This standard is about ensuring that sources and supplies of science or technology-based products meet the appropriate quality specification and are safe to use. It involves controlling and monitoring the supply of raw materials and intermediate products in science manufacturing and processing industries. It covers the inspection and checking of items to ensure they meet standard operating requirements and specifications on delivery and prior to use during manufacture or processing.

You will need to be able to check items on arrival and ensure that it conforms to product specifications.

| ***Performance Criteria*** *You must be able to:* | **Evidence 1** | **Evidence 2** | **Evidence 3** |
|---|---|---|---|
| **P1** ensure that the supplies conform to internal and external quality specifications | | | |
| **P2** ensure all checks relating to packaging design and materials are within agreed product specification | | | |
| **P3** ensure all incoming supplies meet the specified quality criteria | | | |
| **P4** respond to deficiencies, discrepancies or non-conformance identified in the process of quality checking and auditing | | | |
| **P5** ensure all batch production deviations (planned or unintended) covering all manufacturing facilities, equipment, operations. distribution, procedures, systems and record keeping should be reported and investigated for corrective and preventative action (CAPA) | | | |
| **P6** ensure accurate records are maintained in line with Good Manufacturing & Good Distribution Practices (GDP) and Good Documentation Practice (GDocP) | | | |
| **P7** ensure all relevant documentation provided by suppliers is complete and accurate in accordance to supply chain procedures | | | |
| **P8** ensure issues outside your authority are escalated to the appropriate level to ensure expedient action in resolving issues | | | |
| **P9** monitor and record information in line with internal procedures and supplier auditing requirements | | | |
| **P10** identify where regular inconsistencies in supplies occur and ensure resolution to these issues | | | |
| **P11** make recommendations to colleagues and technical staff where failure against specifications suggests that a new source of supply is needed | | | |
| **P12** make recommendations to colleagues and technical staff regarding the suitability of the criteria used as a measure of acceptance | | | |

| ***Knowledge and Understanding Criteria*** *You need to know and understand:* | **Evidence 1** | **Evidence 2** | **Evidence 3** |
|---|---|---|---|
| **K1** the policies, guidelines and legislation relating to sources and supply of raw materials relevant to the workplace and products within manufacturing and storage | | | |
| **K2** your organisation's supply chain assurance guidelines, policies, audit requirements, and how they are applied | | | |
| **K3** the principles of corrective and a preventative action process (CAPA) | | | |

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|---|---|---|---|
| **K4** the principles and implementation of GMP, GDP and GDocP | | | |
| **K5** the types and sources of raw materials, intermediates items and products | | | |
| **K6** the agreed criteria for acceptance and non-acceptance of supplies required for products | | | |
| **K7** the critical control points for transport, receipt and acceptance of supplies | | | |
| **K8** the control and sampling methods appropriate to type and source of supply | | | |
| **K9** how control and sampling methods used by the business should be applied | | | |
| **K10** the potential methods, sources and types of product contamination that can be encountered during product transportation and delivery | | | |
| **K11** how contamination during transportation and delivery can be identified | | | |
| **K12** the range of checks that can be applied to ensure that delivery is safe | | | |
| **K13** the recording systems that are in place to record data related to accepted and declined deliveries | | | |
| **K14** the impact that external audit requirements have upon the acceptance | | | |
| **K15** the range of data that is used to support external audits | | | |
| **K16** the requirements for certificates of conformity | | | |
| **K17** the procedures to ensure product and manufacturing traceability | | | |
| **K18** the product specifications for raw materials and supplies | | | |
| **K19** the corrective actions to be taken when an item is received that does not conform with product specification | | | |

| **Assessor Comments/Feedback** |
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| COGSQO-13 | **Conduct Scientific or Technical Sampling and Testing Operations**<br>*(Level 5, 6 Credits)* |
|---|---|

**Overview**

This standard covers the competences you need to carry out sampling or complex scientific technical testing operations in a science or technology related work activity, in accordance with approved procedures and practices.

You will be required to demonstrate that you can select the appropriate testing or sampling methods from the relevant standard operating procedures and other regulatory or licence agreements.

| ***Performance Criteria*** *You must be able to:* | **Evidence 1** | **Evidence 2** | **Evidence 3** |
|---|---|---|---|
| **P1** be compliant with the health and safety requirements of the areas in which you are carrying out the scientific or technical activities | | | |
| **P2** ensure that your work is carried out in accordance with workplace standard operating procedures (SOPs) and other relator or licence agreements | | | |
| **P3** use the appropriate personal protection equipment (PPE) when performing scientific or technical activities | | | |
| **P4** ensure plant, equipment and environment conditions are safe for scientific and/or technical sampling and/or testing | | | |
| **P5** ensure the appropriate equipment and materials are available and ready for safe use in the sampling and testing procedures | | | |
| **P6** ensure all appropriate isolations have taken place to safely take samples from process or manufacturing plant and vessels | | | |
| **P7** collect samples in accordance with the standard operating procedures (SOP) (including appropriate use of PPE) ensuring all samples are correctly labelled | | | |
| **P8** maintain the condition of the sample appropriately in preparation for testing using any specialist handling and stage container to maintain integrity of sample | | | |
| **P9** establish the requirements for the scientific or technical tests and appropriate testing methods | | | |
| **P10** prepare the test samples in accordance with the procedures and check their integrity before commencement of testing procedure | | | |
| **P11** carry out the required tests in accordance with the procedures, noting results and recording as described in SOPs | | | |
| **P12** respond to test results communicating and acting when results are outside of acceptable parameters or constitute a hazard to personnel, plant, products or equipment | | | |
| **P13** communicate the required information about the work done, in accordance with departmental and organisational procedures | | | |
| **P14** safety dispose of, or store samples in accordance with environment procedures and SOPs | | | |
| **P15** return all test areas to clean state in preparation for next test procedure | | | |

| ***Knowledge and Understanding Criteria*** *You need to know and understand:* | **Evidence 1** | **Evidence 2** | **Evidence 3** |
|---|---|---|---|
| **K1** the health and safety requirements of the area in which you are carrying out the scientific or technical activities | | | |
| **K2** the implications of not taking account of legislation, regulations, standards and guidelines when conducting scientific or technical activities | | | |
| **K3** the scientific or technical techniques and processes you must use correctly in the workplace | | | |
| **K4** the importance of wearing protective clothing, gloves and eye protection for scientific or technical activities | | | |
| **K5** the importance of correct identification, and any unique workplace coding system | | | |
| **K6** the security of the workplace environment in accordance with SOPs and the organisational requirements | | | |
| **K7** the lines of communication and responsibilities in your department, and their links with the rest of the organisation | | | |
| **K8** the importance of following safe operating procedures when using equipment and or materials and know the limits of your own authority and understand how and when to escalate problems and issues | | | |
| **K9** the use and range of equipment and procedures in sampling and testing | | | |
| **K10** the principles and purposes of testing, and the specific use to which the test results are to be put | | | |
| **K11** the relevant testing methods that can be used to achieve the purpose of testing | | | |
| **K12** why calibration is important and how to check calibration | | | |
| **K13** how to check the sample identity and its integrity | | | |
| **K14** the range of methods used to prepare samples | | | |
| **K15** how to identify defective equipment and the appropriate action to take | | | |
| **K16** the methods used for controlling test variables | | | |
| **K17** the concepts of repeatability and reproducibility | | | |
| **K18** the potential impact of the test on health, safety and the environment | | | |
| **K19** the methods used for dealing with the handling, storage and disposal of materials | | | |
| **K20** the cleaning materials and the methods for their use | | | |
| **K21** the methods of safe storage that can be used | | | |
| **K22** the document control and reporting procedures that should be used | | | |
| **K23** the reasons why effective communication is important and the methods used for communicating effectively | | | |

**Assessor Comments/Feedback**

| COGSQO-02 | **Analyse and Interpret Data in Science or Technology Related Industries** *(Level 7, 9 Credits)* |
|---|---|

**Overview**

This standard covers the competences you need to analyse and interpret data in science or technology related industries.

You will be required to demonstrate that you can perform accurate preparation and analysis of samples, identify appropriate analysis techniques, analyse data, analyse non-conformance and write technical reports to communicate data information within the organisation.

| ***Performance Criteria*** *You must be able to:* | **Evidence 1** | **Evidence 2** | **Evidence 3** |
|---|---|---|---|
| **P1** ensure that your work is carried out in accordance with good documentation practices (GDocP), regulatory, legislative, licenses and organisations procedures and policies | | | |
| **P2** use appropriate Manufacturing Information Management Systems (MIMS) database to access data and information required to perform the analysis | | | |
| **P3** maintain security and integrity requirements when accessing computer systems in data searches and analysis | | | |
| **P4** use correct search procedures and methodology to review data and information required in the data retrieval process. | | | |
| **P5** perform quality checks on the data in accordance with organisational protocols, policies and procedures | | | |
| **P6** compile the results of the analysis and check for any variances in the data | | | |
| **P7** resolve variation issues within your range of responsibility, escalating the issue, if not resolved, to the appropriate person | | | |
| **P8** report any variance issues to the appropriate people and deal with them in accordance with organisational policies and procedures | | | |
| **P9** carry out the report writing within the agreed timeline and in accordance with the GDocP and the organisations reporting procedures | | | |
| **P10** use statistical techniques to analyse data | | | |
| **P11** employ statistical process control techniques to monitor quality of manufactured products | | | |
| **P12** input data into Manufacturing Information Management Systems | | | |
| **P13** communicate the analysis report in accordance with the department and organisational procedures | | | |

| ***Knowledge and Understanding Criteria*** *You need to know and understand:* | **Evidence 1** | **Evidence 2** | **Evidence 3** |
|---|---|---|---|
| **K1** the health and safety requirements of the area in which you are carrying out your science work related activity and your personal responsibilities with regards to safety | | | |
| **K2** the requirements of regulatory, legislative, licenses and organisations procedures and policies and why it is important to follow them | | | |
| **K3** the principles of good manufacturing practices (GMP) and good document control practices (GDocP) used in the science workplace | | | |

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|---|---|---|---|
| **K4** the latest technological developments relevant to the science industry and how to keep up-to date with them | | | |
| **K5** the strategic direction of the industrial sciences agenda across the UK and globally and how this will influence the organisation | | | |
| **K6** the organisational structure including roles and responsibilities and line of communication in your department and the wider business environment | | | |
| **K7** how to review analysis information and interpret data in science related work activities | | | |
| **K8** the different methodologies used to analyse data | | | |
| **K9** types of variation that can occur with data and the causes | | | |
| **K10** what to do when variations in data occur | | | |
| **K11** how to write a report in accordance with organisation procedures and GDocP practices | | | |
| **K12** the different types of reports and who to issue the reports to | | | |
| **K13** when, why and how to make amendments to analysis, documents and reports within the area of responsibility | | | |
| **K14** how to communicate effectively, and how to identify key information when recording and reporting information | | | |
| **K15** the test codes, coded comments, requester, location codes and product comment codes required for accurate data input | | | |
| **K16** the use of statistical techniques to analyse data | | | |
| **K17** the principles of statistical process control techniques | | | |

| **Assessor Comments/Feedback** |
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| COGLATA3-09 | **Carry out Scientific or Technical Investigations** *(Level 7, 9 Credits)* |
|---|---|

**Overview**

This standard covers the competences you need to carry out scientific or technical investigations in a science related work activity, in accordance with approved procedures and practices.

You will be required to demonstrate you can show you have selected and used appropriate scientific or technical skills, methods and procedures. You will use appropriate investigation to inform actions and review how effective these methods have been in accordance with the relevant workplace procedures.

| ***Performance Criteria*** *You must be able to:* | **Evidence 1** | **Evidence 2** | **Evidence 3** |
|---|---|---|---|
| **P1** ensure that your work is carried out in accordance with workplace procedures | | | |
| **P2** use safe practices and the appropriate personal protection equipment (PPE) when performing scientific or technical activities | | | |
| **P3** obtain and collate appropriate scientific or technical information which assists the investigation | | | |
| **P4** analyse the information correctly and evaluate it against the objective of the investigation | | | |
| **P5** prioritise the tasks within the investigation and follow the appropriate procedures | | | |
| **P6** use the specified resources required to complete the investigations | | | |
| **P7** follow set procedures to deal with contingencies arising during investigations | | | |
| **P8** conduct investigations in accordance with the established plans | | | |
| **P9** communicate the required information about the work done, in accordance with departmental and organisational procedures | | | |

| ***Knowledge and Understanding Criteria*** *You need to know and understand:* | **Evidence 1** | **Evidence 2** | **Evidence 3** |
|---|---|---|---|
| **K1** the health and safety requirements of the area in which you are carrying out the scientific or technical activities | | | |
| **K2** the implications of not taking account of legislation, regulations, standards and guidelines when conducting scientific or technical activities | | | |
| **K3** the scientific or technical techniques and processes you must use correctly in the workplace | | | |
| **K4** the importance of wearing protective clothing, gloves and eye protection for scientific or technical activities | | | |
| **K5** the importance of correct identification, and any unique workplace coding system | | | |
| **K6** the organisational requirements for maintaining the security of the workplace | | | |
| **K7** the lines of communication and responsibilities in your department, and their links with the rest of the organisation | | | |
| **K8** the limits of your own authority and to whom you should report if you have problems that you cannot resolve | | | |

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|---|---|---|---|
| **K9** the principles and procedures for investigations | | | |
| **K10** the techniques that are relevant to the scientific or technical investigation | | | |
| **K11** how to source and access relevant standards | | | |
| **K12** the acceptable operating conditions for conducting investigations | | | |
| **K13** the implications of deviations from set procedures | | | |
| **K14** the essential features of an investigation plan and why this must be followed | | | |
| **K15** the range of equipment used for investigations | | | |
| **K16** the procedures for recording and reporting the investigations done | | | |
| **K17** how to identify and deal with contingencies | | | |
| **K18** the limits and constraints for investigations that are done | | | |
| **K19** the procedures used to deal with deviations from investigation plans | | | |
| **K20** what the procedures are for using contingency plans when deviations from investigation plans occur | | | |
| **K21** the document control and reporting procedures that should be used | | | |
| **K22** the reasons why effective communication is important, and the methods used for communicating effectively | | | |

**Scope/Range**

**1.** carry out investigations into one of the following:

**1.1** a non-compliance problem
**1.2** the properties of a new material
**1.3** applications of a new material
**1.4** identifying a substance
**1.5** resolution technical problem
**1.6** cost reduction programme
**1.7** quality assurance review
**1.8** hazard/accident

**2.** evaluation information from two of the following sources:

**2.1** new external standards/regulations
**2.2** manufacturer's instructions
**2.3** equipment technical reviews
**2.4** material technical reviews
**2.5** COSHH data sheets
**2.6** environmental reports
**2.7** in-company archives
**2.8** operating procedures
**2.9** test reports

**2.10** accident reports
**2.11** health and safety documentation

**3.** use two of the following resources to complete the investigations:

**3.1** other staff
**3.2** equipment
**3.3** materials
**3.4** allotted time

**4.** deal with contingencies for one of the following:

**4.1** equipment failure
**4.2** changes in variables
**4.3** delays
**4.4** safety/environmental change

**5.** record and communicate details of work done, to the appropriate people, using:

**5.1** verbal report plus one method from the following:
**5.2** written or typed report
**5.3** computer-based record
**5.4** specific workplace documentation
**5.5** electronic mail

| **Assessor Comments/Feedback** |
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| COGLS11 | **Solve problems in life sciences related work activities** *(Level 6, 7 Credits)* |
|---|---|

**Overview**

This standard identifies the competences you need to solve problems in life sciences related work activities in accordance with approved procedures. You are required to take prompt and appropriate action to the problem.

You will be required to investigate the problem, obtaining all the necessary information to enable you to identify and evaluate possible solutions, and their effects on the work being carried out. You will also be expected to decide on a plan of action, and to communicate this to the relevant people. During this work you must take account of the relevant worksite operational requirements, procedures and safe working practices AS THEY APPLY TO YOU.

| ***Performance Criteria*** *You must be able to:* | **Evidence 1** | **Evidence 2** | **Evidence 3** |
|---|---|---|---|
| **P1** ensure that your life sciences related work activity is carried out in accordance with organisational policies and procedures | | | |
| **P2** wear the personal protection equipment (PPE) appropriate for the work area | | | |
| **P3** identify the nature and extent of the problem | | | |
| **P4** obtain all the relevant information relating to the problem | | | |
| **P5** inform the relevant people about the problem | | | |
| **P6** ensure you have adequate resources to deal with the problem you are dealing with | | | |
| **P7** present and evaluate solutions to individuals that are appropriate for the situation | | | |
| **P8** identify the most effective solution to rectify the problems and get authorisation from the appropriate people to sign off agreed way forward | | | |
| **P9** ensure the solutions are implemented correctly and promptly according to organisational policies and procedures | | | |
| **P10** record the problem and the solution | | | |

| ***Knowledge and Understanding Criteria*** *You need to know and understand:* | **Evidence 1** | **Evidence 2** | **Evidence 3** |
|---|---|---|---|
| **K1** why it's important to understand and keep up with the strategic direction of the life sciences agenda across the UK and globally and how this will influence the organisation | | | |
| **K2** how to develop internal and external networks within the life sciences community for the area you are working in | | | |
| **K3** why it's important to understand the latest technological developments in the life sciences industry and how to keep up-to-date with them | | | |
| **K4** the impact of cost effectiveness within the life sciences industry | | | |
| **K5** the health and safety requirements of the area in which you are working | | | |
| **K6** the implications of not taking account of legislation, regulations, standards and guidelines | | | |

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|---|---|---|---|
| **K7** the importance of correct identification numbers and coding used by the organisation | | | |
| **K8** the lines of communication and responsibilities in your department, and their links with the rest of the organisation | | | |
| **K9** the limits of your own authority and to whom you should report if you have problems that you cannot resolve | | | |
| **K10** how to obtain details of problems that can arise in the work activities | | | |
| **K11** the criticality of different types of problems, and how to prioritise the problems to be solved | | | |
| **K12** how to obtain any necessary resources to support the investigation or solution to the problem under investigation | | | |
| **K13** the methods and techniques involved in problem solving | | | |
| **K14** the methods and techniques involved in evaluating information | | | |
| **K15** how to retrieve necessary data from company information systems | | | |
| **K16** the types of monitoring systems/techniques available, and their application | | | |
| **K17** the factors that must be considered when selecting the solution to a problem | | | |
| **K18** how to record the problem and the solution carried out | | | |

| **Assessor Comments/Feedback** |
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|---|---|
| COGLATA4-05 | **Plan and run scientific or technical projects for workplace activities** *(Level 7, 5 Credits)* |

**Overview**

The standard covers competences you need to plan and run scientific or technical projects for the workplace activities in accordance with approved procedures and practices.

You will be required to demonstrate that you can plan and run scientific or technical projects using meticulous planning involving management, colleagues, customers/clients and a wide range of resources. You will meet objectives, deadlines and targets in accordance with workplace procedures.

| ***Performance Criteria*** *You must be able to:* | **Evidence 1** | **Evidence 2** | **Evidence 3** |
|---|---|---|---|
| **P1** ensure that your work is carried out in accordance with workplace procedures | | | |
| **P2** use safe practices and the appropriate personal protection equipment (PPE) where scientific or technical activities are performed | | | |
| **P3** identify and agree the business and scientific or technical requirements of your role in the workplace | | | |
| **P4** establish processes that deliver scientific or technical outcomes based on organisational goals and aims | | | |
| **P5** evaluate available information and consult with others to prepare project plans for the delivery of scientific or technical activities | | | |
| **P6** submit proposed projects to the relevant people in the organisation, for approval and to assist the overall planning process | | | |
| **P7** use the agreed project plans to start, monitor and control delivery of scientific or technical activities | | | |
| **P8** evaluate variances between what was planned and what happened on the project | | | |
| **P9** take prompt corrective action, obtaining agreement from the relevant people if required to deliver the critical project outcomes | | | |
| **P10** propose revisions to the project plan, if necessary, in response to variances and/or significant or unforeseen developments, and discuss and agree the revisions with the relevant people in the organisation | | | |
| **P11** provide ongoing information on performance against the project plan to relevant people in your organisation | | | |
| **P12** gather information from implementation of the project plan to assist in the preparation of future project plans | | | |
| **P13** present the results of the work done to the appropriate people, in accordance with departmental and organisational procedures | | | |

| ***Knowledge and Understanding Criteria*** *You need to know and understand:* | **Evidence 1** | **Evidence 2** | **Evidence 3** |
|---|---|---|---|
| **K1** the health and safety requirements of the area in which you are carrying out the scientific or technical activities | | | |
| **K2** the implications of not taking account of legislation, regulations, standards and guidelines when conducting scientific or technical activities | | | |
| **K3** the scientific or technical techniques and processes you must use correctly in the workplace | | | |
| **K4** the importance of wearing protective clothing, gloves and eye protection for scientific or technical activities | | | |
| **K5** the importance of correct identification, and any unique workplace coding system | | | |
| **K6** the organisational requirements for maintaining the security of the workplace and keeping confidential documents | | | |
| **K7** the workplace business aims and goals and the planning process | | | |
| **K8** the workplace organisational structure, its values and culture | | | |
| **K9** how your scientific or technical activities add value through delivering workplace products, services and processes | | | |
| **K10** the lines of communication and responsibilities in your department, and the links with the rest of the organisation | | | |
| **K11** the limits of your own authority and to whom you should report if you have problems that you cannot resolve | | | |
| **K12** how to identify and assess the scientific or technical requirements of your work role | | | |
| **K13** the different ways in which you have set your agreed personal work objectives | | | |
| **K14** the different perspectives and approaches that are important when exercising autonomy or judgement about scientific or technical activities used | | | |
| **K15** the types of investigation initiated and used to review the effectiveness or appropriateness of methods, action and results of your scientific or technical work | | | |
| **K16** the consequences of breaches of quality procedures | | | |
| **K17** how to identify hazards and what action to take | | | |
| **K18** what systems are used to ensure quality within the workplace and the projects delivered | | | |
| **K19** the methods used to plan projects and the activities and tasks associated with them | | | |
| **K20** what standards and workplace procedures are appropriate to scientific or technical projects | | | |
| **K21** who are the project customers, and how to elicit and confirm their requirements | | | |
| **K22** how to develop and monitor detailed project objectives from plans | | | |
| **K23** how to clarify and agree project objectives with the customer | | | |
| **K24** why it is important to explore and evaluate alternative project plans | | | |
| **K25** who needs to be consulted when planning and resourcing project plans | | | |

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| **K26** how to write the project plan, incorporating all necessary details into the plan | | | |
| **K27** how to make efficient use of resources | | | |
| **K28** how to evaluate variances between plans and what was actually being delivered on the project | | | |
| **K29** the range of corrective actions that can be used when delivery of the critical outcomes may be under threat | | | |
| **K30** how to update and revise project plans in response to variances and/or significant or unforeseen developments, and who should be consulted | | | |
| **K31** how to provide information/reports on performance during and after projects | | | |
| **K32** the document control and reporting procedures that should be used | | | |
| **K33** the reasons why effective communication is important, and the methods used for communicating effectively | | | |

**Scope/Range**

**1.** prepare a project plan for scientific or technical activities that:

**1.1** can deliver outcomes in line with workplace goals and aims plus all the following:
**1.2** identifies and explores alternative strategies for delivery
**1.3** consider the views of the project team and any other relevant people
**1.4** incorporates all relevant time, cost and delivery measures/milestones
**1.5** makes efficient use of available resources

**2.** devise project plans with two of the following components:

**2.1** multi stage/activity operations
**2.2** high level of skill/experience needed
**2.3** multitasking requirements
2.4 constraints (e.g., resources, regulatory)
2.5 multi-parameter or control factors
**2.6** critical path dependencies

**3.** consult two of the following people during the preparation and running of projects:

**3.1** supervisor
**3.2** team leader
**3.3** teacher or trainer
**3.4** manager
**3.5** head of department
**3.6** customer
**3.7** the project team
**3.8** health and safety officer

**4.** confirm project objectives are all the following:

**4.1** specific
**4.2** measurable
**4.3** achievable
**4.4** realistic
**4.5** time bound

**5.** quantify four of following resource requirements for projects:

**5.1** materials
**5.2** equipment
**5.3** financial
**5.4** time
**5.5** personnel

**6.** deliver projects with two of the following critical outcomes:

**6.1** specified output quality
**6.2** within defined budget
**6.3** against fixed timescale

**7.** record and communicate details of the work done, to the appropriate people, using:

**7.1** verbal report plus one method from the following:
**7.2** written or typed report
**7.3** computer-based record
**7.4** specific workplace documentation
**7.5** electronic mail

| **Assessor Comments/Feedback** |
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| COGLATA3-11 | **Diagnose faults, repair and maintain scientific or technical equipment for workplace activities** *(Level 7, 8 Credits)* |
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**Overview**

This standard covers the competences you need to maintain and control stocks of all resources, equipment and consumables for workplace scientific or technical activities in accordance with approved procedures and practices.

You will be required to demonstrate that you can accurately identify equipment faults. You will perform repairs and maintain in accordance with manufacturer's drawings/instructions. You will ensure equipment is returned into service in accordance with the relevant workplace procedures.

| ***Performance Criteria*** *You must be able to:* | **Evidence 1** | **Evidence 2** | **Evidence 3** |
|---|---|---|---|
| **P1** ensure that your work is carried out in accordance with workplace procedures | | | |
| **P2** use safe practices and the appropriate personal protection equipment (PPE) when doing scientific or technical activities | | | |
| **P3** confirm that the scientific or technical equipment is in a safe and usable condition, according to established procedures | | | |
| **P4** identify accurately any equipment faults or problems and report those outside your control to the relevant people | | | |
| **P5** identify and interpret the required information from the manufacturers' instructions and diagrams, in accordance with established operating procedure | | | |
| **P6** employ the appropriate test equipment and measurement to locate the source of the fault | | | |
| **P7** perform repair or maintenance in accordance with manufacturers' instructions, diagrams and relevant health and safety procedures | | | |
| **P8** organise the repair of defective equipment when other specialists are required | | | |
| **P9** dispose of defective equipment that is beyond repair, in accordance with workplace procedures | | | |
| **P10** test and confirm that the equipment is operating correctly, within calibration specifications, in accordance with workplace procedures | | | |
| **P11** maintain records of repairs, maintenance and checks completed in accordance with workplace procedures | | | |
| **P12** communicate the required information about the work done, in accordance with departmental and organisational procedures | | | |

| ***Knowledge and Understanding Criteria*** *You need to know and understand:* | **Evidence 1** | **Evidence 2** | **Evidence 3** |
|---|---|---|---|
| **K1** the health and safety requirements of the area in which you are carrying out the scientific or technical activities | | | |
| **K2** the implications of not taking account of legislation, regulations, standards and guidelines when conducting scientific or technical activities | | | |
| **K3** the scientific or technical techniques and processes you must use correctly in the workplace | | | |
| **K4** the importance of wearing protective clothing, gloves and eye protection for scientific or technical activities | | | |

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|---|---|---|---|
| **K5** the importance of correct identification, and any unique workplace coding system | | | |
| **K6** the organisational requirements for maintaining the security of the workplace | | | |
| **K7** the lines of communication and responsibilities in your department, and the links with the rest of the organisation | | | |
| **K8** the limits of your own authority and to whom you should report if you have problems that you cannot resolve | | | |
| **K9** the manufacturers' specifications and recommendations for the maintenance and calibration of the scientific or technical equipment | | | |
| **K10** where to obtain, and how to interpret drawings, circuit diagrams, specifications, manufacturers' manuals and other technical documents needed for the fault-finding or maintenance activities | | | |
| **K11** the methods used for visually checking, and cleaning, of scientific or technical equipment | | | |
| **K12** the different types, condition and quantities of consumables required for the range of scientific or technical equipment maintained | | | |
| **K13** the methods for maintaining personal health and safety during the maintenance of equipment | | | |
| **K14** the methods for maintaining personal hygiene | | | |
| **K15** how to check that the scientific or technical equipment is working correctly and in accordance with the manufacturer's specifications | | | |
| **K16** how to evaluate the different types of equipment fault, and how these must be dealt with | | | |
| **K17** how to use appropriate tools and equipment to locate the source of a fault or carry out maintenance activities | | | |
| **K18** the procedures to be followed to investigate faults or maintenance activities | | | |
| **K19** the department or person to whom equipment faults should be reported | | | |
| **K20** the methods used for keeping records of the maintenance, cleaning and calibration of scientific or technical equipment, and why this is important | | | |
| **K21** the procedure for the disposal of any waste produced and any equipment beyond repair | | | |
| **K22** the document control and reporting procedures that should be used | | | |
| **K23** the reasons why effective communication is important, and the methods used for communicating effectively | | | |

**Scope/Range**

**1.** carry out all the following operations

**1.1** adhere to procedures or systems in place for risk assessment, COSHH, use of personal protective equipment, electricity at work and other relevant safety regulations
**1.2** ensure the safe isolation of scientific or technical equipment (such as electrical and fluids supply)
**1.3** follow manufacturers' instructions, drawings and procedures for repair or maintenance
**1.4** check that the tools and equipment used are in a safe and usable condition
**1.5** ensure that the scientific or technical equipment is kept free from foreign objects, dirt or other contamination
**1.6** carry out auditory and visual checks on the operation of the equipment
**1.7** identify fault and isolate components where appropriate to determine the corrective action

**1.8** confirm that the equipment is ready for use
**1.9** return all repair and maintenance tools, equipment and waste to the correct locations on completion of the activities
**1.10** ensure that accurate, complete and legible records are kept of the repair and maintenance activities

**2.** carry out maintenance and cleaning on two of the following scientific or technical categories:

**2.1** biological equipment and/or instruments
**2.2** chemical equipment and/or instruments
**2.3** electronic equipment and/or instruments
**2.4** weighing and measuring equipment and/or instruments
**2.5** information technology equipment
**2.6** engineering machines, equipment and/or instruments
**2.7** other technical equipment or instruments

**3.** record and communicate details of work done, to the appropriate people, using:

**3.1** verbal report plus one method from the following:
**3.2** written or typed report
**3.3** computer-based record
**3.4** specific workplace documentation
**3.5** electronic mail

| **Assessor Comments/Feedback** |
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| COGSQP-09 | **Maintain License Requirements and Good Manufacturing Practice (GMP) to Ensure Compliance** *(Level 7, 8 Credits)* |
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**Overview**

This standard covers the competencies you need to Maintain License requirements and current Good Manufacturing Practice (GMP) to ensure compliance with the UK Statutory Instruments and EU Directives.

You will be required to demonstrate that you can work with the quality (licensing) team to ensure that the appropriate licenses are in place for carrying out life science facilities operations. You will liaise with the licensing authorities to ensure appropriate documents and licenses are available at the time of selling, importing or exporting pharmaceutical products.

| ***Performance Criteria*** *You must be able to:* | **Evidence 1** | **Evidence 2** | **Evidence 3** |
|---|---|---|---|
| **P1** identify and evaluate all regulation and legislation needs for licensing activities in accordance with both the organisational premises (site) operating licence and as a marketing authority holder (MAH) licence | | | |
| **P2** design compliance strategies for all relevant business' areas and activities, including strategy for addressing risks and issues | | | |
| **P3** ensure appropriate licensing activities are implemented for relevant business groups | | | |
| **P4** ensure timely application and approval of licenses and monitor validity and expiry of all licensing documents which are required to carry out export and import operations | | | |
| **P5** monitor and maintain records on all compliance trends, making any recommendations for changes related to company processes and systems | | | |
| **P6** ensure all appropriate reports are completed for medicinal products and manage all communications with licensors | | | |
| **P7** evaluate the effective use of the reporting process and ensure appropriate audits are successfully completed | | | |
| **P8** monitor and review all relevant licensing agreements, communicating and recording compliance and non-compliance in the appropriate organisational record system | | | |
| **P9** maintain and update all distribution lists and manage all correspondence with licensed partners | | | |
| **P10** review reports to carry out the departmental checks in compliance with rules and regulations and other statutory requirements | | | |
| **P11** review and update departmental functions, including cost structures, manufacturing processes and stock management to ensure compliance with rules and regulations and other statutory requirements | | | |
| **P12** ensure regulatory compliance by identifying any variations or deviation from the regulatory guidelines | | | |
| **P13** provide advice on any corrective actions required to ensure deviations or non-compliance to regulations are resolved | | | |
| **P14** ensure communication of updated information on regulatory and licensing needs to different businesses and stakeholders in a timely manner | | | |
| **P15** obtain and exchange information from across teams and businesses need to confirm adherence to compliances | | | |
| **P16** establish, ensure and maintain protocol for sharing of regulatory and statutory-related information for licensing to prevent risk issues | | | |

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|---|---|---|---|
| **P17** ensure and maintain confidentiality of organisational data | | | |

| ***Knowledge and Understanding Criteria*** *You need to know and understand:* | **Evidence 1** | **Evidence 2** | **Evidence 3** |
|---|---|---|---|
| **K1** the strategies in your organisation that ensure compliance in all relevant business operations, processes and activities | | | |
| **K2** the principles of Good Manufacturing Practice (GMP) applied in your organisation | | | |
| **K3** the strategies in your organisation for addressing risks and issues in all relevant business operations, processes and activities | | | |
| **K4** the requirements to meet all relevant internal compliance policies and procedures in your organisation | | | |
| **K5** the requirement to meet all relevant regulatory licensing compliance in your organisation | | | |
| **K6** the documentation policies, templates and any software used in your organisation | | | |
| **K7** the defined procedure for reporting compliance risks and occurrences in your organisation | | | |
| **K8** the range of products and licensing needs associated with them in your organisation | | | |
| **K9** the relationships of your organisation with all other licensors and licensed partners | | | |
| **K10** the communication protocols in your organisation | | | |
| **K11** the legal and contracting procedures pertaining to the product manufacturing | | | |
| **K12** the supply chain management, operations and business in your organisation | | | |
| **K13** the contracts, tariffs and governments import and export regulation in accordance with the marketing authority holder (MAH) licence | | | |
| **K14** the implications of not complying to defined regulations and license agreements | | | |
| **K15** any supply chain best practices | | | |

**Assessor Comments/Feedback**

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|---|---|
| COGSQO-09 | **Maintain and improve quality documentation and processes for science or technology-based industries** *(Level 8, 4 Credits)* |

**Overview**

This standard covers the competences you need to maintain and control stocks of all resources, equipment and consumables for workplace scientific or technical activities in accordance with approved procedures and practices.

You will be required to demonstrate that you can accurately identify equipment faults. You will perform repair and maintenance in accordance with manufacturer's drawings/instructions. You will ensure equipment is returned into service in accordance with the relevant workplace procedures.

| ***Performance Criteria*** *You must be able to:* | **Evidence 1** | **Evidence 2** | **Evidence 3** |
|---|---|---|---|
| **P1** monitor and evaluate the quality of documents and system processes in accordance with Good Documentation Process (GDocP) and Good Manufacturing Processes (GMP) within science or technology related work activity | | | |
| **P2** ensure accurate and complete transfer of quality and regulatory information from the manufacturing process to customer and vice versa | | | |
| **P3** respond to the evaluation process, provide feedback and priority actions from the report findings to the appropriate people for change or improvement approval | | | |
| **P4** ensure recommendations and actions are implemented in accordance with organisational policies and procedures | | | |
| **P5** implement approved improvements to the documentation or processes in accordance with the organisations change management process | | | |
| **P6** ensure that conditions are suitable to implement the improvements in accordance with the change management process | | | |
| **P7** ensure all changes to process and procedures are accurately reflected in standard operating procedures (SOPs) and other relevant organisational documents | | | |
| **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 to achieve the most effective results | | | |
| **P10** ensure that new or improved documentation or processes are implemented according to the change management plan | | | |
| **P11** record the implementation of the improvements | | | |
| **P12** monitor the new or improved documentation or process to ensure satisfactory implementation | | | |
| **P13** ensure the resolution of any problems arising after implementation, recording information and the notifying of all relevant people | | | |
| **P14** assess and record the impact of the improvements on the quality related documentation or processes | | | |

| ***Knowledge and Understanding Criteria*** *You need to know and understand:* | **Evidence 1** | **Evidence 2** | **Evidence 3** |
|---|---|---|---|
| **K1** the health and safety requirements of the area in which the activities are being carried out | | | |
| **K2** the relevant legislation, regulations, product licence and organisational rules and procedures used in the science or technology related work activities | | | |

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| **K3** the importance of using the organisations change management system and the actions and responsibilities required in the change process | | | |
| **K4** the principles of GDocP and GMP when considering changes to documentation of processes | | | |
| **K5** latest technological developments relevant to the sciences or technology industry and how to keep up-to-date with them | | | |
| **K6** how to analyse the impact of bringing in new science technology or processes into the business | | | |
| **K7** the importance of using appropriate documentation control systems and documentation identification and record (paper and computer-based systems) | | | |
| **K8** the organisational requirements for maintaining the security of the workplace | | | |
| **K9** the organisational structure including roles and responsibilities and lines of communication in your department, and the wider business environment | | | |
| **K10** the limits of your own authority and to whom you should report to if you have problems that you cannot resolve | | | |
| **K11** the quality criteria (GDocP, GMP & QMS) that could be used for different types of documentation or processes within the sciences or technology related work activities | | | |
| **K12** how to obtain and interpret records, charts, specifications, equipment manuals, history and technical support reports and other documents needed for the implementation of quality improvements | | | |
| **K13** the science or technology related processes and standard operating procedures (SOPs) in the area associated with the quality issues | | | |
| **K14** the factors that must be considered when selecting the solution to a science or technology manufacturing quality process problem | | | |
| **K15** methods and techniques involved in quality improvement implementation | | | |
| **K16** methods and techniques involved in evaluating information | | | |
| **K17** organisational reporting procedures and documentation, and their application | | | |
| **K18** whom to inform of actions taken, and by what means | | | |
| **K19** how to retrieve the necessary data from company information systems | | | |
| **K20** the types of impact assessment systems and techniques available, and their application | | | |

| **Assessor Comments/Feedback** |
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| COGLS9 | **Make presentations for life sciences related work activities** *(Level 8, 8 Credits)* |
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**Overview**

This standard covers the competences you need to make presentations, for life sciences related work. This will include establishing the scope of the presentation and how it will need to reflect audience and work practices.

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

| ***Performance Criteria*** *You must be able to:* | **Evidence 1** | **Evidence 2** | **Evidence 3** |
|---|---|---|---|
| **P1** establish the scope and purpose of the presentation to be delivered within the life sciences environment | | | |
| **P2** determine the resources needed to deliver the presentation | | | |
| **P3** establish the type and length of presentation that will be required | | | |
| **P4** establish if any pre or post presentation information is required to be distributed to the audience | | | |
| **P5** establish if you need to align your presentation with any other presentations | | | |
| **P6** calculate time to prepare presentation taking account of your current workload | | | |
| **P7** prepare presentation to meet the established requirements | | | |
| **P8** ensure relevant feedback is incorporated into the feedback | | | |
| **P9** get the presentation signed off by the appropriate people in accordance with policies and procedures | | | |
| **P10** ensure you have the resources appropriate for delivering the type of presentation you will deliver | | | |
| **P11** deliver the prepared presentation in the correct media for the audience | | | |

| ***Knowledge and Understanding Criteria*** *You need to know and understand:* | **Evidence 1** | **Evidence 2** | **Evidence 3** |
|---|---|---|---|
| **K1** why it's important to understand and keep up with the strategic direction of the life sciences agenda across the UK and globally and how this will influence the organisation | | | |
| **K2** how to develop internal and external networks within the life sciences community for the area you are working in | | | |
| **K3** why confidentiality is important within the life sciences industry | | | |
| **K4** when, whom and how to apply confidentiality | | | |
| **K5** how your life sciences related work activities affect others within the department, organisation and the community | | | |
| **K6** the lines of communication and responsibilities in your department, and their links with the rest of the organisation | | | |

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|---|---|---|---|
| **K7** the limits of your own authority and to whom you should report if you have problems that you cannot resolve | | | |
| **K8** the different types of audience, and how to meet their needs | | | |
| **K9** the purpose of the presentation, and your key messages | | | |
| **K10** the time available to make the presentations | | | |
| **K11** the advantages and disadvantages of different methods of presentation delivery | | | |
| **K12** the materials that are appropriate to support presentations (such as hand-outs, summary of presentation) | | | |
| **K13** if pre or post presentation information is required | | | |
| **K14** how to use the presentation equipment | | | |
| **K15** how you might need to tailor your presentation if other people are presenting | | | |
| **K16** the questions you might expect to receive because of the presentation | | | |
| **K17** factors that can affect or influence the impact of a presentation (such as room configuration, audio-visual systems (including microphones), dress code) | | | |
| **K18** the venue health and safety considerations to be considered at any presentation | | | |
| **K19** who the appropriate people are to sign off the presentation | | | |

| **Assessor Comments/Feedback** |
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| COGREG-02 | **Analyse audits and inspections to ensure compliance to regulations in a Life Science Environment** *(Level 8, 6 Credits)* |
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**Overview**

This standard covers the competencies you need to analyse the business operations to ensure compliance to regulatory and site licensing requirements in accordance to current Good Manufacturing Practice (GMP) to maintain compliance with the UK Statutory and EU Directives.

You will be required to analyse audits and inspections to ensure compliance to regulations in a Life Science Environment and demonstrate that systems are in place to ensure compliance to the appropriate regulators, site licenses, internal and external procedures for carrying out life science operations within the manufacturing and quality environments.

| ***Performance Criteria*** *You must be able to:* | **Evidence 1** | **Evidence 2** | **Evidence 3** |
|---|---|---|---|
| **P1** analyse the results of audits, inspections and checks ensuring they are within the regulatory and product license requirements | | | |
| **P2** respond to deficiencies, discrepancies or non-conformance identified in the process of quality checking and auditing | | | |
| **P3** monitor batch and continuous production records for deviations in manufacturing, equipment, operations, distribution, and product quality | | | |
| **P4** maintain accurate records of all audits and actions related to compliance and non-compliance to regulatory requirement | | | |
| **P5** instigate and communicate actions for corrective and preventative actions (CAPA) because of non-conformance or quality issues | | | |
| **P6** maintain regulatory and quality practices in line with Manufacturing & Good Distribution Practices (GMP & GDP) and Good Documentation Practice (GDocP) | | | |
| **P7** ensure all relevant documentation provided by suppliers and other external agents is complete and accurate in accordance to supply chain procedures | | | |
| **P8** ensure issues outside your authority are escalated to the appropriate level to enable action in resolving issues | | | |
| **P9** monitor actions and activities | | | |
| **P10** monitor and record information in line with internal procedures and supplier auditing requirements | | | |
| **P11** identify where regular inconsistencies in supplies occur and ensure resolution to these issues | | | |
| **P12** make recommendations to colleagues and technical staff where failure against specifications suggests that a new source of supply is needed | | | |
| **P13** make recommendations to colleagues and technical staff regarding the suitability of the criteria used as a measure of acceptance | | | |

| ***Knowledge and Understanding Criteria*** *You need to know and understand:* | **Evidence 1** | **Evidence 2** | **Evidence 3** |
|---|---|---|---|
| **K1** the policies, guidelines and legislation relating to sources and supply of raw materials relevant to the workplace and products within manufacturing and storage | | | |
| **K2** your organisation's supply chain assurance guidelines, policies, audit requirements, and how they are applied | | | |
| **K3** the principles of corrective and a preventative action process (CAPA) | | | |

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|---|---|---|---|
| **K4** the principles and implementation of GMP, GDP and GDocP | | | |
| **K5** the types and sources of raw materials, intermediates items and products manufactured or distributed by the organisation | | | |
| **K6** the control and sampling methods appropriate to type and source of supply or manufactured products | | | |
| **K7** the potential methods, sources and types of product contamination that can be encountered during product manufacture, transportation and delivery | | | |
| **K8** how contamination during transportation and delivery can be identified | | | |
| **K9** the range of checks that can be applied to ensure that delivered is safe | | | |
| **K10** the recording systems that are in place to record data related to accepted and declined deliveries | | | |
| **K11** the impact that external audit requirements have upon the acceptance | | | |
| **K12** the range of data that is used to support external audits | | | |
| **K13** the requirements for certificates of conformity | | | |
| **K14** the procedures to ensure product and manufacturing traceability | | | |
| **K15** the product specifications for raw materials and supplies | | | |
| **K16** the corrective actions to be taken when an item is received that does not conform with product specification | | | |

| **Assessor Comments/Feedback** |
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| COGREG-05 | **Gather, collate and provide information & guidance to meet organisational compliance** *(Level 8, 7 Credits)* |
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**Overview**

This standard covers the competencies you need to provide information and guidance to meeting organisational compliance in the business and to ensure regulatory and site quality requirements are in place and in accordance to current best practices, including Good Manufacturing Practice (GMP) to maintain compliance.

You will be required to demonstrate that systems are able to gather information and guidance and ensure this information is available, delivered and used to meet organisational compliance ensure compliance to the appropriate regulators, site licenses, internal and external procedures for carrying out science operations within the business environments.

| ***Performance Criteria*** *You must be able to:* | **Evidence 1** | **Evidence 2** | **Evidence 3** |
|---|---|---|---|
| **P1** determine the extent of the information and guidance required to support the regulatory compliance needs | | | |
| **P2** ensure the requirements for health, safety and security in the work environment are identified | | | |
| **P3** identify the legal, license and regulatory requirements relevant to your area of work responsibility | | | |
| **P4** work to and implement best practices including Good Manufacturing Practice (GMP) and Good Distribution Practice (GDP) | | | |
| **P5** identify the social, environmental and ethical responsibilities | | | |
| **P6** obtain accurate interpretations of legal and regulatory requirements from specialists in your area of work internal and external to the organisation | | | |
| **P7** identify the organisation structure of accountability for legal, regulatory and quality responsibilities in your organisation | | | |
| **P8** identify the risks involved in non-compliance or non-conformance to regulatory or license requirements | | | |
| **P9** provide accessible, up-to-date information to the organisation and appropriate teams to ensure compliance and regulatory needs are met | | | |
| **P10** agree organisational responsibilities with decision makers, key people and stakeholders and how they will be demonstrated | | | |
| **P11** develop clear and accessible plans for how your area of responsibility will comply with its legal, regulatory and license requirements | | | |
| **P12** ensure that systems are developed to monitor and maintain regulatory compliance and license requirements | | | |
| **P13** evaluate information and feedback about how your area of work performs in complying with responsibilities | | | |
| **P14** provide information to decision makers about how your area of work complies with its responsibilities | | | |
| **P15** make recommendations about changes or improvements to regulatory and compliance systems or processes | | | |
| **P16** provide feedback and reports on regulatory compliance information, including non-compliance data | | | |

| ***Knowledge and Understanding Criteria*** *You need to know and understand:* | **Evidence 1** | **Evidence 2** | **Evidence 3** |
|---|---|---|---|
| **K1** the European, UK and country specific legislation, statutory codes, standards, frameworks and guidance relevant to the legal, license and regulatory requirements relevant to your area of work | | | |
| **K2** how to use and apply best working practices including Good Manufacturing Practice (GMP) and Good Distribution Practice (GDP) | | | |
| **K3** how to identify, collect, analyse, measure and assess data | | | |
| **K4** how to promote your organisations legal and regulatory responsibilities | | | |
| **K5** the requirements of health, safety and security in the work environment | | | |
| **K6** the social, environmental and ethical responsibilities relevant to your area of work | | | |
| **K7** the organisation structure of accountability for legal, regulatory and quality responsibilities in your organisation | | | |
| **K8** the compliance risks involved in work processes and the effects of non-compliance to regulatory or license requirements | | | |
| **K9** the organisations risk assessment process | | | |
| **K10** how to identify, collate and communicate information to the organisation and appropriate teams and stakeholders | | | |
| **K11** how to develop plans and instructions for your area of responsibility | | | |
| **K12** develop systems to monitor and maintain regulatory compliance and license requirements | | | |
| **K13** how to develop or use systems to communication regulatory information and feedback in your area of work | | | |
| **K14** the organisations change management system | | | |
| **K15** improvement and problem-solving techniques | | | |
| **K16** how to manage ethical dilemmas and conflicts resulting from promoting organisational responsibilities | | | |
| **K17** how to obtain accurate and timely reports of your organisations performance in complying with regulatory and license requirements | | | |
| **K18** how to develop strategies to ensure compliance | | | |
| **K19** how to manage and promote effective communication with colleagues, individuals and other stakeholders | | | |

| **Assessor Comments/Feedback** |
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| COGREG-06 | **Ensure compliance and respond to issues or deviation from standards or best practice in a Life Science Environment**<br>*(Level 8, 8 Credits)* |

**Overview**

This standard covers the competencies you need to support the business operations to ensure the effective handling of complaints, issues and non-conformances to maintain compliance with regulatory UK Statutory and EU Directives and site licensing requirements in accordance to current Good Manufacturing Practice (GMP).

You will be required to support the resolution of non-compliance, or deviation from standard or best practice, record, liaise and communicate externally with the regulators and internally with business management because of issues or complaints

| ***Performance Criteria*** *You must be able to:* | **Evidence 1** | **Evidence 2** | **Evidence 3** |
|---|---|---|---|
| **P1** work in accordance with organisational procedures and documentation for non-compliance issues | | | |
| **P2** work in accordance with organisational procedures and best practice to action corrective or preventative work | | | |
| **P3** consider historical compliance issues to develop new strategies and standard operating procedures (SOPs) to prevent reoccurrence of problems | | | |
| **P4** ensure validation processes are in place and appropriately monitored and reviewed in line with SOPs | | | |
| **P5** maintain routine monitoring and auditing requirements as specified by SOPs and in accordance with GMP | | | |
| **P6** keep and maintain good quality and compliance records | | | |
| **P7** check that equipment used in manufacturing or testing is performing correctly and safe to use | | | |
| **P8** ensure an appropriate escalation process is in place for consideration of corrective and preventive actions outside the areas of your responsibility | | | |
| **P9** identify non-compliance to relevant standards or deviation from approved procedures | | | |
| **P10** report non-compliance to relevant standards or deviation from approved procedures to appropriate persons or department for further action | | | |
| **P11** take appropriate corrective and or preventative actions in response to compliance issues | | | |
| **P12** communicate appropriately internally and or externally to the organisation any corrective and or preventative actions in response to compliance Issues | | | |
| **P13** monitor compliance improvement work through inspection, meetings and correspondence | | | |
| **P14** develop communication channels with internal teams and external regulatory groups, including the Inspection Action Group (IAG) to ensure expedient handling of issues and non-conformance | | | |
| **P15** support the development of good practices, including the support in writing of appropriate SOPs to ensure maintenance of quality systems and regulatory compliance | | | |
| **P16** plan and conduct regular audits and inspections of systems, process and procedures | | | |
| **P17** support the audit process conducted by external bodies, including the regulatory inspector | | | |

| ***Knowledge and Understanding Criteria*** *You need to know and understand:* | **Evidence 1** | **Evidence 2** | **Evidence 3** |
|---|---|---|---|
| **K1** the life science regulatory environment in which the organisation operates | | | |
| **K2** the Principles of Good Manufacturing Practice and associated guidelines and standards | | | |
| **K3** the relevant organisations Standard Operating Procedures (SOPs) relevant to compliance, quality control and regulatory requirements | | | |
| **K4** your personal responsibilities and accountabilities | | | |
| **K5** the scientific knowledge and expertise that relate to the product and/or process of the non-conformance being reported to Marketing Authority (MA) | | | |
| **K6** the up-to-date regulations and how to keep abreast with the latest regulatory environment | | | |
| **K7** the principles of problem solving and able to resolve issues or escalate to appropriate persons | | | |
| **K8** the formats and methods of submitting non-conformance applications to the regulatory authority including paper and electronic systems | | | |
| **K9** how and when to communicate to the internal and external organisations, regulator, MA and other stakeholder parties in the event of issues or nonconformities | | | |
| **K10** how to analyse, collate and prepare data and information to write technical reports and submission | | | |
| **K11** how to consider previous conformance issues and how to develop new procedures and strategies to prevent reoccurrence | | | |

**Glossary**

Preventive action: to eliminate the cause of potential nonconformity or another undesirable potential situation

- There can be more than one cause for a potential nonconformity
- Preventive action is taken to prevent occurrence whereas corrective action is taken to prevent recurrence

Corrective action: to eliminate the cause of a detected nonconformity or other undesirable situation

- There can be more than one cause for a nonconformity
- Corrective action is taken to prevent recurrence whereas preventive action is taken to prevent occurrence
- There is a distinction between correction and corrective action

Correction: to eliminate a detected nonconformity

- A correction can be made in conjunction with a corrective action
- A correction can be, for example, rework

**Assessor Comments/Feedback**

# *Notes*

# *Notes*


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