National Unit Specification: general information

UNIT Health Sector: Life Sciences Industry and the Health Sector (SCQF level 5)

CODE F88F 11

SUMMARY

This Unit has been designed as a mandatory Unit of the SCQF level 5 Health Sector Course, but can also be taken as a freestanding Unit. It is suitable for candidates who have no previous experience of the Health Sector.

This Unit is designed to introduce candidates to the contribution of the life sciences industry in the diagnosis and treatment of illness. Candidates will investigate the safety of pharmaceutical products made by the life sciences industry and the health and safety responsibilities of employers and employees in the life sciences industry. Candidates will also undertake a risk assessment in relation to production, storage or use of products made by the life sciences industry.

The Health Sector includes the National Health Service (NHS) (primary and secondary care), Independent Healthcare, Complementary Therapies, the Life Sciences and Retail Pharmaceutical Industries and the Community and Voluntary Sector.

OUTCOMES

1 Investigate the contribution of the life sciences industry to a specified patient journey.
2 Investigate the safety of pharmaceutical products made by the life sciences industry.
3 Explain health and safety responsibilities in the life sciences industry.
4 Carry out a risk assessment to a given brief.

RECOMMENDED ENTRY

Entry is at the discretion of the centre.

Administrative Information

Superclass: RH

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National Unit Specification: general information (cont)

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CREDIT VALUE

1 credit at SCQF level 5 (6 SCQF credit points at SCQF level 5*).

**SCQF credit points are used to allocate credit to qualifications in the Scottish Credit and Qualifications Framework (SCQF). Each qualification in the Framework is allocated a number of SCQF credit points at an SCQF level. There are 12 SCQF levels, ranging from Access 1 to Doctorates.*

CORE SKILLS

Achievement of this Unit gives automatic certification of the following:

Complete Core Skill	None
Core Skill component	Critical Thinking at SCQF level 4

There are also opportunities to develop aspects of Core Skills which are highlighted in the Support Notes of this Unit Specification.

National Unit Specification: statement of standards

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Acceptable performance in this Unit will be the satisfactory achievement of the standards set out in this part of the Unit Specification. All sections of the statement of standards are mandatory and cannot be altered without reference to SQA.

OUTCOME 1

Investigate the contribution of the life sciences industry to a specified patient journey.

Performance Criteria

(a) Identify the main stages of a specified patient journey.
(b) Explain the contribution of a product made by the life sciences industry at each appropriate stage of a specified patient journey.

OUTCOME 2

Investigate the safety of pharmaceutical products made by the life sciences industry.

Performance Criteria

(a) Identify the essential features of pharmaceutical products.
(b) Describe the phases of testing a new pharmaceutical product.
(c) Describe the responsibilities of consumers when using pharmaceutical products.

OUTCOME 3

Explain health and safety responsibilities in the life sciences industry.

(a) Explain the health and safety responsibilities of employees in the life sciences industry.
(b) Explain the health and safety responsibilities of employers in the life sciences industry.

OUTCOME 4

Carry out a risk assessment to a given brief.

(a) Identify the main hazards present.
(b) Explain the associated risks.
(c) Identify a control measure for each risk.

National Unit Specification: statement of standards (cont)

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EVIDENCE REQUIREMENTS FOR THIS UNIT

Written and /or recorded oral evidence and performance evidence which covers all Outcomes and Performance Criteria is required for this Unit.

Outcome 1 — Written and/or oral evidence

Evidence for Outcome 1 will be gathered in open-book conditions at appropriate points throughout the Unit. Candidates will investigate a patient journey for a specified medical condition and the contribution of a product made by life sciences industry at **each** stage of the journey. The patient journey to be investigated will be negotiated and agreed with the teacher/lecturer. Evidence will be gathered in a candidate folio. Candidates will be given a brief for the investigation.

Candidates are required to:

- identify **four** stages of **one** patient journey
- explain the contribution of **one** product made by the life sciences industry at **each** appropriate stage of the specified patient journey

The stages of the patient journey will be selected from the range below:

- prevention
- screening
- investigation
- diagnosis
- treatment
- follow up
- maintenance of health

Outcome 2 — Written and/or oral evidence

Evidence for Outcome 2 will be gathered at appropriate points throughout the Unit. Evidence will be gathered under supervision in open-book conditions with the candidates having access to notes.

Candidates are required to:

- identify **four** essential features of pharmaceutical products
- describe **three** phases of testing of a new pharmaceutical product
- describe **three** responsibilities of consumers when using pharmaceutical products

Examples of essentials features of pharmaceutical products made by the life sciences industry and the responsibilities of consumers when using pharmaceutical products are given in the Support Notes.

Outcome 3 — Written and/or oral evidence

Evidence for Outcome 3 will be gathered at an appropriate point in the Unit. Evidence will be gathered under supervision in open-book conditions with candidates having access to notes.

Candidates are required to:

- explain **two** health and safety responsibilities of employees in the life sciences industry
- explain **four** health and safety responsibilities of employers in the life sciences industry

Outcome 4 — Written and/or oral evidence

Evidence for Outcome 4 will be gathered under supervision in open-book conditions at appropriate points in the Unit. Candidates will be provided with a brief specifying the context within which the risk assessment will be carried out. The context must be in relation to production, storage or use of products made by the life sciences industry.

Candidates are required to:

- identify **three** hazards
- explain **one** risk associated with each hazard
- identify **one** control measure for each risk

The evidence for Outcome 4 must be presented in the form of a completed risk assessment. The risk assessment will be carried out in a real or simulated setting under supervision at an appropriate point in the Unit. Guidance on appropriate settings is provided in the support notes.

Candidates must organise and present findings in an appropriate format. A template for the risk assessment will be provided.

The National Assessment Bank (NAB) pack provided for this Unit illustrates the standard that should be applied. It contains an investigation pro forma, candidate brief, series of structured questions and a risk assessment template. If a centre wishes to design its own assessments for this Unit, they should be of a comparable standard.

National Unit Specification: support notes

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This part of the Unit Specification is offered as guidance. The support notes are not mandatory.

While the exact time allocated to this Unit is at the discretion of the centre, the notional design length is 40 hours.

GUIDANCE ON THE CONTENT AND CONTEXT FOR THIS UNIT

This Unit has been designed as a mandatory Unit of the SCQF level 5 Health Sector Course, but can also be taken as a freestanding Unit. It is suitable for candidates who have no previous experience of the Health Sector.

This Unit is designed to introduce candidates to the contribution of the life sciences industry in the diagnosis and treatment of illness. Candidates will investigate the safety of pharmaceutical products made by the life sciences industry and the health and safety responsibilities of employers and employees in the life sciences industry. Candidates will also undertake a risk assessment in relation to production, storage and use of products made by the life sciences industry.

The Health Sector includes the National Health Service (NHS) (primary and secondary care), Independent Healthcare, Complementary Therapies, the Life Sciences and Retail Pharmaceutical Industries and the Community and Voluntary Sector.

The Unit will involve candidate research which will encourage the development of time management, information retrieval and research skills.

Outcome 1

A patient journey describes the route taken by a patient from screening or initial symptoms through a variety of tests to confirm the presence of a specific disease or condition to treatment, discharge and follow up and monitoring of the condition. Candidates will investigate a typical patient journey for a specified medical condition and outline the contribution of the life sciences industry to that journey. The stages of the patient journey are specified within the Evidence Requirements.

Examples of patient journeys are provided in the Guidance on Learning and Teaching Approaches section of this Unit Specification.

The folio could be produced in a variety of formats, eg a presentation, display, poster or leaflet. The language and materials used throughout should promote equality and diversity and avoid cultural stereotypes. Candidates should be encouraged to identify ways in which their folio or presentation of information reflects and promotes equality and diversity. This could include the use of signs, symbols, pictures etc.

National Unit Specification: support notes (cont)

UNIT Health Sector: Life Sciences Industry and the Health Sector (SCQF level 5)

Outcome 2

Drug discovery is the discovery, development and approval of new chemical compounds or biological products that can be used to treat human disease. The life sciences industry develops and produces pharmaceutical products including drugs. The essential features of pharmaceutical products include the requirements that they should be:

- safe to use for patients and staff
- effective
- reliable
- acceptable to use for patients and staff
- cost effective
- have minimal side effects
- be comfortable to use
- have no adverse effects
- ethically produced and tested

Drug trials refer to the process by which medicines are developed. Before a drug is tested on humans, it would have been through laboratory and/or animal testing. Medicines are also tested for toxicity before being given to people. There are then three stages of drug testing on humans — and any such trials have to be approved by the ethics committee.

- **Phase one** — this stage tests for safety. A small number of people, sometimes healthy, and sometimes with a medical condition, are given a tiny dose of the drug under careful supervision, not to test if the drug works, but in order to check for any side effects.
- **Phase two** — the drug is given to people who have the condition to see if it does indeed help them.
- **Phase three** — large scale studies usually involving tens or thousands of people. Participants are often randomly allocated to either get the drug or a dummy version. In most cases neither the scientists nor the patients know who has got the real drug so that the results cannot be skewed by expectations.

Candidates should be encouraged to discuss and debate issues around the development of new drugs and vaccines to treat and prevent illness and disease. They should research current stories in the news and media about trials of new drugs and vaccines and issues around animal testing.

Consumers of pharmaceutical products are responsible for ensuring that pharmaceutical products are used and stored correctly.

The responsibilities of consumers when using pharmaceutical products include:

- take medicines only as prescribed by a doctor or pharmacist
- keep all medicines in their original containers
- store medicines and biomedical devices according to instructions
- use biomedical devices as instructed
- discard of used medicines as instructed
- do not take medication or use biomedical devices prescribed for another person
- keep out of the reach of children
- report any adverse effects to a doctor
- do not take medication during pregnancy unless approved by a doctor
- ensure biomedical devices are stored, cleaned and maintained according to instructions

Outcome 3

The health and safety of employees in the life sciences industry is ensured by risk assessment Teachers/lecturers should ensure that candidates are informed that the Health and Safety at Work Act is the main piece of legislation covering health and safety in the workplace. Both employers and employees have responsibilities in relation to health and safety.

The responsibilities of employees in relation to health and safety include:

- to co-operate with the employer, attend relevant training and follow the company's health and safety policies
- to take care of own health and safety and the safety of others
- to report any injuries
- to tell your employer if anything happens that might affect your ability to do the job

The responsibilities of employers in relation to health and safety include:

- to make the workplace safe
- to prevent risks to health
- to ensure machinery is safe to use and safe working practices are set up and followed
- ensure materials are handled, stored and used safely
- to tell employees about any potential hazards from the work they do, chemicals and other substances used by the firm, and give information, instructions, training and supervision as needed
- to provide protective clothing or equipment free of charge if risks can't be removed or adequately controlled by any other means
- to ensure that the right warning signs are provided

National Unit Specification: support notes (cont)

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Outcome 4

Candidates should be made aware of the difference between a hazard and a risk. A definition is provided below:

- a hazard is something with the potential to cause harm
- a risk is the likelihood of harm from that hazard

Candidates should learn about risk assessments and how these are carried out using current health and safety guidelines.

The five steps in a risk assessment are:

- identify the hazards
- decide who might be harmed and how
- evaluate the risks and decide on precautions
- record your findings and implement them
- review your assessment and update if necessary

Candidates will learn how to carry out a risk assessment in relation to production, storage or use of products made by the life sciences industry for use in the Health Sector.

The risk assessment could be in relation to:

- the storage of biomedical devices in a practical room or Health Sector environment
- a visit by the class to a life sciences facility
- a medicine cabinet and contents
- the use of products made by the life sciences industry in the Health Sector

Candidates will be given a brief specifying the risk assessment to be carried out. The risk assessment will be carried out in a real or simulated environment.

Employability Skills

In this Unit candidates will generate evidence for the following employability skills:

- positive attitude to learning and the workplace
- self respect and respect and consideration for others
- understanding of roles and responsibilities in the workplace
- understanding of health and safety
- understand and seek clarification of instructions
- demonstrate an awareness of organisational standards for appearance and behaviour
- understanding of organisational principles and values in the Health Sector

National Unit Specification: support notes (cont)

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Although not directly assessed in this Unit, there may be opportunities to develop the following employability skills:

- awareness of equality and diversity
- reflecting on own abilities
- contribute to team work
- implementation of infection control procedures

These skills can be practised in real or simulated workplace environments and individual or group classroom activities.

GUIDANCE ON LEARNING AND TEACHING APPROACHES FOR THIS UNIT

Outcome 1

Candidates must identify the stages of the patient journey they are investigating. Evidence could be presented in the form of a diagram illustrating the involvement of the life sciences industry throughout the patient journey. The following are examples of the beginning of patient journeys:

- a woman being called for a routine mammogram as part of the breast cancer screening programme
- a woman who thinks she may be pregnant
- a young man in an accident resulting in a broken leg
- a man being told he may have diabetes
- a man complaining of toothache
- an elderly person needing a hip replacement
- an elderly person being investigated for Alzheimer's Disease
- a young person having a test for HIV

The needs of patients and their health problems differ as they move through their journey from diagnosis through care and treatment to recovery. Visiting speakers and workplace visits can provide valuable insight into the contribution of the life sciences industry to the treatment of patients. Candidates should be encouraged to work in groups and share information.

Outcome 2

Visiting speakers and workplace visits can provide valuable insights into the ways that the life sciences industry ensures the safety of its products. Candidates should be encouraged to discuss topical issues in relation to the testing of new drugs such as vaccines for the H1N1 virus, Human Papilloma virus or new cancer treatments.

Outcome 3

Teachers/lecturers should ensure that candidates understand that the health and safety responsibilities of employers and employees in the life science industry are the same as in any other industry.

Outcome 4

As part of learning and teaching a range of scenarios could be devised demonstrating the hazards and risks associated with the manufacture, storage and use of products made by the life sciences industry for use in the Health Sector. The scenarios could be presented to candidates in the form of written descriptions, multimedia presentations, illustrations, computer simulations, real work environments and classroom mock ups. It is essential that candidates experience health and safety as an interactive process and delivery should be based on practical scenarios wherever possible.

Delivery of this Unit could incorporate a variety of teaching and learning methods including:

- teacher/lecturer presentations and demonstrations
- group work and discussions
- handouts
- visiting speakers
- workplace visits
- practical activities
- individual and group research
- Internet searches
- DVD presentations
- interviews with health professionals/patients/relatives/workers

OPPORTUNITIES FOR CORE SKILL DEVELOPMENT

In this Unit candidates will be involved in an investigation. There may be opportunities for candidates to work with others which would enable them to develop effective communication and interpersonal skills. If the candidate uses a computer while undertaking any part of this Unit, they will have the opportunity to develop *Information and Communication Technology* skills.

GUIDANCE ON APPROACHES TO ASSESSMENT FOR THIS UNIT

Outcome 1

The evidence will be gathered in a candidate folio which will include information on a patient journey.

The information will include:

- identification of **four** stages of the identified patient journey
- explanation of the contribution of **one** product made by the life sciences industry at each appropriate stage of the specified patient journey

The evidence will be gathered in open-book conditions at appropriate points throughout the Unit.

National Unit Specification: support notes (cont)

UNIT Health Sector: Life Sciences Industry and the Health Sector (SCQF level 5)

Outcome 2

The evidence will be produced in supervised open-book conditions. The evidence will be produced by the candidate on their own at an appropriate point during the Unit. Evidence could be gathered in response to a series of structured questions, within the time limit of one hour.

Outcome 3

The evidence will be produced in supervised open-book conditions. The evidence will be produced by the candidate on their own at an appropriate point during the Unit. Evidence could be gathered in response to a series of structured questions, within the time limit of one hour.

Outcome 4

Candidates will be supplied with a brief. The brief will specify the setting within which the risk assessment will be carried out.

Candidates are required to:

- identify **three** hazards
- explain **one** risk associated with each hazard
- identify **one** control measure for each risk

The risk assessment will be carried out in a real or simulated setting under supervision at an appropriate point in the Unit. Candidates should be supplied with an appropriate template to record the risk assessment.

The National Assessment Bank (NAB) pack provided for this Unit illustrates the standard that should be applied. It contains an investigation pro forma, candidate brief, series of structured questions and a risk assessment template. If a centre wishes to design its own assessments for this Unit, they should be of a comparable standard.

Opportunities for the use of e-assessment

E-assessment may be appropriate for some assessments in this Unit. By e-assessment we mean assessment which is supported by Information and Communication Technology (ICT), such as e-testing or the use of e-portfolios or e-checklists. Centres which wish to use e-assessment must ensure that the national standard is applied to all candidate evidence and that conditions of assessment as specified in the Evidence Requirements are met, regardless of the mode of gathering evidence. Further advice is available in *SQA Guidelines on Online Assessment for Further Education (AA1641, March 2003), SQA Guidelines on e-assessment for Schools (BD2625, June 2005).*

National Unit Specification: support notes (cont)

UNIT Health Sector: Life Sciences Industry and the Health Sector (SCQF level 5)

DISABLED CANDIDATES AND/OR THOSE WITH ADDITIONAL SUPPORT NEEDS

The additional support needs of individual candidates should be taken into account when planning learning experiences, selecting assessment instruments, or considering whether any reasonable adjustments may be required. Further advice can be found on our website **www.sqa.org.uk/assessmentarrangements.**