Science Manufacturing Technician 2023

Level 3 Apprenticeship Standard (ST1406)

Specification

This guide describes the different types of End-Point Assessment tests, the test rules and who should be involved. Preparing for End-Point Assessment and working with SIAS are also covered.

SIAS is the science industry assessment service. It is part of the Cogent Skills Group.

For further information about apprenticeship standards and Trailblazers please contact info@siasuk.com.

Version History

Version	Updates
1.0	This document relates to the Science Manufacturing Technician 2023 assessment plan version 1.0

Contents

Objective

The aim of this End-Point Assessment (EPA) is to ensure that the apprentice is occupationally competent against the knowledge, skills and behaviours outlined in the assessment plan for this standard.

Science manufacturing technicians are found in the process manufacturing sector.

This is a core and options apprenticeship. An apprentice must complete the core and one option relevant to their occupation. The options are:

- Option 1. Biotechnology manufacturing technician
- Option 2. Aseptic pharmaceuticals manufacturing technician

Biotechnology manufacturing technicians produce biological products such as proteins, antibodies, and DNA. These may be used in pharmaceuticals, agricultural products, food and feed, detergents, paper, textiles, and biofuels. The final product may be solid or liquid and may be filled into small volume bottles or large bulk containers. Typically, batch processing is used. They may work in a controlled environment, such as laboratory or clean room, or production facilities. Biotechnology has an important role to play in helping to address many global problems, such as climate change. For example, synthetic biology is already contributing to the development of many biological systems producing drugs, chemicals, and fuels without using fossil fuels.

Aseptic pharmaceuticals manufacturing technicians are involved in the manufacture of pharmaceutical products - medicines or drugs. They may be involved in part or all of the process including active pharmaceutical ingredients (API) production and final formulation. APIs are the medical ingredient that goes into medicines. Formulations typically involves the blending of the API and other ingredients. Production may be continuous or batch. Technicians work in highly controlled process areas. This could be in large process plant or small rooms depending on the type of medicine being made and the stage of the process. Typically, they will work in a clean room where air particulates are controlled to stop potential contamination of the product.

Both biotechnology and aseptic pharmaceuticals manufacturing technicians run and maintain the process or processes in line with operational parameters. They conduct quality assurance, resolving or escalating any issues, and complete records. Maintaining workplace safety by following health, safety and environmental risk and management systems is a vital part of the role. They also take part in risk assessment and improvement activities, and support audits.

On a daily basis, they work with other members of the process team. They also have contact with people in other teams for example, laboratory, maintenance, process engineering, supply chain, and warehouse. They may also have contact with external people such as, customers, service providers, and regulators.

They must ensure that the process and products meet quality specifications and are produced to schedule. They must work to external manufacturing regulations to protect the process, product, plant and equipment, company employees, and the environment. They must also consider sustainability. They may need to wear specialist PPE to protect the product or

themselves. This may include, safety glasses, chemical resistant gloves, suits and footwear, and breathing apparatus. They may work alone or part of a team. They work with minimal supervision, taking responsibility for the quality and accuracy of their work.

Prior Learning and Qualifications

Employers will set their own entry requirements. Typically, they require applicants to have GCSE science grade C or 4. An employer may require applicants to have a health screening to ensure suitability for working in some work environments.

Overview

This is a core and options apprenticeship. An apprentice must be trained and assessed against the core and one option. The options are:

- Biotechnology manufacturing technician
- Aseptic pharmaceuticals manufacturing technician

A full-time science manufacturing technician 2023 apprentice typically spends 36 months on-programme. The apprentice must spend at least 12 months on-programme and complete the required amount of off-the-job training in line with the apprenticeship funding rules.

The EPA should be completed within an EPA period lasting typically 3 months.

The apprentice must complete their training and meet the gateway requirements before starting their EPA. The EPA will assess occupational competence.

This EPA has 3 assessment methods. The grades available for each assessment method are below.

Assessment method 1 - observation with questions:

- fail
- pass
- distinction

Assessment method 2 - interview underpinned by a portfolio of evidence:

- fail
- pass
- distinction

Assessment method 3 - multiple-choice test:

- fail
- pass

The result from each assessment method is combined to decide the overall apprenticeship grade. The following grades are available for the apprenticeship:

- fail
- pass
- merit

- distinction

Competence Evaluation

During the apprenticeship, regular evaluation of the competence of the apprentice against the apprenticeship standard will help to ensure that they achieve full occupational competence by the end of their training, and they are ready for EPA. Confirmation from the employer that the apprentice is fully competent is needed before EPA can take place.

As competence evaluation is an in-programme activity, the process that is used for this has not been mandated. It is for the employer supported by their training provider to decide how they wish to do this. To help with this SIAS has produced the SIAS Competence Tracker.

Gateway Requirements

The apprentice's employer must be content that the apprentice is occupationally competent. That is, they are deemed to be working at or above the level set out in the apprenticeship standard and ready to undertake the EPA. The employer may take advice from the apprentice's training provider, but the employer must make the decision. The apprentice will then enter the gateway.

The gateway requirements for the EPA are:

- achieved English and mathematics qualifications in line with the apprenticeship funding rules.
- for the interview underpinned by a portfolio of evidence, the apprentice must have submitted a portfolio of evidence.

Assessment Methods

The EPA has three assessment methods.

1. Observation with questions
2. Interview underpinned by a portfolio of evidence
3. Multiple-choice test

Assessment Method 1: Observation with Questions

In the observation with questions, an end-point assessor observes the apprentice in their workplace and asks questions. The apprentice completes their day-to-day duties under normal working conditions. Simulation is not allowed.

The observation with questions must be structured to give the apprentice the opportunity to demonstrate the KSBs mapped to this assessment method to the highest available grade.

An end-point assessor must conduct and assess the observation with questions.

SIAS will give the apprentice 2 weeks' notice of the observation with questions.

The observation must take 3 hours.

The end-point assessor can increase the time of the observation with questions by up to 10%. This time is to allow the apprentice to complete a task or respond to a question if necessary.

The apprentice may choose to end any assessment method early. The apprentice must be confident they have demonstrated competence against the assessment requirements for the assessment method. The end-point assessor or SIAS must ensure the apprentice is fully aware of all assessment requirements. The end-point assessor or SIAS cannot suggest or choose to end any assessment methods early (unless in an emergency). SIAS is responsible for ensuring the apprentice understands the implications of ending an assessment early if they choose to do so. The end-point assessor may suggest the assessment continues. The end-point assessor must document the apprentice's request to end any assessment early.

The observation may be split into discrete sections held on the same working day.

SIAS will manage invigilation of the apprentice during the assessment, to maintain security of the EPA, in line with their malpractice policy. This includes breaks and moving between locations.

The end-point assessor must explain to the apprentice the format and timescales of the observation with questions before it starts. This does not count towards the assessment time.

The end-point assessor should observe the following during the observation:

Core

- Organise own work.
- Maintain the work area.
- Apply control room procedures.
- Conduct first line routine maintenance.
- Communicate with others.
- Complete process documentation.

Option 1. Biotechnology manufacturing technician

- Run and maintain biotechnology process.
- Conduct biotechnology quality assurance.

Option 2. Aseptic pharmaceuticals manufacturing technician

- Run and maintain aseptic pharmaceutical process.
- Conduct aseptic pharmaceutical quality assurance.

Activities may relate to the same process or product, or different processes or products.

These activities provide the apprentice with the opportunity to demonstrate the KSBs mapped to this assessment method.

The end-point assessor must ask questions. Questioning can occur both during and after the observation.

The purpose of the questions is to assess the apprentice's level of competence against the grading descriptors.

The time for questioning is included in the overall assessment time. The end-point assessor must ask at least 5 questions. To remain as unobtrusive as possible, the end-point assessor should ask questions during natural stops between tasks and after completion of work rather than disrupting the apprentice's flow. Follow-up questions are allowed where clarification is required.

The end-point assessor must ask questions about KSBs that were not observed to gather assessment evidence. These questions are in addition to the above set number of questions for the observation with questions and should be kept to a minimum.

The end-point assessor must make the grading decision and assess the observation and responses to questions holistically when deciding the grade.

The end-point assessor must keep accurate records of the assessment. They must record:

- the KSBs observed.
- the apprentice's answers to questions.
- the KSBs demonstrated in answers to questions.
- The grade achieved.

The observation with questions must take place in the apprentice's normal place of work for example, their employer's premises or a customer's premises. Equipment and resources needed for the observation **must** be provided by the employer and be in good and safe working condition.

Questioning that occurs after the observation should take place in a suitable environment, for example a quiet room, free from distractions and influence.

Observation with Questions Grading Descriptors

KSBs	Pass	Distinction
Core Organise own work K25 S1 S2	**P1** Reviews instructions or information to understand the task's requirements. (S1) **P2** Plans tasks and identifies and organises resources required to complete it using planning, prioritising, and time management techniques with consideration for safety, environmental impact, quality, and cost. (K25, S2)	**D1** The balance of safety, environmental impact, quality, and cost factors in their planning decisions is justified. (K25, S2)

KSBs	Pass	Distinction
Core Maintain the work area K4 K6 S3 S4 S7 S10 B1	**P3** Identifies health and safety and environmental hazards and risks in the workplace, and personal safety and mitigation measures with consideration of hierarchy of control and emergency procedures. **P4** Prioritises and applies health, safety, and environmental procedures in compliance with regulations, standards and guidance mitigating against risks including use of personal protective equipment. (K4, K6, S3, S4, B1) **P5** Segregates resources for reuse, recycling, and waste handling in line with company procedures. (S7) **P6** Stores tools and equipment in line with company procedures. (S10)	**D2** Explains the importance of applying health, safety and environmental procedures in their work. (K4, K6, S4)
Core Apply control room procedures K11 S5	**P7** Applies controlled environmental procedures in line with the need and requirements for clean rooms in manufacturing including protocols for entering, gowning, working in, exiting, and material flows. (K11, S5)	None
Core Conduct first line routine maintenance K17 S9	**P8** Applies first line maintenance practices in line with their company's preventative and reliability maintenance practices. (K17, S9)	**D3** Explains the benefits of applying preventative and reliability maintenance practices. (K17, S9)
Core Communicate with others K22 S21	**P9** Uses verbal communication techniques suitable for the context. (K22, S21)	None

KSBs	Pass	Distinction
Core Complete process documentation K13 S17	**P10** Records or enters data for work tasks - paper based or electronic - in line with company procedures for documentation control and auditable records. (K13, S17)	None
Biotechnology technician Option 1. Run and maintain biotechnology process K26 K27 K28 K43 S24 S25 S26 S27 S28 S29 S33	**P11** Selects, checks, and prepares raw materials for biotechnology process or processes in line with task requirements and standard operating procedures. **P12** Conducts pre-checks of hand tools, equipment, and machinery for biotechnology process or processes, including calibration record where applicable, required for task in line with standard operating procedures. **P13** Connects service connections for biotechnology process or processes in line with task requirements and standard operating procedures. **P14** Operates biotechnology equipment and sets and adjusts biotechnology process parameters using process control system and its constituent components to maintain standard operating conditions for the task in line with standard operating procedures. **P15** Removes and replaces disposable components and checks functionality to ensure no equipment errors.	**D4** Justifies their approach to running biotechnology process in terms of effectiveness or efficiencies of practice and the impact of their actions on others. (K26, S24)

KSBs	Pass	Distinction
	(K26, K27, K28, K43, S24, S25, S26, S27, S28, S29, S33)	
Biotechnology technician Option 1. Conduct biotechnology quality assurance K29 K31 S30 S31 S32 B4	**P16** Checks calibration and calibrates analytical equipment in line with standard operating procedures. **P17** Takes responsibility for the quality of own work by conducting at point analysis of product using laboratory techniques (bench top analysis) and applying quality assurance procedures in line with quality standards and on-line and off-line quality control requirements that take account of the main factors influencing quality assurance in biotechnology process industries. (K29, K31, S30, S31, S32, B4)	None
Aseptic pharmaceutical technician Option 2. Run and maintain aseptic pharmaceutical process K46 K47 K48 K49 K63 S36 S37 S38 S39 S40 S42	**P18** Selects, checks, and prepares raw materials for aseptic process in line with task requirements and standard operating procedures. **P19** Conducts pre-checks of hand tools, equipment, and machinery for aseptic process, including calibration record where applicable, required for task in line with standard operating procedures. **P20** Operates aseptic process equipment and sets and adjusts aseptic process parameters using process control system and its constituent components to maintain standard operating conditions for the task in line with standard operating	**D5** Justifies their approach to running aseptic process in terms of effectiveness or efficiencies of practice and the impact of their actions on others. (K46, S36)

KSBs	Pass	Distinction
	procedures and start up and shut down procedures. (K46, K47, K48, K49, K63, S36, S37, S38, S39, S40, S42)	
Aseptic pharmaceutical technician Option 2. Conduct aseptic pharmaceutical quality assurance K50 K51 K62 S41 S43 S44 S45 S46 B5	**P21** Conducts pre and in-process checks in line with aseptic services checking requirements. **P22** Takes responsibility for the quality of own work by applying quality assurance procedures in line with quality standards and on-line and off-line quality control requirements that take account of the main factors influencing quality assurance in pharmaceutical process industries. **P23** Cleans equipment and process areas in-between production in line with standard operating procedures to avoid cross-contamination in line with company procedures. **P24** Conducts volume checks in line with company procedures. **P25** Calibrates analytical equipment in line with standard operating procedures. (K50, K51, K62, S41, S43, S44, S45, S46, B5)	

Fail – An apprentice will fail where they do not demonstrate all the pass descriptors.

Observation with Questions Knowledge, Skills and Behaviours

Ref	KSB Statement
Core Knowledge	
K4	Science process manufacturing safety hazards – risks they pose and their management: temperature, pressure, and vapours. Risk assessment and safe

	systems of work. Personal Protective Equipment (PPE) requirements. Emergency procedures.
K6	Environmental hazards that can arise from process. Hierarchy of control.
K11	Need and requirements for clean rooms in manufacturing. Protocols for entering, gowning, working in, exiting, and material flows.
K13	Documentation requirements: documentation control, auditable records.
K17	Preventative and reliability maintenance practices.
K22	Verbal communication techniques.
K25	Planning, prioritising, and time management techniques.
Pathway Specific Knowledge - Biotechnology manufacturing technician	
K26	Standard operating procedures (SOP) - what they are and why they are important.
K27	Standard operating conditions (SOC) - what they are and why they are important.
K28	Process control systems and their constituent components.
K29	Quality standards. On-line and off-line quality control.
K31	Main factors influencing quality assurance in biotechnology process industries.
K43	. Purpose and operation of biotechnology equipment.
Pathway Specific Knowledge - Aseptic pharmaceuticals manufacturing technician.	
K46	Standard operating procedures (SOP) - what they are and why they are important.
K47	Standard operating conditions (SOC) - what they are and why they are important.
K48	Process control systems and their constituent components.
K49	Start up and shut down procedures.
K50	Main factors influencing quality assurance in pharmaceutical process industries.
K51	Quality standards. On-line and off-line quality control.
K62	Pre and in-process checking within aseptic services.
K63	Purpose and operation of aseptic pharmaceutical equipment.

Core Skills	
S1	Review instructions or information to understand the task.
S2	Plan tasks. Identify and organise resources with consideration for safety, environmental impact, quality, and cost.
S3	Identify hazards and risks in the workplace and personal safety and mitigation measures.
S4	Apply health, safety, and environmental procedures in compliance with regulations, standards, and guidance.
S5	Apply controlled environment procedures for example, gowning, isolators, contamination control, and sanitisation.
S7	Segregate resources for reuse, recycling, and waste handling.
S9	Apply first line maintenance practices.
S10	Store tools and equipment.
S17	Record or enter information - paper based or electronic.
S21	Communicate with others verbally for example, colleagues and stakeholders.
Pathway Specific Skills - Biotechnology manufacturing technician	
S24	Apply standard operating procedures (SOPs).
S25	Select, check, and prepare raw materials for biotechnology process for example, weighing, measuring, control and blending, conditioning, dissolving, and sanitisation.
S26	Conduct pre-checks of hand tools, equipment and machinery for biotechnology process including calibration record where applicable.
S27	Connect service connections for biotechnology process such as water, electrical, pneumatic, hydraulic.
S28	Operate biotechnology equipment for example, start-up, shut down, or cleaning mode.
S29	Set and adjust biotechnology process parameters such as agitation revolutions per minute, temperature, pressure, flow rate or time.
S30	Check calibration and calibrate analytical equipment.
S31	Conduct at point analysis of the product using laboratory techniques (bench top analysis) for example, pH, conductivity measurement, optical density measurements, and protein concertation.
S32	Apply quality assurance procedures. For example, conduct parameter checks (size, colour, weight), and take samples for laboratory testing.
S33	Remove and replace disposable components and check functionality for example, break lines, isolators, and tri-clamps and tube welding.
Pathway Specific Skills – Aseptic pharmaceutical manufacturing technician	
S36	Apply standard operating procedures (SOPs).
S37	Select, check, and prepare raw (incoming) materials for aseptic process for example, weighing, measuring, conditioning, dissolving, and sanitisation.

S38	Conduct pre-checks of hand tools, equipment and machinery for aseptic process including calibration record where applicable.
S39	Operate aseptic process equipment for example, start-up and shut-down.
S40	Set aseptic process parameters such as temperature, and pressure.
S41	Conduct pre and in-process checks such as environmental monitoring.
S42	Make adjustments to aseptic process parameters.
S43	Apply quality assurance procedures. For example, conduct parameter checks (size, colour, weight), and take samples for laboratory testing.
S44	Clean equipment and process areas in-between production to avoid cross-contamination.
S45	Conduct volume checks.
S46	Calibrate analytical equipment.
Core Behaviours	
B1	Prioritise health, safety, and environment.
Pathway Specific Behaviours - Biotechnology manufacturing technician	
B4	Take responsibility for the quality of their own work.
Pathway Specific Behaviours - Aseptic pharmaceuticals manufacturing technician	
B5	Take responsibility for the quality of their own work.

Assessment Method 2: Interview Underpinned by a Portfolio of Evidence

In the interview, an end-point assessor asks the apprentice questions. It gives the apprentice the opportunity to demonstrate the KSBs mapped to this assessment method.

The apprentice can refer to and illustrate their answers with evidence from their portfolio of evidence.

This assessment method is being used because:

- it assesses KSBs holistically and objectively.
- it allows for the assessment of KSBs that do not occur on a predictable or regular basis.
- it allows for the assessment of responses where there are a range of potential answers.
- it can be conducted remotely, potentially reducing cost.

The interview must be structured to give the apprentice the opportunity to demonstrate the KSBs mapped to this assessment method to the highest available grade.

The purpose of the end-point assessor's questions is to assess the apprentice against the following themes:

Core

- role and responsibilities
- in process or post manufacturing procedures
- sustainability

- problem solving and fault finding
- continuous improvement
- written communication
- information and digital technology
- teamwork
- continued professional development

Option 1. Biotechnology manufacturing technician

- biotechnology process operations
- shutting down and preparing for maintenance

Option 2. Aseptic pharmaceuticals manufacturing technician

- maintenance requirements

SIAS will give an apprentice 2 weeks' notice of the interview.

The end-point assessor must have at least 2 weeks to review the supporting documentation.

The apprentice must have access to their portfolio of evidence during the interview.

The apprentice can refer to and illustrate their answers with evidence from their portfolio of evidence however, the portfolio of evidence is not directly assessed.

The interview must last for 60 minutes. The end-point assessor can increase the time of the interview by up to 10%. This time is to allow the apprentice to respond to a question if necessary.

The apprentice may choose to end any assessment method early. The apprentice must be confident they have demonstrated competence against the assessment requirements for the assessment method. The end-point assessor or SIAS must ensure the apprentice is fully aware of all assessment requirements. The end-point assessor or SIAS cannot suggest or choose to end any assessment methods early (unless in an emergency). SIAS is responsible for ensuring the apprentice understands the implications of ending an assessment early if they choose to do so. The end-point assessor may suggest the assessment continues. The end-point assessor must document the apprentice's request to end any assessment early.

The end-point assessor must ask at least 8 questions and must use the questions from SIAS' question bank. Follow-up questions are allowed where clarification is required.

The end-point assessor must make the grading decision.

The end-point assessor must keep accurate records of the assessment. They must record:

- the apprentice's answers to questions.
- the KSBs demonstrated in answers to questions.
- the grade achieved.

The interview must take place in a suitable venue selected by SIAS for example, the employer's premises.

The interview should take place in a quiet room, free from distractions and influence.

SIAS will ensure that the apprentice has a different set of questions in the case of re-sits or re-takes.

Interview underpinned by a Portfolio of Evidence Grading Descriptors

Theme **KSBs**	**Pass** The apprentice must demonstrate all of the pass descriptors for the core and their option	**Distinction** The apprentice must demonstrate all of the pass and distinction descriptors for the core and their option
Core Role and responsibilities K2 K14 S13 S16 B6	**P1** Describes their role as a science manufacturing technician including their limits of responsibility, how they escalate issues, and how they respond and adapt to work demands in line with organisational requirements. **P2** Outlines the impact of an operator's competence on product quality. **P3** Outlines change control requirements and why they are important. (K2, S16, B6) **P4** Describes how they perform second person witness and second person checks for critical tasks in line with company requirements. (K14, S13)	**D1** Explains the importance of applying second person witness and second person checks for critical tasks and aseptic techniques in production. (K14, S13)
Core In process or post manufacturing procedures S8	**P5** Describes how they apply in process or post-process manufacturing procedures in line with task requirements. (S8)	None
Core Sustainability K8 S6 B2	**P6** Describes how they consider and apply the principles of sustainability and the circular economy when using resources and carrying out processes including resource	**D2** Explains how they have supported the development or implementation of sustainability practice in the workplace beyond their role for example, through promoting good practice to others,

Theme KSBs	Pass The apprentice must demonstrate all of the pass descriptors for the core and their option	Distinction The apprentice must demonstrate all of the pass and distinction descriptors for the core and their option
	efficiency, reuse of materials, and recycling and control of emissions and waste. (K8, S6, B2)	identifying improvement to practice. (K8, S6, B2)
Core Problem solving and fault finding K18 K19 S14 S15	**P7** Describes how they identify issues and apply problem solving and fault-finding techniques to establish the root cause of common faults in processing including flow, blockages, instrumentation failures, seals, and human factors. (K18, K19, S14, S15)	**D3** Assesses the value of specific fault-finding and problem solving techniques for different issues. (K18, K19, S14, S15)
Core Continuous improvement K20 S19	**P8** Describes how they have applied continuous improvement (CI) techniques and a made a viable suggestion for improvement in their work to support CI systems. (K20, S19)	**D4** Justifies the potential impact of the improvement suggestion with consideration to benefits and any potential risks. (K20, S19)
Core Written communication K23 S22	**P9** Describes how they apply written communication and report writing techniques to produce communications in their work suitable for context. (K23, S22)	None
Core Information and digital technology K21 S18	**P10** Describes how they use information and digital technology in work tasks in compliance with cyber security requirements and GDPR. (K21, S18)	None
Core Teamwork K24 S20 B3	**P11** Describes how they apply team working principles to meet work goals in line with their company's policy on equality, diversity, and inclusion. (K24, S20, B3)	**D5** Justifies how their team focus approach helped to achieve a positive outcome in a team activity. (K24, S20, B3)
Core Continued professional development S23 B7	**P12** Describes the planned and unplanned learning and development activities they have carried out and recorded to meet personal development	None

Theme KSBs	Pass The apprentice must demonstrate all of the pass descriptors for the core and their option	Distinction The apprentice must demonstrate all of the pass and distinction descriptors for the core and their option
	needs, showing a commitment to future CPD. (S23, B7)	
Biotechnology technician Option 1. Biotechnology process operations K33 S34	**P13** Describes how they conduct aseptic method in line with task requirements to avoid common contamination routes in line with standard operating procedures. (K33, S34)	None
Biotechnology technician Option 1. Shutting down and preparing for maintenance K30	**P14** Explains their company's requirements for shutting down and preparing for maintenance. (K30)	None
Aseptic pharmaceutical technician Option 2. Requirements for maintenance K65	**P15** Explains their company's requirements for full maintenance. (K65)	None

Fail – An apprentice will fail where they do not demonstrate all the pass descriptors.

Interview underpinned by a Portfolio of Evidence Knowledge, Skills and Behaviours

Ref	KSB Statement
Core Knowledge	
K2	Role and limits of responsibility. Escalation procedures. Impact of operators' competence on product quality. Change control requirement.
K8	Principles of sustainability and circular economy. Resource (energy, water, and waste) efficiency and reuse of materials. Principles of control and management of emissions and waste.
K14	Requirements for a second person witness and second person checks.
K18	Common faults and causes in processing: flow, blockages, instrumentation failures, seals and human factors.
K19	Problem solving and fault-finding techniques: root cause analysis, 5-Whys.
K20	Continuous improvement (CI) systems and techniques.

K21	Information and digital technology to support science manufacturing operations. Cyber security requirements. General data protection regulation (GDPR).
K23	Written communication techniques. Technical report writing techniques.
K24	Principles of team working. Principles of equality, diversity, and inclusion in the workplace.
Pathway Specific Knowledge - Biotechnology manufacturing technician	
K30	Requirements for shutting down and preparing for maintenance.
K33	Common contamination routes during biotechnology production.
Pathway Specific Knowledge - Aseptic pharmaceuticals manufacturing technician.	
K65	Requirements for full equipment maintenance.
Core Skills	
S6	Apply sustainability principles for example, minimising waste.
S8	Conduct in process or post-manufacturing procedure for example, labelling, packing, storage, visual inspection, discharge.
S13	Perform second person witness and second person checks for critical tasks.
S14	Identify issues for example, defects, deviations, process variance, and maintenance requirements.
S15	Apply problem solving and fault-finding techniques.
S16	Escalate issues outside limits of responsibility.
S18	Use information and digital technology for example, management information systems, human machine interfaces, word processing, spreadsheet, email, virtual learning platforms, document sharing platforms. Comply with cyber security requirements and GDPR.
S19	Apply continuous improvement techniques. Make a suggestion for improvement.
S20	Apply team working principles.
S22	Produce written documents for example, handover notes or emails, non-conformances, design change requests.
S23	Plan how to meet personal development needs. Carry out and record planned and unplanned learning and development activities.
Pathway Specific Skills – Biotechnology manufacturing technician	
S34	Conduct aseptic method for example, aseptic technique or aseptic sampling.
Core Behaviours	
B2	Consider sustainability when using resources and carrying out processes.
B3	Team-focus to meet work goals including support for equality, diversity and inclusion.
B6	Respond and adapt to work demands.
B7	Committed to continued professional development.

Assessment Method 3: Multiple-Choice Test

In the multiple-choice test, the apprentice answers questions in a controlled and invigilated environment. It gives the apprentice the opportunity to demonstrate the knowledge mapped to this assessment method.

This assessment method is being used because:

- it can assess knowledge.

- it is easy to administer.
- it can be conducted remotely and administered to multiple apprentices at the same time, potentially reducing cost.

The multiple-choice test must be structured to give the apprentice the opportunity to demonstrate the knowledge mapped to this assessment method to the highest available grade.

The test can be computer or paper based.

The test will consist of 40 multiple-choice questions.

Multiple-choice questions must have four options, including one correct answer.

The apprentice must be given at least 2 weeks' notice of the date and time of the test.

The apprentice must have 60 minutes to complete the test.

The test is closed book which means that the apprentice cannot refer to reference books or materials whilst taking the test.

The following equipment is allowed to be used during the test:

- a scientific calculator

The test must be taken in the presence of an invigilator who is the responsibility of SIAS. SIAS have an invigilation policy setting out how the test must be conducted. This will state the ratio of apprentices to invigilators for the setting and allow the test to take place in a secure way.

SIAS will verify the apprentice's identity and ensure invigilation of the apprentice for example, with 360-degree cameras and screen sharing facilities. SIAS is responsible for the security of the test including the arrangements for on-line testing and will ensure that our security arrangements maintain the validity and reliability of the test.

The test must be marked by an end-point assessor or marker employed by SIAS. They must follow a marking scheme produced by SIAS. Marking by computer is allowed where question types support this.

A correct answer gets 1 mark, and any incorrect or missing answers get zero marks.

SIAS is responsible for overseeing the marking of the test.

The apprentice must take the test in a suitably controlled and invigilated environment that is a quiet room, free from distractions and influence. SIAS will check the venue is suitable.

The test could take place remotely if the appropriate technology and systems are in place to prevent malpractice.

SIAS will ensure that the apprentice has a different set of questions in the case of re-sits or re-takes.

Multiple-Choice Test Grading Boundaries

Grade	Minimum marks required	Maximum marks required
Fail	0	27
Pass	28	40

Multiple-Choice Test Knowledge, Skills and Behaviours

Ref	KSB Statement
Core Knowledge	
K1	Science process manufacturing sector awareness: range of products, manufacturing environments, types of customers.
K3	Health and safety regulations, standards, and guidance: Control of Substances Hazardous to Health (COSHH), Dangerous Substances and Explosive Atmospheres Regulations (DSEAR), Electrical safety and compliance, Fire safety, Health and Safety at Work Act – responsibilities, incident and near miss reporting and investigation, Lifting Operations and Lifting Equipment Regulations (LOLER), Legionella, Lone working, Management of health and safety at work, Manual handling, Noise regulation, Permits to work, Provision and Use of Work Equipment Regulations (PUWER), Safety signage and purpose, Slips trips and falls, The Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR), Working in confined spaces, and Working at height.
K5	Health and safety management systems; key performance indicators (KPIs) and learning from incidents.
K7	Environmental management systems standard. Environmental Protection Act. Environmental signage and notices.
K9	Continuous and batch techniques. Production requirements: product specification, processing specification, rate of production. Material safety data sheet, product labelling and product codes; the importance of identifying non-conforming materials and products. Overall Equipment Effectiveness (OEE). Stock control. Current Good Manufacturing Practice (cGMP).
K10	Medicines and Healthcare products Regulatory Agency (MHRA): their role and requirements.
K12	Numerical approximations and unit conversion tables. Areas, volumes, and pressure and flow rates calculations. Statistical data.
K15	How customer feedback can be used to assess quality performance. Purpose of audits. Non-conformance reports (NCR). Corrective Action Preventive Action (CAPA).
K16	Principles of laboratory quality procedures: calibration requirements for quality control, representative sampling, and common methods of analysis.
Pathway Specific Knowledge - Biotechnology manufacturing technician.	
K32	Microbiology: classifications, characteristics. Sterility assurance.
K34	The different types of cells that make up living organisms. The advantages and disadvantages of each cell type for commercial manufacturing.
K35	Proteins: ammino acids, protein structures, and antibodies.
K36	Molecular biology: DNA (deoxyribonucleic acid), RNA (ribonucleic acid), genetics, and methods of manipulation.

K37	Chemistry and biochemistry: chemical bond types, acid and bases and conductivity.
K38	Biotechnology processes: cell mass commercial manufacture, separation from the remaining cellular material, common methods of purification of product.
K39	Immunology: diseases and body response and how these are used to create new medicines.
K40	The thermal properties of solids, liquids, and gases.
K41	The structure and properties of elements, mixtures, compounds.
K42	Types of water and its use: cooling water, purified water, water for injection.
K44	Utilities on site purpose and interaction with equipment: alarms, condensers, compressors, coolers, driers, electrical equipment, filters, heat exchange (heat transfer and fluid flow principles), heating services (steam generation and distribution principles), pipe work, plant control systems, pressure relief, process control instrumentation and their calibration requirements, pumps, reactors, receivers, vacuum pumps, and valves.
K45	Conventions for drawings and graphical information.
Pathway Specific Knowledge – Aseptic pharmaceuticals manufacturing technician.	
K52	Science in aseptic processing: microbiology, classifications and characteristics.
K53	Sources, types and the impact of contamination.
K54	Science in aseptic processing: chemistry principles.
K55	Science in aseptic processing: biological principles.
K56	Science in aseptic processing: anatomy and physiology.
K57	Science in aseptic processing: pharmaceuticals and formulations, radio pharmacy and clinical pharmacy.
K58	Aseptic manufacturing regulation and legislation; licensing regulations, Good Manufacturing Practice (GMP), Good Documentation Practise (GDP).
K59	Manufactured products within a licensed aseptic environment; types, use, and classifications.
K60	. Manufactured products within a non-licensed aseptic environment; types, use, and classifications.
K61	Materials within aseptic manufacturing; preparation, storage and stock management.
K64	Utilities on site purpose and interaction with equipment: alarms, facility monitoring systems, filters, heating, ventilation and air conditioning (HVAC), and electrical equipment.
Core Skills	
S11	Conduct calculations for example, conversations, tare weight, charge weights, yield calculations.
S12	Interpret data for example, process data, quality control and test procedure data.
Pathway Specific Skills - Biotechnology manufacturing technician.	
S35	Interpret drawings and graphs.

Final Grade

Performance in the EPA determines the overall grade of:

- fail
- pass
- merit
- distinction

An end-point assessor must individually grade the observation with questions and interview underpinned by a portfolio of evidence.

SIAS will combine the individual assessment method grades to determine the overall EPA grade.

If the apprentice fails one assessment method or more, they will be awarded an overall fail.

To achieve an overall pass, the apprentice must achieve at least a pass in all the assessment methods. To achieve an overall EPA merit, the apprentice must achieve a distinction in one assessment method (observation with questions, or interview underpinned by a portfolio of evidence), and a pass in the other two assessment methods. To achieve an overall EPA distinction, the apprentice must achieve a distinction in the observation with questions, a distinction in the interview underpinned by a portfolio of evidence, and a pass in the multiple-choice test.

Grades from individual assessment methods must be combined in the following way to determine the grade of the EPA overall.

OBSERVATION WITH QUESTIONS	INTERVIEW UNDERPINNED BY A PORTFOLIO OF EVIDENCE	MULTIPLE-CHOICE TEST	OVERALL GRADING
Any grade	Any grade	Fail	Fail
Any grade	Fail	Any grade	Fail
Fail	Any grade	Any grade	Fail
Pass	Pass	Pass	Pass
Distinction	Pass	Pass	Merit
Pass	Distinction	Pass	Merit
Distinction	Distinction	Pass	Distinction

Moderation

Assessment organisations will undertake moderation of end-point assessor decisions through observations and examination of documentation on a risk sampling basis. Results cannot be confirmed until moderation has been completed.

Re-takes and re-sits

If the apprentice fails one assessment method or more, they can take a re-sit or a re-take at their employer's discretion. The apprentice's employer needs to agree that a re-sit or re-take is appropriate. A re-sit does not need further learning, whereas a re-take does. The apprentice should have a supportive action plan to prepare for a re-sit or a re-take.

The employer and SIAS should agree the timescale for a re-sit or re-take. A re-sit is typically taken within 2 months of the EPA outcome notification. The timescale for a re-take is dependent on how much re-training is required and is typically taken within 4 months of the EPA outcome notification.

Failed assessment methods must be re-sat or re-taken within a 6-month period from the EPA outcome notification, otherwise the entire EPA will need to be re-sat or re-taken in full.

Re-sits and re-takes are not offered to an apprentice wishing to move from pass to a higher grade.

The apprentice will get a maximum EPA grade of if pass they need to re-sit or re-take one or more assessment methods, unless SIAS determines there are exceptional circumstances.

Certification

The outcomes from the End-Point Assessment will be reviewed and a grade conferred by SIAS in accordance with SIAS QA procedures, which are available from SIAS. SIAS will notify the employer of the outcome of each of the assessments.

SIAS will apply for the apprentice's certificate, which will be sent by ESFA. The certificate confirms that the apprentice has passed the End-Point Assessment, has demonstrated full competency across the standard and is job-ready.

Assessment Specification

The assessment specification can be found in the published assessment plan for the standard. Details of which elements of the apprenticeship standard will be tested by each test are given in the Mapping Knowledge, Skills, and Behaviours section of this guide.

Mapping of Knowledge, Skills, and Behaviours

Key:	
Observation with Questions	Obs
Interview Underpinned by a Portfolio of Evidence	Int
Multiple-Choice Test	MCT

Ref	KSB to be assessed	Assessment Method
Core Knowledge		
K1	Science process manufacturing sector awareness: range of products, manufacturing environments, types of customers.	MCT
K2	Role and limits of responsibility. Escalation procedures. Impact of operators' competence on product quality. Change control requirement.	Int
K3	Health and safety regulations, standards, and guidance: Control of Substances Hazardous to Health (COSHH), Dangerous Substances and Explosive Atmospheres Regulations (DSEAR), Electrical safety and compliance, Fire safety, Health and Safety at Work Act – responsibilities, incident and near miss reporting and investigation, Lifting Operations and Lifting Equipment Regulations (LOLER), Legionella, Lone working, Management of health and safety at work, Manual handling, Noise regulation, Permits to work, Provision and Use of Work Equipment Regulations (PUWER), Safety signage and purpose, Slips trips and falls, The Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR), Working in confined spaces, and Working at height.	MCT
K4	Science process manufacturing safety hazards – risks they pose and their management: temperature, pressure, and vapours. Risk assessment and safe systems of work. Personal Protective Equipment (PPE) requirements. Emergency procedures.	Obs
K5	Health and safety management systems; key performance indicators (KPIs) and learning from incidents.	MCT
K6	Environmental hazards that can arise from process. Hierarchy of control.	Obs
K7	Environmental management systems standard. Environmental Protection Act. Environmental signage and notices.	MCT

Ref	KSB to be assessed	Assessment Method
K8	Principles of sustainability and circular economy. Resource (energy, water, and waste) efficiency and reuse of materials. Principles of control and management of emissions and waste.	Int
K9	Continuous and batch techniques. Production requirements: product specification, processing specification, rate of production. Material safety data sheet, product labelling and product codes; the importance of identifying non-conforming materials and products. Overall Equipment Effectiveness (OEE). Stock control. Current Good Manufacturing Practice (cGMP).	MCT
K10	Medicines and Healthcare products Regulatory Agency (MHRA): their role and requirements.	MCT
K11	Need and requirements for clean rooms in manufacturing. Protocols for entering, gowning, working in, exiting, and material flows.	Obs
K12	Numerical approximations and unit conversion tables. Areas, volumes, and pressure and flow rates calculations. Statistical data.	MCT
K13	Documentation requirements: documentation control, auditable records.	Obs
K14	Requirements for a second person witness and second person checks.	Int
K15	How customer feedback can be used to assess quality performance. Purpose of audits. Non-conformance reports (NCR). Corrective Action Preventive Action (CAPA).	MCT
K16	Principles of laboratory quality procedures: calibration requirements for quality control, representative sampling, and common methods of analysis.	MCT
K17	Preventative and reliability maintenance practices.	Obs
K18	Common faults and causes in processing: flow, blockages, instrumentation failures, seals and human factors.	Int
K19	Problem solving and fault-finding techniques: root cause analysis, 5-Whys.	Int
K20	Continuous improvement (CI) systems and techniques	Int
K21	Information and digital technology to support science manufacturing operations. Cyber security requirements. General data protection regulation (GDPR).	Int
K22	Verbal communication techniques.	Obs
K23	Written communication techniques. Technical report writing techniques.	Int
K24	Principles of team working. Principles of equality, diversity, and inclusion in the workplace.	Int

Ref	KSB to be assessed	Assessment Method
K25	Planning, prioritising, and time management techniques.	Obs
Pathway Specific Knowledge - Biotechnology manufacturing technician		
K26	Standard operating procedures (SOP) - what they are and why they are important.	Obs
K27	Standard operating conditions (SOC) - what they are and why they are important.	Obs
K28	Process control systems and their constituent components.	Obs
K29	Quality standards. On-line and off-line quality control.	Obs
K30	Requirements for shutting down and preparing for maintenance.	Int
K31	Main factors influencing quality assurance in biotechnology process industries.	Obs
K32	Microbiology: classifications, characteristics. Sterility assurance.	MCT
K33	Common contamination routes during biotechnology production.	Int
K34	The different types of cells that make up living organisms. The advantages and disadvantages of each cell type for commercial manufacturing.	MCT
K35	Proteins: ammino acids, protein structures, and antibodies.	MCT
K36	Molecular biology: DNA (deoxyribonucleic acid), RNA (ribonucleic acid), genetics, and methods of manipulation.	MCT
K37	Chemistry and biochemistry: chemical bond types, acid and bases and conductivity.	MCT
K38	Biotechnology processes: cell mass commercial manufacture, separation from the remaining cellular material, common methods of purification of product.	MCT
K39	Immunology: diseases and body response and how these are used to create new medicines.	MCT
K40	The thermal properties of solids, liquids, and gases.	MCT
K41	The structure and properties of elements, mixtures, compounds.	MCT
K42	Types of water and its use: cooling water, purified water, water for injection.	MCT
K43	Purpose and operation of biotechnology equipment.	O
K44	Utilities on site purpose and interaction with equipment: alarms, condensers, compressors, coolers, driers, electrical equipment, filters, heat exchange (heat transfer and fluid flow principles), heating services (steam generation and distribution principles), pipe work, plant control systems, pressure relief, process control	MCT

Ref	KSB to be assessed	Assessment Method
	instrumentation and their calibration requirements, pumps, reactors, receivers, vacuum pumps, and valves.	
K45	Conventions for drawings and graphical information.	MCT
Pathway Specific Knowledge - Aseptic pharmaceuticals manufacturing technician		
K46	Standard operating procedures (SOP) - what they are and why they are important.	Obs
K47	Standard operating conditions (SOC) - what they are and why they are important.	Obs
K48	Process control systems and their constituent components.	Obs
K49	Start up and shut down procedures.	Obs
K50	Main factors influencing quality assurance in pharmaceutical process industries.	Obs
K51	Quality standards. On-line and off-line quality control.	Obs
K52	Science in aseptic processing: microbiology, classifications and characteristics.	MCT
K53	Sources, types and the impact of contamination.	MCT
K54	Science in aseptic processing: chemistry principles.	MCT
K55	Science in aseptic processing: biological principles.	MCT
K56	Science in aseptic processing: anatomy and physiology.	MCT
K57	Science in aseptic processing: pharmaceuticals and formulations, radio pharmacy and clinical pharmacy.	MCT
K58	Aseptic manufacturing regulation and legislation; licensing regulations, Good Manufacturing Practice (GMP), Good Documentation Practise (GDP).	MCT
K59	Manufactured products within a licensed aseptic environment; types, use, and classifications.	MCT
K60	Manufactured products within a non-licensed aseptic environment; types, use, and classifications.	MCT
K61	Materials within aseptic manufacturing; preparation, storage and stock management.	MCT
K62	Pre and in-process checking within aseptic services.	Obs
K63	Purpose and operation of aseptic pharmaceutical equipment.	Obs
K64	Utilities on site purpose and interaction with equipment: alarms, facility monitoring systems, filters, heating, ventilation and air conditioning (HVAC), and electrical equipment.	MCT

Ref	KSB to be assessed	Assessment Method
K65	Requirements for full equipment maintenance.	Int
Core Skills		
S1	Review instructions or information to understand the task.	Obs
S2	Plan tasks. Identify and organise resources with consideration for safety, environmental impact, quality, and cost.	Obs
S3	Identify hazards and risks in the workplace and personal safety and mitigation measures.	Obs
S4	Apply health, safety, and environmental procedures in compliance with regulations, standards, and guidance.	Obs
S5	Apply controlled environment procedures for example, gowning, isolators, contamination control, and sanitisation.	Obs
S6	Apply sustainability principles for example, minimising waste.	Int
S7	Segregate resources for reuse, recycling, and waste handling.	Ons
S8	Conduct in process or post-manufacturing procedure for example, labelling, packing, storage, visual inspection, discharge.	Int
S9	Apply first line maintenance practices.	Obs
S10	Store tools and equipment.	Obs
S11	Conduct calculations for example, conversations, tare weight, charge weights, yield calculations.	MCT
S12	Interpret data for example, process data, quality control and test procedure data.	MCT
S13	Perform second person witness and second person checks for critical tasks.	Int
S14	Identify issues for example, defects, deviations, process variance, and maintenance requirements.	Int
S15	Apply problem solving and fault-finding techniques.	Int
S16	Escalate issues outside limits of responsibility.	Int
S17	Record or enter information - paper based or electronic.	Obs
S18	Use information and digital technology for example, management information systems, human machine interfaces, word processing, spreadsheet, email, virtual learning platforms, document sharing platforms. Comply with cyber security requirements and GDPR.	Int
S19	Apply continuous improvement techniques. Make a suggestion for improvement.	Int
S20	Apply team working principles.	Int

Ref	KSB to be assessed	Assessment Method
S21	Communicate with others verbally for example, colleagues and stakeholders.	Obs
S22	Produce written documents for example, handover notes or emails, non-conformances, design change requests.	Int
S23	Plan how to meet personal development needs. Carry out and record planned and unplanned learning and development activities.	Int
Pathway Specific Skills - Biotechnology manufacturing technician		
S24	Apply standard operating procedures (SOPs).	Obs
S25	Select, check, and prepare raw materials for biotechnology process for example, weighing, measuring, control and blending, conditioning, dissolving, and sanitisation.	Obs
S26	Conduct pre-checks of hand tools, equipment and machinery for biotechnology process including calibration record where applicable.	Obs
S27	Connect service connections for biotechnology process such as water, electrical, pneumatic, hydraulic.	Obs
S28	Operate biotechnology equipment for example, start-up, shut down, or cleaning mode.	Obs
S29	Set and adjust biotechnology process parameters such as agitation revolutions per minute, temperature, pressure, flow rate or time.	Obs
S30	Check calibration and calibrate analytical equipment.	Obs
S31	Conduct at point analysis of the product using laboratory techniques (bench top analysis) for example, pH, conductivity measurement, optical density measurements, and protein concertation.	Obs
S32	Apply quality assurance procedures. For example, conduct parameter checks (size, colour, weight), and take samples for laboratory testing.	Obs
S33	Remove and replace disposable components and check functionality for example, break lines, isolators, and tri-clamps and tube welding.	Obs
S34	Conduct aseptic method for example, aseptic technique or aseptic sampling.	Int
S35	Interpret drawings and graphs.	MCT
Pathway Specific Skills - Aseptic pharmaceuticals manufacturing technician		
S36	Apply standard operating procedures (SOPs).	Obs
S37	Select, check, and prepare raw (incoming) materials for aseptic process for example, weighing, measuring, conditioning, dissolving, and sanitisation.	Obs
S38	Conduct pre-checks of hand tools, equipment and machinery for aseptic process including calibration record where applicable.	Obs

Ref	KSB to be assessed	Assessment Method
S39	Operate aseptic process equipment for example, start-up and shut-down.	Obs
S40	Set aseptic process parameters such as temperature, and pressure.	Obs
S41	Conduct pre and in-process checks such as environmental monitoring.	Obs
S42	Make adjustments to aseptic process parameters.	Obs
S43	Apply quality assurance procedures. For example, conduct parameter checks (size, colour, weight), and take samples for laboratory testing.	Obs
S44	Clean equipment and process areas in-between production to avoid cross-contamination.	Obs
S45	Conduct volume checks.	Obs
S46	Calibrate analytical equipment.	Obs
Core Behaviours		
B1	Prioritise health, safety, and environment.	Obs
B2	Consider sustainability when using resources and carrying out processes.	Int
B3	Team-focus to meet work goals including support for equality, diversity and inclusion.	Int
B6	Core. Respond and adapt to work demands.	Int
B7	Core. Committed to continued professional development.	Int
Pathway Specific Behaviours - Biotechnology manufacturing technician		
B4	Take responsibility for the quality of their own work.	Obs
Pathway Specific Behaviours - Aseptic pharmaceuticals manufacturing technician		
B5	Take responsibility for the quality of their own work.	Obs

Further Information

For information about SIAS policies, quality assurance, re-sits, appeals, complaints and general enquiries please see our website: www.siasuk.com

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