Assessor's guidelines for the SVQs in Scientific Manufacture at levels 2, 3 and 4

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About this guide

This guide provides some practical examples of how to assess your candidates for the **SVQs in Scientific Manufacture at levels 2, 3 and 4**. You may be able to think of other ways of assessing your candidates and recording your decisions about their competence.

Using assessments based on these examples does not guarantee successful verification — it is still your responsibility to ensure that internal quality assurance procedures are followed.

Introduction

This introduction provides a brief overview of SVQs and how they are assessed in the workplace. If you are already familiar with the concept of SVQs, you may wish to go to the next section.

About SVQs

Scottish Vocational Qualifications (SVQs) are work-based qualifications which set the level of occupational competence for each sector of the economy. The qualifications have been designed by standards-setting bodies made up of experienced practitioners who represent employers, professional bodies, trade unions, education and voluntary organisations.

Each standards-setting body is responsible for developing national standards which define *what* employees (or potential employees) must be able to do, *how well*, and *in what circumstances*, to show that they are competent in their work.

Each SVQ which a standards-setting body develops has to fit into a broad framework which allows qualifications in the UK and throughout Europe to be compared. SVQs are specified at five levels which reflect the various technical and supervisory skills knowledge and experience, which employees should have as they progress in their industry.

Explanation of levels

Level 1 Defines competent performance in a range of activities which are largely routine and predictable.

Level 2 Specifies that competent performance must be shown in a broader range of work activities which are less routine and predictable. The employee will have more autonomy and responsibility, and may have to work as part of a team.

Level 3 Specifies that competent performance must involve the employee in carrying out a broad range of varied work activities, most of which are complex and non-routine. There is considerable autonomy and responsibility, including the possibility of controlling or guiding others.

Level 4 Specifies competence as complex technical or professional work activities which require a substantial degree of personal autonomy or responsibility. Managing staff and other resources is often involved.

Level 5 Specifies competent performance as involving the employee in carrying out a significant range of activities in a wide variety of situations which are often unpredictable. Substantial responsibility and autonomy is involved in the work, which requires decision-making in the allocation of resources and the work of others. This will require complex skills such as analysis, design and evaluation.

How are standards defined in SVQs?

All SVQs consist of standards which can be broken down into various parts.

Units define the broad functions carried out in the sector, and are made up of a number of **Specific Areas (Sector, Organisational and Equipment/Process)**. These **Specific Areas** describe the activities which employees have to perform, and will require candidates to demonstrate certain skills or knowledge and understanding.

The quality of performance in what people must be able to do — how well they have to perform — is described by **Performance Criteria**. These may also be called **statements of competence** or **what candidates should do**.

The section on **knowledge and understanding** says what candidates must know and understand, and how this knowledge applies to their jobs.

You may also come across standards containing statements on **scope**. These statements could, for example, list the equipment that candidates are expected to be familiar with and use in their occupational area.

Increasingly, you may see changes to this format as standards become more user-friendly and are written in plain English. For example, there may be some standards containing **Range Statements** or **Evidence Requirements**, but over time these should disappear. You may, however, find that information on the context, nature and amount of evidence which is required to prove competence (which used to be given in Range Statements and Evidence Requirements) is now defined in the **assessment guidance** for the qualification. Assessment guidance is drawn up by the awarding body and is packaged along with the standards to form the SVQ.

Who is involved in SVQs?

There are several roles:

- **the candidate:** the person who wants to achieve the SVQ (eg an employee)
- **the assessor*:** the person who assesses the candidates and decides if they are competent (eg supervisor)
- **the internal verifier*:** an individual nominated by the centre (eg a company) who ensures that assessors apply the standards uniformly and consistently (eg supervisor's line manager)

- **the external verifier*:** an individual appointed by SQA who ensures that standards are being applied uniformly and consistently across all centres offering the SVQ

*Assessors and verifiers in centres will be asked by SQA to prove they have the appropriate occupational competence to assess and verify the SVQ. Occupational competence has been defined by the standards-setting body in the assessment strategy for these SVQs — see SQA's website: **www.sqa.org.uk**

Assessors and verifiers are also expected to obtain an appropriate qualification in assessment and verification — this can be the Assessor/Verifier Units (the national standards for assessment and verification), or an alternative qualification which SQA also recognises.

The steps involved in assessing a candidate for an SVQ

In deciding whether a candidate should get an SVQ, you will go through these stages:

- planning for assessment
- generating and collecting evidence of the candidate's competence in the Units
- judging the evidence of the candidate's ability and making an assessment decision based on the evidence
- recording the assessment decision and the candidate's achievement

1: The SVQs in Scientific Manufacture

The SVQs in **Scientific Manufacture** have been developed by SEMTA (Sector Skills Council for science, engineering and manufacturing technologies) and are intended for people working in the biomanufacturing environment.

These people may be working as Biomanufacturing/Process Technicians. They will require skills and knowledge in aseptic techniques, regulatory compliance as in FDA (Food and Drug Administration) and cGMP (current Good Manufacturing Practice).

The SVQs are designed to be assessed in the workplace, or in conditions of the workplace. Examples of the settings or centres in which the SVQs are likely to be delivered include: companies in the pharmaceutical and biotechnology sectors, biomanufacturing research centres, University Development Centres. Delivery may be supported through partnerships with colleges, particularly with respect to knowledge requirements.

Structure of the SVQs

This section lists the Units which form the SVQs in Scientific Manufacture at levels 2, 3 and 4.

Mandatory Units

SQA Ref	SCQF level	SSC Ref	Title
F7Y8 04		Unit 01	Maintaining Health and Safety in a Biomanufacturing Environment
F7Y6 04		Unit 02	Maintaining Effective and Efficient Biomanufacturing Working Relationships
F7XX 04		Unit 03	Following Aseptic Procedures in a Biomanufacturing Environment

Pathways

Scientific Manufacture (Biotechnology Operations) at level 2 G9JC 22
Four Optional Units including two from Group B.

Group A Optional Units

SQA Ref	SCQF level	SSC Ref	Title
F80A 04		Unit 04	Preparing the Biomanufacturing Area and Process Equipment
F80N 04		Unit 05	Transferring Materials in a Biomanufacturing Environment
F7YG 04		Unit 06	Measuring, Weighing and Preparing Compounds and Solutions For Biomanufacturing Use
F7XD 04		Unit 15	Assisting with the Routine Maintenance, Cleaning, Disinfecting and Calibration of Biomanufacturing Equipment
F7XH 04		Unit 18	Carrying out Sampling Operations in a Biomanufacturing Environment

Group B Optional Units

SQA Ref	SCQF level	SSC Ref	Title
F808 04		Unit 07	Preparing Culture Media and Solutions for Biomanufacturing Upstream Processing
F80C 04		Unit 08	Producing Biomaterial Using Bioreactors in Biomanufacturing Upstream Processing
F7Y0 04		Unit 09	Harvesting Biomaterial Into Sterile Containers from a Bioreactor for Biomanufacturing Downstream Processing
F80H 04		Unit 10	Separating Harvested Biomaterial for Biomanufacturing Downstream Processing Using Continuous Flow Centrifugation
F803 04		Unit 11	Obtaining Biomaterial in Biomanufacturing Downstream Processing Using Lysis of Cells
F80J 04		Unit 12	Separating Harvested Biomaterial in Biomanufacturing Downstream Processing Using Normal Filtration
F7XK 04		Unit 13	Concentrating and Diafiltrating Harvested Biomaterials in Biomanufacturing Downstream Processing Using Tangential Flow Filtration (TFF)
F80F 04		Unit 14	Purifying Harvested Biomaterial in Biomanufacturing Downstream Processing (DSP) Using Chromatography

Scientific Manufacture (Filling/Finishing Operations) G9J9 22
Four Optional Units including two from Group B.

Group A Optional Units

SQA Ref	SCQF level	SSC Ref	Title
F80A 04		Unit 04	Preparing the Biomanufacturing Area and Process Equipment
F80N 04		Unit 05	Transferring Materials in a Biomanufacturing Environment
F7YG 04		Unit 06	Measuring, Weighing and Preparing Compounds and Solutions for Biomanufacturing Use
F7XH 04		Unit 18	Carrying out Sampling Operations in a Biomanufacturing Environment

Group B Optional Units

SQA Ref	SCQF level	SSC Ref	Title
F7XD 04		Unit 15	Assisting with the Routine Maintenance, Cleaning, Disinfecting and Calibration of Biomanufacturing Equipment
F7XW 04		Unit 16	Filling Containers with Processed Biomaterials in Secondary Biomanufacturing Operations Using Automated Machinery
F805 04		Unit 17	Packing Filled Biomaterial Containers in Secondary Biomanufacturing Operations By Manual Methods

Scientific Manufacture (Biotechnology Processing) at level 3 G9JE 23

Mandatory Units

SQA Ref	SCQF level	SSC Ref	Title
F7Y8 04		Unit 01	Maintaining Health and Safety in a Biomanufacturing Environment
F7Y6 04		Unit 02	Maintaining Effective and Efficient Biomanufacturing Working Relationships
F7YK 04		Unit 03	Monitoring and Following Aseptic Procedures in a Biomanufacturing Environment

Five Optional Units including two from Group A.

Group A Optional Units

SQA Ref	SCQF level	SSC Ref	Title
F7WL 04		Unit 04	Analysing and Inputting Biomanufacturing Data in a Manufacturing Information Management System (MIMS)
F80D 04		Unit 05	Providing Leadership for a Biomanufacturing Team
F7XT 04		Unit 06	Encouraging Problem Solving and Innovation in a Biomanufacturing Team
F7YD 04		Unit 07	Managing Budgets for Biomanufacturing Projects
F7YA 04		Unit 22	Making Biomanufacturing Development/Research Presentations

Group B Optional Units

SQA Ref	SCQF level	SSC Ref	Title
F81N 04		Unit 11	Monitoring the Preparation of Culture Media and Solutions for Biomanufacturing Upstream Processing
F7WY 04		Unit 12	Monitoring the Production of Biomaterial Using Bioreactors in Biomanufacturing Upstream Processing.
F7YP 04		Unit 13	Monitoring the Harvesting of Biomaterial Into Sterile Containers from a Bioreactor for Biomanufacturing Downstream Processing
F800 04		Unit 14	Monitoring the Separating of Harvested Biomaterial for Biomanufacturing Downstream Processing Using Continuous Flow Centrifugation
F7YT 04		Unit 15	Monitoring the Obtaining of Biomaterial in Biomanufacturing Downstream Processing Using Lysis of Cells.
F801 04		Unit 16	Monitoring the Separating of Harvested Biomaterial in Biomanufacturing Downstream Processing Using Normal Filtration
F7YM 04		Unit 17	Monitoring the Concentration and Diafiltration of Harvested Biomaterial in Downstream Processing Using Tangential Flow Filtration (TFF)
F7YX 04		Unit 18	Monitoring the Purification of Harvested Biomaterial in Biomanufacturing Downstream Processing Using Chromatography
F7YY 04		Unit 19	Monitoring the Routine Maintenance, Cleaning, Disinfecting and Calibration of Biomanufacturing Equipment

Scientific Manufacture (Filling/Finishing Operations) at level 3
G9JD 23
Five Optional Units including two from Group A.

Mandatory Units

SQA Ref	SCQF level	SSC Ref	Title
F7Y8 04		Unit 01	Maintaining Health and Safety in a Biomanufacturing Environment
F7Y6 04		Unit 02	Maintaining Effective and Efficient Biomanufacturing Working Relationships
F7YK 04		Unit 03	Monitoring and Following Aseptic Procedures in a Biomanufacturing Environment

Group A Optional Units

SQA Ref	SCQF level	SSC Ref	Title
F7WL 04		Unit 04	Analysing and Inputting Biomanufacturing Data in a Manufacturing Information Management System (MIMS)
F80D 04		Unit 05	Providing Leadership for a Biomanufacturing Team
F7XT 04		Unit 06	Encouraging Problem Solving and Innovation in a Biomanufacturing Team
F7YD 04		Unit 07	Managing Budgets for Biomanufacturing Projects

Group B Optional Units

SQA Ref	SCQF level	SSC Ref	Title
F7YL 04		Unit 08	Monitoring Preparation of the Biomanufacturing Area and Equipment
F802 04		Unit 9	Monitoring the Transfer of Materials in the Biomanufacturing Environment
F7YR 04		Unit 10	Monitoring the Measuring, Weighing and Preparing of Compounds and Solutions for Biomanufacturing Use
F7YY 04		Unit 19	Monitoring the Routine Maintenance, Cleaning, Disinfecting and Calibration of Biomanufacturing Equipment
F7YN 04		Unit 20	Monitoring the Filling of Containers with Processed Biomaterials in Secondary Biomanufacturing Operations Using Automated Machinery
F7YV 04		Unit 21	Monitoring the Packing of Filled Biomaterial Containers in Secondary Biomanufacturing Operations by Manual Methods

Scientific Manufacture (Biotechnology Process Management) at level 4
G9JF 24

Mandatory Units

SQA Ref	SCQF level	SSC Ref	Title
F7Y8 04		Unit 01	Maintaining Health and Safety in a Biomanufacturing Environment
F7Y6 04		Unit 02	Maintaining Effective and Efficient Biomanufacturing Working Relationships
F7YK 04		Unit 03	Monitoring and Following Aseptic Procedures in a Biomanufacturing Environment
F7XJ 04		Unit 04	Monitoring and Evaluating Performance Data from a Manufacturing Information Management System (MIMS)

Five Optional Units including two from Group A.

Group A Optional Units

SQA Ref	SCQF level	SSC Ref	Title
F7Y1 04		Unit 08	Identifying Appropriate Biological Routes for Manufacture of Existing/New Products
F80M 04		Unit 09	Supervising Existing/New Biological Product Manufacturing for Development Purposes
F804 04		Unit 10	Optimising a Chosen Biological Manufacturing Process for Product Development

Group B Optional Units

SQA Ref	SCQF level	SSC Ref	Title
F7XP 04		Unit 05	Determining Manufacturing Methods for a Biomanufacturing Environment
F7XG 04		Unit 06	Assuring Quality Methods and Procedures in a Biomanufacturing Environment
F7Y2 04		Unit 07	Improving Product and Process Quality in a Biomanufacturing Environment
F7YF 04		Unit 11	Managing Projects in Biomanufacturing Operations
F80L 04		Unit 12	Solving Engineering Problems in a Biomanufacturing Environment
F7XL 04		Unit 13	Contributing to a Team Feasibility Review for Existing/New Product Development in a Biomanufacturing Environment
F7YH 04		Unit 14	Measuring, Weighing and Preparing Compounds and Solutions for Laboratory Use
F80V 04		Unit 15	Writing Biomanufacturing Technical Reports
F7YD 04		Unit 16	Managing Budgets for Biomanufacturing Projects

An assessment strategy for the SVQ

As part of its review of the SVQs, the standards-setting body SEMTA has developed an assessment strategy which defines a range of requirements:

- the occupational expertise of assessors and verifiers
- a definition of simulation
- definition of the workplace
- information on a model of independent assessment or external quality control

The relevant parts of the assessment strategy are published on SQA's website (**www.sqa.org.uk**), and both SQA and centres must comply with these requirements.

Why would people be interested in the SVQ?

People will take SVQs for a variety of reasons: to gain promotion, to prove their job competence, or for personal development. There will be other reasons too. One of the first things to do is to find out why your candidates want to do the SVQ, and to advise them of the appropriateness of the qualification. If anyone is acting as a coach or mentor to your candidates, they might help you to do this.

How do candidates begin?

Choosing the SVQ

You should make sure that candidates get guidance before starting out on an SVQ — they need advice to ensure that their existing job remit, skills, experience, and their plans for progression, are matched to the SVQ selected. It does not have to be you as the assessor, who carried out the matching process, but whoever has responsibility for this should ensure that the assessment opportunities available to the candidate are also considered.

An example

Kerry had worked in the laboratory area for the company for two years. Due to expansion in the company she had been given the opportunity to move into the Scientific Manufacturing area where her skills working in aseptic conditions and with biomaterial would be beneficial to the team. Kerry would be trained in the manufacturing area with a view to becoming a shift team leader within the facility. The new group being trained had a mixture of production experience and laboratory experience. This would require an element of cross training to bring the two skill groups together to form a skilled team. The SVQ structure would be used to show

competence in this area and would provide external verification of competence for regulatory bodies auditing the working practices of the company.

When the Production Manager matched Kerry's job remit and existing skills and experience with the SVQ in Biotechnology Processing at level 3, it emerged that Kerry should be able to generate sufficient evidence to meet the requirements of the following SVQ Units:

- Maintaining Health and Safety in a Biomanufacturing Environment
- Monitoring and Following Aseptic Procedures in a Biomanufacturing Environment
- Monitoring the Preparation of Culture Media and Solutions for Biomanufacturing Upstream Processing

The Production Manager arranged for an assessor within the company to provide Kerry with guidance on how to collect evidence and construct a portfolio to achieve these Units.

Kerry also had some experience in relation to two further Units; however, some planning was required in order to provide her with the opportunity to demonstrate competence in these areas.

The Units were:

- Analysing and Inputting Biomanufacturing Data in a Manufacturing Information System (MIMS)
- Encouraging Problem Solving and Innovation in a Biomanufacturing Team

Kerry had no experience of the areas covered by the final three Units, which were:

- Maintaining Effective and Efficient Biomanufacturing Working Relationships
- Monitoring the Production of Biomaterial Using Bioreactors in Biomanufacturing Upstream Processing
- Monitoring the Harvesting of Fermented Biomaterial into Sterile Containers from a Bioreactor for Biomanufacturing Upstream Processing

All these arrangements were agreed by everyone involved and then written up in an assessment plan for Kerry.

2: Preparing to assess the SVQ

This section offers practical advice on how to begin to go about assessing you candidates for the SVQ. This advice is offered as examples of good practice — you may develop your own approaches to assessing your candidates which also work well.

Your role and your candidate's role

Assessing the SVQ will involve several stages. Both you and the candidate should be clear on your roles in the assessment process before you begin.

Your role

- ensure candidates understand what is to be assessed and how it is to be assessed
- ensure the conditions and resources required for assessment are available
- help candidates to identify and gather evidence
- observe and record candidates carrying out the activities described in the standards — records should say what has been observed, how it was carried out, and what it demonstrates
- assess products of the candidate's own work
- question candidates and record results
- help candidates to present evidence
- authenticate the evidence candidates provide
- judge evidence and make assessment decisions
- identify gaps or shortfalls in candidates' competence
- provide feedback to candidates throughout the assessment process
- record achievement

Candidates' role

- prepare for assessment — become familiar with the standards, what is to be assessed and how it is to be assessed
- help to identify sources of evidence and how these could be assessed
- carry out activities, and/or produce products of own work, and/or answer questions
- gather and present evidence
- receive and act on feedback from the assessor

Planning

In planning for assessment, you will find it helpful to meet with your candidate and plan what is to be assessed, in what way, and when and where the assessment is to take place. This discussion can be confirmed in the form of an agreed assessment plan between you and your candidate.

You should treat assessment plans as working documents — they can be updated and changed as you review progress with your candidate.

As you are planning assessment, don't forget to make the most of opportunities to *integrate* assessment. This means planning to assess an activity which draws on the contents of different Units or Elements. It can be a practical and cost-effective way of assessing your candidate's competence.

If you are a new assessor working towards your A/V Units (the national standards in assessment and verification) you will need copies of completed assessment plans as part of your evidence.

To help you plan for assessment, we have produced an assessment plan which covers Unit:

- Monitoring and Following Aseptic Procedures in a Biomanufacturing Environment

You will notice that we have included spaces to enter dates when the assessment plan has been reviewed. Any gaps identified during these reviews should be discussed with your candidates and noted for action in the assessment plan.

Assessment plan

Unit: Monitoring and Following Aseptic Procedures in the Biomanufacturing Environment					
Activities	**Performance Statements**	**Method of assessment/Sources of evidence**	**Date of assessment**	**Evidence already available**	**Links to other Units (Performance Statements and Scopes)**
Monitoring and following aseptic procedures in a biomanufacturing environment	PS a-g	Observation Questioning	25/05/09 27/05/09	Successful completion of in-house training programme.	Maintaining Health and Safety in a Biomanufacturing Environment.
Questioning for knowledge and understanding not apparent from performance to be identified from 2nd review	PS h still to be covered				

Assessor's signature: *Alan Borthwick*

Candidate's signature: *Kerry McFarlane*

Date of agreement: *18/05/09*

1st review due: *25/06/09*

2nd review due:

Date of completion:

Selecting methods of assessment

The methods of assessment you use should be valid, reliable and practicable.

- By *valid* we mean that the assessment method should be appropriate to the standards.
- By *reliable* we mean that the assessment method should ensure consistent results when used with different candidates, different assessors and on different occasions.
- By *practicable* we mean that the method ensures that the assessment makes best use of available resources, equipment and time.

Before you assess a candidate, you must make sure that the methods of assessment you have chosen to use, along with any assessment materials (such as questions and sample answers) have been agreed within your centre through its system of internal quality assurance. This system is often called *internal verification* — its purpose is to help to ensure that assessment methods are valid, reliable and practicable.

There are both benefits and challenges when you are assessing SVQs in the workplace, or in conditions in the workplace. When you select methods of assessment, you should try to offer the candidate the benefits of workplace assessment and minimise any potential difficulties.

The benefits might be:

- familiar surroundings and working environment
- candidate at ease with colleagues and assessor
- can be planned for routine working
- candidate-driven, therefore planned at time to suit candidate

The challenges might be:

- shift working
- production deadlines
- lack of production
- restricted access

Example

You might agree with a candidate working in a biomanufacturing environment, who has to demonstrate how to monitor and follow aseptic procedures, that this will be carried out by observation when the candidate is next due to enter the plant area. If you are an assessor working in this area then you should be well placed to observe the candidate's performance. It is normal during observation to use a checklist to check off the steps as they are performed. However, in this situation due to the nature of the environment and the restriction of material in and out of the area, it may be necessary to complete

the paperwork after the assessment is completed in an area outside the plant environment. An Expert Witness may be used to observe this activity as they may be best placed to observe the activity. The Expert Witness must meet the criteria specified in the assessment strategy for Scientific Manufacture.

Methods of assessment

Assessment may involve a range of assessment methods. For SVQs, some of the most commonly used methods are observation, product evidence, and questioning.

Observation

Observation by an assessor is considered to be the most valid and reliable method of assessment. It can be organised in a variety of ways:

- working alongside the candidate
- arranging to visit when naturally-occurring activities are carried out by the candidate
- arranging for activities to take place

Observation by the assessor can often be supplemented by other types of assessment methods such as questioning. For example, it may be appropriate to ask oral questions of candidates as they carry out naturally-occurring activities.

Observation could be used to demonstrate the candidate's competence in aseptic techniques. The assessor is able to authenticate the candidate's evidence against the Performance Statements by seeing the candidate follow the procedures required.

Product evidence

As candidates work towards achieving the SVQ, they will produce evidence in the form of products of their work. The nature of this evidence can vary widely depending on what the candidate's job entails, but examples of product evidence include:

- completed batch records to cGMP standards
- product produced within quality control parameters
- computer records from Manufacturing Information Management System

Product evaluation can be used when the procedure being assessed is fairly lengthy and it may not be possible for the assessor to shadow the candidate for this length of time. The candidate is set the task and is judged on the final result, ie the work product. This would obviously be done when the assessor has judged that the candidate has shown the required skills over a period of time. The assessor must be satisfied that the evidence is authentic, valid and reliable.

Questioning

Candidates have to show that they can meet the knowledge specifications for the SVQs. For these SVQs, knowledge and understanding is specified for each unit. Much of a candidate's knowledge and understanding will be apparent from what they do or produce as part of their work, but this will not always be the case, and questioning can be a useful way of confirming what candidates know and understand.

Questions can be asked in a variety of forms, such as oral questions, short answer written questions, and multiple choice.

You should be careful that the method of questioning does not go beyond the competence required for the SVQ and become a barrier to fair assessment. For example, some candidates will feel more comfortable with oral questions than written.

Questions can be used to check that candidates understand why they are doing something, or that they know what to do if something unexpected happens. It checks that they can adapt to situations rather than just follow instructions. It shows the background knowledge that should have been given during training and can identify gaps that may need to be filled in the training.

Examples

Q Why is it important to sign and date all stages of production as they are carried out?

A This is required to comply with cGMP procedures and allow an audit trail to be followed for all stages of the manufacture in the event of future investigations.

Q If a product to be used in the manufacture is found to be out of date what would you do?

A The relevant form would be completed and the material would be removed from stock and placed in the quarantine area. A new batch in date would be used for the production.

Other methods of assessment

These methods, like questioning, are often used for authentication. See section 3 for more about authenticating candidates' evidence.

Personal statements

You might sometimes find it helpful to ask a candidate to give an account of why they did an activity in a certain way or how they produced a product of their work. This is often referred to as a *personal statement*. You should take care to ensure that by asking candidates to produce such statements, you are not asking them to demonstrate competence beyond what is required by the standards. You should also be selective in the use of personal statements, and make sure they have not been produced as a substitute to a more valid, reliable and practical method of assessment.

An example

A personal statement describes how the candidate would deal with, or has dealt with, a specific situation, ie the candidate may encounter an issue during production which is not routine and is therefore an unplanned action. This may happen on shift when the assessor is not available to witness the situation. The candidate would give a full account of the situation explaining what they did and the outcome of the activity. The personal statement should be confirmed by a reliable witness and/or further questioning by the assessor for authentication purposes.

Professional discussion

This can be used for evidence where it is not always possible to plan an assessment, for example when things happen unexpectedly, or are one-offs. The candidate can be involved in an incident or problem solving exercise during routine working. They can write up this experience and use a record of professional discussion by a reliable witness or assessor who can endorse the role played by the candidate to state what the candidate did and how they handled the situation.

Witness testimony

For practical reasons, you may not be able to observe all the activities carried out by your candidates, but might feel that other people may be able to provide a statement on what your candidates have been doing or producing as part of their work. Statements of this kind are called *witness testimony*, and are often used to support other evidence produced by candidates. If witness testimony is used, you should, ideally, identify witnesses and opportunities for using their testimony as part of assessment planning.

You should bear in mind that the weight of the evidence will vary, depending on the knowledge and expertise of the person providing the witness testimony. You will have to take these factors into account as you make your judgement.

Strongest	Someone with considerable occupational expertise in the candidate's area of work and who is familiar with the standards. This person may also be an assessor or internal verifier qualified with the A/V Units or 'D-Units'.
	Someone with considerable occupational expertise in the candidate's area of work and who is familiar with the standards.
	Someone with considerable occupational expertise in the candidate's area of work, but with no knowledge of the standards.
	Someone who may be a colleague of the candidate, but with no knowledge of the standards.
Weakest	Someone with no or little knowledge of the candidate's work or no knowledge of the standards.

Witness testimony is unlikely to be sufficient in itself for a decision about the candidate's competence, and would normally be supplemented by questioning candidates.

Witness testimony can be used when it is not always possible for the assessor to be present or available. The expert witness must have expertise in the area being assessed and have been given guidance into the SVQ procedures and standards they are being asked to witness. The assessor may not have the detailed knowledge of certain equipment or systems that others in the team have and it is therefore advisable to utilise the knowledge of the expert witness to carry out the assessment or provide the underpinning questions required to confirm competence.

It is not necessary for the expert witness to hold assessor qualifications, as a qualified assessor must make the assessment decision on the evidence submitted. However if the expert witness is likely to be used on a regular basis it can be good practice to encourage them to do the assessor award (A1) as professional development.

Simulation
Simulation is any structured assessment exercise involving a specific task which reproduces real-life situations.

On some occasions, it may not be practical to assess a candidate in real work. Examples might be where the standards require candidates to carry out emergency or contingency procedures, or where client confidentiality is an issue, or where a candidate's job role does not cover all aspects of the qualification.

SEMTA has defined what it regards as simulation, and has specified in the standards when simulation is and is not acceptable. The standards also state when candidates must demonstrate competence in the workplace.

For more details on simulation and what constitutes performance in the workplace, look at the assessment strategy on SQA's website: **www.sqa.org.uk**.

Assessment environment
Simulation for this award is permitted in occurrences such as:

- emergency scenarios
- health, safety and environmental issues
- infrequent operations at work
- responding to faults and problems where no opportunity has occurred for the use of naturally-occurring workplace evidence

Other sources of evidence

Other sources of evidence can be previous experience or learning, case studies or assignments.

SQA's *Guides to Assessment and Quality Assurance* (see section 5) have more advice on methods of assessment and how to ensure that your assessment is valid, reliable and practicable.

3: Generating evidence

The methods of assessment you use should generate sufficient evidence to demonstrate the candidate's competence.

We described earlier the circumstances in which you might choose to use different methods of assessment. Starting on the next page, this section gives you examples of forms which you can use to record and present evidence of:

- observation (by the assessor)
- questions and candidate responses
- personal statement (produced by the candidate)
- witness testimony

There are blank forms which you can copy and use in assessment in Appendix 1.

Observation

For observation, note that the form asks you to record the skills and activities observed. This helps you to make a judgement on how the activity was carried out and what it demonstrates.

Observation record

Unit/Element(s): Monitoring and Following Aseptic Procedures in a Biomanufacturing Environment
Candidate: Kerry McFarlane **Date of observation:** 25/05/09
Evidence index number: 1A

Skills/activities observed:	Performance Statements covered:
Works safely at all times complying with health and safety, company regulations, COSHH etc.	a
Ensures all necessary equipment and materials are available for procedure.	a
Dresses in the appropriate manner with correct PPE.	b
Carries out required checks.	c
Carries out correct procedure for entry and exit of area in accordance with company policy and guidelines.	d
Follows aseptic techniques throughout procedures.	e
Clears all equipment and disposes of any waste in accordance with procedures.	f
Records information.	g
Informs those who require information or need to act on information in an appropriate and timely manner.	g, h

Knowledge and understanding apparent from this observation:
Sector Specific — S1, S3 and S4
Organisational Specific — O2,O3,05,07
Equipment/Process Specific — E1,E2,E3,E5,E6,E7,E10,E11,E12,E13,E14,E15,E16 and E17

Other Units to which this evidence may contribute:
Unit 01 Maintaining Health and Safety in a Biomanufacturing Environment.

Assessor's comments and feedback to candidate:
Kerry was observed entering the manufacturing facility, carrying out routine working and leaving the facility. Kerry showed excellent understanding of the procedures to be followed and explained what she was doing and why for a lot of the procedures as she worked through them. She worked confidently and covered most of the scope and knowledge required for this Unit. A question and answer session following this observation will confirm the underpinning knowledge of any areas not covered by the observation. A competent piece of work.

I can confirm the candidate's performance was satisfactory.

Assessor's signature: *Alan Borthwick* Date: *25/05/09*
Candidate's signature: *Kerry McFarlane* Date: *25/05/09*

Questions and candidate responses

This form can be used to record any questions you might ask the candidate to establish what they know and understand. You should note the candidate's responses on this form too.

Note that there is a space near the top of the form for you to record when, where, how and why you asked the questions.

Where you want to give the candidate written questions, this form could also be used.

Record of questions and candidate's answers

Unit: Monitoring And Following Aseptic Procedures in a Biomanufacturing Environment	**Unit Knowledge Statements:** S2, O1, O4, E4
Evidence index number: 1B	
Circumstances of assessment: Following entry to the manufacturing area, routine working and exit of the area the following questions are used to check the underpinning knowledge.	

List of questions and candidate's responses:

Q: Why is it important to have all equipment prepared prior to starting clean room procedure?

A: Once you have entered the clean area, if you have to leave to collect any other equipment this would require disposal of PPE applied and re-entry using new PPE which is wasteful and very time consuming, therefore planning is a vital part of the procedure.

Q: Why is it important to follow the clothing procedures in the stated order?

A: To ensure compliance with protocol and to avoid possible contamination breaches.

Q: What would you do in the event of airflow failure in the area?

A: Cease all work and leave it in a safe state, leave the area using the correct procedures as laid down in the company policy. Report the issue to the relevant supervisor and do not re-enter until the correct conditions are restored.

Q: Why is it important to identify all materials used and record all stages of the process?

A: To meet cGMP compliance and ensure audit trail is maintained in the event of any enquiry/problems from end user or regulatory bodies.

Q: How is waste material from the clean room dealt with?

A: Disposable items are bagged and sent out for incineration, and any reusable items are placed in appropriate sealed bags and sent for laundering.

Assessor's signature: *Alan Borthwick* Date: *26/05/09*

Candidate's signature: *Kerry McFarlane* Date: *26/05/09*

Candidate's personal statement

If a personal statement is being used as evidence, it should be completed by the candidate. The statement should record what they did, how and why they chose to carry out an activity or produce work in a certain way. Where other people may have been present during an activity and they may be able to provide witness testimony, the candidate should record how the statement links to other evidence in the column provided.

Personal statement

Date	Evidence index number	Details of statement	Links to other evidence (enter numbers)	Unit, Performance Statements covered
18/07/09	1C	During my shift on 18/07/09 while working in the biomanufacturing area the airflow system in the facility failed. This is the first time while working I had experienced this happening and although I had been trained in what to do if this happened I had never had to put this into practice. The team I was with promptly put everything required in a safe state as per the procedures and I ensured everyone left the area following the decontamination procedures. I contacted the relevant supervisor and reported the incident to enable the fault to be passed onto maintenance personnel for repair. The required non-conformance paperwork was completed to record the incident and to ensure compliance with cGMP. I feel I handled this situation well and while I hope not to come across this very often I was glad of the opportunity to experience it for real. It has given me confidence in my ability to handle the unexpected.	1A,1B	Unit 01 PS a–e, g, h, k & l Unit 03 PS a, b, d, f, g & h

Signed (candidate): Kerry McFarlane

Date: 19/07/09

Witness testimony

Remember when you begin to use witness testimony that it must be capable of being authenticated — even if the testimony itself is being used to authenticate a candidate's claim to competence.

To make sure the witness testimony is genuine, you must ensure that you have a record of who is acting as a witness, their relationship to the candidate (eg supervisor, client) address, telephone number and the date. There are spaces for this information in the form.

Witness testimony

SVQ title and level:	Scientific Manufacture level 3
Candidate's name:	Kerry McFarlane
Evidence index no:	1D
Index no of other evidence which this testimony relates to (if any):	1A
Unit(s):	Unit 01 and Unit 03
Date of evidence:	18/07/09
Name of witness:	Norman Fletcher
Designation/relationship to candidate:	Senior colleague

Details of testimony:

During our shift on 18/07/09 there was a failure in the airflow system within the biomanufacturing area. Kerry was first to act on this and she ensured everything was placed in a safe state and that everyone left the area in the designated manner. Kerry then contacted the relevant personnel to report the failure and initiate the rectification of the fault. All relevant paperwork was completed and the incident was dealt with and resolved in a timely and efficient manner. This is not a regular occurrence and not something that many people have had to deal with in a live situation. I feel Kerry handled this in a confident and efficient manner and would be happy to confirm her competence in this task.

I can confirm the candidate's evidence is authentic and accurate.
Signed by witness: *Norman Fletcher* Date: 19/07/09

Witness (please tick the appropriate box)**:**

☐ Holds A1 or D32/D33 qualifications

☑ Is familiar with the SVQ standards to which the candidate is working

Filling the gaps

There may come a time when your candidate has provided evidence for most of the Unit (or SVQ), but there are some gaps. For example, you may find that certain situations, such as handling contingencies, have not arisen during assessment. Often these will relate to dealing with health and safety issues, or unexpected problems with workflow like delays in receiving information from another part of the organisation.

In this SVQ, such gaps are likely to occur in generating evidence for:

- dealing with spillages
- seeing a particular part of the process due to shift patterns

You may be able to overcome these by:

- simulation
- change of shift

Simulation would be required to demonstrate the appropriate responses in the event of a spillage and should be carried out to duplicate as much as possible the same pressures and responses that would occur in the real event, eg using inert substances as a substitute for the hazardous material in question, but going through the full scenario in real time.

Some process cycles can mean that some shifts may not see certain procedures for long periods. In this instance it may be necessary to change a candidate's shift for a period to allow them to experience the procedure and gain practical experience.

Guidance and support to candidates

At all times during the assessment process — from planning through to making your assessment decision — feedback should be on-going, clear and constructive. Feedback should be given against the national standards by relating it to the evidence provided, including the knowledge specifications.

Where there are any shortfalls in a candidate's competence, you should discuss these with your candidate and make plans for re-assessment.

Judging candidate evidence and making an assessment decision

In judging candidate evidence, you must be satisfied that your candidates can work consistently to the required standard, and that the evidence they have produced is their own. You must consider whether your candidate understands and applies the knowledge evidence and how this links to performance evidence.
Evidence must:

- be relevant to the SVQ
- be authentic
- show current competence
- be sufficient to help you form a decision about the candidate's competence

Insufficient evidence

You have to judge whether the candidate has produced enough evidence required by the standards for you to reach a decision about their evidence.

Where there is insufficient evidence, you should say this to your candidate. You should tell them that it is not that they are not yet competent — there is simply not enough evidence on which to make a decision.

In this situation, your feedback to your candidates must help them produce more evidence and/or plan for further assessment.

Authenticating candidates' evidence

Authentication is required where you have not observed candidates' performance at first hand.

You can check whether a candidate has produced evidence which they claim shows their competence by questioning them or, if this is appropriate, asking them to produce a personal statement, using witness testimony, or seeking peer reports from other colleagues of the candidate.

Example

Due to the nature of the business and the need for company confidentiality, a candidate may have referenced documents that they have signed and completed as evidence of competence in a particular Unit but they are unable to include these in their portfolio. In these cases the candidate should indicate what the evidence is and where it can be located in order that the Assessor, Internal or External Verifier can access this information in order to authenticate the evidence, but also keep the evidence secure.

4: Recording achievement

You should retain all evidence — clearly referenced — for internal and external verification.

The candidate's evidence is normally kept in a file, often called a *portfolio*. These documents help you and your candidates to collect, present and cross-reference the evidence to the national standards. They are also a means of recording your assessment decisions, and they tell an external verifier what stage a candidate has reached in achieving the SVQ.

Examples of recording documents are included in this pack 'Should you choose to use your own recording material, this has to be approved by us or by the awarding partner (where this is a requirement).'

Recording documents do not need to be paper-based — it is possible to use an electronic format for collecting and structuring the evidence. Whatever format you and your candidates choose to use, the documents must show what evidence was generated, the assessment decisions you made, how the evidence meets the standards, and where the evidence can be located. You should avoid photocopying items simply to put them in a portfolio — a clear explanation of where the evidence can be found (for example, in a filing cabinet) may be sufficient for the external verifier to follow it up and include it in the visit.

There are various reasons why record-keeping is so important:

- it provides a way of tracking a candidate's progress in achieving an SVQ
- it helps candidates to make claims for certification of their competence
- internal verifiers and external verifiers use the records to sample assessment decisions
- it helps us to monitor the quality assurance of our qualifications

If your candidates' evidence is incomplete, or cannot be located, or if there is inaccurate cross-referencing to the standards, there is a risk that an internal verifier or external verifier will be unable to confirm your assessment decisions.

To help you and your candidate present evidence and record your assessment decision, we have provided examples of the forms which you and your candidate might use to compile the portfolio.

- Completing the Unit progress record
- Using the evidence index
- Completing the Unit achievement record

These forms are also used in SQA's portfolio.

Completing the Unit progress record

You should complete this form each time your candidate achieves a Unit from the SVQ by adding your signature and the date next to the relevant Unit.

At this stage, candidates should make sure they have completed the recording documents correctly and that their evidence can be easily located. Only then should they circle the relevant Unit number at the top of the form. This enables both of you to see at a glance what stage the candidate is at in their SVQ.

Unit progress record

Qualification and level: Scientific Manufacturing (Biotechnology Processing) at level 3

Candidate: Kerry McFarlane

To achieve the whole qualification, you must prove competence in 3 **mandatory** Units and 5 **optional** Units.

Unit Checklist

Mandatory	**01**	**02**	**(03)**									
Optional	**(04)**	**06**	**(11)**	**12**	**13**							

Mandatory Units achieved

Unit Number	Title	Assessor's Signature	Date
01	Maintaining Health and Safety in a Biomanufacturing Environment	*Alan Borthwick*	*18/08/09*
02	Maintaining Effective and Efficient Biomanufacturing Working Relationships		
03	Monitoring and Following Aseptic Procedures in a Biomanufacturing Environment	*Alan Borthwick*	*20/07/09*

Optional Units achieved

04	Analysing and Inputting Biomanufacturing Data in a Manufacturing Information Management System (MIMS)	*Alan Borthwick*	*15/10/09*
06	Encouraging Problem Solving and Innovation in a Biomanufacturing Team.		
11	Monitoring the Preparation of Culture Media and Solutions for Biomanufacturing Upstream Processing.	*Alan Borthwick*	*10/01/10*
12	Monitoring the Production of Biomaterial using Bioreactors in Biomanufacturing Upstream Processing.		
13	Monitoring the Harvesting of Biomaterial into Sterile Containers from a Bioreactor for Biomanufacturing Downstream Processing.		

Using the index of evidence

The purpose of the index of evidence is to help you locate and work through the candidate's evidence. It should give you a summary of what evidence the candidate has collected, and where (eg in a portfolio) it can be found.

The index of evidence should be completed by entering:

- the index number for each piece of evidence
- a description of each piece of evidence
- the place or location where it can be found
- the initials of the internal verifier and the date (if they have sampled the candidate's evidence)

Ideally, it should be candidates themselves (with your support and encouragement) who complete the index.

You must make sure that the information in the evidence index is accurate when your candidates' portfolios are presented for assessment and verification — particularly the information about where the evidence can be located. This is important because we suggest that anything which has been produced as day-to-day work is kept in its normal location, but anything which has been produced through assessment for the SVQ, eg observation checklists, is filed in the candidate's portfolio. In this way, your candidate can avoid having to photocopy work products just for the sake of including them in a portfolio. It also means that evidence produced as a result of assessment is kept safely in a central file.

If the index of evidence is not completed with an accurate description and location of the evidence, there is a risk that an internal verifier or external verifier might be unable to confirm your assessment decisions.

Index of evidence

SVQ title and level: Scientific Manufacture at level 3

Evidence number	Description of evidence	Included in portfolio (Yes/No) If no, state location	Sampled by the IV (initials and date)
1A	Observation — Unit 03	Y	AS 18/08/09
1B	Questions and Answer sheet — Unit 03	Y	AS 18/08/09
1C	Personal statement — dealing with airflow failure	Y	AS 18/08/09
1D	Witness Testimony — dealing with airflow failure	Y	AS 18/08/09

Completing the Unit achievement record

To help you and your candidates cross-reference the evidence to the standards of the SVQs, we have provided records similar to those produced in the SQA portfolio. Use one record for each Element. The grids should be completed by:

- entering the evidence index number in the first column
- giving a brief description of the evidence in the second
- ticking the relevant boxes for the Performance Statements and Scopes
- entering the areas of knowledge and understanding (knowledge statements) the piece of evidence covers

If integrated assessment is used (linking Performance Statements or Scopes across different Units) the evidence should be cross-referenced back to the relevant Units.

We have provided a completed example to show how to use the record.

Unit achievement record

Unit: 03 Monitoring and Following Aseptic Procedures in a Biomanufacturing Environment

Evidence Index No	Description of Evidence	Performance Statements								Knowledge Statements																												
		a	b	c	d	e	f	g	h	S1	S2	S3	S4	01	02	03	04	05	06	07	E1	E2	E3	E4	E5	E6	E7	E8	E9	E10	E11	E12	E13	E14	E15	E16	E17
1A	Observation	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓		✓	✓		✓			✓	✓	✓		✓	✓	✓			✓	✓	✓	✓	✓	✓	✓	✓
1C	Personal statement	✓	✓		✓		✓	✓	✓	✓		✓	✓		✓			✓	✓	✓	✓	✓	✓		✓			✓	✓	✓							
1B	Question & Answer										✓			✓			✓							✓														

Unit: 03 Monitoring and Following Aseptic Procedures in a Biomanufacturing Environment

Notes/Comments

This Unit has been assessed by direct observation, question and answer, personal statement and witness testimony and the Assessor is satisfied that the evidence presented satisfies the criteria set by the awarding body.

The candidate has satisfied the Assessor and Internal Verifier that the performance evidence has been met.

Candidate:	Kerry McFarlane	Date:	20/11/09
Assessor:	Alan Borthwick	Date:	20/11/09
Internal Verifier:	Amir Shah	Date:	30/11/09

5: Further information

What else should I read?

The publications listed here provide additional information on how to implement SVQs. Details of these and other SQA publications are available on our website at **www.sqa.org.uk** on the 'Publications, Sales and Downloads' section. They can be ordered from SQA's Customer Contact Centre — telephone 0845 279 1000. Please note that there may be a charge for some of these publications.

Assessor/Verifier Units: assessment guidance

External Assessment Moderation in National Qualifications and Higher National Qualifications: a guide for centres

Guide to Assessment and Quality Assurance for Colleges of Further Education

Guide to Assessment and Quality Assurance for Employers and Training Providers

Arrangements for Candidates with Disabilities and/or Additional Support Needs in Examinations and Assessments

Quality Assurance Principles, Elements and Criteria

Operational Help Centre

The Operational Guide for Centres has been replaced by the online Operational Help Centre on **www.sqa.org.uk**

Appendix 1: Blank recording forms

Unit progress record

Qualification and level:

Candidate:

To achieve the whole qualification, you must prove competence in ___ **mandatory** Units and ___ **optional** Units.

Unit Checklist

Mandatory										
Optional										

Mandatory Units achieved

Unit	Assessor's Signature	Date

Optional Units achieved

Index of evidence

SVQ title and level:

Evidence number	Description of evidence	Included in portfolio (Yes/No) If no, state location	Sampled by the IV (initials and date)

Unit achievement record

Unit:

Evidence Index No	Description of Evidence	Performance Statements						Knowledge Statements												

Unit:

Performance Statements:

Notes/Comments

The candidate has satisfied the Assessor and Internal Verifier that the performance evidence has been met.

Candidate:	**Date:**
Assessor:	**Date:**
Internal Verifier:	**Date:**

Personal statement

Date	Evidence index number	Details of statement	Links to other evidence (enter numbers)	Unit, Performance Statements covered

Signed by candidate:

Date:

Observation record

Unit:

Candidate:

Date of observation:

Evidence index number:

Skills/activities observed:	**Performance Statements covered:**

Knowledge and understanding apparent from this observation:

Other Units to which this evidence may contribute:

Assessor's comments and feedback to candidate:

I can confirm the candidate's performance was satisfactory.

Assessor's signature: **Date:**

Candidate's signature: **Date:**

Witness testimony

SVQ title and level:	
Candidate's name:	
Evidence index no:	
Index no of other evidence which this testimony relates to (if any):	
Units:	
Date of evidence:	
Name of witness:	
Designation/relationship to candidate:	
Details of testimony:	
I can confirm the candidate's evidence is authentic and accurate. **Signed by witness:** **Date:**	

Witness (please tick the appropriate box)**:**

☐ Holds A1/A2 Units or D32/D33 Award

☐ Is familiar with the SVQ standards to which the candidate is working

Record of questions and candidate's answers

Unit:	**Performance Statements**
Evidence index number:	
Circumstances of assessment:	
List of questions and candidate's responses:	
Assessor's signature:	**Date:**
Candidate's signature:	**Date:**