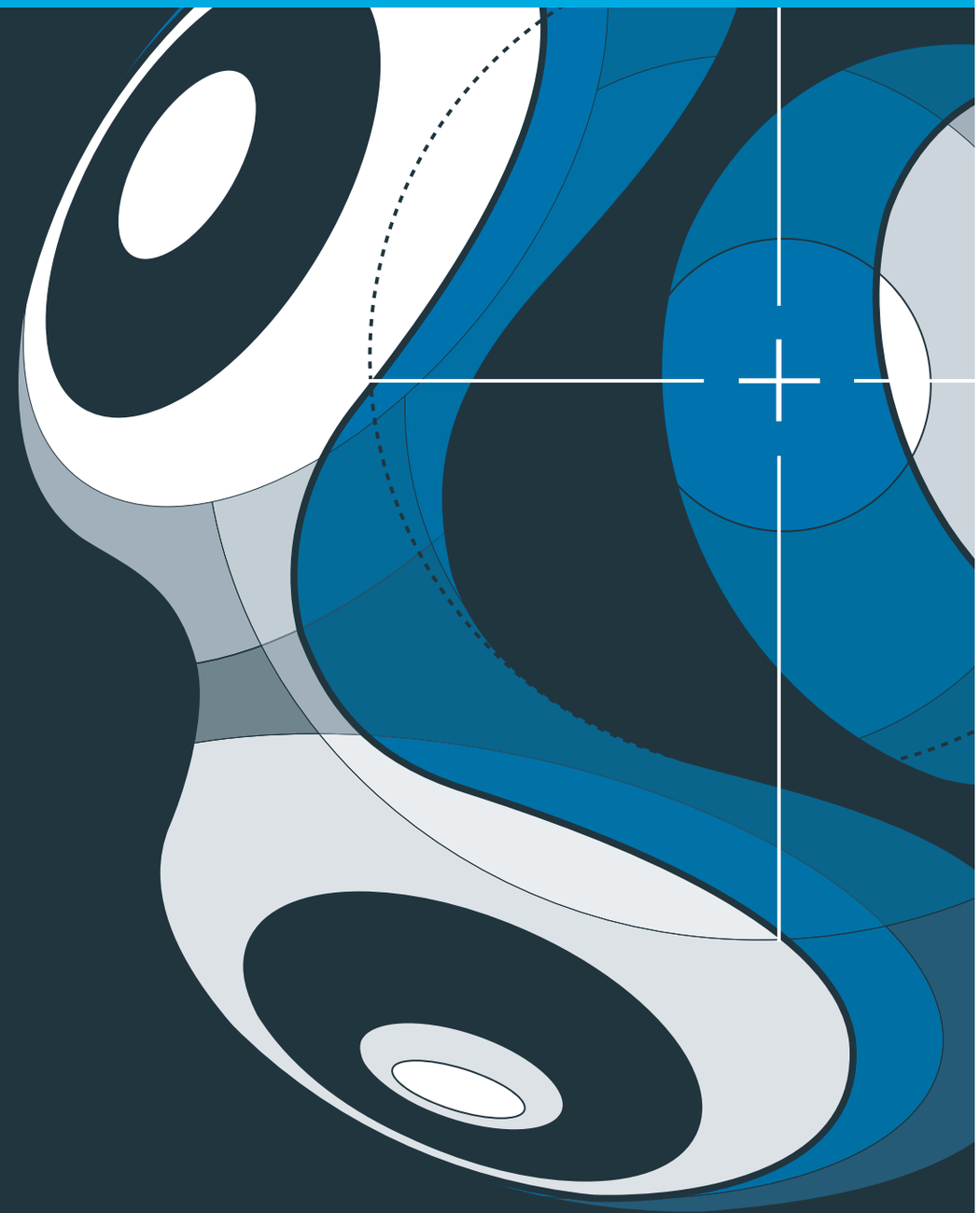
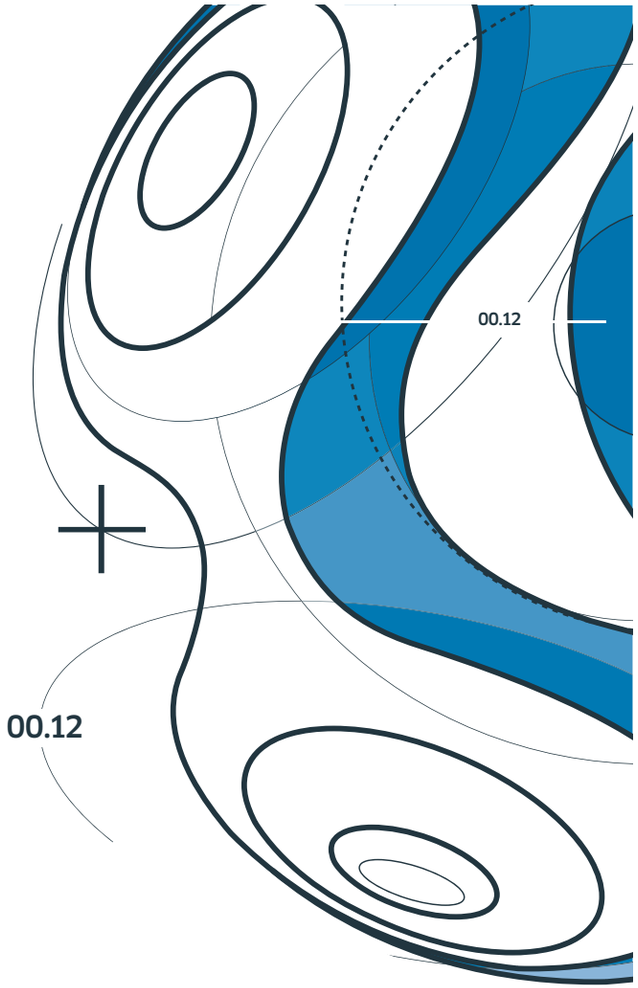
Engineering Doctorate in Biopharmaceutical Process Development

00. Course Information



EngD Biopharmaceutical Process Development



We need enthusiastic, students and engineers with enquiring minds who want to learn more and work well in teams. Could you be one of the annual intake of 12 students?

This innovative, highly prestigious four year course offers all the benefits of being a student whilst also gaining industrial training. It has been developed entirely in response to industry demand and places students with industry partners for three and a half years following six months of training. This builds on existing skills with the latest scientific and engineering techniques and management skills to enable them to work at the interface between disciplines.

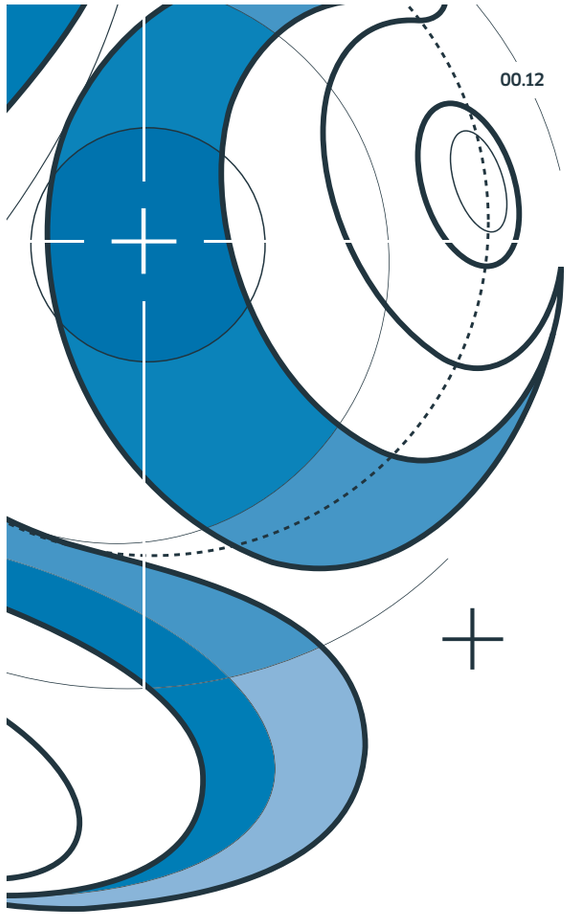
This inter-disciplinary research philosophy aims to evolve techniques to more rapidly progress biopharmaceutical products through the development chain. Bioscientists and engineers working together will acquire an understanding of the business environment and will deliver significant technological advances to the UK biopharmaceutical industry.

In industry, methods of working, the environment and the culture are inevitably different to academia. Some of the great challenges for PhDs when they are first qualified and come into industry is understanding how industry thinks, what industry is looking for, industrial timescales and challenges.

In contrast to a more traditional PhD, the EngD has an industry focus so the the students gain valuable experience engaging in the challenges and time constraints of the workplace prior to gaining their Doctorate.

Support from the UK Engineering and Physical Sciences Research Council (EPSRC) has established an Engineering Doctorate (EngD) Programme.

Up to twelve fully funded industrially collaborative four year studentships (tax free stipend £18,940) are available for October 2009 entry.



00.01 Course Structure

The EngD programme is designed to provide the interdisciplinary training that will furnish the breadth of capability that builds on first degree science and engineering education to enable cross disciplinary industrial research to be undertaken.

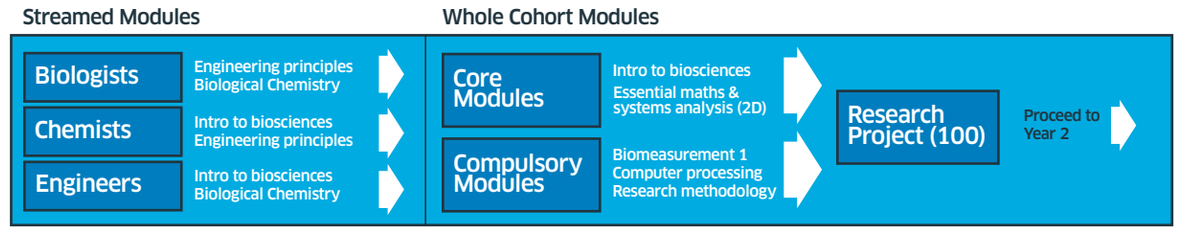
During the first year of the EngD the researchers will be undertake a blend of taught modules allowing them to acquire a broader knowledge of the sector and an industrially focused research project that forms the basis of the EngD industrial research study.

Following this, the EngD students will tackle their industrial targeted research project splitting their time between the industrial and academic environment. This allows them to supplement skills gained in year one with further technical and professional skills modules in the academic institution, while developing their research capabilities working with their industrial host.

The Modules - Training through taught courses

The four year training programme comprises a combination of taught courses, providing students with the required technical and professional skills for a successful research career, and supervised research in the areas of bioengineering, biopharmaceuticals and bioprocessing.

YEAR 1



Year 1

Students will be required to take two of the following streamed modules dependent on their background – Bioprocess Engineering Principles, Fundamentals of Biological and Medicinal Chemistry and/ or Fundamentals of Cell and Molecular Biology. All other modules in Year 1 are compulsory with two being core, Introduction to Bioprocessing and Essential Mathematics and Systems Analysis.

Bioprocess Engineering Principles: Coverage of mass/heat transfer, mass/energy balances, reactors and reaction engineering alongside safety & environmental aspects of plant design & operability.

Fundamentals of Biological and Medicinal Chemistry: Fundamental overview of biologically relevant organic chemistry, structures and function of proteins, nucleic acids, lipids and carbohydrates, enzyme structures and catalysis principles, fundamentals of replication, transcription and translation.

Fundamentals of Cell and Molecular Biology: Basic understanding of the fundamental issues in biochemistry and microbiology and covers the fundamental issues of cell composition, metabolism, reproduction and related issues.

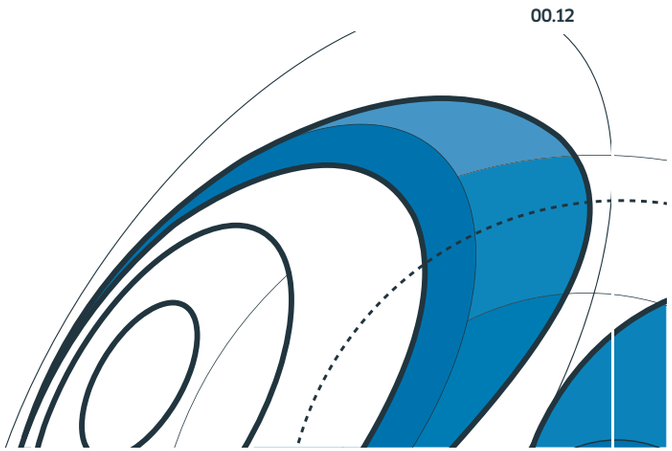
Introduction to Bioprocessing: Biomanufacturing processing including raw material selection, sterilisation and containment issues, bioreactor design, monitoring and control, polishing downstream processing steps and advanced methods of processing (e.g. tissue engineering, stem cell processing and disposable processing).

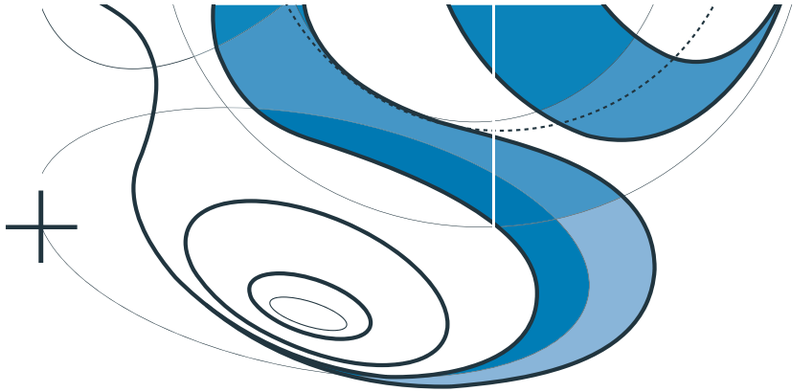
Essential Mathematics and Systems Analysis: Underpinning the mathematics behind systems analysis including differential equations and numerical solutions, dynamics, time series analysis and modelling, introduction to optimisation and symbolic mathematics and the use of Matlab and Simulink in systems analysis.

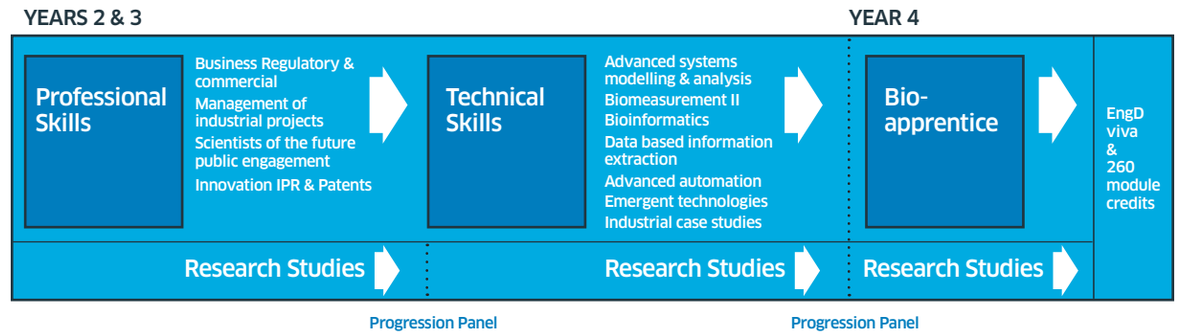
Biomeasurement Technologies I: Analytical techniques and basic chemometrics in analysing data, including qualitative and quantitative analysis; selectivity; calibration and validation. Spectroscopic techniques including gas and liquid chromatography; UV/visible, near and mid-infra-red spectrometry; Raman spectrometry; mass spectrometry; nuclear magnetic resonance spectrometry; fluorescence; and acoustics.

Computer Processing of Data: Computer based analysis, this module is predominantly project based and will be designed to enhance the skills of the research students through program design or in gaining skills in a new language (e.g. C++ or Matlab).

Research Methodology / Experimental Design: This module covers topics including; the nature of enquiry and explanation in science; qualitative and quantitative methods, dealing with experimental data; error and variability quantification; hypothesis testing; importance of design in industry; factorial designs; response surface methodology.







Years 2 & 3

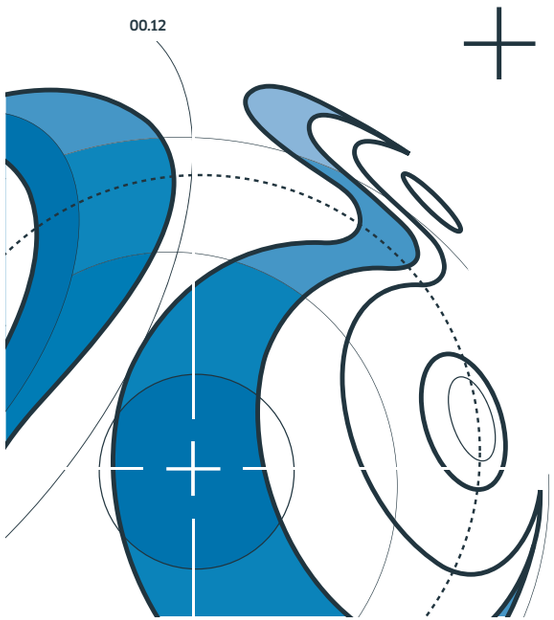
The modules offered in years 2 and 3 build on the fundamental knowledge gained in year 1 and are divided into professional skills – which are all compulsory modules and technical competencies where students choose from a range of options.

Professional Skills Modules

Business, Regulatory and Commercial: Using case histories and insights from industrial contributors, the module will explore the impacts of business, regulatory and commercial realities on the design, execution and delivery of research and development of bioprocessing projects in multi-site collaborations between academic and industrial institutions.

Management of Industrial Projects: Contrast will be made between project management models in current academic and industrial bioprocessing R&D with a focus on examples of best practice in academic-industrial collaborations.

Scientists of the Future – Public Engagement: Students will undertake a number of public outreach activities within a week long 10 credit module including school visits and assisting in Headstart and Dragonfly hands-on activities.



Innovation, IPR and Patents: This module will examine models of and routes to innovation including; users as design drivers, benchmarking; ergonomics; market research and marketing. Ethical concerns such as copyright; Intellectual Property; licensing; technology acquisition and collaborative ventures as well as business issues including business and financial planning; barriers to growth; global issues; organisational and business systems.

Technical Competency Modules
Advanced Systems Modelling & Analysis: Statistical analysis is used in understanding the inherent variability seen in biological processes. Areas covered will include the handling of inhomogeneous data, modelling techniques, the general principles of statistical inference, simulation and Bayesian inference.

Biomeasurement Technologies II: Explores the basics of array technology by outlining existing and developing formats (e.g. membrane-based OFRmer macroarrays, and OFRmer and oligomer-based microarrays). Image and data analysis will also be introduced with respect to standardisation, reproducibility, background subtraction, signal-to-noise ratios, expression profiling and transcriptomic databases.

Bioinformatics: The basic concepts of molecular biology, sequence analysis as well as concepts behind modern postgenomic bioinformatics will be introduced. The theoretical component is complemented by practical sessions including an introduction to sequence editing analysis, protein analysis, gene prediction, and sequence alignment.

Data-bases and Information Extraction: Introducing data modelling and database design techniques including data normalisation and the creation of a three tier architecture. The next stage will be to introduce key data mining tools that are fundamental to information extraction from these systems and the use of data schema and web services.

Advanced Automation: Topics include metrics of measurement: control strategy specification: principles of measurement; common sensor design features, criteria for sensor selection, installation, operation and use: analytical measurements: control valves; characteristics & sizing: digital communications; industrial standards.

Emergent Technologies in Bioprocessing: Case histories examine emerging bioprocess technologies as solutions for practical problems, looking at the impact of regulatory constraint and the commercialization of 'horizon' products in delivering extant and 'horizon' biopharmaceuticals (e.g. therapeutic proteins and regenerative medical products).

Industrial Case Studies in Bioprocess Development: Examining established biopharmaceutical products such as insulin, monoclonal antibodies, and human growth hormone. Comparison will be made with emerging nanoplex (e.g. flu and cervical cancer vaccines) and regenerative medicine (e.g. replacement skin and corneal tissues) products emphasising the importance of product development in the biopharmaceutical supply chain.

Year 4

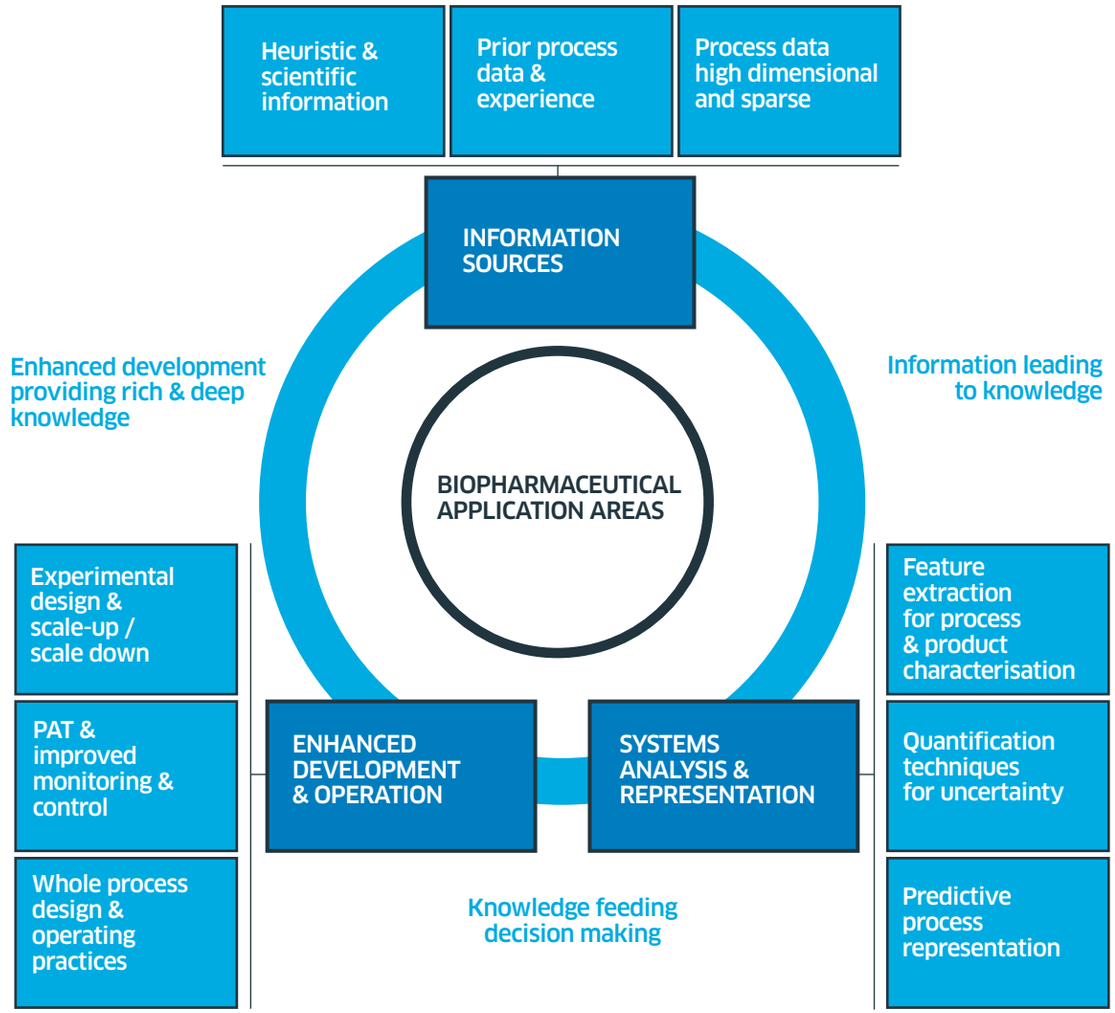
Throughout their studies, the doctorate students will be encouraged to contextualise their knowledge in terms of business application. The Bio-Apprentice module sees students divided into competing teams, tasked with finding solutions to 'real-life' business world scenarios such as how to market a new product, surviving an FDA visit or winning a contract as a contract manufacturing organisation (CMO). The prize for the winners will be a five day study trip to Purdue University in the U.S. or to Singapore.

00.02 Research Projects

The research projects will consider improvement opportunities for both established biopharmaceutical production routes and horizon products such as stem cells and marine biotechnology. In seeking improved development three overarching areas of focus will be considered:

- Measurement, data and knowledge management. Process analytical technology, data management, new measurement and analysis techniques, signal pre-processing and complex data interpretation
- Systems analysis and building process representations. Enhancing biosystems understanding, bioinformatics, Feature extraction, data visualisation, process modeling and representation, risk based analysis
- Enhanced development and operational strategies. Experimental design strategies, whole process design, process monitoring, control and optimisation, improved operational strategies.

00.00 Course Study Areas



00.04 Who Should Apply – Entry Requirements

Given the interdisciplinary diversity of the EngD programme, a broad range of first degree disciplines are appropriate. Successful candidates will have a strong desire to work at interdisciplinary interfaces and the nature of the EngD research areas requires high levels of numeracy and computer aptitude.

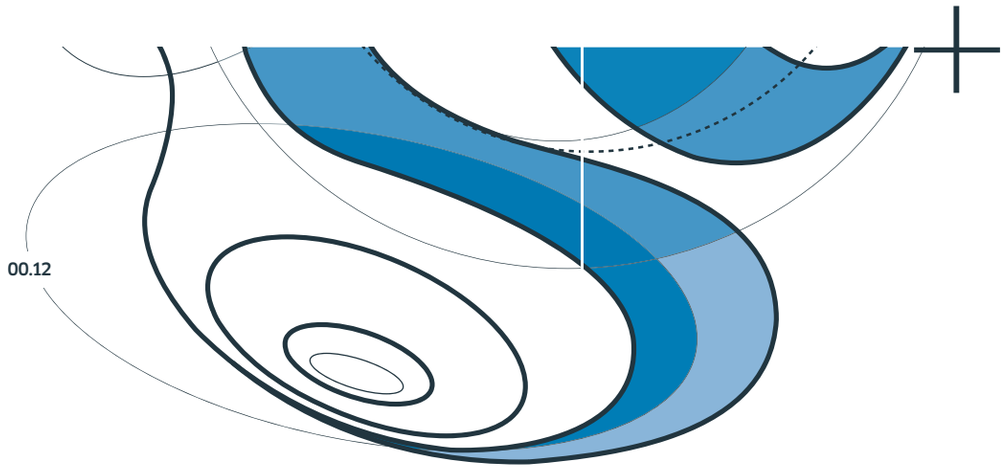
The EPSRC funded EngD project studentships are available to those that satisfy their eligibility criteria www.epsrc.ac.uk/PostgraduateTraining/StudentEligibility.htm

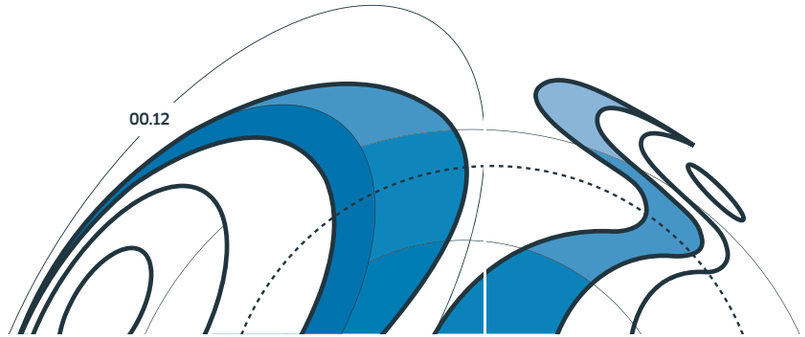
Two prestigious Newcastle University funded EngD positions are available to candidates who do not satisfy the criteria but can demonstrate academic excellence.

00.05 How to Apply

Application queries can be addressed to queries@nclbiosystems.net

Formal applications made using the University application portal www.ncl.ac.uk/postgraduate/apply/applicationforms/





Be one of the twelve

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