SIAS Science Manufacturing Technician (ST0250)

Level 3 Apprenticeship Standard

End-Point Assessment Specification







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This specification describes the end-point assessment tests, the test rules and who should be involved. Preparing for end-point assessment including gateway requirements 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.

In this guide, the term "employer" is used to refer to the host employer, which is the company where the apprentice gains their competency experience. It does not refer to an organisation such as an Apprenticeship Training Agency (ATA) that has the employment contract with the apprentice.



Qualification Objective

The aim of this qualification 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 work in a wide range of companies, including, but not exclusively, chemical, primary and secondary pharmaceutical, biotechnology, formulated products and nuclear manufacturing. A science manufacturing technician will operate the systems and equipment, involved in the production of products. They may work in varied conditions including wearing specialist safety equipment, shift work and on sites running 365-day operations. Many companies operate under highly regulated conditions and a premium is placed on appropriate attitudes and behaviours to ensure employees comply with organisational safety and regulatory requirements.

Prior Learning and Qualifications

There are no requirements for previous knowledge or qualifications before a learner begins this qualification.



A Summary of Science Manufacturing Technician End-Point Assessment

There are two suggested phases of training. The **Foundation Phase**, which is typically months 1 - 9, will focus on developing the apprentice's core skills, knowledge, and behaviours, specifically around working safely, complying with internal and external regulations, and following quality procedures. This training may take place in the workplace or in a largely simulated working environment. It will culminate in Gateway 1, a review of skills by suitably qualified and experienced personnel from the employer or their nominated training partner that will provide assurance that the apprentice has the understanding of the principles of working safely whilst following quality systems within a regulated environment. Whilst specific qualifications are not mandatory, evidence of completion of this gateway is



confirmed in a log that is a record of their continuous competence evaluation. Completion of this log will be a pre-requisite for participation in the formal end assessment.

The Consolidation Phase, which is typically months 10 - 27, will focus on developing further skills capability supported by further guided learning, enabling the apprentice to eventually work effectively and independently with minimum supervision. The apprentice will work towards a qualification recognised by a professional body as suitable for registration for RsciTech or EngTech. Achievement of this qualification will also be a pre-requisite for participation in the formal end assessment. At the end of the Consolidation Phase the apprentice will have completed their training and through ongoing competence evaluation, including behaviours evaluation, they will have generated a range of evidence to show they meet the apprenticeship standard. A suitably qualified and experienced assessor from the employer will sign off a log that is a record of their continuous competence evaluation to show they are ready for the formal end assessment. This assessor must be approved by the assessment organisation as meeting the required assessor standards.

About 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 end-point assessment. Confirmation from the employer that the apprentice is fully competent is needed before end-point assessment 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.

Competence Evaluation Log (CEL)

The evidence that the apprentice is ready for end-point assessment is the signed SIAS Competence Evaluation Log (CEL). The CEL covers the knowledge, skills and behaviours specified in the apprenticeship standard. The signed log shows that the apprentice has demonstrated to the employer they are fully competent at the end of their training. It has the same status as a qualification certificate. Along with the qualification certificates, a signed completed CEL is one of the requirements for the Gateway.

Readiness for End-Point Assessment (EPA) – Gateway

The apprentice will be assessed at several stages during their apprenticeship. As well as the assessment / examination that is required for the knowledge qualification, there should be on-going competence evaluation during an apprentice's training programme that will be marked by two gateways, commonly taking place at the end of the first third and at the end of their training programme.

Gateway 1

Trailblazer employers have stipulated this gateway to provide assurance that the apprentice has demonstrated that they understand the principles of working safely. For new entrants to these safety critical industries and particularly young people, this will provide the necessary foundation on which to embed the skills they will need to be able to work safely under supervision whilst following quality systems within a regulated environment.

To demonstrate this gateway has been completed the employer may choose to use the IOSH working safely certificate or an equivalent course or internal training appropriate to their organisation. Completion of Gateway 1 will be recorded in the competence evaluation log.

Gateway 2



By Gateway 2 the apprentice must have completed a specified qualification, a vocational competence evaluation log and a behaviours evaluation log.

Qualification: The apprentice must complete a qualification that is recognised for RSciTech, which is relevant to the occupation. The qualification must be at level 3 or higher and provide the theoretical knowledge needed for the apprenticeship standard. For example:

- BTEC Level 3 Diploma in Applied Science (QCF)
- BTEC Level 3 Extended Diploma in Applied Science (QCF)
- BTEC Level 3 Subsidiary Diploma in Applied Science (QCF)
- BTEC Level 4 HNC Diploma in Applied Chemistry (QCF)
- BTEC Level 4 HNC Diploma in Applied Biology (QCF)
- BTEC Level 3 Diploma in Operations and Maintenance Engineering (QCF)
- BTEC Level 3 Diploma in Manufacturing Engineering (QCF)
- Level 3 Diploma in Process Technology (QCF)
- Level 3 Certificate in Laboratory Technical Skills (QCF)

A range of qualifications may be used to fulfil the requirement for the knowledge component of the apprenticeship standard. This allows employers the flexibility to tailor the apprenticeship to meet their specific local needs, whilst meeting the minimum requirements of the apprenticeship standard.

The application of theoretical knowledge will be tested during the formal end assessment. Therefore, the apprentice must have completed the qualification before the end assessment occurs. The qualification will not contribute to the grading of the apprenticeship award.

Vocational Competence Evaluation Log (CEL)

By the end of the apprenticeship a record of competence evaluation should be captured in a log. This log will be a summary record of in-programme evaluation of competence against the work-based learning guide. It is through this process that the apprentice is able to demonstrate competence against the whole apprenticeship standard. This reflects the industry practice of competence management through on-going employer competence evaluation. This is all covered in the SIAS CEL document.

Behaviours Evaluation Log

During their training, the apprentice's behaviours should be evaluated against the apprenticeship standard. It is recommended that this is carried out a minimum of three times. This should be at the end of the foundation phase, at the midpoint of the consolidation phase and at gateway two. The outcome from the last evaluation should be brought as evidence to the vocational competence discussion and will contribute to the grading of the apprenticeship award.

Stages of End-Point Assessment

On completion of Gateway 1 and 2 the employer will sign off the apprentice as ready for the formal end assessment, which must be conducted in the workplace. Formal end assessment, which will take place during the last 3 months of the apprenticeship will comprise:

- Review of behaviours evaluation log
- Synoptic assessment test (SAT)
- Vocational competence discussion



• Scenario case study

Review of Behaviour Evaluation Log

During their training, an apprentice's behaviours will be evaluated on at least 3 occasions. The evaluation will be across seven categories:

- Personal Responsibility
- Communication
- Teamwork
- Independence and Responsibility
- Impact of work
- Time management
- Change Management

Outcome	Description
Does not meet Expectations	Apprentice failed to demonstrate an acceptable level of behaviour. Improvement is required.
Meets Expectation	Apprentice demonstrated acceptable level of behaviour and meets the minimum level of behaviour expected.
Exceeds Expectation	Apprentice demonstrated consistent and positive behaviours in this area that reflect those expected of outstanding apprentices.

The outcome from the final evaluation at gateway 2 will be reviewed during the vocational competence discussion and will contribute to grading of the apprenticeship award.

Synoptic Assessment Test (SAT)

The end-point assessment will include a synoptic assessment test (SAT) through workplace observation and discussion with the registered assessor. Part of the SAT must be observed by a SIAS assessor.

The employer will be able to select one of these SATs to suit the assessment context:

SMT SAT 1 – Start up process

- Demonstrate either independently or within a team start-up of a manufacturing batch or continuous process in line with appropriate Standard Operating Procedures (SOP), ensuring work is carried out safely, and quality procedures are followed whilst complying with appropriate regulations.
- Control and monitor the process or plant and equipment, effectively, efficiently, and securely, and resolve any problems or correct abnormal conditions that may arise.
- Demonstrate an understanding of the principles of operation through workplace discussion.

SMT SAT 2 – Operate process

• Demonstrate either independently or within a team operation of a manufacturing batch or continuous process in line with appropriate Standard Operating Procedures (SOP), ensuring work is carried out safely, and quality procedures are followed whilst complying with appropriate regulations.



- Control and monitor the process or plant and equipment, effectively, efficiently, and securely, and resolve any problems or correct abnormal conditions that may arise.
- Demonstrate an understanding of the principles of operation through workplace discussion

SMT SAT 3 – Shutdown process

- Demonstrate either independently or within a team shut down / complete a run of a manufacturing batch or continuous process in line with appropriate Standard Operating Procedures (SOP), ensuring work is carried out safely, and quality procedures are followed whilst complying with appropriate regulations.
- Control and monitor the process or plant and equipment, effectively, efficiently, and securely, and resolve any problems or correct abnormal conditions that may arise.
- Demonstrate an understanding of the principles of operation through workplace discussion

Purpose

The purpose of the synoptic assessment test is to validate the apprentice's competence by observing him / her carrying out his / her job role in a normal working environment under normal conditions. The following aspects should be displayed:

- Working safely
- Following procedures / work instructions
- Complying with regulations
- Following quality systems
- Using appropriate vocational skills

Test Methodology

The test will be in the form of an observation in the workplace under the following conditions:

- a. observation carried out by a registered assessor
- b. a timescale of between two and four hours on a single occasion
- c. with no coaching or mentoring from colleagues
- d. in the normal working environment
- e. under observation by the external assurer
- f. where the situation demands it, simulation will be allowed
- g. walk through / talk through of the simulation should be conducted by the assessor and noted on the documentation
- h. previously planned to ensure that the proposed activity / activities meet the SAT specification
- i. the outcomes are documented using SIAS's standard documentation.

A full list of the assessment rules can be found in the assessment plan.

The registered assessor must use the following assessment criteria:

Grade	Description
Fail	For one or more elements of the specification the apprentice has an incomplete understanding, approaches tasks mechanistically and needs supervision to complete them.



Pass	For all elements of the specification, the apprentice has a good working and
	background understanding, sees actions in context, able to complete work
	independently to a standard that is acceptable.

Vocational Competence Discussion

Following the SAT, the apprentice will take part in a vocational competence discussion led by the external assurer. This will cover the whole apprenticeship standard including behaviours and the apprentice may draw on evidence from the SAT and evidence generated during the vocational competence evaluation process. The assessment specification makes clear which elements of the standard must be covered.

The vocational competence discussion will cover the whole apprenticeship standard. It also provides the opportunity for presentation of evidence to support specific elements from the standard that it has not been possible to demonstrate during the SAT. As the discussion will be graded, Trailblazer employers have specified the following as areas where the apprentice may wish to provide evidence to contribute to grading:

- Control and monitor a process or plant and equipment, effectively, efficiently, and securely, and resolve problems or correct abnormal conditions.
- Complete documentation relevant to the manufacturing process including relevant calculations.
- Participate in continuous performance improvement.

Purpose

The purpose is to determine the extent to which the apprentice understands the requirements of his / her role as defined by the work-based learning guide and to explore understanding of areas not observed or explained during the SAT.

Test Methodology (conditions)

The VCD

- a. will be in the format of a 1:1 discussion with the external assurer.
- b. will last between 1 and 1.5 hours.
- c. will take place in a room, free from distractions with no other people present.
- d. may be recorded with the agreement of the employer and the apprentice.

Eligible Evidence

The apprentice may bring along any of the following to refer to during the VCD:

- Vocational competence evaluation log
- Training records
- NVQ Portfolio
- Qualification assessments
- Company specific documents (e.g., risk assessments, SOPs).
- E-portfolios
- Reflective learning logs
- Behaviours evaluation log

A full list of the assessment rules can be found in the assessment plan.



The apprentice will achieve a mark for this element of the end assessment that will contribute to the final grade of the apprenticeship award.

Scenario Case Study

The case study will describe a scenario where the apprentice has to adapt quickly and function effectively after minimal instruction on new equipment or in a new environment or under revised working practices. Whilst they will not be expected to know how to operate the particular equipment, they will be expected to demonstrate the correct procedures to ensure they work safely, such as following safe systems of work, using appropriate personal protective equipment, finding, and following standard operating procedures. The apprentice will be provided with a description of the scenario, which may be a narrative, or a video and they will have to respond to situational analysis questions.

Purpose

To ensure that the apprentice is able to transfer the knowledge and skills learnt during the apprenticeship to a prescribed situation. This assessment will take the form of a situational analysis of a given case study.

Test Methodology (conditions)

- a. The case study will be invigilated by the external assurer.
- b. The case study will last for 2.5 hours.
- c. The case study will take place in a room, free from distractions.
- d. The apprentice will record his / her analysis on the documentation prescribed for the case study.
- e. The case study will be marked by the external assurer and moderation of the marked / graded paper will be conducted by the assessment organisation.
- f. The case study will be given to the apprentice at the beginning of the assessment and not before.
- g. At the end of the assessment, the case study will be collected by the external assurer

A full list of the assessment rules can be found in the assessment plan.

Moderation

Assessment organisations will undertake moderation of independent examiner and technical experts' decisions through observations and examination of documentation on a risk sampling basis, i.e., a minimum of 20% for experienced examiners / technical experts and 100% for new examiners / experts or where inconsistencies have been identified or where the technical expert has been recruited from the employer due to site requirements. Results cannot be confirmed until moderation has been completed.

Re-takes / re-sits

Re-takes / re-sits will only be available to apprentices who fail an end-point assessment element(s) i.e., they are not offered to apprentices wishing to move from Pass to Distinction. Apprentices may re-take / re-sit one or more elements within the six-month end-point assessment period. Re-take / re-sits outside of the six-month end-point assessment period would require all elements to be re-assessed. Re-sits / re-takes will not be awarded a grade higher than Pass. Apprentices must have a supportive action plan to prepare for the re-take / re-sit. Further re-takes / re-sits would be at the discretion of the employer following a 1:1 review with the apprentice to determine the suitability of the apprentice for further testing.



Final Grade

This formal end assessment for the apprenticeship award is graded and an apprentice must achieve a pass to gain a certificate of completion. The grading metrics are:

Apprenticeship Awarding Grading Matrix	Pass A pass will be awarded to individuals that achieve the specified level in all four elements.	Distinction A distinction will be awarded to individuals that achieve the specified level in all four elements
Synoptic Assessment Test	Pass	Pass
Behaviours Evaluation Log Gateway 2 score	Meets Expectations	Exceeds Expectations
Vocational Competence Discussion Up to 80 marks	Minimum 40	60 or above
Case Study Up to 60 marks	Minimum 30	45 or above

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 to the employer. 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 Core Competencies section of this document.



Core Competencies

Std	Competences that need to be achieved by anyone being trained for the occupation. All elements are mandatory	except
Ref	those marked as optional, which should be included only when required for a specific job role or sector.	
S1	Both independently and within a team, start-up a manufacturing batch or continuous process in line with appro	oriate
	Standard Operating Procedures (SOP), understanding the principles of operation.	
S2	Both independently and within a team, operate a manufacturing batch or continuous process in line with appropriate a manufacturing batch or continuous process in line with appropriate a manufacturing batch or continuous process in line with appropriate a manufacturing batch or continuous process in line with appropriate a manufacturing batch or continuous process in line with appropriate a manufacturing batch or continuous process in line with appropriate a manufacturing batch or continuous process in line with appropriate a manufacturing batch or continuous process in line with appropriate a manufacturing batch or continuous process in line with appropriate a manufacturing batch or continuous process in line with appropriate a manufacturing batch or continuous process in line with appropriate a manufacturing batch or continuous process in line with appropriate a manufacturing batch or continuous process in line with appropriate a manufacturing batch or continuous process in line with appropriate a manufacturing batch or continuous process in line with appropriate a manufacturing batch or continuous process in line with appropriate a manufacturing batch or continuous process in line with appropriate a manufacturing batch or continuous process in line with appropriate a manufacturing batch or continuous process in line with appropriate a manufacturing batch or continuous process in line with appropriate a manufacturing batch or continuous process in line with appropriate a manufacturing batch or continuous process in line with appropriate a manufacturing batch or continuous process in line with appropriate a manufacturing batch or continuous process in line with appropriate a manufacturing batch or continuous process in line with appropriate a manufacturing batch or continuous process in line with approximate a manufacturing batch or continuous process in line with approximate a manufacturing batch or continuous process in line with approximate a manufacturing batch or continuous process in line with approximate	oriate
60	Standard Operating Procedures, understanding the principles of operation.	
53	Both independently and within a team, shut down / complete a run of the manufacturing batch or continuous pre-	ocess in line
Proces	s Operations	
FIUCES	s operations	inte to inh
1	Understand the principles of the operating environment that may include specialist environments and conditions appropriately for example Florence language language language appropriate specialist environments and conditions appropriately for example Florence language language language appropriate specialist environments and conditions appropriately for example Florence language language language appropriate specialist environments and conditions appropriately for example Florence language language appropriate specialist environments and conditions appropriate specialist environments environments appropriate specialist environments envinonments environments environments environments enviro	late to job
2	Propage process materials or foods for start-up and between production stages according to work instructions	
2	Clean and property items of plant, facility, and equipment	
3	Drepare to start up a presses / batch or prepare the area and presses any imment	
4	Prepare to start up a process / batch or prepare the area and process equipment	
5	Start up a process / batch or plant and systems in accordance with any SOPs and communicate, if required, with relevan	nt personnel
6	Monitor and control process or plant and equipment and resolve problems or correct abnormal conditions	
7	Access, use and interpret documentation and logs, and pass on information, for example during handover	
8	Prepare to shut down a process / batch or prepare the area and process equipment	
9	Complete / shutdown a process / batch or plant and systems in accordance with any SOPs	
10	Separate & dispose of by-products and waste as appropriate	
Labora	tory Safety and Housekeeping	
11	Follow procedures for handover of the processes for maintenance	
12	Prepare work areas for maintenance in line with Standard Operating Procedures	
13	Undertake maintenance activities within own areas of responsibility	
14	Reinstate the working area after completing maintenance	
15	Understand the principles of planned maintenance and routine calibration in asset care	Optional
16	Understand the principles of change management	Optional
17	Decontaminate plant equipment where appropriate	Optional
18	Calibrate plant and equipment within own areas of responsibility	Optional



Std Bof	Competences that need to be achieved by anyone being trained for the occupation. All elements are mandatory except
S4	Work safely in a science manufacturing environment, understanding personal responsibility for Health. Safety and the
54	Environment and principles of risk management
S5	Understand and follow quality procedures to meet the requirements of quality standards relevant to the workplace.
S6	Understand the internal and external regulatory environment pertinent to the sector and the employer and comply with
	regulations proficiently
Genera	I Workplace Health & Safety
19	Understand and comply with foundations of health and safety including responsibility for health and safety under HASWA
20	Understand the procedures for first aid relevant to your workplace
21	Understand and comply with risk assessment & control
22	Appropriate use of personal protective equipment e.g., respirators, breathing air hoods, PVC suits
23	Understand and practise site / plant safety requirements including for example:
	• Fire
	• COSHH
	Working at Height
	Confined Spaces
	Permits to work
Process	s Safety
24	Understand foundations of process safety
25	Understand the safe operating conditions of the plant
26	Work safely in a process environment or in a bio-manufacturing environment
27	Describe common risks and control measures
28	Understand systems to prevent loss of containment within your area of responsibility
29	Carry out key plant integrity checks within own area of responsibility
30	Understand and comply with emergency response procedures participating in exercises pertinent to role
31	Understand Hazardous area classification & DSEAR regulations and how they apply within area of responsibility Optional
Environ	imental Management
32	Understand the foundations of environmental management
33	Understand the principles of control of emissions
34	Understand Management and control of waste
35	Understand environmental risk assessments (impact assessment)



Std	Competences that need to be achieved by anyone being trained for the occupation. All elements are mandatory except		
Ref	those marked as optional, which should be included only when required for a specific job role or sector.		
36	Understand the concepts of resource efficiency applied to energy, water, and waste		
Product	Product Quality		
37	Maintain product quality throughout manufacture		
38	Understand management of change principles and the impact of change on product quality		
Regulat	tory Environment		
39	Understand the internal regulations pertinent to the sponsoring company & relative specialism in which they operate		
40	Understand the external regulatory environment pertinent to the sponsoring company & relative specialism in which they (e.g., COMAH, NII, MHRA)	operate	
41	Understand the external regulatory environment pertinent to the sponsoring company & relative specialism in which they (e.g., COMAH, NII, MHRA)	operate	
S7	Control and monitor a process or plant and equipment, effectively, efficiently, and securely, and resolve problen correct abnormal conditions.	ns or	
42	Monitor and control a process or plant and equipment		
43	Identify and resolve abnormal process conditions		
44	Demonstration of one or more problem solving techniques		
S8	Complete documentation relevant to the manufacturing process including relevant calculations.		
45	Complete documentation proficiently including relevant calculations		
46	Understand correction techniques and error reporting		
S9	Understand the business environment in which the company operates including personal role within the organis	sation,	
	ethical practice, and codes of conduct.		
47	Understand the business environment (customers, competitors etc.) in which the company operates		
48	Understand personal role in the company and industry and those of others		
S10	Participate in continuous performance improvement.		
49	Demonstrate the application of principles of continuous improvement to own performance		
50	Understand the principles of continuous improvement and the techniques that may be used	Optional	
51	Participate in the application of a continuous improvement technique	Optional	
52	Basic knowledge of relevant software packages e.g., MS WORD, EXCEL, LIMS where appropriate to role	Optional	
S11	Develop and apply theoretical knowledge of relevant science and technology and its application to the required	sector &	
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Std	Competences that need to be achieved by anyone being trained for the occupation. All elements are mandatory except
Ref	those marked as optional, which should be included only when required for a specific job role or sector.
53	Theoretical knowledge of the relevant science or technology required for the role i.e., Chemistry, Science, Engineering to a named qualification
S12	Demonstrate the required attitudes, behaviours and interpersonal skills associated with the professional workplace
	To meet Behaviours Evaluation Assessment Criteria

A full list of the competencies can be found in the Work Based Learning Guide.

Specialisms

In addition to the core competences, specialisms are specific to a work context. Mapped to the core competences, they articulate how these may be interpreted for anyone being trained for a job role in that work context. The following specialisms are included:

- SMT Biotechnology
- SMT Pharmaceutical / Formulation
- SMT Process + 1st Line Maintenance
- SMT Chemical / Petrochemical
- SMT Polymers
- SMT Aseptic Pharmaceuticals
- SMT Coatings
- SMT Bulk Liquid Storage Terminal Technician

Std Ref	Α	SMT – Biotechnology Specialism - Competencies
6	A1	Understand the principles of operating in aseptic or clean room conditions
1, 2, 3	A2	 Understand and be able to carry out bio-technology operations using one or more of the following techniques such as: preparing culture media and solutions producing biomaterial using bioreactors transferring materials sampling biomaterial into sterile containers separating biomaterial using continuous flow centrifugation or normal filtration obtaining biomaterial using lysis of cells



Std	Α	SMT – Biotechnology
Ref		Specialism - Competencies
		concentrating and dia-filtrating biomaterials using tangential flow filtration
		 purifying harvested biomaterial using chromatography
		 measure, weigh and prepare compounds and solutions
		 fill containers with processed biomaterials using automated machinery
		 pack filled biomaterial containers by manual methods
		 assist with the routine maintenance, cleaning, disinfecting and calibration of equipment

В	SMT – Pharmaceutical / Formulation
B1	A theoretical knowledge of the regulatory requirements and business environment for manufacture of industry specific formulated products
B2	A theoretical knowledge of the scientific and technical aspects for manufacture of formulated products for specific industry applications
B3	 Understand and be able to contribute to the use of one or more specific techniques used within the industry such as: perform simple quality control (qc) and standard analytical tests on formulated products according to industry norms or international standards (e.g., ISO) interpret the results from simple quality control (qc) and standard analytical tests make decisions on how to modify the formulated product based on the interpretation of the process or quality data apply the principles of experimental design assist in commissioning and qualification of new equipment or processes
B4	 Understand the principles which underpin the manufacture of formulated products and demonstrate practical experience of one or more techniques including: comminution, crystallisation, granulation, fluidisation powder and liquid mixing technologies suspension and dispersion techniques powder and liquid handling and storage flow through packed beds and porous media solid-liquid separation processes compaction and mechanical properties of solid products
B5	Understand the principles of process control and instrumentation including:
	B B1 B2 B3 B4 B4 B5



Std	В	SMT – Pharmaceutical / Formulation
Ref		Specialism - Competencies
		 powder or liquid flow measurements
		 use of computer software relevant to process control
		 temperature, humidity & pressure measurement
		 process measurements such as viscosity, friability, pH, solid fraction
11	B6	Understand the principles of process operation including:
		 critical step analysis and in-process controls
		 impact of formulation design on process equipment

Std Ref	С	SMT – Process + 1 st Line Maintenance
1, 2, 3	C1	Demonstrate practical knowledge of the following:
		 safely use all necessary equipment to complete the maintenance activity
		 prepare the work area for maintenance of plant, systems, or components
		 carry out planned and unplanned maintenance activities
		 deal with variations and defects efficiently
		 utilise diagnostic techniques to identify faults in plants, systems, and components
		 reinstate the work area after completing the maintenance of plant, systems, and components
		conduct safe and effective hand over of plant and equipment to others and accept and confirm responsibility for the
		control of the plant and equipment within the work area isolation boundary
		identify obsolescence and end-of-life issues
1, 2, 3	C2	Understand 1st line maintenance documentation including:
		 how to read and extract information from engineering drawings, specification diagrams and maintenance manuals
		 technical details relating to the individual's specialist discipline (mechanical, electrical, instrumentation)
Optional	C3	The individual may require competence in a number of specialist operations including:
		hot working fire watch
		asbestos awareness



Std Ref	D	SMT – Chemical / Petrochemical
6	D1	A theoretical knowledge of the regulatory requirements and business environment for manufacture of industry specific
		chemicals / petrochemicals
11	D2	A theoretical knowledge of the scientific and technical aspects for manufacture of chemicals / petrochemical products for
		secondary downstream applications
10	D3	Understand and be able to contribute to the use of one or more specific techniques used within the industry such as:
		• perform simple quality control (qc) by sampling plant chemicals or products and conducting standard analytical tests
		 interpret the results from simple quality control (qc) and standard analytical tests
		 make decisions on how to modify the control of plant processes based on the interpretation of the process or quality.
		data
		apply the principles of process problem solving techniques
		 assist in the response to process upsets to achieve steady state operation
1, 2, 3	D4	Understand the principles which underpin the manufacture of chemical / petrochemical products and demonstrate practical
		experience of one or more techniques including:
		distillation
		electrolysis
		refrigeration
		reaction
		gas compression
		heat exchange
		furnaces / boilers
		flammable liquid / gas handling
		corrosive liquid / gas handling
		toxic liquid / gas handling
1, 2, 3	D5	Understand the principles of process control and instrumentation including:
		 measurement terminology: variables controlled and measured
		liquid or gas flow measurements
		use of computer software relevant to process control
		temperature, level & pressure measurement
		process measurements such as viscosity, conductivity, pH, density
11	D6	Understand the principles of process operation including:
		critical step analysis and in-process controls



Std Ref	D	SMT – Chemical / Petrochemical	
		 impact of equipment operation and maintenance on process reliability techniques of valve operation on pressurised process systems 	

Std Ref	E	SMT – Polymers
6, 11	E1	A theoretical knowledge of:
		• the regulatory requirements and business environment for manufacture of industry specific polymer materials and
		products
		 the scientific and technical aspects for design and manufacture of polymer products for the specific industry sector
10	E2	Understand and be able to carry out tasks specific to the polymer industry such as:
		 measurement and charting techniques
		 problem solving techniques
		 workplace organisation and systems
		continuous improvement techniques
7	E3	Understand and be able to contribute to the use of one or more specific techniques used within the industry such as:
		 perform simple quality control sampling and standard testing on polymer materials / products according to industry
		norms or international standards
		 interpret the results from simple quality control and standard test procedures
		 make decisions on how to modify the polymer process based on the interpretation of the process or quality / test
		data
		 apply the principles of experimental design / process improvement
		assist in commissioning and qualification of new equipment or processes
11	E4	Understand the principles which underpin the manufacture of polymer materials / products and demonstrate practical
		experience / knowledge of three or more techniques / characteristics including:
		 polymer materials technology, material types, structure, characteristics, and processing requirements
		 semi crystalline / amorphous polymers and effects of morphological structure on products and processing
		 relevance of material transitions (Ig / Im) and phase changes on processing
		cross linking of polymer products and materials for use as elastomers, thermosets, or composite materials
		• polymerisation techniques for polymer materials e.g., addition, condensation reactions, catalysts, and reactive
		agents



Std Ref	Е	SMT – Polymers
		• preparation of materials for processing e.g., formulations, drying, weighing, conveying, mixing, blending, and
		colouring of polymers
		rheological aspects / considerations in polymer processing
11	E5	Understand the principles which underpin the processing of polymer materials / products and demonstrate practical
		experience / knowledge of three or more techniques / processes including:
		polymerisation techniques
		polymer compounding
		injection moulding
		extrusion
		blow moulding
		blown film
		compression moulding
		rotational moulding
		 processing of polyurethane
		thermoforming
		 internal mixing of polymer compounds
		milling (two roll mill)
		• calendaring
		manual and automated layup techniques for elastomers and composites
		other processes

Std Ref	F	SMT – Aseptic Pharmaceuticals
6	F1	A theoretical knowledge of the regulatory requirements, legislation and standards that govern the pharmaceutical manufacturing industry
40, 41	F2	GMDP - Demonstrate theoretical and practical knowledge of Good Manufacturing Practice and explain its implications in the pharmaceutical manufacturing unit
5, 37	F3	 QA / QC - Demonstrate theoretical and practical knowledge of the following: process validation documentation



Std Ref	F	SMT – Aseptic Pharmaceuticals
		SOPs
		• DRFs
		CAPA
		audits
		releasing
		investigations
		environmental monitoring
		ICH Q9 Quality Risk Management
		ICH Q10 Guidance on pharmaceutical quality system
4	F4	Personnel - Demonstrate theoretical and practical knowledge of the following:
		personal hygiene
		hand washing
		PPE & gowning
4.4		cleanroom behaviours
11	F5	Premise & Equipment - Demonstrate theoretical and practical knowledge of the following:
		 microbiology - types of microbes found in clean rooms, implications of contamination, microbial control / monitoring physical size quality monitoring, limita, and testing schedules
		 physical all quality monitoring, limits, and testing schedules alcoprogram design monitoring, elegning & contraction air bandling, onvironmental monitoring
		 Cleanfoorns – design, maintenance, cleaning & samuzation, an handling, environmental momental momental LAECs, isolators, Biological Safety Cabinets - design, maintenance, cleaning & sanitization, air bandling
1 2 3	F6	 LAFCS, Isolators, biological Salety Cabiners - design, maintenance, cleaning & samuzation, air nandling Production: Sterile Manufacture - Demonstrate theoretical and practical knowledge of the following:
1, 2, 0	10	 transfer procedures / material flow – spray & wine transfer batches sanitization processes controlled and
		uncontrolled spaces
		 assembly, reconciliation, inspection & checking
		 preparation of sterile products; syringes, infusers, small volume & large volume infusions, eve drops, topical
		preparations knowledge of various types of sterilization
		• preparation of non-sterile products - solid dose forms, topical solutions, internal solution, semi solids (creams,
		ointments, pessaries, suppositories, and lotions)
8	F7	Production: Planning and Scheduling - Demonstrate theoretical and practical knowledge of the following:
		 materials management – receiving, checking, ordering, packing, stock rotation, quarantine, shipping (good store keeping practice)
		 planning scheduling – order receipt and logging label generation & worksheets start-up approvals transcribing
		stock control, archiving, calculations



Std	F	SMT – Aseptic Pharmaceuticals
Ref		
11	F8	Radio-pharmacy - Demonstrate theoretical and practical knowledge of the following:
	Optional	 types of radiation, radiation safety, operator protection and special precautions
6	F9	GCP - Demonstrate theoretical and practical knowledge of the following:
	Optional	 GCP practices, documentation, training, clinical trials

Std Ref	G	SMT – Coatings
5, 6, 9	G1	A knowledge of the regulatory requirements and business environment for the manufacture of industry specific coatings products e.g., ISO Standards
11	G2	A knowledge of the scientific and technical aspects for the manufacture of coatings products and intermediates for secondary downstream applications
5, 11	G3	Understand the principles of compatibility, cleanliness, contamination, and plant hygiene
5, 7, 10	G4	 Understand and be able to contribute to the use of one or more specific techniques used within the industry such as: Perform required quality control (qc) by sampling product and conducting standard analytical tests according to industry norms or international standards and Interpret Make decisions on how to modify the control of plant processes and / or product based on the interpretation of the process or quality / test data
1, 2, 3, 11	G5	Understand the principles which underpin the manufacture of coatings products and demonstrate practical experience of all applicable techniques from the following: Dispersion Mixing and blending Heat processes / temperature control Filling, packing, and labelling Volumetric, gravimetric, and other measuring methodology Sampling of materials Storage and handling Manual handling techniques and limitations
		 Understanding of the specific safe systems of work (SSOW)



Std Ref	G	SMT – Coatings
1, 2, 3,	G6	Understand the principles of process control and instrumentation, for example:
7		 Process capability, variation, and impact on quality and / or health and safety
		 Measurement and interpretation of e.g., viscosity, rheology, specific gravity, surface appearance, colour
		measurement, colour standards and colour specification
4, 5	G7	Personnel: Demonstrate theoretical and practical knowledge of the following:
		Personal hygiene
		Hand washing
		• PPE
		Cleanliness
1, 2, 3	G8	Production: Materials management - Demonstrate theoretical and practical knowledge, if applicable, of one or more of the
(2, 4, 7,		following: receiving, checking, ordering, packing, stock rotation, quarantine, shipping (good store keeping practice)
9)		
8	G9	Production: Planning scheduling - Demonstrate theoretical and practical knowledge, if applicable, of one or more of the
		following: order receipt and logging, label generation and worksheets, start-up approvals, transcribing, stock control,
		archiving, calculations
4, 12	G10	Personnel: understand limits of autonomy and when to refer, and to whom, within the industry workplace
1, 2, 3,	G11	Assist in the commissioning and qualification of new equipment or processes
7, 10		

Std Ref	н	SMT – Bulk Liquid Storage Terminals
1, 2, 3, 5, 7, 11	H1	 Understand the principles which underpin the storage, treatment, and transfer of bulk liquid products to or from a storage tank including: Route Ullage Product Transfer rates Simple process operations, e.g., blending
1, 2, 3	H2	Demonstrate practical experience in one or more of the following, as applicable: • Bulk transfer to / from ship



Std Ref	н	SMT – Bulk Liquid Storage Terminals
		Bulk transfer via pipeline
		Bulk transfer to / from road tanker
		Bulk transfer to / from rail tanker
		Bulk transfer tank to tank
4	H3	Understand the principles which govern and maintain a safe working environment:
		The importance of personal hygiene
		 Major accident hazards (MAH) at a bulk liquid storage terminal
		 Safety critical tasks and equipment
		Lone working
		 Safe systems of work (SSoW)
		 Role in mitigating the impact of major accident (e.g., Emergency Response)
5, 6, 7	H4	Understand and demonstrate simple quality control sampling and standard testing on bulk liquid products, including:
		 Product quality documentation and procedures
		 Sampling and dipping techniques
		Sample analysis and reporting
		Contamination control
1, 2, 3,	H5	Understand the importance of asset utilisation in bulk liquid storage
7		 Selection and appropriate effective use of plant equipment (Why and how best to use the equipment and plant in
		process / operation)
4, 7	H6	Understand the principles and operation of:
		 Safety Instrumented Systems (SIS) and functional safety
		Emergency Shut-Down systems (ESD)
8	H7	Demonstrate theoretical and practical knowledge if applicable of one or more of the following:
		Ship to shore checklist
		Product movement sheets
		Stock control
		Labelling and Bill of Laden (BOL)
		Planning & product scheduling
		Shift handover
4, 9	H8	Understand the importance of leadership in process safety, performance indicators, learning and sharing information.

Behaviours Evaluation Assessment Criteria

	Does Not Meet Expectation Apprentice failed to demonstrate an acceptable level of behaviour. Improvement is required	Meets Expectations Apprentice demonstrated an acceptable level of behaviour and meets the minimum level of behaviour expected	Exceeds Expectations Apprentice demonstrated consistent and positive behaviours in this area that reflect those expected of outstanding apprentices
Personal Responsibility	Demonstrate personal responsibility towards safety systems (incl. risk management and environment)		
Assessment Criteria	Little evidence of personal responsibility to safety systems.	Good personal responsibility towards safety systems.	Exhibits high standards of personal responsibility toward safety systems. Seeks to influence the behaviour of others.
	Tries to play down incidents in which they are involved.	Responds positively to suggestions for own improvements in personal responsibility for safety issues.	Actively monitors the safety of self and others, challenging and making suggestions where appropriate.
Communication	Communicate effectively using a full range of skills: speaking; listening; writing; body language; presentation		
Assessment Criteria	Misinterprets or is slow to comprehend oral and / or written instructions.	Readily comprehends oral and / or written instructions when first presented.	Superior comprehension of oral and / or written instructions. Checks back to avoid any misunderstanding.
	Communications are vague or poorly written or spoken. Difficulty conveying meaning to others.	Passes on information both verbal and written, in a way that is easily understood	Is able to adapt both verbal and written communication to be understood by different audiences (e.g., peer, supervisor, senior manager, and visitor).
	Will not ask questions and demonstrates little willingness to listen.	Listens and will question and challenge appropriately to enhance own understanding.	Listens and questions to enhance own and others understanding.



	Does Not Meet Expectation Apprentice failed to demonstrate an acceptable level of behaviour. Improvement is required	Meets Expectations Apprentice demonstrated an acceptable level of behaviour and meets the minimum level of behaviour expected	Exceeds Expectations Apprentice demonstrated consistent and positive behaviours in this area that reflect those expected of outstanding apprentices
			Supports and acknowledges contributions from others
	Unable to effectively present personal viewpoint.	Able to effectively present personal viewpoint.	Able to influence others to see personal viewpoint.
	Unwilling to see other people's point of view	Receptive to other people's point of view.	Ability to reason from different points of view.
Teamwork	Work and interact effectively within a team		
Assessment Criteria	Unwilling to contribute during team discussions / problem solving.	Makes a useful contribution during team discussions / problem solving.	Contributes and willing to lead team-based discussions / problem solving.
	Can reduce morale and enthusiasm within the team.	A good team member gets on well with colleagues.	Builds working relationships between team and other groups. Seeks to diffuse conflict situations
			where they arise.
	Exhibits negative behaviour concerning team / organisational mission.	Demonstrates knowledge and understanding of team / organisation mission.	A strong team player helps bind the team together to achieve team / organisation mission.
	Does not accept responsibility for own impact on team performance.	Works cooperatively with others to achieve overall team goals.	Puts team goals ahead of personal achievement and recognition.
Independence and Responsibility	Work independently and take responsibility for initiating and completing tasks		
Assessment Criteria	Inclined to wait for direction on work tasks.	Normally does not need to be told what to do next, can be trusted to complete tasks.	Looks ahead and progresses work in areas of the job.

	Does Not Meet Expectation Apprentice failed to demonstrate an acceptable level of behaviour. Improvement is required	Meets Expectations Apprentice demonstrated an acceptable level of behaviour and meets the minimum level of behaviour expected	Exceeds Expectations Apprentice demonstrated consistent and positive behaviours in this area that reflect those expected of outstanding apprentices
	Regularly needs to be told what to do or how to do it.	Identifies obstacles to achieving work assigned and escalates.	Will seek to resolve obstacles to achieving work assigned themselves before escalating.
	Supervision required to progress work.	Can be relied on to manage their work with little supervision.	Holds themselves accountable for their own performance.
	Over reliance on supervisor for motivation.	Self-motivated and deals with work / learning balance in a positive way.	Maintains motivation and encourages others to do the same
Impact of Work	Understand impact of work on others, especially where related to diversity and equality		
Assessment Criteria	Others feel the need to recheck their work or have to finish off the job after them.	Works to the required standard of accuracy, neatness, and thoroughness.	Has a reputation within the work group for doing jobs right first time, every time.
	Work rarely makes a contribution to team quality.	Often makes valued contributions to team quality.	Consistently makes a valued contribution to team quality.
	Little respect for the values of others.	Respects the value of others.	Actively encourages work group to respect the values of others
	Has difficulty being tactful, considerate, and respectful in dealing with others.	Usually tactful, considerate, and respectful in dealing with others.	Always tactful, considerate, and respectful in dealing with others.
Time Management	Accepts responsibility for managing own time and workload within a given plan to complete work to schedule		
Assessment Criteria	Does not deliver consistently and can waste time on non-essentials.	Continually demonstrates efficient use of work time.	Continuously strives for improved productivity.
	Unreliable timekeeping	Timekeeping complies with company protocols.	Encourages others to comply with company timekeeping protocols.

	Does Not Meet Expectation Apprentice failed to demonstrate an acceptable level of behaviour. Improvement is required	Meets Expectations Apprentice demonstrated an acceptable level of behaviour and meets the minimum level of behaviour expected	Exceeds Expectations Apprentice demonstrated consistent and positive behaviours in this area that reflect those expected of outstanding apprentices
	Not fully prepared in advance holds up group activities.	Always prepares in advance ready to participate in group activities.	Encourages others to prepare in advance for group activities
Change Management	Ability to handle change and respo	ond to change management process	es
Assessment Criteria	Has difficulty adjusting to changes in workload or assignments.	Is flexible, willing, and able to respond to changes in work situations and / or learn new skill.	Capable of supporting others with change in work situations and or learning new skill.
	Resists change or innovation or takes a "wait and see" approach.	Works hard to implement successful change in areas of responsibility as directed by supervisor.	Recommends changes to improve own work and work of others and implements as agreed with supervisor.
	Does not value own contribution.	Able to demonstrate examples of situations when they have changed practice or personal behaviour.	Evidence of influencing change of practice or personal behaviour by others.



Further Information

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

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