Academy of Pharmaceutical Sciences Accreditation Process

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Introduction

The Academy of Pharmaceutical Sciences (APS) is the UK-based professional membership body for Pharmaceutical Scientists. We represent individuals and organisations from around the globe, throughout their development, in the delivery of excellence in the pharmaceutical science sector. Pharmaceutical scientists are experts in the research, development and manufacture of medicines. They have a major role in the regulation of medicines and understanding their use in patients

Our four key strategic themes, which are the foundation of all APS activities, are:

- Establish and promote the reputation of Pharmaceutical Sciences and Scientists
- Influence policy
- Further scientific knowledge
- Promote careers

Accreditation is one of the mechanisms through which APS can promote good practice in the training and development of pharmaceutical scientists and supports two of the APS strategic themes: establishing and promoting the reputation of pharmaceutical sciences and scientists and promoting careers.

Over the last few years we have been approached by number of Institutions providing degrees in pharmaceutical science or combined with other disciplines to look at accrediting their courses.

The board recognised that APS has members that could provide this service, and in consultation established the following guidelines for accreditation.

The guidelines cover process, key learning outcomes, accreditation team and timelines.

If you are interested in discussing this process further, please contact APS at info@apsgb.org and you will be linked to one of the accreditation team.

Guidelines for the APS Accreditation Process

These guidelines for institutions, employers and students describe what is required in a degree programme that is submitted for accreditation. The key requirements are defined that set minimal standards and an indicative syllabus provides guidance on course content but flexibility is an important element of the accreditation process.

APS recognises that several Institutions are providing degrees with pharmaceutical science and other disciplines, for example business studies. The accreditation process will seek assurance that the pharmaceutical science level does not drop below 65% of the course and that this is maintained during each year of the course. For adjunct subject areas, APS reserve the right to seek specialist opinion and may consult external examiners.

The use of standards to assure quality and to reflect competencies builds on best practice in design and delivery of modern degree structures and the accreditation process will look for evidence that such standards have been developed and used.

It is expected that accreditation by APS will be seen as helpful by both Institutions and employers and that it will have a substantial benefit in the employability of students achieving success on the approved course.

Accreditation

Accreditation of degree programmes by professional and statutory bodies is a mark of assurance that standards are met. There are a wide range of organisations offering accreditation, some of which, notably in the health professions are rigorous and provided by official regulatory bodies whilst others are more 'light touch' but which nevertheless provide assurance that content and delivery of courses are appropriate to provide graduates with recognised levels of competence.

The APS process is created and run by professional pharmaceutical scientists with many years of experience in both academia and industry and will provide institutions with a credible and independent mechanism to differentiate between degree courses and as such will benefit both students and employers.

The APS accredits degrees at Bachelor level (1st cycle) and Masters level programmes (2nd cycle). Pharmaceutical science degrees are multifaceted and the APS is uniquely placed to provide assurance across the full range of disciplines covered.

The APS recognises international and national standards in its accreditation process. The Bologna process in Europe has created 'the Framework for Qualifications of the European Higher Education Area' and nationally we have taken account of UK's Quality Assurance

Agency for Higher Education who issued two relevant Benchmark Statements on Pharmacy and on Chemistry.

Accreditation is usually for a period of 5 years, after which a new submission is required. Should an accredited course fail to achieve re-accreditation, the Academy of Pharmaceutical Sciences (APS) will work with students who are already enrolled on the course to ensure that their achievements and qualifications are appropriately recognised.

Accreditation Process Overview

A pharmaceutical scientist qualification is a significant first step for many aspiring pharmaceutical scientists. It opens doors to a career in practical science or positions within the wider graduate employment market.

The accredited programmes are expected to provide students with

- a broad and balanced appreciation of key pharmaceutical science concepts
- a range of practical skills so that they can understand and assess risks and work safely in the laboratory
- the ability to apply standard methodology to the solution of problems in pharmaceutical science
- the knowledge and skills base which leads to graduate employment or to further study in terms of professional qualification

The course descriptors should cover the academic and extracurricular support processes as well as the detailed course content based on the indicative syllabus provided by APS but this should not be seen as exclusive by an Institution

Key Learning Outcomes for accreditation are

Breadth of knowledge
Evidence of study of the main branches of pharmaceutical science is provided and developed at appropriate times during the course.
Programme outcomes should include a breadth of understanding of pharmaceutical sciences with the ability to solve problems at the threshold level of competence

Depth of knowledge
Programmes should build on the delivered knowledge base to allow students to appreciate developments, in some areas, at the forefront of the discipline

Practical skills
Students must develop a range of practical laboratory skills, including the use of mathematical and statistical processes and show competency in them

Competencies

Students must be able to demonstrate to others that they can show both knowledge and the skills to use it across the whole field of the course

Project work

Programmes must incorporate some independent investigative methodology

- These are open ended activities which require students to manage their own learning.
- Activities should require students to apply information that they have learned earlier in the programme in order to consolidate and extend their knowledge and understanding of pharmaceutical sciences
- One or more activities can be incorporated and could include:
    - research project
    - literature investigation
    - collaborative project work
    - external placement

These activities would typically account for 25% of student workload in the final year.

Placement

Any external placements must be subject to assessment against explicit criteria with universities retaining control and supervision of its students

Professional skills

Programmes must develop a broad range of transferable key skills

Transferable skills development is an essential feature of all degree programmes.

Requisite transferable skills cross reference to generic skills. These incorporate written and oral communication, data handling, numerical and mathematics skills, time management and an ability to interact with other people.

Programmes should promote a sense of proper scientific conduct and ethical responsibility.

Collectively students' generic skills should provide a basis to undertake further training of a professional nature.

Students' competence in the exercise of transferable skills must be assessed and appropriately rewarded.

Assessment

Assessment should be varied, appropriate and rigorous, and require students to apply their knowledge and solve problems

Universities are encouraged to use a wide range of assessment techniques matched to particular aspects of the programme which have been carefully designed and applied to ensure validity and reliability as discriminators.

Programmes should seek to ensure students are encouraged to

- complete various forms of in-course assessment with particular, but not exclusive, evaluation of practical competence

- apply their understanding of earlier fundamental principles at advanced stages of the programme;
- complete assessments in a diverse range of topics
- demonstrate their problem solving abilities
- critically analyse information, construct synopses, and devise solutions
- deal with topics expansively using reason and argument

An appropriate proportion of marks linked to key concepts should be assigned on the basis of formal examination conducted under controlled conditions. Such examinations can be open or closed book.

Progression to subsequent stages of a programme should only be possible when a minimum competence has been demonstrated in pre-requisite areas.

Title

The title of a programme should be indicative of content and address the assumptions an employer will make on the graduates' abilities based on the title. The course must have a minimum of 65% of the content in the pharmaceutical sciences.

Quality Assurance

Universities must have robust quality assurance mechanisms in place for all aspects of its programmes

A clear quality assurance framework should be in place and actively applied to ensure that outcome standards are appropriate, consistent and fair.

QA processes must at least assure that

- programmes are adequately supported by learning resources
- agreed specifications are followed
- assessments are set at the appropriate standard
- assessment processes are impartial and robust
- successful students achieve the stated learning outcomes and are graded accordingly
- students can progress fairly and effectively
- content and assessments are regularly reviewed

Resources

Resources devoted to a programme should provide students with a suitably supportive environment so enabling them to be successful in achieving the stated learning outcomes

- Accredited degree programmes must be delivered by an appropriate level of fully-qualified full and/or part-time staff (academic, administrative and technical) who are knowledgeable and suitably skilled in the areas they are teaching and able to set assessments to an appropriate standard
- Universities are expected to provide evidence that students on an accredited programme are adequately supported by appropriate learning resources and support such as computing and communication facilities (access to software, internet and email) and suitable library provision, including appropriate accessibility to key

textbooks, major online relevant databases and the primary literature, such as the range of peer-reviewed journals
- Lecture theatres and classrooms should have demonstration facilities, projection capabilities and internet access. Laboratories should adhere to strict safety guidelines and should house appropriate instrumentation for teaching and research, which should be up to date, high quality and properly maintained
- Ultimately, adequate support is judged by whether or not the resources devoted to a programme provide students with a suitably supportive environment so enabling them to be successful in achieving the stated learning outcomes

APS Accreditation Process Timetable

Initial consultation
Discussions with the accreditation team to comment on potential for accreditation and then process needs and timetable

Application
Provision of
- Programme specification
- Module descriptors
- External examiners' reports
- Assessment strategy
- Examination papers, model answers and laboratory bench books
- Projects
- QA reports
- Staff involved in course and SSRs
- Student handbook

Accreditation Team
Each course will be reviewed by a minimum of three assessors, at least one of which will have experience in course design at degree level and at least one of which will be an experienced assessor in a related professional field. There will be a paper review followed by a campus visit.

Campus visit
- Usually up to one day, with 2-3 members of the APS accreditation team
- Reviews initial comments on application (precirculated)
- Meeting with staff (pre-agreed)
- Meeting with students
- Feedback meeting

Decision on application
- Made by APS Board on recommendation of accreditation team
- May include conditions or recommendations

Accreditation Team

Will consist of three individuals selected from a panel of 12 members from academic, industrial and regulatory strands

Indicative syllabus

Applied Physical, Chemical and Biological sciences
(Bio) Analytical principles and methods
Drug design and discovery
Cell and molecular biology
Microbiology
Immunology
Pharmaceutical chemistry

Pharmacology, pharmacokinetics & pharmacodynamics
Contraindications, adverse reactions and drug interactions
Absorption, distribution, metabolism and excretion (ADME)
Pharmacokinetic modelling
Bioavailability and bioequivalence
Prediction of drug properties
Pharmacogenetics and pharmacogenomics
Drug and substance misuse
Clinical toxicology and drug-over-exposure
Molecular basis of drug action
Metabolism
Pharmacology

Pharmaceutical technology including manufacturing & engineering science Biotechnology
Manufacturing methods
Quality assurance processes, including raw materials and products in laboratory and manufacturing environments
Sterilisation and asepsis
Environmental control in manufacturing

Formulation and material science
Materials used in formulations and devices
Dosage forms
Formulation principles
Biopharmaceutics, developmental pharmaceutics, pre-formulation and formulation studies
Design and standardisation of medicines
Microbiological contamination
Contamination control
Product stability
Medical devices

Therapeutics
Routes of administration
New therapeutic advances
Infection control
Complementary therapies
Clinical therapeutic uses of drugs

Medicines regulation

Evaluation and regulation of new drugs and medicines
Pharmacopoeial specifications and biological standards
Medicines licensing
Product quality, safety and efficacy
Ethical issues

Clinical governance
Standard Operating Procedures (SOPs)
Research methodology / research ethics
Risk & quality management

Workplace Regulation
Health & Safety
Equality Act 2010
Freedom of Information Act (FOIA)

Core and professional skills
Professionalism
Research (including research methods)
Critical appraisal
- Audit and learning from errors
- analysis of evidence
- Evaluation of the literature

Problem solving
- Study skills
- Team-working skills
- Integrating knowledge from multiple sources

Accurate record keeping
Reflective practice [including continuing professional development]
Effective communication
Interpersonal skills
Interpret & interrogate clinical/scientific data
Analyse & use numerical data
Literature searching

Acknowledgements

APS has used recognised accreditation processes developed by others in an attempt to achieve uniformity of approach to accreditation at graduate and postgraduate levels. In particular the work of the Royal Society of Chemistry and the General Pharmaceutical Council has been particularly useful and material from their documentation has been used in the compilation of this guidance to APS accreditation.