SVQ in Bioprocessing Operations in the Science Industries at SCQF level 7

Qualification Reference Number GV4K 47

Personal Competence Summary

Name	Company/Centre
Job Title	GQA Registration Number

Unit Number	Title	Level	Credit Value	Assessor Signature	Date
Mandatory Units					
COGSCIM2_01	Maintain health and safety in a biomanufacturing environment	5	7		
COGSCIM3_04	Analyse and input biomanufacturing data in a Manufacturing Information Management System	6	5		
COGSCIM3_19	Monitor the routine maintenance, cleaning, disinfecting and calibration of biomanufacturing equipment	5	4		
COGSCIM3_03	Monitor and follow aseptic procedures in a biomanufacturing environment	6	14		
COGSCIM2_02	Maintain effective and efficient biomanufacturing working relationships	6	5		
Optional Units - Candidates must take 5 units					

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

Who is this Qualification for?

This qualification is suitable for those individuals working within a processing environment in the chemical, pharmaceutical, petrochemical or nuclear sector.

The qualification has been developed from the Processing Industries Operations National Occupational Standards and has been structured to make it as widely available as possible.

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.

This qualification is at level 7 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:

What is required from candidates?

Candidates should achieve all the mandatory units listed below, plus 5 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
COGSCIM2_01	Maintain health and safety in a biomanufacturing environment	5	7
COGSCIM3_04	Analyse and input biomanufacturing data in a Manufacturing Information Management System	6	5
COGSCIM3_19	Monitor the routine maintenance, cleaning, disinfecting and calibration of biomanufacturing equipment	5	4
COGSCIM3_03	Monitor and follow aseptic procedures in a biomanufacturing environment	6	14
COGSCIM2_02	Maintain effective and efficient biomanufacturing working relationships	6	5
Optional Units Group A – 3 Units Required			
COGSCIM3_06	Encourage problem solving and innovation in a biomanufacturing team	7	16
COGSCIM4_14	Make biomanufacturing development/research presentations	7	10
COGSCIM3_11	Monitor the preparation of culture media and solutions for biomanufacturing upstream processing	7	11
COGSCIM3_13	Monitor the harvesting of biomaterial into sterile containers from a bioreactor for biomanufacturing downstream processing	7	10
COGSCIM3_15	Monitor the obtaining of biomaterial in biomanufacturing downstream processing using lysis of cells	7	13

Optional Units Group B – 2 Units Required			
COGSCIM3_16	Monitor the separation of harvested biomaterial in biomanufacturing downstream processing using normal filtration	8	17
COGSCIM3_17	Monitor the concentration and diafiltration of harvested biomaterial in downstream processing using tangential flow filtration	8	18
COGSCIM3_18	Monitor the purification of harvested biomaterial in biomanufacturing downstream processing using chromatography	8	21
COGSCIM3_12	Monitor the production of biomaterial using bioreactors in biomanufacturing upstream processing	8	15
COGSCIM3_14	Monitor the separation of harvested biomaterial for biomanufacturing downstream processing using continuous flow centrifugation	8	17

Assessment Guidance

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

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 make a decision 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 actually required. GQA recommend holistic assessment.

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

- is authentic – i.e., actually 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 makes a decision 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 actually 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 of 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 with regard to the company/centre Equal Opportunities Policy.

Candidate Signature ……

Date ……..

COGSCIM2_01	**Maintain Health and Safety in a Biomanufacturing Environment** *(Level 5, 7 Credits)*

Overview

This standard covers the competences you need to maintain health and safety in a biomanufacturing environment. You are required to observe all legal, statutory and organisational requirements, and you must be able to identify any potential hazards and risks to health and safety. You must also know what actions to take in case of an emergency and, as well as ensuring your own safety, you must show responsibility towards your colleagues and others. You will be required to work to the relevant standard operating procedures, legislation and organisational policy, and to follow Good Manufacturing Practice (GMP).

Your responsibilities will require you to comply with health and safety requirements and organisational policy and procedures for the manufacturing work that is undertaken. You must be able to recognise the limitations of your own competence with the manufacturing work and ask for appropriate help and advice when it is needed. You will need to take responsibility for your own actions and for the quality and accuracy of the work that you carryout.

Your underpinning knowledge will provide an understanding of your manufacturing work, to apply safely the appropriate scientific principles and practices. You will be competent in the safe use of the materials, equipment, consumables and instruments used to perform the manufacturing operations, and with the procedures appropriate to your job.

You will understand the safety precautions required when carrying out the manufacturing activities for scientific operations
and processes. You will be required to demonstrate safe working practices throughout and will understand your responsibility for taking the necessary safeguards to protect yourself and others 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 standard operating procedures (SOP)			
P2 accurately assess health and safety in relation to your work and the biomanufacturing work environment			
P3 use the appropriate personal protective clothing and equipment for the work			
P4 make safe any health and safety hazards, and report them to the appropriate person as soon as possible			
P5 maintain the security of the biomanufacturing work environment, in accordance with organisational procedure			
P6 ensure that you maintain your work area to a standard of health and safety which is consistent with local policies and legal requirements			
P7 maintain and use equipment and materials in accordance with manufacturers' instructions and local safety regulations			
P8 dispose of hazardous materials, waste and waste containers, safely and correctly			
P9 prepare, use and dispose of disinfectants, safely and correctly			
P10 carry out decontamination of work surfaces and floors effectively			
P11 take the appropriate precautions to protect yourself and others during working hours			
P12 follow the correct procedure, without delay, if an emergency arises or is suspected			

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 manufacturing activities			
K2 the implications of not taking account of legislation, regulations, standards and guidelines when conducting manufacturing activities			
K3 the standard operating procedures (SOP), as set down in local manufacturing operating manuals			
K4 the importance of following manufacturers' instructions			
K5 the principles of Good Manufacturing Practice (GMP) applied in the workplace			
K6 the importance of wearing protective clothing, gloves and eye protection when handling materials (including biochemical substances, biological pathogens and/or antigens), and the equipment used to contain and process them			
K7 the specific safety precautions to be taken when working with biomanufacturing 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 (including lighting, seating, positioning of equipment), and repetitive strain injury (RSI))			
K8 the identity of health and safety representatives (including the Manufacturing Safety Officer, Staff health and safety representatives and first-aiders)			
K9 the location and correct use of emergency equipment (including fire extinguishers and situations in which different types of fire extinguisher are used)			
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 why risks in the biomanufacturing work environment should be assessed, and the correct action to be taken			
K14 local procedures for escape (including escape routes and assembly points)			
K15 the location of fire alarms, and how to operate them			
K16 the location of spillage kits, and the procedures to follow in the event of spillages of chemicals and/or biological fluids			
K17 the control of substances hazardous to health (COSHH) regulations, and their application in the biomanufacturing work environment			
K18 the types of hazards which may occur in the manufacturing setting, and how these can be minimised			
K19 the correct storage and disposal procedures for hazardous materials (including flammables, corrosive, harmful and toxic chemicals)			
K20 the hazards associated with disinfectants and other chemicals (including toxicity)			
K21 the meaning of the term's 'disinfection' and 'decontamination', and the use of disinfectants			
K22 the reasons for disinfecting/decontaminating manufacturing surfaces and equipment			
K23 why it is important to differentiate and segregate categories of waste (such as using waste colour-coding)			

K24 the correct procedures for the storage, transport and disposal of waste			

Scope and range for this unit

1. identify health and safety standard operating procedures for all of the following:
1.1 manufacturing hazards
1.2 unsafe practices
1.3 spillages
1.4 manual handling
1.5 VDU & RSI policies
1.6 other (please specify)

2. handle safely three of the following hazardous substances, in accordance with approved procedures:
2.1 flammables
2.2 toxic chemicals
2.3 corrosive chemicals
2.4 biological materials

3. follow established procedures for all of the following emergencies:
3.1 workplace fire
3.2 gas escapes
3.3 spillage of hazardous substances
3.4 other emergencies (please specify)

4. dispose of, safely, two of the following, in accordance with approved procedures:
4.1 sharps
4.2 plastics
4.3 confidential records
4.4 biomaterials (solid and liquid)
4.5 one-use modules/components
4.6 other (please specify)
4.7 metal
4.8 cleaning wipes/tissues
4.9 chemicals (solid and liquid)
4.10 aerosol containers

5. dispose of waste in two the following categories, in accordance with approved practices:
5.1 autoclave
5.2 flushing
5.3 solids for recycling
5.4 addition of chemicals
5.5 fluids for recycling
5.6 other

Assessor Comments/Feedback

COGSCIM3_04	**Analyse and input biomanufacturing data in a Manufacturing Information Management System** (Level 6, 5 Credits)

Overview

This standard covers the competences you need to maintain health and safety in a biomanufacturing environment. You are required to observe all legal, statutory and organisational requirements, and you must be able to identify any potential hazards and risks to health and safety. You must also know what actions to take in case of an emergency and, as well as ensuring your own safety, you must show responsibility towards your colleagues and others. You will be required to work to the relevant standard operating procedures, legislation and organisational policy, and to follow Good Manufacturing Practice (GMP).

Your responsibilities will require you to comply with health and safety requirements and organisational policy and procedures for the manufacturing work that is undertaken. You must be able to recognise the limitations of your own competence with the manufacturing work and ask for appropriate help and advice when it is needed. You will need to take responsibility for your own actions and for the quality and accuracy of the work that you carryout.

Your underpinning knowledge will provide an understanding of your manufacturing work, to apply safely the appropriate scientific principles and practices. You will be competent in the safe use of the materials, equipment, consumables and instruments used to perform the manufacturing operations, and with the procedures appropriate to your job.

You will understand the safety precautions required when carrying out the manufacturing activities for scientific operations and processes. You will be required to demonstrate safe working practices throughout and will understand your responsibility for taking the necessary safeguards to protect yourself and others 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 standard operating procedures (SOP)			
P2 use correct passwords to access the relevant manufacturing databases, and maintain the security and integrity of information			
P3 use correct search procedures to confirm that batch demographic data on samples received are correct with existing data on the manufacturing record system			
P4 follow the correct protocols for registering new batch/product data onto the Manufacturing Information Management System (MIMS)			
P5 select the correct manufacturing data files, and accurately input batch details with the requested quality tests for each product			
P6 resolve the problems that arise when the required batch/sample information and data cannot be found or matched			
P7 perform these tasks in a timely manner, compatible with the manufacturing schedules			
P8 request help from appropriate people when you are unable to resolve problems with mismatched and incomplete batch/sample details			
P9 communicate manufacturing information 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 biomanufacturing activities			
K2 the implications of not taking account of legislation, regulations, standards and guidelines when conducting biomanufacturing activities			
K3 the standard operating procedures (SOP), as set down in local biomanufacturing operating manuals			
K4 the importance of following the equipment manufacturers' operating instructions			
K5 the principles of Good Manufacturing Practice (GMP) applied in the workplace			
K6 the standard operating procedures (SOP), as set down in the local manufacturing process operating manuals			
K7 the data security requirements for different computer applications, and the accessing and storage of data			
K8 how to access and store data, in accordance with standard operating procedures (SOP) and organisational practices			
K9 why it is important to maintain accurate batch and departmental records for products manufactured			
K10 the policies and procedures for the accurate registration of new batches/products on the Manufacturing Information Management System (MIMS)			
K11 the specific safety precautions to be taken when working with computer systems (to include such things as safety guidance relating to the use of visual display unit (VDU) equipment and workstation environment (including lighting, seating, positioning of equipment), repetitive strain injury (RSI); the dangers of trailing leads and cables; how to spot faulty or dangerous electrical leads, plugs and connections)			
K12 why it is important to maintain good housekeeping arrangements (including putting disks, manuals and unwanted items of equipment into safe storage, leaving the work area in a safe and tidy condition)			
K13 the importance of correct identification, and any unique organisational or manufacturing numbers			
K14 the lines of communication and responsibilities in your department, and their links with the rest of the organisation			
K15 the limits of your own authority and to whom you should report if you have problems that you cannot resolve			
K16 the basic set-up and operation of the manufacturing records system, and the peripheral devices that are used (including a mouse, keyboard, VDU, printer and barcode reader)			
K17 the methods used for numbering and labelling liquids, compounds and products received by the manufacturing department, and the quality samples taken during processing (including handwritten or barcoded labels)			
K18 the correct start-up and shutdown procedures to be used for the computer system			
K19 how to access the specific computer Manufacturing Information Management System (MIMS) database to be used, and the use of software manuals and related documents to aid efficient operation of the relevant manufacturing records system			
K20 how to deal with system problems (including error messages received, peripherals which do not respond as expected, obvious faults with the equipment or connecting leads			

K21 how to communicate effectively, and how to identify key information when recording and forwarding messages accurately			
K22 the test codes, coded comments, requestor and location codes, and batch/product comment codes required to input accurately and to request batch/product and manufacturing data appropriate to your area of work			

Scope and range for this unit

1. access and input batch/sample data for all of the following:
1.1 batch number
1.2 manufacturing process being done
1.3 customer number
1.4 quality testing requirements
1.5 product number
1.6 other (please specify)

2. establish data requirements for six of the following:
2.1 product description
2.2 details of the batches/products required
2.3 date of sample
2.4 details of resources/equipment needed
2.5 batch source
2.6 client's location
2.7 MIMS number
2.8 other (please specify)

3. complete two of the following departmental batch/product identification activities:
3.1 writing codes on the batch/products
3.2 checking batch/product codes against MIMS database
3.3 adding barcodes to the batch/product
3.4 scanning barcodes and checking MIMS database

4. record details of work done, and communicate the details to the appropriate people, using:
4.1 verbal report Plus one method from the following:
4.2 written or typed report
4.3 computer-based record
4.4 specific company documentation
4.5 electronic mail

Assessor Comments/Feedback

COGSCIM3_19	**Monitor the routine maintenance, cleaning, disinfecting and calibration of biomanufacturing equipment** (Level 5, 4 Credits)

Overview

This standard covers the competences you need to monitor the routine maintenance, disinfecting, cleaning and calibration of equipment used for biomanufacturing processing operations.

Prior to undertaking the activity, and in accordance with approved procedures and practices, you will be required to carry out all the necessary preparations, within the scope of your responsibility. This may include preparing the work area, ensuring that it is in a safe condition to carry out the intended activities, and that any materials, equipment or other resources required are available and are in a safe and usable condition. You will be required to work to the relevant standard operating procedures (SOP), legislation and organisational policy, and to follow Good Manufacturing Practice (GMP). You will be required to present records and details of your biomanufacturing work to the appropriate people.

On completion of the biomanufacturing activity, you will be required to return your immediate work area to an acceptable condition before undertaking further work. Use of SIP/CIP and autoclave procedures and techniques is an important function in this role. Returning and/or storing any materials and equipment in the correct area, identifying any waste and arranging for its disposal, and reporting any defects or damage to the materials and equipment used are also part of this function.

Your responsibilities will require you to comply with organisational policy and procedures for the equipment maintenance, disinfecting and cleaning undertaken, and to report any problems with the activities, materials or equipment that you cannot personally resolve, or that are outside your permitted authority, to the relevant people.

Your underpinning knowledge will provide a good understanding of your work, and will provide an informed approach to the maintenance, disinfecting and cleaning of equipment in a biomanufacturing environment. You will understand the importance of doing this work efficiently and effectively and will know what to consider when preparing and tidying up the work area before and after the maintenance, disinfecting and cleaning activities. You will also know how to deal with problems, and how to achieve your work objectives and targets, in adequate depth to provide a sound basis for carrying out the activities safely and correctly.

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 (SOP)			
P2 wear the appropriate personal protection equipment (PPE) when working in the biomanufacturing environment			
P3 confirm that the laboratory equipment is in a safe and effective condition according to established procedures			
P4 identify and report any manufacturing equipment faults accurately to the appropriate person			
P5 perform routine maintenance in accordance with manufacturer's instructions and relevant health and safety legislation			
P6 adhere to the set-down hygiene regulations during the cleaning and disinfecting of biomanufacturing equipment			
P7 confirm the correct operation and calibration of the manufacturing equipment in accordance with established procedures			
P8 monitor and lead the quality and delivery of the above outcomes for yourself and your team			
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 biomanufacturing activities			
K2 the implications of not considering legislation, regulations, standards and guidelines when conducting biomanufacturing activities			
K3 the standard operating procedures, as set down in local biomanufacturing operating manuals			
K4 the importance of following equipment manufacturers' operating instructions			
K5 the principles of Good Manufacturing Practice (GMP) applied in the workplace			
K6 the importance of wearing protective clothing, gloves and eye protection when handling materials (including biochemical substances, biological pathogens and/or antigens), and the equipment used to contain and process them			
K7 the biomanufacturing materials and batch process tracking and records system			
K8 the types of handling and sorting system, and the procedures used for materials undergoing processing in the manufacturing facilities			
K9 the importance of correct identification, and any unique organisational or manufacturing 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 how to monitor and lead the quality and delivery of routine maintenance, disinfecting, cleaning and calibration of equipment used for biomanufacturing processes			
K14 the manufacturers' specifications and recommendations for the maintenance and calibration of the biomanufacturing equipment			
K15 the methods used for visually checking and for the cleaning of biomanufacturing equipment			
K16 the different types, condition and quantity of consumables required for the range of biomanufacturing equipment maintained			
K17 the methods for maintaining personal health and safety during the maintenance of the equipment			
K18 the methods for maintaining personal hygiene			
K19 the organisational and departmental infection control policy, as applied to maintenance activities in the biomanufacturing environment			
K20 how to check that the biomanufacturing equipment is working correctly and in accordance with the manufacturer's specifications			
K21 the common types of equipment fault, and how these must be dealt with			
K22 the department or person to whom equipment faults should be reported			
K23 the methods used for keeping records of maintenance, cleaning, disinfecting and calibration of biomanufacturing equipment, and why this is important			

Scope and range for this unit

1. carry out all the following operations:

1.1 adhere to procedures or systems in place for risk assessment, COSHH, personal protective equipment and other relevant safety regulations

1.2 ensure the safe isolation of the biomanufacturing equipment (such as electrical and fluids supply)

1.3 follow manufacturer's instructions, drawings and procedures for routine maintenance

1.4 check that the tools and equipment used are in a safe and usable condition

1.5 ensure that the biomanufacturing equipment is kept free from foreign objects, dirt or other contamination

1.6 carry out disinfection of biomanufacturing equipment in accordance with standard operating procedures

1.7 carry out auditory and visual check on the operation of the biomanufacturing equipment

1.8 confirm that the biomanufacturing equipment is calibrated correctly and ready for use

1.9 return all tools, equipment and waste to the correct location on completion of the maintenance activities

2. use three of the following types of protective clothing and equipment:

2.1 laboratory coat/overalls

2.2 gloves

2.3 head/hair covers

2.4 safety shoes/shoe covers

2.5 safety glasses/visors

2.6 other (please specify)

3. monitor the maintenance, disinfection and cleaning operations on five of the following categories:

3.1 weighing and measuring equipment

3.2 temperature-controlled apparatus

3.3 water purification system

3.4 centrifuges

3.5 fermentation vessels

3.6 other (please specify)

4. monitor the disinfection and cleaning activities with all the following:

4.1 steaming in place/cleaning in place (SIP/CIP)

4.2 Autoclaving

5. record details of the preparation work, and communicate the details 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 company documentation

5.5 electronic mail

Assessor Comments/Feedback

COGSCIM3_03	**Monitor and follow aseptic procedures in a biomanufacturing environment** (Level 6, 14 Credits)

Overview

This standard identifies the competences you need to monitor and follow aseptic or clean room protocols in a biomanufacturing work environment and in accordance with approved procedures. You are required to check the application of aseptic procedures in the manufacturing area. You will be required to work to the relevant standard operating procedures, legislation and organisational policy, and to follow Good Manufacturing Practice (GMP). You will also be required to present records and details of your biomanufacturing work to the appropriate people.

Your responsibilities will require you to ensure compliance with aseptic procedural requirements and organisational policy and procedures for the biomanufacturing work that is undertaken. You will be required to report any problems with the biomanufacturing activities that you cannot personally resolve, or that are outside your permitted authority, to the relevant people.

Your underpinning knowledge will be sufficient to provide a sound basis for your work and will enable you to adopt an informed approach to preparing for work and working in clean rooms. You will understand the attributes and behaviours required for clean room working, in adequate depth to provide a sound background for carrying out the biomanufacturing activities to the required specification.

You will understand the safety precautions required when carrying out the biomanufacturing activities for scientific operations and processes. You will be required to demonstrate safe working practices throughout and will understand your responsibility for taking the necessary safeguards to protect yourself and others 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 standard operating procedures (SOP)			
P2 dress in the appropriate personal protection equipment (PPE) required for the clean room or clean work area environment, in accordance with the correct procedure			
P3 carry out visual quality checks on your personal protection equipment (PPE) prior to entering the working environment			
P4 follow the correct procedures for entering and exiting the clean room or clean work area			
P5 follow aseptic techniques in the workplace			
P6 remove personal protection equipment (PPE) on completion of clean room or clean work area activities, and dispose/store in line with the correct procedure			
P7 monitor and lead the quality and delivery of the above outcomes for yourself and your team			
P8 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 biomanufacturing activities			
K2 the implications of not taking account of legislation, regulations, standards and guidelines when conducting biomanufacturing activities			
K3 the standard operating procedures, as set down in local biomanufacturing operating manuals			
K4 the principles of Good Manufacturing Practice (GMP) applied in the workplace			
K5 the importance of wearing protective clothing, gloves and eye protection when handling materials (including biochemical substances, biological pathogens and/or antigens), and the equipment used to contain and process them			
K6 the manufactured materials and batch process tracking and records system			
K7 the types of handling and sorting system, and the procedures used for materials undergoing processing in biomanufacturing facilities			
K8 the importance of correct identification, and any unique organisational or manufacturing numbers			
K9 the organisational requirements for maintaining the security of the workplace			
K10 the lines of communication and responsibilities in your department, and their 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 monitor the application of aseptic procedures and practices for biomanufacturing operations			
K13 the specific safety precautions to be taken when working in a clean room or clean work area environment			
K14 the correct fitting and use of clothing and personal protective equipment (PPE) that must be worn in a clean room or clean work area (including body, hands, eyes, ears, feet, mouth and face)			
K15 hazards associated with working in a clean room or clean work area with biomanufacturing equipment (including heat, radiation, chemicals, static electricity, high voltages, trapping points on equipment)			
K16 how to put on clean room clothing and footwear correctly			
K17 the scrub-up procedures			
K18 the procedures for entering and exiting the clean room or clean work area, and the authority needed to do so			
K19 the classification of the relevant clean room or clean work area, and how this impacts you			
K20 the industry standards/classifications for clean rooms and clean work areas			
K21 the company requirements for clothing and personal protective equipment (PPE)required, and the reasons why such clothing and equipment must be used			
K22 the procedures and methods for maintaining issued clothing and personal protective equipment (PPE)			
K23 how to apply procedures for dealing with damaged or dirty clothing and personal protective equipment (PPE)			
K24 how to store issued clothing and personal protective equipment (PPE) correctly			

K25 the laundering/cleaning/maintenance procedures relating to the issued clothing and personal protective equipment (PPE)			
K26 the aseptic techniques used in the laboratory			
K27 how to dispose of single-use personal protective equipment (PPE) correctly			
K28 the policy and procedures relating to personal items (including body lotions, makeup, jewellery, contact lenses, footwear, own clothing)			

Scope and range for this unit

1. monitor all the following clean room protocols:
1.1 use the correct issue of job instructions and specifications
1.2 follow risk assessment procedures and COSHH regulations
1.3 ensure that your team are appropriately dressed and uncontaminated before entering the area
1.4 your team carry out your activities in line with organisational procedures
1.5 store records of your team activities, in accordance with appropriate procedures

2. monitor all of the following company clean room/clean work area requirements:
2.1 use appropriate clothing/personal protective equipment (PPE) (such as suits, gowns, coats, hoods, hats, caps, helmets, other headwear, boots, overshoes, other forms of footwear, safety goggles, visors, gloves)
2.2 comply with hazard protection (such as breathing apparatus, gloves, apron/smock, other forms of PPE or clothing required)
2.3 deal appropriately with damaged or dirty clothing/PPE (such as reporting damage, replacement, safe removal and cleaning or disposal, subjected to acid/hazardous substance spills, damaged/dirty labelling)
2.4 store specified clothing/PPE correctly when not in use
2.5 ensure the proper cleaning/laundering/maintenance of clothing/PPE
2.6 dispose of single-use clothing and equipment in the correct location
2.7 report any hazards or breaches of protocol

3. use three of the following types of personal protective equipment for clean room working:
3.1 body suit
3.2 gloves
3.3 air supply
3.4 face mask
3.5 respirator
3.6 other (please specify)

4. monitor use of personal protective equipment in one of the following clean room environments:
4.1 health/disease screening
4.2 drug development
4.3 biochemical processing
4.4 agro-biotech research
4.5 biotechnology processing
4.6 other (please specify)

5. monitor and follow protocol methods and procedures that satisfy all of the following:
5.1 the safety of people
5.2 containment/integrity of the clean room/work area
5.3 containment/integrity of the specimen/product
5.4 appropriate industry standards and protocols

6. record details of the 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 computer-based record

6.4 specific company documentation

6.5 electronic mail

Assessor Comments/Feedback

COGSCIM2_02	**Maintain effective and efficient biomanufacturing working relationships** (Level 6, 5 Credits)

Overview

This standard identifies the competences you need to develop and maintain effective working relationships in a biomanufacturing work environment, in accordance with approved procedures. You will be required to work to the relevant standard operating procedures (SOP), legislation and organisational policy, and to follow Good Manufacturing Practice (GMP). You will be required to present records and details of your biomanufacturing work to the appropriate people.

You will be required to be positive and constructive in your dealings with customers, especially when dealing with any disagreements. You will be expected to keep customers informed about work plans and activities which affect them, and to seek and obtain information from others, when necessary, in a polite and courteous manner. You will respond in a timely and positive way when asked to provide help or information to others.

Your responsibilities will require you to comply with any policies of your organisation in respect of developing and maintaining positive working relationships with clients and customers. You will be required to report any problems with working relationships and the procedures for handling them that you cannot personally resolve, or that are outside your permitted authority, to the relevant people. Your underpinning knowledge will provide a good understanding of your work and will provide an informed approach to working efficiently and effectively in a biomanufacturing environment. You will understand the need to work efficiently and effectively and will know about the things that you need to consider when preparing and tidying up the work area. You will also need to know how to contribute to improvements, deal with problems, maintain effective working relationships, and how to agree and achieve your development objectives and targets, in adequate depth to provide a sound basis for carrying out your activities safely and correctly.

You will understand the safety precautions required when carrying out the biomanufacturing activities for scientific operations and processes. You will be required to demonstrate safe working practices throughout and will understand your responsibility for taking the necessary safeguards to protect yourself and others 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 standard operating procedures (SOP)			
P2 wear the appropriate personal protection equipment (PPE) when working in the biomanufacturing work environment			
P3 establish and maintain productive working relationships			
P4 deal with disagreements in an amicable and constructive way so that good relationships are maintained			
P5 keep others informed about work plans or activities which affect them			
P6 seek assistance from others in a polite and courteous way, without causing undue disruption to normal work activities			
P7 respond in a timely and positive way when others ask for help or information			
P8 communicate the required information about the work done, to authorised people and 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 biomanufacturing activities			
K2 the implications of not taking account of legislation, regulations, standards and guidelines when conducting biomanufacturing activities			
K3 the standard operating procedures, as set down in manufacturing operating manuals			
K4 the regulations that affect how you should treat others and be treated at work (including Equal Opportunities and Equal Pay, Race Relations and Sex Discrimination, Working Time Directive, Disabled Persons Acts, Data Protection)			
K5 the principles of Good Manufacturing Practice (GMP) applied in the workplace			
K6 the importance of wearing protective clothing, gloves and eye protection when handling materials, including biochemical substances, biological pathogens and/or antigens, and the equipment used to contain and process them			
K7 the manufactured materials and batch process tracking and records system			
K8 the types of handling and sorting system, and the procedures used for materials undergoing processing in biomanufacturing facilities			
K9 the importance of correct identification, and any unique organisational or manufacturing 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 industrial, organisational and professional codes of practice, and ethical standards that apply			
K14 the importance of maintaining effective customer relationships, both within the workplace and with outside organisations and customers (including listening attentively to questions asked of you, making sure you ask for help and advice in a polite and courteous manner, responding positively to requests for help from others)			
K15 formal and informal methods of communication, and how to use the most appropriate one in different situations			
K16 how to communicate in a clear, polite, confident way, and why this is important			
K17 the need for customer confidentiality			
K18 your organisation's standards for appearance and behaviour			
K19 techniques for responding to the needs and feelings of others			
K20 the difficulties that can occur in working relationships, and how to resolve them			
K21 the sorts of attitude and request that are likely to create conflict or negative responses			
K22 how to deal with problems that could have an adverse effect on relationships or the business			
K23 dealing with disagreements with others in ways which will help to resolve difficulties and maintain long term relationships			

Scope and range for this unit

1. sustain positive working relationships by all the following:
1.1 working in teams
1.2 being cooperative and flexible
1.3 supporting others
1.4 providing clear and accurate information

2. maintain effective working relationships with two of the following:
2.1 colleagues in your own working group
2.2 colleagues outside your normal working group
2.3 supervisors/managers
2.4 persons external to your organisation
2.5 more senior professionals/scientists

3. review personal development objectives and targets, to include one of the following:
3.1 dual or multi-skilling
3.2 increased responsibility
3.3 training on new equipment/technology
3.4 other specific requirements
3.5 understanding of company working practices, procedures, plans and policies

4. record details of work done, and communicate the details to the appropriate people, using:
4.1 verbal report Plus one method from the following:
4.2 written or typed report
4.3 computer-based record
4.4 specific company documentation
4.5 electronic mail

Assessor Comments/Feedback

COGSCIM3_06	**Encourage problem solving and innovation in a Biomanufacturing Team** (Level 7, 16 Credits)

Overview

This standard identifies the competences you need to encourage and support the identification and practical implementation of ideas from your biomanufacturing team, in accordance with approved procedures. You are required to motivate and support them to achieve the objectives of the team and their personal work objectives. You will be required to work to the relevant standard operating procedures (SOP), legislation and organisational policy, and to follow Good Manufacturing Practice (GMP).

You will be required to present records and details of your laboratory work to the appropriate people. You will be required to think creatively with your team, and to set and agree individual objectives. You will help them solve technical problems, monitor their progress against the objectives you set, and provide feedback and guidance on their innovative ideas.

Your responsibilities will require you to comply with organisational policy and procedures for the encouragement of team problem solving and innovative activities undertaken, and to report any problems with the activities, materials or equipment that you cannot personally resolve, or that are outside your permitted authority, to the relevant people.

Your underpinning knowledge will be sufficient to provide a sound basis for your work and will enable you to adopt an informed approach to biomanufacturing procedures for the introduction of new ideas.

You will understand the safety precautions required when carrying out the biomanufacturing activities for scientific operations and processes. You will be required to demonstrate safe working practices throughout and will understand your responsibility for taking the necessary safeguards to protect yourself and others 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 standard operating procedures (SOP)			
P2 wear the appropriate personal protection equipment (PPE) when working in the biomanufacturing environment			
P3 motivate members of your biomanufacturing team to identify ideas for new products/services and process improvements			
P4 respond enthusiastically to ideas identified by members of your biomanufacturing team, and provide constructive feedback			
P5 encourage members of your biomanufacturing team to share, discuss and work together in developing initial ideas			
P6 identify and pursue opportunities to work with other biomanufacturing teams to generate and develop ideas			
P7 discuss and agree with members of your biomanufacturing team those ideas which should be developed further, how they should be developed and the required resources			
P8 provide ongoing support, encouragement and resources to members of your Biomanufacturing Team who are developing and testing ideas, and help to remove any identified obstacles			
P9 agree the practical implementation of ideas, based on the identified benefits, risks and required resources, when you have the authority to do so			
P10 support members of your biomanufacturing team in submitting formal proposals and plans, for the practical implementation of ideas, to other people for approval			

P11 oversee practical implementation of ideas by your biomanufacturing team, and monitor and report on progress			
P12 encourage and develop the creativity of members of your biomanufacturing team			
P13 encourage members of your biomanufacturing team to take acceptable risks in pursuing innovation, and to recognise the value of making and learning from mistakes			
P14 ensure that the originators and developers of any ideas which are successfully implemented receive recognition for their achievement			
P15 communicate the required information about the work of your biomanufacturing team 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 biomanufacturing activities			
K2 the implications of not taking account of legislation, regulations, standards and guidelines when conducting biomanufacturing activities			
K3 the principles of Good Manufacturing Practice (GMP) applied in the workplace			
K4 the importance of correct identification, and any unique organisational or manufacturing numbers			
K5 the lines of communication and responsibilities in your department, and their links with the rest of the organisation			
K6 the limits of your own authority and to whom you should report if you have problems that you cannot resolve			
K7 the organisational policy and strategy for innovation			
K8 the organisational guidelines and procedures for developing and implementing new ideas			
K9 the benefits of innovation to your team, to the overall organisation and to its customers			
K10 how to make time available for identifying and developing ideas			
K11 how to motivate people to generate and develop ideas			
K12 how to provide constructive feedback on ideas to individuals			
K13 the importance of good communication for innovation, and how to encourage it across your team			
K14 the potential obstacles to creativity, and how they can be minimised			
K15 the importance of giving constructive feedback on initial ideas			
K16 how initial ideas might be further developed and tested			
K17 how to recognise and manage risk in innovation			
K18 how to develop formal proposals and plans for the practical implementation of an idea and how to support others in doing this			

K19 how to develop creativity in yourself and others			
K20 the resources required for creativity and innovation, particularly time?			
K21 how to encourage your laboratory to learn from mistakes associated with new ideas			
K22 how to recognise the achievements of the originators/developers of ideas which have been successfully implemented			

Scope and range for this unit

1. use three of the following types of protective clothing and equipment:
1.1 laboratory coat/overalls
1.2 gloves
1.3 head/hair covers
1.4 safety shoes/shoe covers
1.5 safety glasses/visors
1.6 other (please specify)

2. encourage ideas for all of the following:
2.1 new biomanufacturing products and/or services
2.2 improvements to existing biomanufacturing products and/or services
2.3 improvements to existing biomanufacturing practices, procedures, systems and ways of working

3. encourage problem-solving and innovation, using three of the following:
3.1 force-field analysis
3.2 brainstorming
3.3 cause-effect analysis
3.4 flowcharting analysis
3.5 five `why's analysis
3.6 fault-tree analysis
3.7 mind-mapping
3.8 de Bono's thinking tools
3.9 focus groups
3.10 other (please specify)

4. record and communicate details of work done, to the appropriate people, using:
4.1 verbal report Plus one method from the following:
4.2 written or typed report
4.3 computer-based record
4.4 specific company documentation
4.5 electronic mail

Assessor Comments/Feedback

COGSCIM4_14	**Make biomanufacturing development/research presentations** (Level 7, 10 Credits)

Overview

This standard identifies the competences you need to make biomanufacturing development/research presentations, in accordance with approved procedures and practices. You will be required to work to the relevant standard operating procedures (SOP), legislation and organisational policy, and to follow Good Manufacturing Practice (GMP). You will also be required to present records and details of your biomanufacturing work to the appropriate people.

Your responsibilities will require you to comply with organisational policy and procedures for making presentations for biomanufacturing development/research purposes, and to report any problems, that you cannot personally resolve, to the relevant authority.

Your underpinning knowledge will provide a good understanding of general and discipline-specific existing/new product development principles and processes, and you will also be fully conversant with organisational procedures and systems. You will be required to report any problems with the biomanufacturing activities that you cannot personally resolve, or that are outside your permitted authority, to the relevant people.

Your underpinning knowledge will be sufficient to provide a sound basis for your work and will enable you to adopt an informed approach to making presentations for development/research purposes, in accordance with approved procedures and practices. You will understand the manufacturing methods and principles used, in adequate depth to provide a sound background for carrying out the biomanufacturing activities to the required specification.

You will understand the safety precautions required when carrying out the biomanufacturing activities for scientific operations and processes. You will be required to demonstrate safe working practices throughout and will understand your responsibility for taking the necessary safeguards to protect yourself and others 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 standard operating procedures (SOP)			
P2 wear the appropriate personal protection equipment (PPE) when working in the biomanufacturing environment			
P3 establish the scope and purpose of the development/research presentation to be delivered			
P4 determine quality, cost and delivery issues and the resources needed to deliver the presentation			
P5 present the data in an appropriate presentation format and structure for the audience			
P6 obtain appropriate equipment and resources, and verify their fitness for purpose			
P7 deliver the prepared presentation in the correct medium for the audience			
P8 ensure that the audience has the appropriate post-presentation media to support the presentation			
P9 communicate the required information about the work done, to senior management and other authorised people, in accordance with 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 biomanufacturing activities			
K2 the implications of not taking account of legislation, regulations, standards and guidelines when conducting biomanufacturing activities			
K3 the standard operating procedures, as set down in local biomanufacturing operating manuals			
K4 the importance of following the equipment manufacturers' operating instructions			
K5 the principles of Good Manufacturing Practice (GMP) applied in the workplace			
K6 the importance of wearing protective clothing, gloves and eye protection when handling materials (including biochemical substances, biological pathogens and/or antigens), and the equipment used to contain and process them			
K7 the manufactured product and batch process tracking and records system			
K8 the types of handling and sorting system, and the procedures used for products undergoing processing in the manufacturing facilities			
K9 the importance of correct identification, and any unique organisational or manufacturing 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 different types of laboratory audience, and their needs			
K14 the purpose of the presentation, and your key messages			
K15 the time available to make presentations			
K16 the advantages and disadvantages of different methods of presentation delivery			
K17 the materials that are appropriate to support presentations (including handouts, samples)			
K18 how to use the presentation equipment			
K19 the questions you might expect to receive because of the presentation			
K20 the handouts that can be used to support a development/research presentation			
K21 factors that can affect or influence the impact of a presentation (including room configuration, audio-visual systems (including microphones), dress code)			
K22 any presentation venue health and safety considerations to be considered			

Scope and range for this unit

1. carry out all the following activities:
1.1. plan the presentation in a logical and structured way for the briefing
1.2. prepare the content to meet the needs of the target audience
1.3. rehearse the presentation and amend as appropriate for the content and delivery timescale
1.4. prepare supporting materials (e.g., handouts, copies of slides)
1.5. prepare answers to anticipated questions
1.6. use the equipment correctly to deliver the planned presentation
1.7. answer audience questions
1.8. issue the appropriate handouts to audience following the presentation

2. deliver presentations to both of the following laboratory audiences:
2.1. small groups
2.2. large groups

3. publish technical reports in both of the following formats:
3.1. draft form
3.2. final version

4. record details of the work, and communicate the details to the appropriate people, using:
4.1. verbal report Plus one method from the following:
4.2. written or typed report
4.3. specific company documentation
4.4. computer-based record
4.5. electronic mail

Assessor Comments/Feedback

COGSCIM3_11	**Monitor the preparation of culture media and solutions for biomanufacturing upstream processing** (Level 7, 11 Credits)

Overview

This standard covers the competences you need to monitor the preparing of culture media and solutions for biomanufacturing operations, in accordance with approved procedures. You are required to check the readiness of the manufacturing area and equipment to be used. You will be required to work to the relevant standard operating procedures (SOP), legislation and organisational policy, and to follow Good Manufacturing Practice (GMP). You will also be required to present records and details of your biomanufacturing work to the appropriate people.

You will be required to check that the area and equipment are clear, cleaned and prepared correctly, and that the appropriate services are available as stated in the instructions and standard operating procedures (SOP) you are given. You will remove the culture media from cryostorage, revive it and scale-up the media to specification for upstream processing. You will also complete all the required documents and paperwork in accordance with the same instructions and procedures.

Your responsibilities will require you to comply with health and safety requirements and organisational policies and procedures for the biomanufacturing work that is undertaken. You will be required to report any problems with the biomanufacturing activities that you cannot personally resolve, or that are outside your permitted authority, to the relevant people.

Your underpinning knowledge will be sufficient to provide a sound basis for your work and will enable you to adopt an informed approach to the monitoring procedures. You will understand the preparation of culture media and solutions, in adequate depth to provide a sound background for carrying out the biomanufacturing activities to the required specification.

You will understand the safety precautions required when carrying out the biomanufacturing activities for scientific operations and processes. You will be required to demonstrate safe working practices throughout and will understand your responsibility for taking the necessary safeguards to protect yourself and others 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 standard operating procedures (SOP)			
P2 wear the appropriate personal protection equipment (PPE) when working in the biomanufacturing environment			
P3 check that the laminar flow hood work area to be used is clean, tidy and ready for use			
P4 remove the culture from cryostorage to the work area, in accordance with established procedures			
P5 revive the culture for scale-up, in the correct manner			
P6 measure liquids in the correct quantities/batch sizes for scale-up of the culture			
P7 grow the culture in growth solution and scale-up in the correct manner			
P8 take samples to ensure that correct specifications have been reached			
P9 dispose of waste in the correct manner and location, and tidy and clean the work area, in accordance with established procedures			

P10 monitor and lead the quality and delivery of the above outcomes for yourself and your team			
P11 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 biomanufacturing activities			
K2 the implications of not taking account of legislation, regulations, standards and guidelines when conducting biomanufacturing activities			
K3 the standard operating procedures (SOP), as set down in local biomanufacturing operating manuals			
K4 the importance of following equipment manufacturers' operating instructions			
K5 the principles of Good Manufacturing Practice (GMP) applied in the workplace			
K6 the importance of wearing protective clothing, gloves and eye protection when handling materials (including biochemical substances, biological pathogens and/or antigens), and the equipment used to contain and process them			
K7 the biomanufacturing materials and batch process tracking and records system			
K8 the types of handling and sorting systems, and the procedures used for materials undergoing processing in the manufacturing facilities			
K9 the importance of correct identification, and any unique organisational or manufacturing 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 how to monitor and lead the quality and delivery of prepared culture media and solutions for biomanufacturing operations			
K14 the methods used for storing and removing culture media in cryostorage (including low pressure liquid nitrogen)			
K15 how to revive cultures from cryostorage using room temperature			
K16 how to revive cultures from cryostorage using water bath			
K17 how to check that a pipette is clean and ready for use			
K18 how to measure aliquots of solutions using a pipette for small quantities (less than 2ml) and large quantities (greater than 50ml)			
K19 the correct aseptic techniques to be used in the preparation of culture media for upstream processing			
K20 how to use incubators, both with and without shaker, for the scale-up of culture material			
K21 the procedures for taking aseptic samples for measurement during the scale-up of culture			
K22 how to measure and test samples of culture using optical density			

K23 how to measure and test samples of culture using physical cell count (including hemacytometer)			

Scope and range for this unit

1. carry out all of the following operations:
1.1 use the correct issue of job instructions and specifications
1.2 follow risk assessment procedures and COSHH regulations
1.3 use personal protective equipment for the work being done
1.4 use the correct aseptic techniques and practices
1.5 measure culture and growth media into sterile containers in an aseptic manner
1.6 incubate and grow cultures to the required volume
1.7 perform tests to show that the culture has reached the required specification
1.8 store records of your activities, in accordance with appropriate procedures

2. use three of the following types of protective clothing and equipment:
2.1 laboratory coat/overalls
2.2 gloves
2.3 head/hair covers
2.4 safety shoes/shoe covers
2.5 safety glasses/visors
2.6 other (please specify)

3. monitor the reviving of culture media using two of the following methods:
3.1 using room temperature
3.2 using water bath
3.3 other (please specify)

4. monitor the aliquot measurements of solutions using both of the following:
4.1 pipettes measuring less to 2ml
4.2 pipettes measuring greater than 50ml

5. monitor the incubation of culture media using both of the following:
5.1 incubator with shaker
5.2 incubator without shaker

6. monitor the measurement of samples by both of the following methods:
6.1 optical density
6.2 physical cell count using a hemacytometer

7. monitor the scale-up of the culture, as specified by both of the following categories:
7.1 final volume
7.2 final cell count

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

8.1 verbal report Plus one method from the following:

8.2 written or typed report

8.3 computer-based record

8.4 specific company documentation

8.5 electronic mail

Assessor Comments/Feedback

COGSCIM3_13	**Monitor the harvesting of biomaterial into sterile containers from a bioreactor for biomanufacturing downstream processing** (Level 7, 10 Credits)

Overview

This standard covers the competences you need to monitor the harvesting of biomaterial into sterile containers for biomanufacturing downstream processing operations, in accordance with approved procedures. You are required to check the readiness of the manufacturing area and equipment that is used. You will be required to work to the relevant standard operating procedures (SOP), legislation and organisational policy, and to follow Good Manufacturing Practice (GMP). You will be required to present records and details of your biomanufacturing work to the appropriate people.

You will be required to check that the work area and equipment are ready for use, and that the appropriate resources and services are available as stated in the instructions and standard operating procedures (SOP) you are given. You will stop pH control, cool the fermentation vessel and stop oxygen control for upstream processing. You will be required to connect harvest bags and containers, and to fill them in accordance with instructions and procedures. You will also complete all the required documents and paperwork in accordance with these same instructions and procedures.

Your responsibilities will require you to comply with health and safety requirements and organisational policies and procedures for the biomanufacturing work that is undertaken. You will be required to report any problems with the biomanufacturing activities that you cannot personally resolve, or that are outside your permitted authority, to the relevant people.

Your underpinning knowledge will be sufficient to provide a sound basis for your work and will enable you to adopt an informed approach to applying harvesting procedures. You will understand the process for harvesting from a fermentation vessel, in adequate depth to provide a sound background for carrying out the biomanufacturing activities to the required specification.

You will understand the safety precautions required when carrying out the biomanufacturing activities for scientific operations and processes. You will be required to demonstrate safe working practices throughout and will understand your responsibility for taking the necessary safeguards to protect yourself and others 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 standard operating procedures (SOP)			
P2 wear the appropriate personal protection equipment (PPE) when working in a biomanufacturing environment			
P3 prepare the bioreactor for harvesting the biomaterial, in accordance with established practices and procedures			
P4 harvest biomaterials in sealed sterile containers for downstream processing (DSP), in accordance with established practices and procedures			
P5 dispose of waste in the correct manner and location, and tidy and clean the work area, in accordance with established procedures			
P6 monitor and lead the quality and delivery of the above outcomes for yourself and your team			
P7 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 biomanufacturing activities			
K2 the implications of not taking account of legislation, regulations, standards and guidelines when conducting biomanufacturing activities			
K3 the standard operating procedures (SOP), as set down in local biomanufacturing operating manuals			
K4 the importance of following equipment manufacturers' operating instructions			
K5 the principles of Good Manufacturing Practice (GMP) applied in the workplace			
K6 the importance of wearing protective clothing, gloves and eye protection when handling materials (including biochemical substances, biological pathogens and/or antigens), and the equipment used to contain and process them			
K7 the biomanufacturing materials and batch process tracking and records system			
K8 the types of handling and sorting system, and the procedures used for materials undergoing processing in the manufacturing facilities			
K9 the importance of correct identification, and any unique organisational or manufacturing 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 to if you have problems that you cannot resolve			
K13 how to monitor and lead the quality and delivery of harvested biomaterial into sterile containers for biomanufacturing downstream processing			
K14 how to prepare the bioreactor for harvesting biomaterials			
K15 the different sizes and types of sterile container used in the harvesting process (including bags)			
K16 how to connect and remove the various types of sterile container to/from the bioreactor in an aseptic manner			
K17 how to operate the bioreactor valves to harvest the biomaterial			
K18 the correct aseptic techniques to be used during in the harvesting process			
K19 how and where to store the harvested material in preparation for further processing upon completion of the harvesting operations			

Scope and range for this unit

1. prior to entering the clean room, carry out all of the following:
1.1 use the correct issue of job instructions and specifications
1.2 follow risk assessment procedures and COSHH regulations
1.3 use personal protective equipment for the work being done
1.4 use the correct aseptic techniques and practices
1.5 prepare the bioreactor for harvesting operations
1.6 harvest biomaterial into sterile containers from the bioreactor
1.7 store harvested biomaterial in the correct location for further processing
1.8 store records of your activities, in accordance with appropriate procedures

2. use three of the following types of protective clothing and equipment:
2.1 laboratory coat/overalls
2.2 gloves
2.3 head/hair covers
2.4 safety shoes/shoe covers
2.5 safety glasses/visors
2.6 other (please specify)

3. monitor the preparation of the bioreactor for harvesting biomaterial by all of the following:
3.1 stopping pH control
3.2 cooling vessel
3.3 stopping oxygen control

4. monitor the harvesting of biomaterial in both of the following container types:
4.1 sealed sterile bag
4.2 sealed sterile container

5. record details of the work done, and communicate the details to the appropriate people, using:
5.1 verbal report
5.2 written or typed report
5.3 computer-based record
5.4 specific company documentation
5.5 electronic mail

Assessor Comments/Feedback

COGSCIM3_15	**Monitor the obtaining of biomaterial in biomanufacturing downstream processing using lysis of cells** (Level 7, 13 Credits)

Overview

This standard covers the competences you need to monitor the obtaining of biomaterial in biomanufacturing downstream processing operations using lysis of cells, in accordance with approved procedures. You are required to check the readiness of the manufacturing area and equipment that is used. You will be required to work to the relevant standard operating procedures, legislation and organisational policy, and to follow Good Manufacturing Practice (GMP). You will be required to present records and details of your biomanufacturing work to the appropriate people.

You will be required to check that the work area and equipment are ready for use, and that the appropriate resources and services are available as stated in the instructions and standard operating procedures (SOP) you are given. You will separate biomaterial by lysis of cells for downstream processing (DSP). You will be required to lyse cells in accordance with instructions and procedures. You will also complete all the required documents and paperwork in accordance with these same instructions and procedures.

Your responsibilities will require you to comply with health and safety requirements and organisational policy and procedures for the biomanufacturing work that is undertaken. You will be required to report any problems with the biomanufacturing activities that you cannot personally resolve, or that are outside your permitted authority, to the relevant people.

Your underpinning knowledge will be sufficient to provide a sound basis for your work and will enable you to adopt an informed approach to applying procedures for the monitoring of cell lysis. You will understand the cell lysis process, in adequate depth to provide a sound background for carrying out the biomanufacturing activities to the required specification.

You will understand the safety precautions required when carrying out the biomanufacturing activities for scientific operations and processes. You will be required to demonstrate safe working practices throughout and will understand your responsibility for taking the necessary safeguards to protect yourself and others 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 standard operating procedures (SOP)			
P2 wear the appropriate personal protection equipment (PPE) when working in the biomanufacturing environment			
P3 prepare reagents in the correct quantities according to specifications			
P4 obtain biomaterial from the appropriate source			
P5 dispose of waste in the correct manner and location, and tidy and clean the work area, in accordance with established procedures			
P6 monitor and lead the quality and delivery of the above outcomes for yourself and your team			
P7 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 biomanufacturing activities			
K2 the implications of not taking account of legislation, regulations, standards and guidelines when conducting biomanufacturing activities			
K3 the standard operating procedures (SOP), as set down in local biomanufacturing operating manuals			
K4 the importance of following manufacturers' equipment operating instructions			
K5 the principles of Good Manufacturing Practice (GMP) applied in the workplace			
K6 the importance of wearing protective clothing, gloves and eye protection when handling materials (including biochemical substances, biological pathogens and/or antigens), and the equipment used to contain and process them			
K7 the biomanufacturing materials and batch process tracking and records system			
K8 the types of handling and sorting system, and the procedures used for materials undergoing processing in the manufacturing facilities			
K9 the importance of correct identification, and any unique organisational or manufacturing 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 how to monitor and lead the quality and delivery of biomaterial obtained in biomanufacturing downstream processing operations using lysis of cells			
K14 the main principles of different cell lysis methods (detergent, mechanical disruption, liquid homogenisation, sonication, freeze/thaw, mortar and pestle)			
K15 the advantages and disadvantages of the different cell lysis methods			
K16 how to correctly prepare the working reagents for cell lysis			
K17 how to collect biomaterial from a centrifuge and aseptic container			
K18 how to prepare cell lysates from adherent cells			
K19 how to prepare cell lysates from suspension cells			
K20 how and where to store harvested cell lysates for further downstream processing			

Scope and range for this unit

1. prior to entering the clean room, carry out all of the following:
1.1 use the correct issue of job instructions and specifications
1.2 follow risk assessment procedures and COSHH regulations
1.3 use personal protective equipment for the work being done
1.4 use the correct aseptic techniques and practices
1.5 prepare cell lysates using the appropriate lysis method and procedures
1.6 harvest cell debris, and collect biomaterial into aseptic containers for downstream processing
1.7 store filled aseptic containers in the correct location for further processing
1.8 store records of your activities, in accordance with appropriate procedures

2. use three of the following types of protective clothing and equipment:
2.1 laboratory coat/overalls
2.2 gloves
2.3 head/hair covers
2.4 safety shoes/shoe covers
2.5 safety glasses/visors
2.6 other (please specify)

3. control the obtaining of biomaterial from both of the following sources:
3.1 centrifuge
3.2 aseptic containers

4. monitor the obtaining of biomaterial using one of the following cell lysis methods:
4.1 detergent
4.2 freeze/thawing
4.3 liquid homogenisation
4.4 sonication

5. monitor the obtaining of cell lysates from both of the following biomaterial types:
5.1 suspension cells
5.2 adherent cells
5.3 other (please specify)

6. record details of the 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 computer-based record
6.4 specific company documentation
6.5 electronic mail

Assessor Comments/Feedback

COGSCIM3_16	**Monitor the separation of harvested biomaterial in biomanufacturing downstream processing using normal filtration** (Level 8, 17 Credits)

Overview

This standard covers the competences you need to monitor the separation of harvested biomaterial in biomanufacturing downstream processing operations using normal filtration, in accordance with approved procedures. You are required to check the readiness of the manufacturing area and equipment that is used. You will be required to work to the relevant standard operation procedures, legislation and organisational policy, and to follow Good Manufacturing Practice (GMP). You will also be required to present records and details of your biomanufacturing work to the appropriate people.

You will be required to check that the work area and equipment are ready for use, and that the appropriate resources and services are available as stated in the instructions and standard operating procedures (SOP) you are given. You will separate biomaterial from cell debris for downstream (DSP) processing. You will be required to separate biomaterial using filtration in accordance with instructions and procedures.

You will also complete all the required documents and paperwork in accordance with these same instructions and procedures. Your responsibilities will require you to comply with health and safety requirements and organisational policy and procedures for the biomanufacturing work that is undertaken. You will be required to report any problems with the biomanufacturing activities that you cannot personally resolve, or that are outside your permitted authority, to the relevant people.

Your underpinning knowledge will be sufficient to provide a sound basis for your work and will enable you to adopt an informed approach to the application's different filtration procedures. You will understand the harvesting by the normal filtration process, in adequate depth to provide a sound background for carrying out the biomanufacturing activities to the required specification.

You will understand the safety precautions required when carrying out the biomanufacturing activities for scientific operations and processes. You will be required to demonstrate safe working practices throughout and will understand your responsibility for taking the necessary safeguards to protect yourself and others 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 standard operating procedures (SOP)			
P2 wear the appropriate personal protection equipment (PPE) when working in the biomanufacturing environment			
P3 prepare the filter unit and connect to the biomaterial source for downstream processing (DSP), in accordance with established practices and procedures			
P4 pump biomaterial through the filter unit, monitoring and adjusting flow-rate according to specification			
P5 collect filtered biomaterial in the correct aseptic containers and quantities			
P6 perform a filter unit integrity test, in accordance with established practices and procedures			
P7 dispose of waste in the correct manner and location, and tidy and clean the work area, in accordance with established procedures			
P8 monitor and lead the quality and delivery of the above outcomes for yourself and your team			
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 biomanufacturing activities			
K2 the implications of not taking account of legislation, regulations, standards and guidelines when conducting biomanufacturing activities			
K3 the standard operating procedures, as set down in local biomanufacturing operating manuals			
K4 the importance of following equipment manufacturers' operating instructions			
K5 the principles of Good Manufacturing Practice (GMP) applied in the workplace			
K6 the importance of wearing protective clothing, gloves and eye protection when handling materials (including biochemical substances, biological pathogens and/or antigens), and the equipment used to contain and process them			
K7 the biomanufacturing materials and batch process tracking and records system			
K8 the types of handling and sorting system, and the procedures used for materials undergoing processing in the manufacturing facilities			
K9 the importance of correct identification, and any unique organisational or manufacturing 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 how to monitor and lead the quality and delivery of separated harvested biomaterial in biomanufacturing downstream processing using normal filtration			
K14 the different types of filter units, with and with-out pre-equilibrate, that are used in biomanufacturing			
K15 how to assemble and disassemble filter units for biomaterial processing			
K16 how to switch on the pump, vent air from the filter unit and monitor the flow-rate during processing			
K17 the maximum flow rate for the common filter units used in biomanufacturing			
K18 how to recognise the signs of filter blocking			
K19 how to recover biomaterial from the filter unit by buffer solution washing			
K20 the main differences between a disposable filter unit and a filter unit with module interchange			
K21 how to store filled biomaterial containers for further processing			

Scope and range for this unit

1. prior to entering the clean room, carry out all of the following:
1.1 use the correct issue of job instructions and specifications
1.2 follow risk assessment procedures and COSHH regulations
1.3 use personal protective equipment (PPE) for the work being done
1.4 use the correct aseptic techniques and practices
1.5 assemble and disassemble the filter unit to/from the fermentation vessels or biomaterial containers
1.6 switch on the pump, vent air and collect biomaterial in a sterile container
1.7 monitor flow-rate, pressure and output of biomaterial
1.8 wash the filter unit with buffer solution to recover biomaterial
1.9 store filled biomaterial containers in the correct location and quantities for further processing
1.10 store records of your activities, in accordance with appropriate procedures

2. use three of the following types of protective clothing and equipment:
2.1 laboratory coat/overalls
2.2 gloves
2.3 head/hair covers
2.4 safety shoes/shoe covers
2.5 safety glasses/visors
2.6 other (please specify)

3. control the separation of biomaterial by one of the following filter types:
3.1 disposable complete filter unit
3.2 filter unit with module interchange

4. monitor the use of both of the following types of filter unit:
4.1 filters with pre-equilibrate
4.2 filters without pre-equilibrate

5. record details of the work done, and communicate the details 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 company documentation
5.5 electronic mail

Assessor Comments/Feedback

COGSCIM3_17	**Monitor the concentration and diafiltration of harvested biomaterial in downstream processing using tangential flow filtration** (Level 8, 18 Credits)

Overview

This standard covers the competences you need to monitor the concentration and diafiltration of harvested biomaterial in biomanufacturing downstream processing operations using tangential flow filtration, in accordance with approved procedures. You are required to check the readiness of the manufacturing area and equipment that is used. You will be required to work to the relevant standard operating procedures, legislation and organisational policy, and to follow Good Manufacturing Practice (GMP). You will also be required to present records and details of your biomanufacturing work to the appropriate people.

You will be required to check that the work area and equipment are ready for use, and that the appropriate resources and services are available as stated in the instructions and standard operating procedures (SOP) you are given. You will concentrate and diafiltrate biomaterial in downstream processing operations (DSP. You will be required to separate biomaterial using filtration in accordance with instructions and procedures.

You will also complete all the required documents and paperwork in accordance with these same instructions and procedures. Your responsibilities will require you to comply with health and safety requirements and organisational policy and procedures for the biomanufacturing work that is undertaken. You will be required to report any problems with the biomanufacturing activities that you cannot personally resolve, or that are outside your permitted authority, to the relevant people.

Your underpinning knowledge will be sufficient to provide a sound basis for your work and will enable you to adopt an informed approach to the application of procedures for the monitoring of tangential flow filtration. You will understand harvesting by the filtration process, in adequate depth to provide a sound background for carrying out the biomanufacturing activities to the required specification.

You will understand the safety precautions required when carrying out the biomanufacturing activities for scientific operations and processes. You will be required to demonstrate safe working practices throughout and will understand your responsibility for taking the necessary safeguards to protect yourself and others 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 standard operating procedures (SOP)			
P2 wear the appropriate personal protection equipment (PPE) when working in the biomanufacturing environment			
P3 prepare the tangential flow filtration system in accordance with established practices and procedures			
P4 correctly sterilise equipment in accordance with established practices and procedures			
P5 pump biomaterial through the filtration system, monitoring and adjusting flow-rate according to specification			
P6 collect filtered biomaterial in the correct sterile containers and quantities			
P7 dispose of waste in the correct manner and location, and tidy and clean the work area, in accordance with established procedures			
P8 monitor and lead the quality and delivery of the above outcomes for yourself and your team			
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 biomanufacturing activities			
K2 the implications of not taking account of legislation, regulations, standards and guidelines when conducting biomanufacturing activities			
K3 the standard operating procedures (SOP), as set down in local biomanufacturing operating manuals			
K4 the importance of following equipment manufacturers' operating instructions			
K5 the principles of Good Manufacturing Practice (GMP) applied in the workplace			
K6 the importance of wearing protective clothing, gloves and eye protection when handling materials (including biochemical substances, biological pathogens and/or antigens), and the equipment used to contain and process them			
K7 the biomanufacturing materials and batch process tracking and records system			
K8 the types of handling and sorting system, and the procedures used for materials undergoing processing in the manufacturing facilities			
K9 the importance of correct identification, and any unique organisational or manufacturing 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 how to monitor and lead the quality and delivery of concentrated and diafiltrated harvested biomaterial in biomanufacturing downstream processing operations using tangential flow filtration			
K14 the basic principles of tangential flow filtration (TFF) operation			
K15 how to set up a TFF system, insert the membrane and torque it correctly			
K16 the procedure for preparing the TFF system using cleaning in place (CIP)			
K17 the different methods that can be used for doing CIP			
K18 how to conduct a clean water flux measurement test			
K19 how to equilibrate the TFF system membrane with the appropriate buffer solution			
K20 how to add biomaterial to the TFF system tank, and how to operate the system correctly			
K21 how to calculate trans-membrane pressure (TMP)			
K22 how to recover biomaterial from the TFF system and membrane			
K23 how to dispose of waste material correctly			
K24 how to store filled biomaterial containers for further processing			

Scope and range for this unit

1. carry out all of the following:
1.1 use the correct issue of job instructions and specifications
1.2 follow risk assessment procedures and COSHH regulations
1.3 use personal protective equipment (PPE) for the work being done
1.4 set up the filtration system, insert the membrane and torque correctly
1.5 prepare the system using cleaning in place (steam in place (SIP), hot water or chemicals)
1.6 conduct a clean water flux measurement test
1.7 equilibrate the system membrane with the appropriate buffer solution
1.8 add biomaterial to the system tank, and start up the filtration process correctly
1.9 monitor the system instruments and adjust controls to optimal settings
1.10 process biomaterial to the required concentration
1.11 run diafiltration to required volumes
1.12 switch off correctly and recover biomaterial from the system into sterile containers
1.13 store filled biomaterial containers in the correct location and quantities for further processing
1.14 rinse the membrane to recover biomaterials, and clean the system for next use
1.15 store records of your activities, in accordance with appropriate procedures

2. use three of the following types of protective clothing and equipment:
2.1 laboratory coat/overalls
2.2 gloves
2.3 head/hair covers
2.4 safety shoes/shoe covers
2.5 safety glasses/visors
2.6 other (please specify)

3. monitor and adjust system settings for all of the following:
3.1 pressure
3.2 pump setting
3.3 flow

4. complete all of the following procedures:
4.1 monitor retentate pressure
4.2 calculate trans-membrane pressure
4.3 monitor permeate pressure

5. record details of the work done, and communicate the details 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 company documentation
5.5 electronic mail

Assessor Comments/Feedback

COGSCIM3_18	**Monitor the purification of harvested biomaterial in biomanufacturing downstream processing using chromatography** (Level 8, 21 Credits)

Overview

This standard covers the competences you need to monitor the purification of biomaterial in biomanufacturing downstream processing using chromatography, in accordance with approved procedures. You are required to check the readiness of the manufacturing area and equipment that is used. You will be required to work to the relevant standard operating procedures (SOP), legislation and organisational policy, and to follow Good Manufacturing Practice (GMP). You will be required to present records and details of your biomanufacturing work to the appropriate people.

You will be required to check that the work area and equipment are ready for use, and that the appropriate resources and services are available as stated in the instructions and standard operating procedures (SOP) you are given. You will purify biomaterial using chromatography for downstream (DSP) processing. You will be required to prepare media for the size of column, to assemble and check column components, and to fill and prepare the column in accordance with instructions and procedures.

You will also complete all the required documents and paperwork in accordance with these same instructions and procedures. Your responsibilities will require you to comply with health and safety requirements and organisational policy and procedures for the biomanufacturing work that is undertaken. You will be required to report any problems with the biomanufacturing activities that you cannot personally resolve, or that are outside your permitted authority, to the relevant people.

Your underpinning knowledge will be sufficient to provide a sound basis for your work and will enable you to adopt an informed approach to applying procedures for the monitoring of biomaterial purification by chromatography. You will have an understanding of the purifying of biomaterial by the chromatography process, in adequate depth to provide a sound background for carrying out the biomanufacturing activities to the required specification.

You will understand the safety precautions required when carrying out the biomanufacturing activities for scientific operations and processes. You will be required to demonstrate safe working practices throughout and will understand your responsibility for taking the necessary safeguards to protect yourself and others 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 standard operating procedures (SOP)			
P2 wear the appropriate personal protection equipment (PPE) when working in the biomanufacturing environment			
P3 prepare chromatography system and connect to biomaterial source for downstream processing, in accordance with established practices and procedures			
P4 collect purified biomaterial in the correct aseptic containers and required quantities			
P5 dispose of waste in the correct manner and location, and tidy and clean the work area, in accordance with established procedures			
P6 monitor and lead the quality and delivery of the above outcomes for yourself and your team			
P7 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 biomanufacturing activities			
K2 the implications of not taking account of legislation, regulations, standards and guidelines when conducting biomanufacturing activities			
K3 the standard operating procedures (SOP), as set down in local biomanufacturing operating manuals			
K4 the importance of following equipment manufacturers' operating instructions			
K5 the principles of Good Manufacturing Practice (GMP) applied in the workplace			
K6 the importance of wearing protective clothing, gloves and eye protection when handling materials (including biochemical substances, biological pathogens and/or antigens), and the equipment used to contain and process them			
K7 the biomanufacturing materials and batch process tracking and records system			
K8 the types of handling and sorting system, and the procedures used for materials undergoing processing in the manufacturing facilities			
K9 the importance of correct identification, and any unique organisational or manufacturing 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 how to monitor and lead the quality and delivery of the purification of biomaterial in biomanufacturing downstream processing using chromatography			
K14 the basic principle of purification using large-scale chromatography			
K15 the procedures for loading, packing and setting plungers for optimal height in large-scale chromatography			
K16 how to conduct packing tests (including inject, asymmetry and HETP)			
K17 how to set pressure limits and flow rates of the buffer solution			
K18 how to connect pipework to the system for processing			
K19 how to monitor the system instrumentation			
K20 how to store fractions and collect samples			
K21 how to store, separate and dispose of waste in the correct manner			
K22 the main differences between uniform and density gradient column materials			
K23 how to store filled biomaterial containers for further processing			

Scope and range for this unit

1. carry out all of the following procedures:
1.1 use the correct issue of job instructions and specifications
1.2 follow risk assessment procedures and COSHH regulations
1.3 prepare media for the size of column, and wash it
1.4 assemble and check column components
1.5 pour chromatography material into the column, seal the column and set the plunger
1.6 conduct a packing test, set the pressure limit and flow rate of the buffer solution
1.7 connect pipework to the column and prepare for loading and collection of fractions
1.8 run the program for loading, and monitor the system instruments
1.9 store fractions in sterile containers and send samples for analysis
1.10 stop the processing, clean in place and dispose of waste
1.11 store containers with fractions in the correct location and required quantities for further processing
1.12 store records of your activities, in accordance with appropriate procedures

2. use three of the following types of protective clothing and equipment:
2.1 laboratory coat/overalls
2.2 gloves
2.3 head/hair covers
2.4 safety shoes/shoe covers
2.5 safety glasses/visors
2.6 other (please specify)

3. control the loading of columns by both of the following methods:
3.1 manual loading
3.2 automated loading

4. control the filling of columns with both of the following filter types:
4.1 uniform matrix
4.2 density gradient

5. conduct a packing test, to include all of the following:
5.1 inject
5.2 asymmetry
5.3 height equivalent to a theoretical plate (HETP)

6. monitor the setting of the system pressure limit for all of the following:
6.1 media type
6.2 column type
6.3 system type

7. monitor the collection of fractions in all of the following:
7.1 sterile bags
7.2 sterile containers
7.3 sterile tubes

8. monitor all the following system parameters:
8.1 pressure
8.2 fraction
8.3 pH
8.4 conductivity
8.5 flow rate
8.6 collection
8.7 UV
8.8 temperature

9. control the separation of outputs into all of the following categories:
9.1 waste for autoclaving
9.2 waste for flushing
9.3 waste for chemical cleaning
9.4 biomaterial product

10. record details of the work done, and communicate the details to the appropriate people, using:
10.1 verbal report Plus one method from the following:
10.2 written or typed report
10.3 computer-based record
10.4 specific company documentation
10.5 electronic mail

Assessor Comments/Feedback

COGSCIM3_12	**Monitor the production of biomaterial using bioreactors in biomanufacturing upstream processing** (Level 8, 15 Credits)

Overview

This standard covers the competences you need to monitor the production of biomaterial using bioreactors in biomanufacturing upstream processing operations, in accordance with approved procedures. You are required to check the readiness of the manufacturing area and bioreactor equipment to be used. You will be required to work to the relevant standard operating procedures, legislation and organisational policy, and to follow Good Manufacturing Practice (GMP). You will also be required to present records and details of your biomanufacturing work to the appropriate people.

You will be required to check that the work area and equipment are ready for use, and that the appropriate resources and services are available as stated in the instructions and standard operating procedures (SOP) you are given. You will weigh and measure materials correctly, sterilise equipment in place (where applicable), add growth media, add culture and set growth parameters to specification for upstream processing. You will be required to make regular checks on growth parameters during fermentation, regularly take samples, add additional media when required, and harvest in accordance with instructions and procedures. You will also complete all the required documents and paperwork in accordance with these same instructions and procedures.

Your responsibilities will require you to comply with health and safety requirements and organisational policy and procedures for the biomanufacturing work that is undertaken. You will be required to report any problems with the biomanufacturing activities that you cannot personally resolve, or that are outside your permitted authority, to the relevant people.

Your underpinning knowledge will be sufficient to provide a sound basis for your work and will enable you to adopt an informed approach to applying biomanufacture monitoring procedures. You will understand the fermentation process in adequate depth to provide a sound background for carrying out the biomanufacturing activities to the required specification.

You will understand the safety precautions required when carrying out the biomanufacturing activities for scientific operations and processes. You will be required to demonstrate safe working practices throughout and will understand your responsibility for taking the necessary safeguards to protect yourself and others 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 standard operating procedures (SOP)			
P2 wear the appropriate personal protection equipment (PPE) when working in the biomanufacturing environment			
P3 correctly sterilise equipment, in accordance with established practices and procedures			
P4 prepare the bioreactor, in accordance with established practices and procedures			
P5 correctly add culture and growth media in the correct quantities and at required levels in the bioreactor			
P6 establish growth parameters, and set controls correctly for the required production run			
P7 monitor and run the bioreactor, in accordance with established practices and procedures, until the required biomaterial specifications are reached			
P8 dispose of waste in the correct manner and location, and tidy and clean the work area, in accordance with established procedures			

P9 monitor and lead the quality and delivery of the above outcomes for yourself and your team			
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 you are carrying out the biomanufacturing activities			
K2 the implications of not taking account of legislation, regulations, standards and guidelines when conducting biomanufacturing activities			
K3 the standard operating procedures, as set down in local biomanufacturing operating manuals			
K4 the importance of following equipment manufacturers' operating instructions			
K5 the principles of Good Manufacturing Practice (GMP) applied in the workplace			
K6 the importance of wearing protective clothing, gloves and eye protection when handling materials (including biochemical substances, biological pathogens and/or antigens), and the equipment used to contain and process them			
K7 the biomanufacturing materials and batch process tracking and records system			
K8 the types of handling and sorting system, and the procedures used for materials undergoing processing in the manufacturing facilities			
K9 the importance of correct identification, and any unique organisational or manufacturing 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 how to monitor and lead the quality and delivery of biomaterial produced using bioreactors in biomanufacturing upstream processing			
K14 how the fermentation vessel operates, its controls and main component parts			
K15 the safety equipment and procedures to follow when sterilising a bioreactor using steaming in place (SIP)			
K16 how to sterilise an empty bioreactor correctly, and the steps to be followed			
K17 how to pump culture and grown media into a bioreactor			
K18 how to set and check growth parameters on a bioreactor (including pH, dissolved oxygen, stirrer speed, temperature and pressure)			
K19 the procedures for taking biomaterial samples for measurement during the growth cycle			
K20 how to measure and test samples of biomaterial using optical density			

K21 how to measure and test samples of biomaterial using physical cell count and a hemocytomete			
K22 how to make additions to the bioreactor during the production run			

Scope and range for this unit

1. carry out all of the following:
1.1 Use the correct issue of job instructions and specifications
1.2 Follow risk assessment procedures and COSHH regulations
1.3 Use personal protective equipment for the work being done
1.4 Use the correct aseptic techniques and practices
1.5 Sterilise the bioreactor using steaming in place (SIP)
1.6 Pump in growth media and culture media
1.7 Check growth parameters during the production cycle
1.8 Perform regular sampling and tests until the biomaterial has reached the required specification
1.9 Store records of your activities, in accordance with appropriate procedures

2. use three of the following types of protective clothing and equipment:
2.1 laboratory coat/overalls
2.2 gloves
2.3 head/hair covers
2.4 safety shoes/shoe covers
2.5 safety glasses/visors
2.6 other (please specify)

3. monitor the sterilising of a fermentation vessel for two of the following circumstances:
3.1 vessel empty (e.g., mammalian growth)
3.2 vessel full (e.g., microbial growth)
3.3 other (please specify)

4. fill the fermentation vessel to the required levels, measuring by both of the following controls:
4.1 sight glass
4.2 automatic level indicators

5. monitor the setting and checking of four of the following growth parameters:
5.1 pH
5.2 stirrer speed
5.3 pressure
5.4 dissolved oxygen (DO2)
5.5 temperature
5.6 other (please specify)

6. monitor the measurement of samples by both of the following methods:
6.1 optical density
6.2 physical cell count using a hemacytometer

7. monitor the fermenting of biomaterial in both of the following categories:

7.1 no additional media required during fermentation

7.2 additional media required at a fixed point

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

8.1 verbal report Plus one method from the following:

8.2 written or typed report

8.3 computer-based record

8.4 specific company documentation

8.5 electronic mail

Assessor Comments/Feedback

COGSCIM3_14	**Monitor the separation of harvested biomaterial for biomanufacturing downstream processing using continuous flow centrifugation** (Level 8, 17 Credits)

Overview

This standard covers the competences you need to monitor the separation of harvested biomaterial biomanufacturing downstream processing operations using continuous flow centrifugation, in accordance with approved procedures. You are required to check the readiness of the manufacturing area and equipment that is used. You will be required to work to the relevant standard operating procedures, legislation and organisational policy, and to follow Good Manufacturing Practice (GMP). You will be required to present records and details of your biomanufacturing work to the appropriate people.

You will be required to check that the work area and equipment are ready for use, and that the appropriate resources and services are available as stated in the instructions and standard operating procedures (SOP) you are given. You will separate biomaterial particles for downstream processing (DSP). You will be required to connect up the centrifuge in accordance with instructions and procedures. You will also complete all the required documents and paperwork in accordance with these same instructions and procedures.

Your responsibilities will require you to comply with health and safety requirements and organisational policy and procedures for the biomanufacturing work that is undertaken. You will be required to report any problems with the biomanufacturing activities that you cannot personally resolve, or that are outside your permitted authority, to the relevant people.

Your underpinning knowledge will be sufficient to provide a sound basis for your work and will enable you to adopt an informed approach to applying biomaterial harvest monitoring procedures. You will understand the continuous flow centrifugation process, in adequate depth to provide a sound background for carrying out the biomanufacturing activities to the required specification.

You will understand the safety precautions required when carrying out the biomanufacturing activities for scientific operations and processes. You will be required to demonstrate safe working practices throughout and will understand your responsibility for taking the necessary safeguards to protect yourself and others 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 standard operating procedures			
P2 wear the appropriate personal protection equipment (PPE) when working in the biomanufacturing environment			
P3 prepare the centrifuge for the separation of biomaterial particles, in accordance with established practices and procedures			
P4 harvest the biomaterial particles in sealed aseptic containers for downstream processing (DSP), in accordance with established practices and procedures			
P5 dispose of waste in the correct manner and location, and tidy and clean the work area, in accordance with established procedures			
P6 monitor and lead the quality and delivery of the above outcomes for yourself and your team			
P7 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 biomanufacturing activities			
K2 the implications of not taking account of legislation, regulations, standards and guidelines when conducting biomanufacturing activities			
K3 the standard operating procedures, as set down in local biomanufacturing operating manuals			
K4 the importance of following equipment manufacturers' operating instructions			
K5 the principles of Good Manufacturing Practice (GMP) applied in the workplace			
K6 the importance of wearing protective clothing, gloves and eye protection when handling materials (including biochemical substances, biological pathogens and/or antigens), and the equipment used to contain and process them			
K7 the biomanufacturing materials and batch process tracking and records system			
K8 the types of handling and sorting system, and the procedures used for materials undergoing processing in the manufacturing facilities			
K9 the importance of correct identification, and any unique organisational or manufacturing 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 how to monitor and lead the quality and delivery of separated harvested biomaterial in biomanufacturing downstream processing using continuous flow centrifugation			
K14 the main principles of operation for the different types of continuous flow centrifuge (disc stack, tubular centred, multi-chamber types)			
K15 the main component parts of the centrifuge (including the different types of rotor and cores, the inlet/outlet connection points for the edge and centre)			
K16 how to distinguish between product and waste streams from the centrifuge			
K17 how to dismantle and re-assemble a continuous flow centrifuge correctly (not appropriate for disc stack centrifuge)			
K18 how to connect equipment and the centrifuge for loading and unloading cushion or step gradient			
K19 how to connect equipment and the centrifuge for continuous flow centrifugation			
K20 how to harvest particles where the required biomaterial in suspended in the liquid			
K21 how to harvest particles where the required biomaterial in suspended in the solids			

Scope and range for this unit

1. prior to entering the clean room, carry out all the following:
1.1 use the correct issue of job instructions and specifications
1.2 follow risk assessment procedures and COSHH regulations
1.3 use personal protective equipment for the work being done
1.4 use the correct aseptic techniques and practices
1.5 operate the continuous flow centrifuge for the separating operations
1.6 identify which centrifuge stream is biomaterial and which is waste
1.7 harvest the biomaterial into sterile containers for downstream processing
1.8 store centrifuged biomaterial in the correct location for further processing
1.9 store records of your activities, in accordance with appropriate procedures

2. use three of the following types of protective clothing and equipment:
2.1 laboratory coat/overalls
2.2 gloves
2.3 head/hair covers
2.4 safety shoes/shoe covers
2.5 safety glasses/visors
2.6 other (please specify)

3. control the separation of biomaterial particles by one of the following types:
3.1 disc stack centrifuge
3.2 tubular centred centrifuge
3.3 multi-chamber centrifuge

4. monitor the separation of biomaterial particles by one of the following techniques:
4.1 pelleting and clarifying
4.2 cushion sedimentation
4.3 banding in a gradient

5. record details of the work done, and communicate the details 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 company documentation
5.5 electronic mail

Assessor Comments/Feedback

Notes

Notes

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