

# Science Manufacturing Process Operative Apprenticeship Standard, Level 2 End-point Assessment Plan

October 2017

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## Introduction & Overview

This document sets out the requirements for end-point assessment (EPA) for the science manufacturing process operative apprenticeship standard, level 2. It is written for end point assessment organisations (EPAOs), who need to know how EPA for this apprenticeship must be operated. It will also be of interest to apprentices undertaking the apprenticeship, their employers and training providers.

Full time apprentices new to the role will typically spend 18-24 months on-programme working towards the apprenticeship standard, with 20% off-the-job training.

Apprentices must meet pre-requisite gateway requirements prior to taking the EPA. They must have a completed evidence portfolio and vocational competence log. In addition, apprentices without English and mathematics at level 2 must achieve level 1 English and mathematics and take the tests for level 2 prior to taking their EPA. The EPA must only start once the employer has confirmed that the apprentice has developed all the knowledge, skills and behaviours (KSBs) defined in the apprenticeship standard and the gateway requirements can be evidenced to an end point assessment organisation.

The EPA must be carried out by independent assessors appointed by an EPAO.

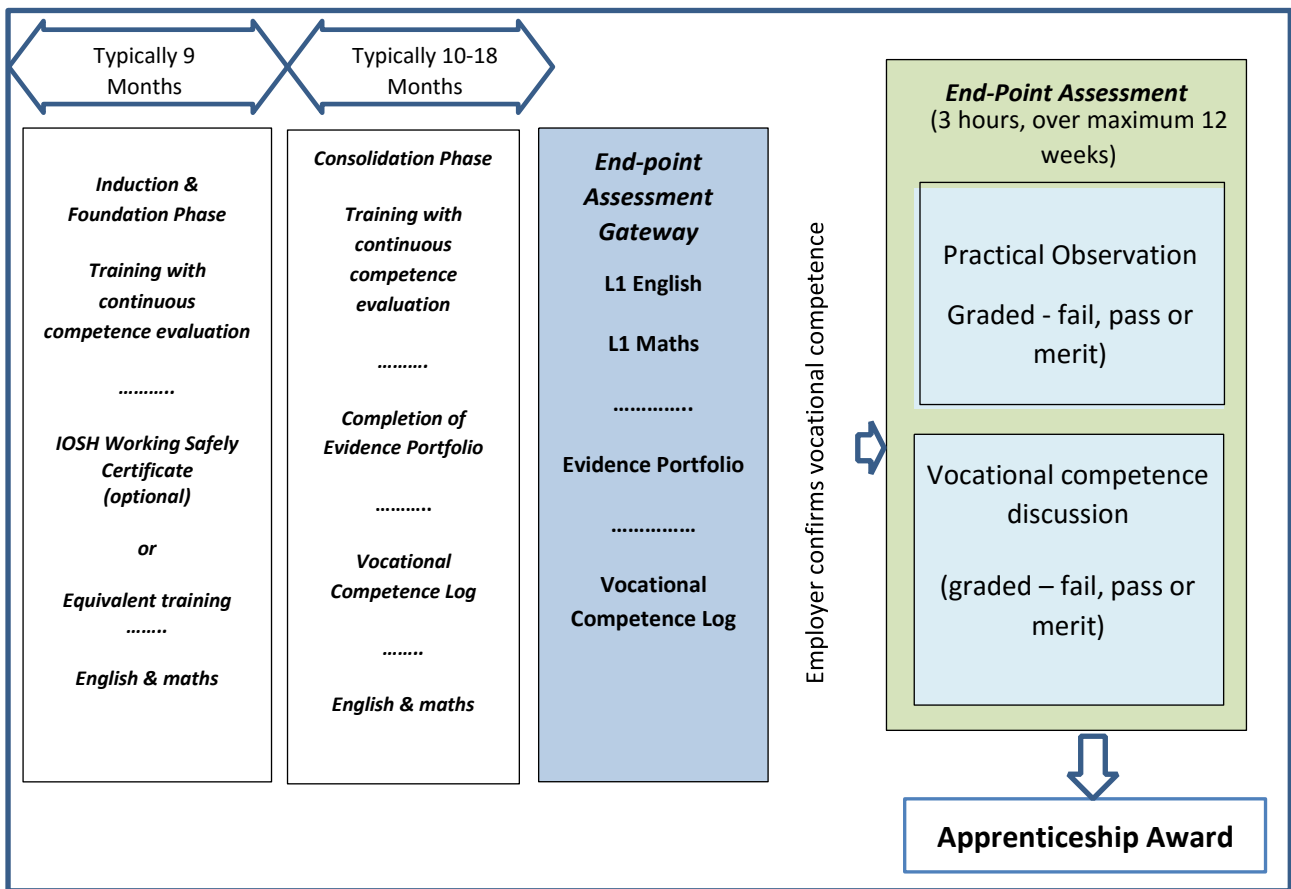
The EPA consists of 2 distinct assessment methods:

1. Practical Observation (PO), with questioning
2. Vocational competence discussion (VCD), a structured discussion, underpinned by the apprentice's portfolio

The EPA must be completed within a 12-week period, after the EPA gateway, with the maximum assessment time totalling 3 hours for both assessment methods.

Performance in the EPA will determine the apprenticeship grade of fail, pass or merit.

A typical apprentice journey is shown in the diagram below.



## Work-based learning guides

The Life Science & Industrial Science (LS&IS) Trailblazer employers have developed a work based learning guide that describes the detailed competence sets that underpin each element of the apprenticeship standard. Based on national occupational standards, the work based learning guide provides a detailed specification of the level of KSBs required to achieve occupational competence in the on-programme phase of the apprenticeship. It is recommended that an apprenticeship training plan is mapped to the work based learning guide for the apprenticeship standard. The work based learning guide is available alongside the standard and this EPA plan at [www.siasuk.com](http://www.siasuk.com).

## **End-point Assessment Gateway**

The EPA should only commence once the employer has confirmed that the apprentice has developed all the KSBs defined in the apprenticeship standard and they have met the requirements below. Employers may wish to take advice from a training provider.

English & maths: apprentices without English and mathematics at level 2 must achieve level 1 English and mathematics and take the tests for level 2 prior to taking their EPA.

Evidence Portfolio (portfolio): during the on-programme period the apprentice must compile an evidence portfolio. It must contain evidence mapped against the standard's KSBs, with at least one piece of evidence mapped to each KSB. Evidence may be mapped against more than one KSB. Evidence sources may include, performance reviews, training records/certificates, photographs, production reports or appropriate documents; this list is not definitive. During the VCD the apprentice will have the opportunity to refer to the portfolio.

Vocational competence evaluation log (log): A summary record of on-programme vocational competence evaluation, signed off by a technical expert (see below) nominated by the apprentice's employer, must be recorded in a log. The log must signpost to the evidence, which is held in the portfolio that was used to confirm the apprentice demonstrated competence. This signed log will be used as the evidence that the employer has confirmed the apprentice is competent. The signed log is a mandatory gateway requirement and it must be provided to the EPAO gateway in order for EPA to go ahead. It is not assessed as part of the EPA. EPAOs must provide guidance on what format the log might take.

## **The End-point Assessment Roles & Responsibilities**

An apprentice's employer must select an EPAO from the Education & Skills Funding Agency (E&SFA) register of end point assessment organisations (RoEPAO), which is approved to deliver EPA for this apprenticeship standard.

EPAOs must appoint independent assessors to conduct EPAs, who must meet the requirements as detailed in page 12.

Independent assessors, in discussion with an apprentice's employer, must draw up an EPA schedule. It must detail the date(s) for the practical observation and the VCD, who will be involved and contexts that will be observed during the practical observation.

EPAOs must ensure that the assessments are conducted in accordance with the assessment specifications detailed below.

Independent assessors have responsibility for making assessment decisions for the 2 assessment methods.

The practical observation will be assessed by an independent assessor, in the presence of a technical expert nominated by the apprentice's employer. Independent assessors are responsible

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for making the assessment decisions, following discussion with the technical expert whose role is to facilitate the practical observation and advise on workplace practices and procedures. The technical expert must not participate in the assessment decision or assist the apprentice in any way.

Technical experts will generally be employed by the apprentice's employer. In some instances, the employer, for example an SME, may wish to contract a technical expert from outside their company if they do not have the capacity or capability to provide one.

VCDs will be conducted by an independent assessor only.

## **End-point Assessment Methods & Timescales**

The end-point assessment consists of 2 distinct assessment methods:

1. Practical Observation (PO), with questioning
2. Vocational Competence Discussion (VCD), underpinned by the portfolio

See Annex A for KSBs to be assessed by each assessment method.

The order in which apprentices can take assessments is not fixed, to allow EPAOs flexibility and efficiency in scheduling. It is anticipated that the PO and VCD will take place on the same day and be assessed by the same independent assessor; however, this is not a requirement.

### **Practical Observation, with questioning**

A practical observation, with questioning will assess the apprentice holistically against a range of knowledge and skills in their workplace setting.

The independent assessor following discussion with the employer should select the 2 contexts to be observed as part of the PO, in either a batch or continuous process, from the following:

1. Prepare
2. Start-up
3. Perform
4. Shut down
5. Assemble & finish

EPAOs must work with employers to ensure the planned tasks meet the specification for the PO, whilst fitting in with the operational needs of the business. EPAOs must ensure all POs are of the same size and complexity.

The PO will be assessed by an independent assessor. During or after the observed activities, the independent assessor will ask the apprentice 6-8 open questions to assess knowledge and understanding relating to the observed activities and any contexts not observed. They may ask follow up questions to seek clarification where required. Independent assessors will select questions from their EPAO's question bank.

Example questions:

- What is the science behind the process/s used in the observed task/s?
- Describe the function and operating features of the manufacturing plant and equipment used for the task(s)
- What is the relationship of the task to the overall manufacturing process?

EPAOs must develop a question bank, with a minimum of 30 open questions appropriate to the level of the standard. The question bank must be reviewed and updated as a minimum every 3 years.

The PO will be conducted in the apprentice's workplace under the following conditions:

- a. PO carried out one-on-one by an independent assessor, supported by a technical expert
- b. a timescale of at least 1.5 hours and a maximum of 2 hours, to reflect the operational context(s), to include the observed activity and questioning; the time-period does not have to be continuous
- c. no coaching or mentoring from colleagues/technical expert
- d. in the normal working environment
- e. previously planned to ensure that the proposed activity/activities meet practical observation specification
- f. the outcomes are documented using EPAO documentation
- g. the independent assessor must grade the PO using the grading criteria in Annex B

### **Vocational Competence Discussion, underpinned by the portfolio**

Apprentices will take part in a VCD on a one-to-one basis with an independent assessor. This will be a structured discussion supported by the portfolio with 4 questions, one from each of these areas from the standard:

- Working safely
- Regulatory compliance
- Problem solving
- Process manufacturing improvement techniques

Questioning will explore underpinning behaviours and the independent assessor may ask follow-up questions for clarification. The apprentice must support their response with reference to the evidence held in their portfolio.

Example questions:

- Tell me about a time when there has been a problem in the manufacturing process, what was the problem, what action did you take and why?
- Tell me how you would shut down a science manufacturing process, what do you need to do and why?

- How do you comply with the requirements of the Health, Safety and Environmental regulations, including correct use of Personal Protective Equipment?
- What is your role in the quality control process, including sampling and testing procedures and compliance with your company's quality procedures?
- Explain how you work to and meet the requirements of standard operating procedures relevant to your scope of work.

EPAOs must develop a question bank, with a minimum of 30 open questions appropriate to the level of the standard. The question bank must be reviewed and updated as a minimum every 3 years.

The VCD will be conducted under the following conditions:

1. Be in the format of a 1:1 discussion with the independent assessor
2. Comprise 4 questions
3. Last no more than 1 hour
4. Take place in a room, free from distractions with no other people present; it is permissible for the VCD to be conducted using technology e.g. video-conferencing
5. Be documented or recorded electronically by the independent assessor
6. The independent assessor must grade the VCD using the grading criteria in Annex C

## **Apprenticeship Grading**

Performance in the EPA will determine the apprenticeship grade - fail, pass or merit.

The assessment methods have equal weighing in determining the EPA grade. A fail will be awarded where the apprentice fails one or more assessment method. A pass will be awarded to individuals that achieve at least a pass in both of the assessment methods. A merit will be awarded to individuals that achieve a merit in both assessment methods. See Annex D for apprenticeship grading combinations matrix.

## **Re-takes and Re-sit**

Apprentices who fail an EPA method(s) will be offered the opportunity to take a re-sit/re-take. A re-sit does not require further learning, whereas a re-take does. The employer will need to agree that a re-sit/re-take is an appropriate course of action. Any EPA component re-sit/re-take must be taken within 2 months of the issuing of the EPA result; otherwise the entire EPA must be retaken. They are not offered to apprentices wishing to move from pass to merit. Re-sits/re-takes will not be awarded a grade higher than pass, unless the EPAO determines there were exceptional circumstances accounting for the fail. Apprentices should have a supportive action plan to prepare for the re-sit/re-take.



## End Point Assessment Organisations

Organisations must be approved to deliver this EPA, as shown on the Education & Skills Funding Agency register of end point assessment organisations (RoEPAOs). EPAOs must be able to demonstrate occupational and assessment capacity and capability.

The LS&IS Trailblazer employers have specified the quality criteria for independent assessors, assessment instrument design and internal quality assurance. These quality criteria will ensure a consistent approach.

### Assessment Instrument Criteria

EPAOs will need to develop EPA tools, processes and supporting materials, including:

- a bank of standardised questions for the PO, reviewed and refreshed as a minimum every 3-years to retain their validity
- a bank of standardised questions for the VCD, reviewed and refreshed as a minimum every 3-years to retain their validity
- documentation to record the assessments
- guidance for apprentices and their employers on the EPA, including compiling a portfolio and log.

EPAOs must develop the assessment instruments and supporting materials to reflect the apprenticeship standard and the assessment specifications. It is recommended that the work based learning guide for this standard is also used as a reference.

### Technical Expert and Independent Assessor Criteria

#### Technical Expert Criteria

EPAOs must confirm technical experts meet the following criteria.

| <b><u>Technical Expert Criteria</u></b>                                 |
|---|
| ✓ Vocationally competent and recent continuing professional development |
| Plus  |
| ✓ experience of current working practices                               |
| Plus  |
| ✓ Completed EPAO induction  |

Technical experts must be competent in the science manufacturing process operative occupation. This must be shown through the individual having experience in the occupational area, or having a qualification at a level higher than the level of the apprenticeship standard.

Technical experts must be either working in the science industry itself or they must be able to demonstrate they possess practical and up-to-date knowledge and experience of current working practices appropriate to the sector, and able to provide evidence of at least 4 days of CPD within the last year.

The technical experts must complete an EPAO induction to demonstrate working knowledge of the apprenticeship standard and assessment methodology.

### **Independent Assessor Criteria**

EPAOs must confirm that independent assessors meet the following criteria.

**Independent Assessor Criteria**

- ✓ Independent of the apprentice, their training provider and employer
  
- ✓ Hold a current UK qualification for workplace vocational assessors or workplace competence assessor award
  

plus

- ✓ Vocationally competent with 3 years' relevant experience and recent continuing professional development (CPD)
  

plus

- ✓ Completed EPAO induction

The EPA must be delivered in such a way that no party who has been involved in delivery can make the sole decision on competence. The approach must clearly deliver an impartial result. For this reason, independent assessors appointed by EPAOs must not be linked to the apprentice, their training provider or employer.

Independent assessors must hold a current UK qualification for workplace vocational assessors or a workplace competence assessor award.

Independent Assessors must be competent in the occupation they are assessing. This must be shown through the individual having 3 years' relevant experience and recent CPD, or by holding professional recognition in the occupational area.

Individuals must be able to demonstrate they possess practical and up-to-date knowledge of current working practices, appropriate to the science manufacturing process sector.

Independent assessors must:

- Maintain a continuous, up-to-date and accurate record of their CPD activities;
- Demonstrate that their CPD activities are a mixture of learning activities relevant to current or future practice;
- Seek to ensure that their CPD has benefited the quality of their practice;
- Seek to ensure that their CPD has benefited the users of their work;
- Present a written profile containing evidence of at least 2 days CPD in the last 12 months on request.

Individuals must complete an EPAO induction to demonstrate working knowledge of the apprenticeship standard and assessment methodology.

### **Internal Quality Assurance**

EPAOs must have internal quality assurance arrangements that meet the following minimum requirements.

They must moderate independent assessors' EPA decisions. The EPA grade must not be confirmed until after moderation. As a minimum, 20% of all independent assessors' assessment EPA decisions must be moderated, sampled across different apprentices and employers. Moderation must be higher for in-experienced independent assessors, where moderation has identified inconsistent grading decisions or grading decisions have been disputed.

EPAOs must have an appeals policy and procedures for dealing with disputes in relation to grades. Appeals must be registered with the EPAO within 21 days of receipt of the grade for the EPA. The EPAO must appoint an independent assessor to investigate the appeal. The assessor must be given 21 days in order to study all the available evidence relating to the appeal. The learner should be informed of the outcome within 25 working days of the EPAO receiving the independent assessor's report.

EPAO staff completing moderation must be trained by the EPAO in their quality assurance methodologies.

EPAOs must run induction training for technical experts and independent assessors on appointment covering the apprenticeship standard and assessment methodology. Other training should be provided to meet individual's identified training needs.

Annual standardisation events must be held for independent assessors to ensure consistency in the assessment practice and decisions.

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EPAOs must ensure independent assessors and technical experts meet the qualification and experience requirements detailed above.

## **External Quality Assurance**

External quality assurance arrangements will ensure that EPAOs delivering EPA for this standard operate consistently and in line with this plan.

External quality assurance for this apprenticeship standard will be undertaken by the Institute for Apprenticeships.

## **Implementation**

**Affordability:** It is anticipated that the EPA will cost no more than 20% of the maximum funding band for this apprenticeship, based on costings provided.

**Volumes:** It is anticipated that there will be 75 starts per year on this apprenticeship.

## Annex A – Knowledge, Skills and Behaviours to be assessed by each assessment method

| Key                            |     |
|--------------------------------|-----|
| Practical Observation          | PO  |
| Vocation Competence Discussion | VCD |

### Knowledge

| No | Standard Competency Statement   | Assessment |     |
|----|---|------------|-----|
|    |   | PO         | VCD |
| 1  | Science manufacturing industry plant and equipment, including: pumps, valves, temperature gauges, filtration equipment, tanks, vessels and production/processing machinery such as automated production lines and assembly operations       | PO         | VCD |
| 2  | How to operate the above plant and equipment, to process/manufacture, assemble and finish industry component parts or finished products and materials in a science manufacturing environment.   | PO         |     |
| 3  | Process manufacturing improvement techniques for example 5S Methodology and Good House Keeping improvements and their application in a science manufacturing environment.   |            | VCD |
| 4  | The organisational structure of their science manufacturing company and their role within it.   |            | VCD |
| 5  | Their organisation's ethical practices and codes of conduct.  |            | VCD |
| 6  | Regulatory compliance and policies typically required by science manufacturing employers, for example external GMP and internal polices required for 'clean room' practices.  |            | VCD |
| 7  | The hazards and risks associated with the science manufacturing plant operation and environment and the use of correct personal protective equipment (PPE) and safety equipment to ensure safe plant operation and safety in the workplace. |            | VCD |

## Skills

|    |  |    |     |
|----|--|----|-----|
| 8  | Prepare science manufacturing materials, plant and equipment, for hand or machine based process operations, typically using pumps, valves, temperature gauges, filtration equipment, tanks and vessels; including checking availability and quality of materials, correct conditions and safety checks according to standard operating procedures. | PO |     |
| 9  | Start-up a basic science manufacturing machine based or hand based processes, typically using equipment as above, following process operating instructions.  | PO |     |
| 10 | Perform operations and monitor basic science manufacturing process according to company safe working practices as directed by line manager.  | PO |     |
| 11 | Produce a representative sample of science manufacturing product for quality test purposes and inspect products to ensure quality is maintained in line with company quality procedures  | PO |     |
| 12 | Carry out assembly and finishing operations for a machine or hand based process operation in science manufacturing process.  | PO |     |
| 13 | Make simple adjustments to the science manufacturing process to remedy problems, reporting any problems or abnormal conditions when unable or unauthorised to resolve.   |    | VCD |
| 14 | Shut down/complete a basic science manufacturing process following process operating instructions.   | PO |     |
| 15 | Comply with the Health, Safety and Environmental regulations, including correct use of PPE.  | PO |     |
| 16 | Comply with and meet the requirements of their company quality standards   | PO |     |
| 17 | Work to and meet the requirements of standard operating procedures relevant to their scope of work.  | PO |     |
| 18 | Comply with instructions pertaining to the internal and external regulatory requirements set by the relevant competent authority and/or specified by the company.  | PO |     |
| 19 | Complete routine documentation such as quality inspection sheets and production records.   | PO |     |
| 20 | Perform simple calculations associated with the operation, for example raw material quantity and production calculations.  |    | VCD |

|    |  |  |            |
|----|--|--|------------|
| 21 | Support process manufacturing improvement activities, for example implementing plant improvements as directed and responding to plant and process change requirements. |  | <b>VCD</b> |
|----|--|--|------------|

### **Behaviours**

|    |  |           |            |
|----|--|-----------|------------|
| 22 | Communicates appropriately to support the working of the team                    | <b>PO</b> | <b>VCD</b> |
| 23 | Accepts responsibility of own work and the impact of own work on others          |           | <b>VCD</b> |
| 24 | Displays a willingness to contribute to the work of others                       |           | <b>VCD</b> |
| 25 | Shows respect for others, having regard for diversity and equality               | <b>PO</b> | <b>VCD</b> |
| 26 | Manages own time, being punctual, reliable and completes work to agreed schedule |           | <b>VCD</b> |
| 27 | Responds positively to change in the working environment                         |           | <b>VCD</b> |

## **Annex B – Practical Observation, with questioning assessment criteria**

**Fail criteria**, apprentice does not demonstrate one or more of the following:

- All tasks are completed in line with standard operating procedures
- Planning and methodology are done in a logical order without the need to undo or redo any work already completed
- Working practices ensure the health & safety of self and others
- Product or process output meets manufacturing requirements
- Completes any required documentation fully and accurately
- Maintains a clean and tidy working environment
- Provides an accurate explanation of how the non-observed context activities should be conducted
- Explains the science behind the process/s
- Correctly identifies and safely operates the manufacturing plant and equipment used for the tasks in accordance to operating procedures

**Pass criteria**, apprentice must demonstrate all of the following:

- All tasks are completed in line with standard operating procedures
- Planning and methodology are done in a logical order without the need to undo or redo any work already completed
- Working practices ensure the health & safety of self and others
- Product or process output meets manufacturing requirements
- Completes any required documentation fully and accurately
- Maintains a clean and tidy working environment
- Provides an accurate explanation of how the non-observed context activities should be conducted
- Explains the science behind the process/s



- Correctly identifies and safely operates the manufacturing plant and equipment used for the tasks in accordance to operating procedures

**Merit criteria**, apprentice must meet the pass criteria and in addition demonstrate all of the following:

- Working to the operating plan and understands the escalation process when issues occur
- Understands the impact on other any omissions or transgressions in safe working practices
- The impact of process output and product quality to the wider business effectiveness
- Explains the science behind the process/s and a wider science understanding of the overall manufacturing process
- Can respond to and provide or recommend corrective actions to maintain safe operation

## Annex C - VCD Assessment Criteria

| Area of standard             | Fails  | Pass  | Merit ( in addition to the pass criteria)  |
|------------------------------|--|---|--|
| <b>Working safely</b>        | <ul style="list-style-type: none"> <li>• Cannot explain the hazards and risks associated with science manufacturing industry plant and equipment and the manufacturing process.</li> </ul>   | <ul style="list-style-type: none"> <li>• Explains the hazards and risks associated with science manufacturing industry plant and equipment and the manufacturing process Supports explanation with example of working safely from own practice E.g. use of personal protective equipment.</li> </ul>  | <ul style="list-style-type: none"> <li>• Explains the reasons for safe working practices showing knowledge of how these link to legislation and the implications of not following these for the organisation.</li> </ul>   |
| <b>Regulatory compliance</b> | <ul style="list-style-type: none"> <li>• Cannot explain the organisational structure of their science manufacturing company and their role within it.</li> <li>• Cannot explain their organisation's ethical practices and codes of conduct.</li> <li>• Cannot explain the legislative and regulatory requirements pertaining to their area of operation.</li> </ul> | <ul style="list-style-type: none"> <li>• Explains the organisational structure of their science manufacturing company and their role within it.</li> <li>• Explains their organisation's ethical practices and codes of conduct.</li> <li>• Explains the legislative and regulatory requirements pertaining to their area of operation.</li> <li>• Provides example from own practice of compliance with regulatory policies and procedures e.g. Clean/Sterile room practices, PPE requirements, Good Manufacturing Practice (GMP), Good Laboratory Practice (GLP)</li> </ul> | <ul style="list-style-type: none"> <li>• Explains how compliance with legislative and regulatory, process, safety and environment control impacts on the manufacturing process.</li> <li>• Supports explanation with example of impact on the wider business.</li> </ul> |

|   |  |   |   |
|---|--|---|---|
|   |  | and Good Documentation Practice (GDP).  |   |
| <b>Problem solving</b>                              | <ul style="list-style-type: none"> <li>• Cannot explain how to make simple adjustments to the science manufacturing process to remedy problems.</li> </ul> | <ul style="list-style-type: none"> <li>• Explains how to make simple adjustments to the science manufacturing process to remedy problems.</li> <li>• Supports explanation with example from own practice</li> <li>• Provides examples of performing simple calculations associated with the operation.</li> </ul>   | <ul style="list-style-type: none"> <li>• Explains how proactive problem solving practices benefit the manufacturing process and impacts on the wider business.</li> <li>• Supports explanation with example of simple calculations associated with the operation that shows impact on the manufacturing process.</li> </ul>                             |
| <b>Process manufacturing improvement techniques</b> | <ul style="list-style-type: none"> <li>• Cannot provide an example of supporting process manufacturing improvement activities.</li> </ul>                  | <ul style="list-style-type: none"> <li>• Explains simple process manufacturing improvement activities supported by example from own practice of responding to plant and/or process change requirements.</li> <li>• Explains how process manufacturing improvement systems can be used to maintain efficient and safe manufacturing.</li> <li>• Supports explanation with example from own practice, e.g.</li> </ul> | <ul style="list-style-type: none"> <li>• Explains how continuous improvement and change management processes are used within the organisation.</li> <li>• Explains how root cause analysis supports the continuous improvement process.</li> <li>• Explains how improvement changes can impact other areas of manufacturing or the business.</li> </ul> |

|  |  |  |  |
|--|--|--|--|
|  |  | Good housekeeping, 5 Ss, other<br>change management procedures |  |
|--|--|--|--|

## Annex D - Apprenticeship Grading Combinations Matrix

| <b>Practical Observation Overall Grade</b> | <b>VCD</b> | <b>Apprenticeship Grade</b> |
|--|------------|-----------------------------|
| Fail                                       | Fail       | <b>Fail</b>                 |
| Fail                                       | Pass       | <b>Fail</b>                 |
| Pass                                       | Pass       | <b>Pass</b>                 |
| Pass                                       | Merit      | <b>Pass</b>                 |
| Merit                                      | Pass       | <b>Pass</b>                 |
| Merit                                      | Merit      | <b>Merit</b>                |