Programme Specification

1	**Awarding Institution**	Newcastle University
2	**Teaching Institution**	Newcastle University
3	**Final Award**	Engineering Doctorate
4	**Programme Title**	Biopharmaceutical Process Development
5	**UCAS/Programme Code**	8802F
6	**Programme Accreditation**	To be progressed
7	**QAA Subject Benchmark(s)**	Engineering
8	**FHEQ Level**	Level 8
9	**Last updated**	May 2010

10 Programme Aims

The aim of the Degree programme is to produce Engineering Doctoral (EngD) graduates who have a coherent understanding of biosciences and biochemical/biopharmaceutical engineering, combining a sound theoretical grasp of the subjects with practical industrial experience and an awareness of their responsibilities to society, the sustainability agenda and the environment. EngD graduates will be capable of becoming professional biopharmaceutical and biochemical engineers and scientists in the bioprocess industry or of undertaking further research in an academic career. They will gain the capability to tackle open-ended research problems and arrive at research solutions demonstrating innovative/novel approaches. In doing so they will have the ability to conceptualise, design and implement projects for the generation of significant new knowledge and/or understanding. To meet these aims, the EngD Degree programme has the following objectives:

1. To recruit good students from a range of geographical, social and academic backgrounds.
2. To produce graduates who have vision and the ability to address the challenges posed by society through the deployment of the skills and knowledge gained during their EngD studies.
3. To equip students with foundation knowledge and understanding of inter-disciplinary science and engineering underpinning biopharmaceutical development, including the core material specified by the accrediting professional institutions (The Institution of Chemical Engineers (IChemE) and the International Society for Pharmaceutical Engineering (ISPE)).
4. To provide opportunities for students to acquire further knowledge, both in breadth and depth, and to specialise according to their own interests as they develop over the duration of the EngD programme.
5. To enable students to eventually satisfy the requirements of the accrediting Institutions for Chartered Membership
6. To equip students with appropriate practical skills in biological laboratory experimentation, information processing, data analysis, problem solving, teamwork, and communication skills.
7. To equip students with professional skills in management and business, regulatory and commercial needs.
8. To provide students with the opportunities to acquire research skills and to demonstrate the application of these skills to solve novel bioprocessing

research problems.

9. To encourage students to enhance public awareness of their research, to understand ethical considerations, to develop responsible attitudes towards the needs of society and the environment in the application of their engineering / science and economic knowledge.
10. To ensure that they have particular regard for the importance of safety in their working life.
11. To encourage students to develop professional attitudes towards their own future development.
12. To provide an environment within the University such that students enjoy the University learning experience sufficiently to want to maintain contact in its future recruitment, teaching, research and social activities.
13. To provide a programme of study which meets FHEQ Level 8 and which exceeds the subject benchmarks in QAA Engineering at the Masters level and UK-Spec professional standards.
14. To ensure the research component satisfies Newcastle University's QA framework for research degree programmes

    http://www.ncl.ac.uk/aqss/qsh/research_degree_programmes/PGR_QAF_Policy_and_guidance.pdf

15. To provide an appreciation of the value of research results and routes to their exploitation.

11 Learning Outcomes

The programme provides opportunities for EngD students to develop and demonstrate knowledge and understanding, qualities, skills and other attributes in the area of biopharmaceutical and biochemical engineering and science that are consistent with FHEQ Level 8 study.

Knowledge and Understanding

On completing the programme students should have:

A1 Background knowledge in (bio)chemistry, mathematics and statistical analysis, biology, pharmacology, cell therapies and drug development concepts that is relevant to biopharmaceutical and biochemical engineering.

A2 The fundamental concepts, principles and theories of (bio)engineering relevant to biopharmaceutical and biochemical engineering.

A3 Understanding of the underlying philosophy of Quality by Design (QbD) concepts and the role Process Analytical Technology plays in QbD.

A4 Detailed understanding of measurement technologies and data availability, subsequent strategies for data treatment and process system representation development and their application in bioprocess development

A5 Specific knowledge and understanding gained for the EngD research area of study

A6 Knowledge and understanding of business and management techniques, intellectual property and regulatory issues relevant to biopharmaceutical and biochemical engineering.

A7 Detailed knowledge and understanding of the essential facts, concepts, principles and theories of biopharmaceutical and biochemical engineering.

A8 Knowledge and understanding of the role of biopharmaceutical and biochemical engineers in society and the constraints within which their judgement will be exercised, including the professional and ethical responsibilities of biopharmaceutical and biochemical engineers.

A9 Knowledge and understanding of the environmental and safety issues that affect biopharmaceutical and biochemical engineering and the issues associated with sustainable bioprocessing.

A10 Knowledge and understanding of the conceptual, elemental and detailed design of biopharmaceutical / bioprocessing plant.

A11 Knowledge and understanding of the safe operation of bioprocesses and bioproduction, including the use of IT for design, control and management.

A12 Knowledge and understanding of the codes of practice, design, the assessment of safety and environmental risks, sustainability and the legislative framework for safety and regulation of bioindustry.

Foundation knowledge and understanding are primarily imparted through a combination of lectures, tutorials, example classes, case studies, laboratory experiments, coursework and projects. In some cases, the formal lectures are supplemented by computer assisted learning (CAL). A number of visiting lecturers and professors from the bioindustry and other academic institutions will contribute to A3, A6, A8, A9, A10 and A12.

The EngD research project will build on knowledge gained in A3 and A4 and the background process understanding to deliver against the EngD research requirement while at the same time provide depth of understanding associated with A5. Throughout the EngD research project, students are required to undertake independent reading to deepen, supplement and consolidate their research findings and what is being taught/learnt to broaden their individual knowledge and understanding of the subject. During the research studies, students are required to submit three monthly reports describing their progress and they will be given guidance and direction by the supervisory team. Formal records of training are maintained on the University e-portfolio system. Feedback on reports will allow the student to assess the level of their knowledge and understanding and provide the necessary capability to write the EngD research thesis.

Assessment Strategy

Assessment of the taught modules is through a combination of unseen written examinations and assessed coursework in the form of laboratory experiment write-ups, coursework reports, project reports and presentations. Progression through the research programme is monitored by the EngD Progression Panel. At the panel the student is required to present the current state of their research and their plans for future research and is questioned on these by the panel. Assessment of the EngD thesis is by viva voce by two external examiners and the thesis is assessed against the learning objectives and satisfaction of FHEQ Level 8 criteria. Given the industrial focus of the EngD, one external examiner will be from the industrial sector and the second from an academic institution. The panel will chaired by an independent Chair person.

Intellectual Skills

On completing the programme students should be able to:

B1 Plan, conduct and report a programme of novel investigative work.
B2 Analyse and solve interdisciplinary industrial engineering / scientific problems.
B3 Design/implement a novel solution to meet an industrial process development need.
B4 Be creative and innovative in the solution of problems and in the development of designs.
B5 Evaluate designs and make improvements.
B6 Integrate and evaluate information and data from a variety of sources.
B7 Take a holistic approach to solving problems and designing systems, applying professional judgements to balance risks, costs, benefits, safety, reliability, aesthetics and environmental impact.
B8 Generate new and publishable material.

Teaching and Learning Methods

Intellectual skills are developed through the research, teaching and learning programme outlined above. While the EngD is primarily personal study, team-work is essential in learning the inter-disciplinary skills and for this reason some module assessments are carried out in small groups (3-4) early in the programme. All EngD students are monitored by two academic supervisors with an industrial supervisor providing additional support. Analysis and problem solving skills are further developed through example classes, tutorials, coursework and put into practice in the research project work. Experimental, research and design skills are further developed through coursework activities, laboratory experiments and the research project. Individual feedback is given to students on all assessed module work. With respect to the research project, the scope and definition is approved by the Strategic Steering Committee that comprises academics and industrialists. Students are required, following appropriate guidance, to plan and carry out their investigative work and analyse experimental data in a critical manner. Feedback provided on all submitted work and draft sections of the EngD thesis provides opportunities for students to improve their intellectual skills. In particular, the EngD research project work will provide the opportunity to develop skills B1-B8.

Assessment Strategy

Analysis and problem solving skills are assessed through unseen written examinations, coursework and the EngD thesis viva. Experimental, research and design skills are assessed through laboratory experiment write-ups, coursework reports and project reports, presentations, unseen written examinations and the EngD thesis. Creative and design skills are assessed through the research reported in the EngD thesis.

Practical Skills

On completing the programme EngD students should be able to:
C1 Design a series of experiments to verify a hypothesis and specify experimental and data collection protocols.
C2 Critically analyse experimental or computational results and determine their

strength and validity.

C3 Prepare technical reports, specifications and give technical presentations

C4 Use the scientific literature effectively and to search for information to develop concepts and relate concepts that are in the literature to the solution requirements of the research problems.

C5 Use computational tools and packages to extract information from data, build system representations and design solutions to industrial problems

C6 Produce a conceptual or elemental design or procedure to solve an industrial problem that involves novel solution approaches and generates new capability or understanding.

C7 Identify the required cost, quality, safety, risk, reliability, appearance, fitness for purpose and environmental impact of the application of the design, approach or procedures and critically assess new approaches to existing methods / designs.

C8 Project manage tasks to deliver an Engineering Doctoral thesis in a 4 year period.

Teaching and Learning Methods

Practical skills are developed through laboratory experiments and research project work (C1-C8) and the research undertaken throughout the EngD programme (C1-C8). Lectures, tutorials, case studies and seminars for specific modules will develop skills C5 (Bioprocess Design and all modules that utilise computer based case studies for assignments) and C4-C8 (EngD Project). From the first year, students are required, after appropriate guidance, to search the literature for information and submit all written work in an appropriate scientific and engineering format so that C2-C4 are thoroughly integrated into all submitted work and research reports. Students are encouraged to develop appropriate professional and practical skills (C1-C3) through laboratory sessions during the taught component of the EngD in Year 1 that are built on through their research on their industrially focused project.

Assessment Strategy

Practical skills are assessed through laboratory experiment write-ups, coursework and project reports, presentations, group oral discussions, and unseen written examinations culminating in the assessment of the EngD thesis through a viva. Skills C1-C8 form a major part of the assessment of the EngD research project.

Transferable/Key Skills

On completing the EngD programme students should be able to:

D1 Communicate effectively (verbally and in writing).

D2 Apply mathematical/statistical skills through modelling and analysis.

D3 Work as a member of an interdisciplinary team in an academic and industrial environment

D4 Develop novel ideas and solutions to engineering and scientific problems.

D5 Use information and communications technology.

D6 Manage resources and time, plan, organise and prioritise work effectively to meet deadlines.

D7 Learn independently in familiar and unfamiliar situations with open-

mindedness and in the spirit of critical enquiry.

D8 Learn effectively for the purpose of continuing professional development and in a wider context throughout their career.

Teaching and Learning Methods

Transferable skills are developed through the research programme and the initial teaching and learning components outlined above. Basic communication skills, D1, will acquired through individual and team projects through a number of modules and the research project. These are then developed and enhanced through feedback on written reports and presentations. Skills D1-D3 will be developed in subject-specific modules and the students will obtain feedback to enhance their learning as part of those modules. These skills will be enhanced during the research programme as the project progresses. Students will be required to find information and give oral and/or written presentations throughout their study. Deadlines for submission of coursework and reports are enforced, encouraging students to develop D6. The research project provides the scope and opportunity to develop skills D1, D3-D8.

Assessment Strategy

Transferable and communication skills are assessed through coursework reports, presentations and oral examinations in a number of compulsory and optional modules and progression monitoring activities. The assessment of the EngD thesis includes key skills content.

12 Programme Curriculum, Structure and Features

Basic structure of the programme

The EngD programme is full time lasting four years. The first semester is based at Newcastle University. During Semester 1 the students undertake 60 credits of study. 40 credits of taught study are designed to build up the essential knowledge base that is necessary to tackle the research programme. The remaining 20 credits introduce the research project scope and the determination of the extent of prior knowledge through the undertaking of a literature survey. In the second semester the students undertake a further 40 credits of taught module study. The remainder of the first year is taken up with the introductory year one EngD project. At the end of the first year the students will have to acquire 180 credits and achieve over 60 on average. Those students that fail to achieve these levels may be able to retake any necessary modules and may be eligible for the award of an M.Res. Limited compensation of marks is permitted for non-core module. Further details are contained in the Programme Regulations.

The remainder of the programme will be a predominantly industry focused research project. The predominant location for the research will be discussed with the Engineering Doctorate Director and agreed by the Dean of Postgraduate Study. All students will be required to return to Newcastle University as appropriate to undertake their research studies and to tackle an ongoing programme of week long ten credit modules in professional skills and technical modules to support their

research studies. Progression each year is subject to satisfactory performance as judged by the independent Progression Panel. Satisfactory progress includes effective performance as judged in the assessed modules undertaken in that year. At the end of the fourth year of study, the students will have completed a thesis that will be examined by two external examiners, one academic and one industrialist with awareness of Level 8 requirements.

Key features of the programme (including what makes the programme distinctive)

The EngD Centre will deliver trained doctoral students who have the skills and tools to understand and manipulate biological behaviour to facilitate the rapid and efficient development of products and bioprocesses and hence their manufacture. Particular features of the programme are:

- To provide EngD students with a well-rounded multi-disciplinary research training to promote development of skills in bioengineering, bioprocessing and biopharmaceuticals.
- To provide students with skills, from initial laboratory experimentation and data handling through to high-level modelling and design capability, needed for modern bioengineers to work in an industrial development environment.
- To provide training to EngD students to develop both technical and professional skills to underpin personal development and future career success

Programme regulations (link to on-line version)

http://www.ncl.ac.uk/regulations/programme/

13 Criteria for admission

Entry qualifications

All applicants are considered individually on the basis of past academic performance and potential for achievement. Applicants will be expected to have at least a 2.1 at Integrated Masters level or a BSc/BEng plus MSc awarded with Merit in an appropriate science or engineering discipline. Equivalent qualifications will also be acceptable.

Admissions policy/selection tools

Interviews will be used as part of the selection process, which take into account contextual factors which may affect the academic performance of individual applicants. Interviews will be undertaken by academics and industrialists. The interviews will comprise of a presentation by the applicant followed by panel based questioning and will be undertaken to assess both academic ability and appropriateness for the EngD position including communication skills.

Non-standard Entry Requirements

Students holding lower entry qualification such as applicants with Bachelors level

degrees at 2.1 and above will be considered for entry if they possess significant industrial or equivalent experience.

Additional Requirements

An acceptable academic and personal reference will be required in all cases.
Level of English Language capability - IELTS 6.5 (or equivalent)

14 Support for Student Learning

The Student Services portal provides links to key services and other information and is available at: *http://www.ncl.ac.uk/students/*

Induction

During the first week of the first semester students attend an EngD induction programme that will incorporate aspects of the Faculty of Science, Agriculture and Engineering induction programme. New students will be given a general introduction to University life and the University's principle support services and general information about the Engineering Doctoral programme. The International Office offers an additional induction programme for overseas students.

Study skills support

Students will learn a range of Personal Transferable Skills, including Study Skills, as outlined in the Programme Specification. Some of this material, e.g. time management is covered in the appropriate Induction Programme. Students are explicitly tutored on their approach to both group and individual projects.

Support for EngD thesis writing is provided by the Writing Development Centre with additional support opportunities coordinated by the SAgE Graduate School through the Faculty Research Development programme.

Academic support

The initial point of contact for an EngD student is with their supervisory team. Thereafter the EngD Programme Director or SAgE Dean of Postgraduate Studies may be consulted. Issues relating to the programme may be raised at the Post-graduate Staff-Student Committee, and/or at the Postgraduate Board of Studies.

Pastoral support

All students are assigned two EngD academic supervisors whose responsibility is to monitor the academic performance and overall well-being of their students. In addition the University offers a range of support services, including one-to-one counselling and guidance or group sessions / workshops on a range of topics, such as emotional issues including stress and anxiety, student finance and budgeting and disability matter. There is specialist support available for students with dyslexia and mental health issues. Furthermore, the Union Society operates a Student Advice Centre that can provide advocacy and support to students on a range of topics including housing, debt and legal issues.

Support for students with disabilities

The University's Disability Support Service provides help and advice for disabled students at the University - and those thinking of coming to Newcastle. It provides individuals with: advice about the University's facilities, services and the accessibility of campus; details about the technical support available; guidance in study skills and advice on financial support arrangements; a resources room with equipment and software to assist students in their studies.

Learning resources

The University's main learning resources are provided by the Robinson and Walton Libraries (for books, journals, online resources), and Information Systems and Services, which supports campus-wide computing facilities. For off-site support the Remote Application Server allows connection to information sources outside of the campus network.

All new students whose first language is not English are required to take an English Language Proficiency Test. This is administered by INTO Newcastle University Centre on behalf of Newcastle University. Where appropriate, in-sessional language training can be provided. The INTO Newcastle University Centre houses a range of resources which may be particularly appropriate for those interested in an Erasmus exchange.

15 Methods for evaluating and improving the quality and standards of teaching and learning

Module reviews

All modules are subject to review by questionnaires that are considered by the Engineering Doctorate Strategic Steering Group that will serve as the Board of Studies for the programme. Changes to, or the introduction of new modules are considered by the Engineering Doctorate Strategic Steering Group. Their recommendations are considered by and approval is sought from the Faculty Teaching and Learning Committee. Student opinion is sought at the Postgraduate Staff-Student Committee and its minutes will be acted on by the Engineering Doctorate Strategic Steering Group.

Programme reviews

The Engineering Doctorate Strategic Steering Committee conducts an Annual Monitoring and Review of the taught element of the degree programme and reports to Faculty Teaching and Learning Committee. The strategic delivery against the EngD research objectives is considered by the Strategic Steering Committee and the report is forwarded to the Graduate School Committee who take an overview of all programmes within the Faculty and reports any Faculty or institutional issues to the University Teaching and Learning Committee.

External Examiner reports

External Examiner reports for the taught component are considered by the EngD

Strategic Steering Committee and will respond to these reports through Faculty Teaching and Learning Committee. External Examiner reports on the taught element are shared with institutional student representatives, through the Postgraduate Staff-Student Committee. The EngD Strategic Steering Committee consider the reports and have the responsibility to ensure industrial requirements are being met and EPSRC objectives satisfied on the taught component.

Student evaluations

All modules, and the taught element of the EngD degree programme, are subject to review by student questionnaires. Informal student evaluation is also obtained at the Postgraduate Staff-Student Committee. The results from student surveys are considered as part of the Annual Monitoring and Review of the programme and any arising actions are captured at programme and Faculty / institutional level and reported to the appropriate body.

Mechanisms for gaining student feedback

Feedback is channelled via the Postgraduate Staff-Student Committee and the Engineering Doctorate Strategic Steering Committee on the taught component of the course.

Faculty and University Review Mechanisms

The programme is subject to the University's Internal Subject Review process. Every five years, degree programmes in each subject area are subject to review. This involves both the detailed consideration of a range of documentation, and a two-day visit by a review team which includes an external subject specialist in addition to University and Faculty representatives. Following the review, a report is produced, which forms the basis for a decision by University Teaching and Learning Committee on whether the programmes reviewed should be re-approved for a further five year period.

Additional mechanisms

All staff are subject to periodic peer observation of their teaching. Any issues arising are dealt with by the Engineering Doctorate Strategic Steering Committee.

16 Regulation of assessment

Pass mark
The pass mark is 50 with progression onto the research element requiring a mark of 60.

A candidate's progress shall be reviewed by the Board of Examiners on completion of the first year's taught modules and no later than 12 months after the programme has commenced. In order to progress onto the research element the candidate must (i) after the application of compensation, have obtained a weighted average mark for the taught component of at least 60; (ii) have failed no more than 40 credits and; (iii) have no module marks below 40. A candidate's subsequent progress shall be monitored annually by an independent progress panel in manner which is

consistent with the University's Code of Practice for Research degree Programmes.

Common Marking Scheme

The University employs a common marking scheme for postgraduate modules, which is specified in the Taught Postgraduate Examination Conventions and applies to the taught modules in the Engineering Doctorate, namely:

<50	Fail
50-59	Pass
60-69	Pass with Merit
70 or above	Pass with Distinction

Role of the External Examiner for the Board of Examiners
An External Examiner, a distinguished member of the subject community is appointed by Faculty Teaching and Learning Committee for the taught component of the programme, following recommendation from the Strategic Steering Committee. The External Examiner is expected to:

i. See and approve assessment papers
ii. Moderate examination and coursework marking
iii. Attend the Board of Examiners
iv. Report to the University on the standards of the programme

In addition, information relating to the programme is provided in:

The University Prospectus: http://www.ncl.ac.uk/undergraduate/

The School Brochure (email: enquiries@ncl.ac.uk)
Degree Programme and University Regulations:
http://www.ncl.ac.uk/regulations/docs/

The Degree Programme Handbook

Please note. This specification provides a concise summary of the main features of the programme and of the learning outcomes that a typical student might reasonably be expected to achieve if she/he takes full advantage of the learning opportunities provided. The accuracy of the information contained is reviewed by the University and may be checked by the Quality Assurance Agency for Higher Education.

Mapping of Intended Learning Outcomes onto Curriculum/Modules

		Intended Learning Outcomes			
Module	**Type**	**A**	**B**	**C**	**D**
CME8501	Compulsory	A2	B2	C4	D3,D5
BIO8009	Optional	A1	B2	C4	D3,D5
CHY8827	Optional	A1	B2	C4	D3,D5
CME8502	Optional	A1	B2,B4,B6	C2,C5	D2,D5
CME8503	Core	A1,A2,A7	B2,B4	C2,C4	D3,D5
CME8504	Compulsory	A3,A4	B3,B6	C1,C2,C3,C5	D2,D3,D5
CME8505	Compulsory	A1,A3,A4,A11	B2,B4	C2,C3,C5	D2,D5,D7
CME8506	Compulsory	A3,A4	B1,B5	C1,C3,C8	D1,D2,D3,D5,D8
CME8516	Optional	A1,A2	B5	C3,C4	D3,D5
CME8517	Optional	A1	B2,B4,B6	C2,C5	D2,D5
NBS8180	Compulsory	A6,A12	B7	C3,C7	D6,D7,D8
NBS8181	Compulsory	A6,A8	B7	C3,C7	D6,D7,D8
NBS8182	Compulsory	A6	B7	C3,C7	D6,D7,D8
CME8507	Compulsory	A8	B1,B4	C3,C8	D1,D3,D6,D8
CME8508	Optional	A1,A3,A4,A7	B2,B3,B4,B5	C1,C2,C5	D2,D3,D4,D5
CME8509	Optional	A3,A4	B3,B6	C1,C2,C3,C5	D2,D3,D4,D5
CME8510	Optional	A3,A4	B3,B6	C1,C2,C3,C4,C5	D2,D3,D4,D5
CME8511	Optional	A4,A10,A11	B6	C2,C5,C6	D2,D4,D5
CME8512	Optional	A3,A4,A7,A10,A11,A12	B5,B6,B7	C6,C7	D2,D4,D5,D7
CME8513	Optional	A7,A8,A9,A10,A11,A12	B5	C4,C6,C7	D1,D7,D8
CME8514	Optional	A7,A8,A9,A10,A11,A12	B5,B7	C4,C6,C7	D1,D7,D8
CME8515	Compulsory	A6,A7,A8,A9,A10,A11,A12	B1,B7	C3,C8	D1,D3,D6,D7,D8