

QUALITY REVIEW

September 2018

CASE STUDY

Pharmaceutical and Biopharmaceutical
Engineering

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1. Background/Rationale

The Biopharma industry is one of the fastest growing sectors in Ireland. According to the Expert Group on Future Skills Needs (EGFSN) of the Biopharma Industry in Ireland (EGFSN report, 2016) the term “Biopharma” covers both Pharma chemically processed drugs, and Biologics medicines, which are manufactured in living organisms.

There are a several large sized companies within the industry with around 35 companies comprising 85% of employment (Fig. 1). It is estimated that the number of Biologics manufacturing sites in Ireland has risen from 2 in 2003 to 18 in 2015 (Pharmaceutical Ireland 2015).



Figure 1- Biopharmaceutical Industry in Ireland

The Biopharma industry exported products to the value of €30.2bn in 2015 and contributed €1.7bn in payroll expenditure to the economy in Ireland (EGFSN report, 2016). A significant number of Biopharma investment announcements have been made recently, with capital projects amounting to over €4bn in the pipeline over the coming years, with most being within Biologics manufacturing. An increasing proportion of new medicines are Biologics “large molecule” based, rather than chemically-processed “small molecule”.

The Biopharma industry in 2015 employed an estimated 28,200 people in Ireland; of these 21,500 were engaged in Pharma manufacturing and related services, while 6,700 were employed in Biologics. The sector also creates significant secondary employment in construction and other services while investment in new plant construction is under way. The enormous need for Engineers to work in the pharmaceutical, biopharmaceutical and medical devices industries has been well documented in recent years, most recently by the Expert Group on Future Skills Needs (EGFSN report, 2016).

2. Overview of MEngSc in Pharmaceutical & Biopharmaceutical Engineering programme

The MEngSc in Pharmaceutical & Biopharmaceutical Engineering is a part time taught programme, that leads to the award of a level 9 PG Diploma or MEngSc degree. It can be taken over 24 months, or up to a maximum of 60 months. Part I of the MEngSc consists of 60 ECTS credits or twelve modules on Pharmaceutical & Biopharmaceutical Engineering. Part II is a 30 credit minor thesis module. Candidates of the MEngSc who choose not to proceed to Part II or who do not meet the required standards graduate with the PG Diploma.

The aim of this (NQAI level 9) programme is to fill a need for the Continuing Professional Development and Postgraduate Education of Engineers working in the Pharmaceutical Industry. To date many Engineering graduates (including Chemical & Process Engineering graduates) do not have formal educational qualifications relating specifically to the pharmaceutical industry. This is because many undergraduate Chemical Engineering courses, which are generally broad in nature, do not cover issues of particular concern to the pharmaceutical industry; such as pharmaceutical and Biopharmaceutical production processes, product containment, powder/particle technology, design of API and secondary

production facilities, current Good Manufacturing Practice (cGMP), design of classified facilities, aseptic processing facility design, validation, etc. This is the case to an even greater extent for graduates of other Engineering disciplines.

In Part I students take modules to the value of 60 credits. Taught modules are offered on a cyclical basis as detailed below. Part II consists of a Research Thesis to the value of 30 credits. Part I Modules to a total of 60 credits from the following:

Part I:

Year 1 (2018-2019) Semester 1

Module Code	Module Name	Module Co-ordinator/ Lecturer
CM6010	Introductory Pharmaceutical Chemistry	Dr Humphrey Moynihan
PE6016	Pharmaceutical Industry; Manufacturing & Optimisation	Dr Jorge Oliveira
PE6018	Pharmaceutical Process Validation and Quality	Dr Maria J. Sousa Gallagher/Dr Aidan Sexton
PE6026	Project Management – from Concept to Completion	Dr Maria J. Sousa Gallagher/ Mr Neil Alcock

Year 1 (2018-2019) Semester 2

Module Code	Module Name	Module Co-ordinator
PE6024	Advanced Process Design & Safety	Dr Denis Ring
PE6022	Aseptic Manufacturing Design	Dr Maria J. Sousa Gallagher/Dr Aidan Sexton
PE6025	Advanced Health and Safety Management	Dr Maria J. Sousa Gallagher/ Dr Daniel Gallagher
PF6302	Introduction to Pharmaceutics: Formulation Science	Dr Katie Ryan

Year 1 (2019-2020) Semester 1

Module Code	Module Name	Module Co-ordinator
PE6010	Pharmaceutical Engineering	Dr Denis Ring
PE6011	Biopharmaceutical Engineering	Dr Maria J. Sousa Gallagher
PE6013	Powder and Particle Technology and Unit Operations	Dr John Fitzpatrick
PE6015	Environmental Engineering in the Pharmaceutical Sector	Dr Maria J. Sousa Gallagher/Dr Daniel Gallagher

Year 1 (2019-2020) Semester 2

Module Code	Module Name	Module Co-ordinator
PE6012	Pharmaceutical Process Equipment, Materials and Mechanical Design	Dr Kevin Cronin
PE6027	Advanced Biopharmaceutical Engineering	Dr Maria J. Sousa Gallagher/ Mr Paul Ryan
PE6019	Process Analytical Technology (PAT)	Dr Maria J. Sousa Gallagher/ Dr Eric Moore
PE6023	Pharmaceutical and Biopharmaceutical Utilities	Dr Maria J. Sousa Gallagher/ Dr Aidan Sexton

Part II:

30 ECTS credits

Module Code	Module Name	Module Co-ordinator
PE6021	Dissertation in Pharmaceutical and Biopharmaceutical Engineering	Dr Maria J. Sousa Gallagher

New modules are added as required and older modules retired, to ensure that the programme continues to meet the needs of the students and of industry. Module PE6027, Advanced Biopharmaceutical Engineering was introduced in 2016, as a result of feedback from the students requesting more advanced biopharmaceutical content.

3. Student Feedback and Achievements

Feedback forms are issued to the students at the end of each year, requesting feedback on the programme delivery and content. This, and the oral feedback to the Extern Examiner is used to address any issues with both, and improvements are always being made to course material and content. The following are comments from recent graduates of the programme, provided as part of the formal feedback process for the programme:

'This course has an excellent structure allowing participants to carry out further education whilst still working full-time. The structure of this course should be used as a baseline for other educational institutions as an excellent means of providing further education for full time working professionals.'

'Overall, enjoyed the course, found it relevant to my work in the pharm industry. Would recommend to colleagues.'

'The organisation structure was good the time table, exams were properly laid and it suited me as working fulltime it's really suited me to come down during weekend and study also the exams structure was good.'

'I have recommended this course to colleagues and friends – I hold this course and its content in high regard'

'Prior to the job I am in now, my background was in production management in various other industries. I chose this course as I felt I needed a formal pharmaceutical based qualification and a driver to learn in greater detail the technology I work with every day and the scientific principles behind it. Also, I wanted to have a better understanding of the other facets of this industry, which is difficult to achieve when you are pigeon holed in your own particular area. '

'The thesis element of the course I found the most satisfying as I chose a subject closely related to my work and as a result the level of understanding achieved will stand to me and be a source of encouragement/confidence to continue to learn long after the ink has dried on the parchment.'

Graduate employability is excellent, and the MEngSc has helped graduates to progress in their careers and often they change across to other jobs in the Pharmaceutical and Biopharmaceutical industries.

The degree has been very successful in attracting students and has been very well received across the industries, and often the company recommend and pay in full or part of the programme fees. Around 50 students have graduated since the first cohort in 2010.

A key and important feature of the programme is a strong link with the Pharmaceutical and Biopharmaceutical industry across a number of levels. This range from module lecturers from industry

personnel, industrial case studies being included in several modules, industry-based research topics, development of research takes place in industry, and generally, the students are industrial staff of these industries.

4. Research insofar as it impacts teaching

The PE 6021 Minor Research thesis/ Dissertation has been developed in collaboration with the Pharmaceutical & Biopharmaceutical industry in Ireland. The students in the programme are generally the industrial staff of these industries (e.g., Pfizer, Janssen, MSD, Novartis, Eli Lilly, BioMarin, Gilead, GSK, PM, Merck Millipore, Sanofi etc).



The developed research thesis are industry-based and the topics are of high relevance to the Pharmaceutical & Biopharmaceutical industry. The students have up to 60 months from the registration date to complete the thesis. Since the first research thesis in 2010, we have developed successfully to completion 45 Minor Research thesis/ Dissertations; so far 3 in 2018, 9 in 2017, 4 in 2016, 6 in 2015 and 10 in 2014. Details of completed MEngSc (Minor Research Thesis/Dissertations) in Pharmaceutical & Biopharmaceutical Engineering, Process & Chemical Engineering, School of Engineering, UCC are listed below:

YEAR	Author, Title of thesis
2018	Joe Murphy , "The development of a primeless breath actuated inhaler to achieve comparable product critical quality attributes of a conventional press and breathe inhaler" MEngSc .
2018	Tony Motherway , "CIP Optimization of Ultrafiltration Membranes" MEngSc .
2018	Alan Lyons , "Monitoring of High Shear Wet Milling Particle Size Reduction by FBRM" MEngSc .
2017	Dermot O' Riordan , "Introduction of Biopharmaceuticals to a Pharmaceutical Company" MEngSc .
2017	Padraig Purcell , "Product 'X' Process Scale Optimisation-Batch verses Continuous", MEngSc .
2017	Emmet Gerard Ashe , "Optimization of an Active Pharmaceutical Ingredients (API) particle size at large scale production", MEngSc .
2017	Colin Hughes , "The implementation of a risk based approach to system installation and testing within the pharmaceutical industry", MEngSc .
2017	Paul Ryan , "Analysis of the progress in Implementing new facility design concepts in Biopharmaceutical facilities producing MABs drug products", MEngSc .
2017	Colm O' Brien , "Use of the same process equipment for Pre& Post Viral Purification steps in a Bulk Drug Substance MABs manufacture facility", MEngSc .
2017	Mark McMahon , "Process safety considerations for large scale manufacture of a new active pharmaceutical ingredient (API)", MEngSc .
2017	Elaine Brown , "Process Hazard Analysis of Acetaminophen Process", MEngSc .
2017	Osarenwinda Kennedy Imasogie , "Water Usage Management", MEngSc .
2016	Kevin Warner , "Optimisation of Waste Solvent Incineration at Novartis Ringaskiddy Ltd", MEngSc .
2016	John Roberts , "Additive Manufacturing: The Future of Pharmaceutical tableting", MEngSc .
2016	Irene Baker , "Assessment and Recommendations for Improvement of the Wastewater Treatment Plant", MEngSc .
2016	Luke Duffy , "Efficiency of Packing of Sorbent Materials in a C18 HPLC Column", MEngSc .
2015	John Anthony Healy , "Manufacturing Layout Optimization" MEngSc .

YEAR	Author, Title of thesis
2015	Denise McSweeney , "Qualification of a newly sourced Active Pharmaceutical Ingredient into the Secondary Manufacturing Process of a Hepatitis C Treatment", MEngSc .
2015	Ruairi Goggin , "Microbial Contamination Control in Manufacturing of Parenteral Grade API", MEngSc .
2015	Emma Curran , "Introduction of Acceptance Quality Level (AQL) Sampling on a Secondary Packaging Line" MEngSc .
2015	Jeff Fortune , "Characterisation of Static Charge Dissipation of Blend in DuoResp Reservoir Dry Powder Inhaler", MEngSc .
2015	Edward O'Connell , "Disposal Technology for the Biopharmaceutical Industry", MEngSc .
2014	Jane Maher , "Design of a Disposable Downstream Processing Train for the Manufacture of Monoclonal Antibodies", MEngSc .
2014	Marie Duffy , "Formulation and Manufacturing Process of a Preservative Free Tablet", MEngSc .
2014	Robert McMahan , "Development of Volume of Fill Parameters and Procedures for Multi Dose and Single Dose Vial Images", MEngSc .
2014	Susan O'Neill , "HVAC and Containment System Upgrades Required To Progress From Single Product To Multiproduct Solid Oral Dosage Manufacturing", MEngSc .
2014	Emer O' Mahony , "Roche Ireland's IPPC Compliance Wastewater Treatment Plant Upgrade", MEngSc .
2014	Babatunde Olotu Jubril , "PAT: From Concept to Implementation in IC1 Cast Unit Operation in Company X", MEngSc .
2014	Tony Collins , "Improvement Process for the Isolation of a pharmaceutical compound", MEngSc .
2014	Richard W Mackey , "Establish a technology transfer process and determine the suitability of using co-load buffer during technology transfer to achieve comparable product critical quality attributes", MEngSc .
2014	Stephanie Molloy , "Benefits of the Application of Quality Risk Management to the Commissioning & Qualification of Process Equipment", MEngSc .
2014	Neil Alcock , "Disposable Technologies", MEngSc .
2013	John William Fahy , "Investigate the influence of recycled material in a high shear pelletisation process", MEngSc .
2013	Karen McCarthy , "Design and Implementation of a Clinical Upstream Processing Suite utilizing disposable technology", MEngSc .
2013	Donal Coakley , "Analysis of a Roller Compaction Process Using API Manufactured By Different Manufacturers", MEngSc .
2013	Anthony Muldoon , "The Use of Process Analytical Technology (Pat) To Facilitate Continued Process Verification (Cpv) Of The Biopharmaceutical Manufacturing Process", MEngSc .
2013	Brian McSweeney , "Chromatography Pool Selection Using Online Analysis", MEngSc .
2012	Aoife Larkin , "Evaluation and Optimisation of a VOC Plant", MEngSc .
2012	Robert Foley , "A Mechanistic Model Based Approach to Scale Up of Batch Hydrogenation Reactions In The Pharmaceutical Industry", MEngSc .
2012	Eoin Walsh , "API Material Handling Improvements", MEngSc .
2012	Mark Ivors , "Safe Installation & Operation of a Laboratory Hydrogenator", MEngSc .
2010	Dorothy Robinson , "Quality by design and Assessment of Column Chromatography Performance in the Biotech Industry" MEngSc .
2010	Nicola Sheehan , "Quality by design and Process Validation in the Biotech Industry", MEngSc .
2010	J. Anthony Troy , "Performance of an Aseptic Redundant Filter Train", MEngSc .

5. Impact

The MEngSc in Pharmaceutical and Biopharmaceutical Engineering is meeting a need for strong expertise in the biopharmaceutical sector in particular, as specified in the August 2016 report of the Expert Group on Future Skills Needs. The structure of the programme suits those who are working in local industry, and it is recommended to graduate engineers of companies like BioMarin, GSK and PM Group.

“The course content is relevant to the requirements for the pharma industry today. The ability to choose modules allows one to shape the course to a person’s professional field. Excellent support from lecturers. Already have a colleague in their 2nd year following my recommendation” Marie Duffy, Technical Director GSK Dungarvan

“PM Group encourages all employees to pursue further education for the development of the individual and the company as a whole, through our Educational Assistance Scheme. The MEngSc Pharmaceutical & Biopharmaceutical Engineer course has been undertaken by a large number of people at PM Group. The course has been found to be very useful and challenging by all. Some of our personnel have gone on to lecture for this course, having gotten the benefits themselves.

This course has served to bring Process engineers to the next level whilst also giving engineers of other disciplines a detailed insight to the Pharmaceutical and Biopharmaceutical industries. The course has allowed further discussion and development of technical topics internally through the development of thesis for this course. I would recommend this course to anyone who is currently or who intends to have a career in the Pharmaceutical and Biopharmaceutical industries”, Peter O’Sullivan, Process Group Manager