

PHARMACEUTICALS
INDUSTRY

Cogent Standards and Qualifications Prospectus

Essential information
on qualifications,
standards,
apprenticeships and
awarding bodies



Introduction

This Prospectus lists all the standards and qualifications which are underpinned by the National Occupational Standards (NOS) managed by Cogent or are of relevance to the pharmaceuticals industry.

The National Skills Academy Process Industries is establishing a network of accredited providers through which these standards and qualifications are being delivered.

www.process.nsacademy.co.uk

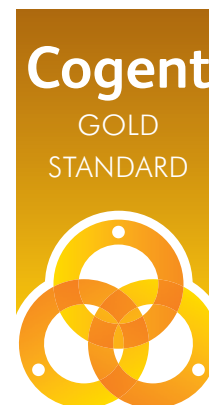
The National Skills Academy Process Industries is an employer-led centre of excellence launched to address skills and training needs throughout the chemical, polymer, pharmaceutical and petroleum industries.



The Cogent Gold Standard

The Gold Standard is a national framework for Continuing Professional Development (CPD) setting out the skills required for world class performance in key job roles in the process industries. Each Gold Standard role sets out the competencies, qualifications and training standards that will provide a route to securing skills across four areas:

- Technical Competence
- Business Improvement
- Compliance
- Functional and Behavioural



Current pharmaceutical industry Gold Standard job roles

| | |
|---------------------|----------|
| Process Operator | Level 2 |
| Process Technician | Level 3 |
| 1st Line Supervisor | Level 3+ |

A full list of all the process industry Gold Standards can be found at www.cogent-ssc.com/Gold_Standard

“Prospective clients must have confidence to enter a contractual agreement with a service provider for contract packaging of pharmaceuticals and clinical trials. The Gold Standard status is an independent validation that Brecon has the people with relevant skills and knowledge.”

Desmond Preece MBE, Systems and Standards Project Manager, Brecon Pharmaceutical

An extract from First Line Supervisor (pharmaceuticals)

| Cogent GOLD STANDARD | The Gold Standard Job Role skills, knowledge and behaviours | Gold Standard Qualifications (Awards, Certificates & Diplomas) & Training Standards |
|-------------------------------------|---|---|
| Technical Competence | <ul style="list-style-type: none"> • develop and monitor plans and procedures • allocate personnel to maintain processing • respond to and solve operational problems • adapt plans and procedures • allocate personnel for maintenance • understand science/technology theory and principles • understand how the process is started, shutdown and maintained • understand the operating procedures & how to manage safety critical process operations | L3 ILM Award in Managing Operations Foundation Degree in Science, Engineering or Technology Industry Training Standard for Pharmaceuticals |
| Business Improvement | <ul style="list-style-type: none"> • understand the theory, principles and practice associated with business improvement techniques • solve process problems using business improvement techniques • encourage innovation | L3 NVQ in Business Improvement Techniques |
| Compliance | <i>understanding of...</i> <ul style="list-style-type: none"> • application of safety management systems the implications and relevance of company policy • responsibilities for controlling workplace hazards and managing the health and safety of others • making plant safe for maintenance or in emergency shutdown • environmental & sustainability responsibilities • Quality management and the use of a Quality Systems approach to QA, GMP and QC | IOSH Managing Safely GMP, GDP, GLP |
| Functional & Behavioural | <ul style="list-style-type: none"> • take responsibility for planning and developing courses of action • exercise autonomy and judgement • develop and implement operational plans • manage diversity & discrimination issues • provide leadership for his/her team • implement change • develop and maintain productive working relationships • allocate and monitor the progress and quality of work • provide learning opportunities for colleagues • manage his/her professional development • put across ideas in clear and concise manner • understand the business environment | L3 ILM Certificate in First Line Management L3 ILM Award in Business Awareness |

Foundation Degrees

Foundation Degrees are degree level qualifications which combine academic study with workplace learning. They are available in England, Wales and Northern Ireland. Equivalent qualifications in Scotland are called Higher National Certificates (HNCs) and Higher National Diplomas (HNDs).

With Cogent's guidance employers are shaping vocational Foundation Degrees to suit their needs. Cogent's ground-breaking collaborative project Working Higher is developing a Framework for Foundation Degrees in Science and Engineering. It includes the FdSc Chemical Science to be delivered by Manchester Metropolitan University and the FdSc in Lifesciences/Bioscience to be delivered by the University of Kent. The new Foundation Degrees are being designed to be a solution to workforce development needs by creating flexible, work-based provision.

Working Higher Foundation Degrees will allow for a step-on, step-off modular approach to learning, allowing employers to easily access knowledge and skills which can lead to an academic qualification. Underpinning knowledge, business, functional and specialist technical skills will be covered within these innovative programmes. Additionally there are a range of existing FDs covering engineering and technology of relevance of the Cogent Sector, which can be accessed via www.ucas.ac.uk.

For further guidance on FDs contact Cogent's HE Curriculum Manager, Pauline Maden.
pauline.maden@cocent-ssc.com

Pharmaceutical industry qualifications

The following qualifications have been developed for or are of relevance to the pharmaceuticals industry. There are four categories of pharmaceuticals qualifications, reflecting the Gold Standard categories.

| Technical Competence | Level 2 | Level 3 | Level 4 |
|---|---------|---------|---------|
| Diploma in Processing Industries Operations | ✓ | ✓ | ✓ |
| Diploma in Process Engineering Maintenance | ✓ | ✓ | |
| Diploma in Operations and Technical Support in the Process Industries | | ✓ | |
| Diploma in Chemical Testing | ✓ | ✓ | |
| Diploma in Carbon Management | ✓ | ✓ | |
| Certificate in Process Technology | ✓ | ✓ | |
| Certificate in Process Industries Maintenance | ✓ | | |
| Certificate in Operations and Technical Support in the Process Industries | ✓ | | |
| Certificate in Chemical and Pharmaceutical Based Process Operations | ✓ | ✓ | |
| Certificate in Chemical and Pharmaceutical Based Process Maintenance | ✓ | | |
| Certificate in Carbon Management | ✓ | ✓ | |
| Certificate for Introduction to Processing Operations in Energy | ✓ | | |
| Award in Chemical and Pharmaceutical Based Process Support (Transfer Materials) | ✓ | | |
| Award in Chemical and Pharmaceutical Based Process Support (Sample and Test Materials) | ✓ | | |
| Award in Chemical and Pharmaceutical Based Process Support (Prepare Process Materials) | ✓ | | |
| Award in Chemical and Pharmaceutical Based Process Support (Clean and Prepare Complex Items of Plant and Equipment) | ✓ | | |
| SVQ in Processing Industries Operations | ✓ | ✓ | ✓ |
| SVQ in Process Engineering Maintenance | ✓ | ✓ | |
| Business Improvement | Level 2 | Level 3 | Level 4 |
| Diploma in Business Improvement Techniques | ✓ | ✓ | ✓ |
| Compliance | Level 2 | Level 3 | Level 4 |
| Award in Workplace Health and Safety | ✓ | | |
| Award in Safety, Health and Environment for the Process Industries | ✓ | | |
| Functional and Behavioural | Level 2 | Level 3 | Level 4 |
| Award in Customer Awareness | ✓ | | |
| Award in Enterprise Awareness | ✓ | | |
| Award in Personal Development | ✓ | | |
| Certificate in Team Leading | ✓ | | |
| Award in Business Awareness | | ✓ | |
| Award in Managing Operations | | ✓ | |
| Certificate in First Line Management | | ✓ | |

Note, certain qualifications are currently going through the development and accreditation process as part of the transition to the new Qualifications and Credit Framework (QCF).

Apprenticeship Frameworks

Cogent is developing Apprenticeship Frameworks that meet employer needs and which are rigorously quality assured. Apprenticeship Frameworks are available in the four UK home nations, but they do not always have the same name. In Wales an Apprenticeship at Level 2 is called a Foundation Modern Apprenticeship. In England it is called an Apprenticeship. In Wales and Scotland a Level 3 Apprenticeship is called a Modern Apprenticeship and in England it is called an Advanced Apprenticeship.

| Apprenticeship Frameworks | Level |
|--|---------|
| Cogent Apprenticeship Frameworks | |
| Apprenticeship In Process Technology | Level 2 |
| Apprenticeship for Laboratory Technicians in Manufacturing, Processes and Education | Level 2 |
| Advanced Apprenticeship in Process Technology | Level 3 |
| Advanced Apprenticeship for Laboratory Technicians in Manufacturing, Processes and Education | Level 3 |
| Semta Apprenticeship Frameworks | |
| Apprenticeship in Engineering | Level 2 |
| Advanced Apprenticeship in Engineering | Level 3 |

Training Standards

Training Standards have been developed to provide industry-wide agreed common training for a range of disciplines across the science-using industries. The development of these important standards has taken place in consultation with many subject area experts. The Training Standards are identified on Cogent's Skills Match web-based benchmarking tool www.cogent-skillsmatch.com

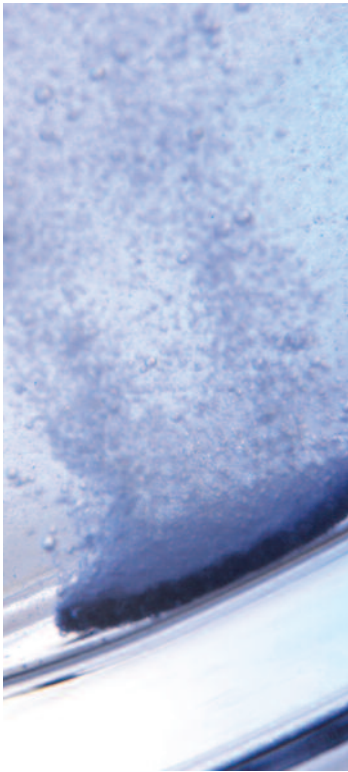
| | |
|--|---|
| Working Safely | To make employees, at all levels, aware of their responsibility for safety toward themselves, colleagues and others affected by their work activities. |
| Managing Safely | Training should offer a broad and very practical introduction to a wide variety of health & safety management issues and concerns and is aimed at middle and first-line managers with direct responsibilities for local safety management. |
| Asbestos Awareness | To provide an awareness and development of knowledge to site based employees of the hazards and risks posed by asbestos containing materials (ACMs) within their everyday working environment and an overview of the legislative measures in place to safeguard themselves and others affected by work activities. |
| First Aid at Work Initial | To enable students to get help and give safe, prompt and effective First Aid to a casualty in the workplace following an injury or illness using materials to hand and HSE approved first aid equipment. |
| First Aid at Work Re-qualifier | To enable students to get help and give safe, prompt and effective First Aid to a casualty in the workplace following an injury or illness using materials to hand and HSE approved first aid equipment. |
| Introduction to Project Management | Successful candidates will be able to understand the language of project management and the structure of a successful project. They will be able to take an active part in a project team and make a positive contribution to any project environment. |
| Foundations of Project Management | Aimed at project managers and aspiring project managers wishing to demonstrate their knowledge of project management. Candidates would be expected to participate in projects from individual assignments, through to large capital projects. |
| Project Management Practitioner | The training standard has been designed to assess the competence of relatively experienced project management professionals in managing non complex projects or running of a key control function of a large-scale project. |
| Industrial Gas Safety Awareness | To provide safety awareness for all personnel who either use, handle or store industrial gases. Courses that meet this standard are aimed Production and other managers with operational responsibilities for safety. Managers, supervisors and staff from all functions who are responsible for the safe use of gases within their department. Anyone responsible for health and safety. |
| Industrial Gas Safety Practice | To provide practical instruction on the correct assembly and pre-use check of oxy-fuel gas systems. Courses that meet this standard are aimed at anyone using oxy fuel gas systems on site including; production and other managers with operational responsibilities for oxy-fuel systems. |
| Ladder Safety | On completion of the training the candidate will be able to demonstrate competence of safe working practices, identify ladder faults and erect and work safely on various types of ladders in accordance with the Occupational Health and Safety Act and Working at Height Regulations. |
| Working at Height | This training standard is about working safely at heights and includes assessing the risks involved, taking all suitable precautions and following the correct procedures. It applies to individuals who work at heights, including those working for example, on containers, gantries, ladders, scaffolding or any other similar structure from where there is a danger of falling. |
| Occupational Health and Safety (Contractors - Engineering Construction) | The Occupational Health and Safety (Contractors - Engineering Construction) training standard details the basic knowledge of Health and Safety and should complement the on-site induction, enabling contractors to work more safely and with lower risk to themselves and others. |
| Occupational Health and Safety (Supervisors - Engineering Construction) | The Occupational Health and Safety (Supervisors - Engineering Construction) training standard aims to highlight some basic management skills for the working Supervisor that will assist them in controlling the safety aspects within their working environment. |

National Occupational Standards (NOS)

Cogent is the custodian of National Occupational Standards (NOS) which are statements of the skills, knowledge and understanding needed in order to carry out a particular job role. Their development is led by employers in the pharmaceutical industry.

A new set of NOS for Chemicals Testing is currently in development to be completed by September 2010.

The NOS currently used by the industry can be found at www.ukstandards.co.uk



Making pharmaceuticals qualifications accessible

Qualifications and Credit Framework

A unitised system – The Qualifications and Credit Framework (QCF) – is the new system for all qualifications which means more flexibility for both learners and employers to create tailored qualifications which are fit-for-purpose. The system allows individuals to gain qualifications at their own pace along flexible routes. QCF qualifications are made up of units. Each unit has a credit value and a level. Levels indicate difficulty and vary from entry at Level 1 to Level 8. One credit represents 10 hours of study. There are three sizes of qualifications available:

Awards (1 to 12 credits)

Certificates (13 to 36 credits)

Diplomas (37 credits or more)

For an interactive guide introducing the QCF go to:

http://www.qcda.gov.uk/resources/qcf_intro_animation/QCF_main.html

Scottish Credit and Qualifications Framework

The Scottish Credit and Qualifications Framework (SCQF) promotes lifelong learning in Scotland. Also a unitised system, the SCQF helps people of all ages and circumstances understand, gain access to and compare different types of qualifications and learning. The framework is based on level and credit. Level indicates the complexity of the course, from access at Level 1 to Level 12. Credit indicates learning time with 1 credit representing 10 notional learning hours.

For an overview of the SCQF go to:

<http://www.scqf.org.uk/AbouttheFramework/Overview-of-Framework.aspx>

All the standards and qualifications outlined in this Prospectus will soon be available at www.cogent-prospectus.com



Awarding Bodies

Cogent and Awarding Bodies work together to ensure a transparent qualifications system meeting the needs of employers and learners.

The Awarding Organisations which offer the specialist qualifications for the Cogent Sector are listed below:

Accredited Skills for Industry: www.asfi.org.uk

Offers signmaking and polymer qualifications

City and Guilds: www.cityandguilds.com

Offers process and downstream petroleum, oil and gas and business improvement qualifications

Edexcel: www.edexcel.com

Offers technical, knowledge-based qualifications for Cogent's apprenticeship frameworks

ILM: www.i-l-m.com

Offers leadership and management and functional and behavioural qualifications

NEBOSH: www.nebosh.org.uk

Offers Health and Safety qualifications

PAA\VQ-SET: www.paa-uk.org

Offers process, polymer, sign making, nuclear, downstream, oil and gas and business improvement qualifications

PIABC: www.piabc.org.uk

Offers packaging qualifications

FDQ: www.fdq.org.uk

Offers packaging qualifications

SQA: www.sqa.org.uk

Offers SVQs in process, downstream, petroleum and oil and gas

Contact Us

For general enquiries on any of the qualifications and standards outlined in this Prospectus contact Cogent's Qualifications Reform Manager:

matthew.hardy@kogent-ssc.com Tel: 01925 515 200

For information on undertaking any of the qualifications outlined in this Qualifications Prospectus contact:

National Skills Academy Process Industries

enquiries@process.nsacademy.co.uk Tel: 01325 740 900



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