



THE ORGANISATION
FOR PROFESSIONALS IN
REGULATORY AFFAIRS

MSc

in Regulatory Affairs

PROSPECTUS



Prifysgol Cymru
University of Wales

MSc

in Regulatory Affairs



MSc in Regulatory Affairs
validated by the University of Wales

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This part-time course is designed to meet the postgraduate educational and vocational needs of personnel employed in the field of Regulatory Affairs in the pharmaceutical and allied industries.

Five two-day modules are held per academic year. Thirteen modules of relevance to the pharmaceutical industry have been established. An outline of the syllabus for each module is provided in this brochure. The MSc is organised and operated by TOPRA – The Organisation for Professionals in Regulatory Affairs. It is validated by the University of Wales and the qualifications are awarded by the University of Wales.

To obtain the MSc a student, who may enrol at any module, must take eight modules over a maximum period of five years and satisfy the other requirements stated in the schedule of assessment, including the completion of a research-based dissertation.

Regulations for the Scheme of Study Leading to the MSc in Regulatory Affairs

Introduction

The MSc in Regulatory Affairs, offered by TOPRA and validated by the University of Wales, provides an unique opportunity to study aspects of Regulatory Affairs at an advanced level.

The course was established in 1989, and is designed for professionals working in Regulatory Affairs who have already gained first-hand experience of handling regulatory issues. Such experience may be in one area of Regulatory Affairs that could be developed and broadened by studying for the MSc. Alternatively, your experience may cover a wide regulatory area but would benefit from the in-depth considerations of the topics covered in the course.

Studying for the MSc can therefore benefit the younger person at a relatively early stage in his or her career in Regulatory Affairs, or the more mature person who has perhaps worked in other industrial functions before specialising in Regulatory Affairs.

Stand-alone modules can also be studied for Continuing Professional Development (CPD).

TOPRA takes full responsibility for the operation and management of the course, which is fully validated and approved by the University of Wales.

The MSc qualification is awarded by the University of Wales.

TOPRA has used over 25 years' experience of providing training courses to produce a structured, continuing development programme of courses, meetings and seminars to meet the needs of regulatory professionals at all stages in their careers.



This degree is validated and awarded by the federal University of Wales, UK. For further details regarding the University and its validation services, please log on to www.wales.ac.uk/validation or email validation@wales.ac.uk

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Entry Requirements

To be admitted to the MSc, candidates will normally have 2 years' experience in Regulatory Affairs and hold a science degree (or cognate discipline), or the equivalent in the opinion of the Admissions Panel.

Candidates whose first language is not English must also demonstrate knowledge of written and spoken English sufficient to enable them to undertake the course. An IELTS (International English Language Testing System) certificate may be required. Information on IELTS can be found at www.ielts.org and www.britishcouncil.org

TOPRA makes no distinctions in its admissions policy with regard to disability. TOPRA will make every reasonable effort to supply students with services that meet their needs.

Course Structure

The MSc course consists of a series of free-standing modules. Five modules are offered each year. The aim is to provide flexibility and choice for students, but students cannot attend more than four modules per year. Students studying for the MSc are required to attend eight modules within a minimum of two and maximum of five years. Students are required to satisfy the examiners in eight modules by completion of a course journal and written assignments for each module. Students must then submit an MSc dissertation of 18,000 – 20,000 words. Dissertations must not exceed the stated word limits. For those not wishing to complete the full MSc, exit awards are available – a Pg.Cert. (Postgraduate Certificate) for successfully completing 4 modules and a Pg.Dip. (Postgraduate Diploma) for successfully completing 8 modules. Only one award can be claimed for any single period of on-going study.



Modules

Structure of the Individual Modules

Each module lasts two and a half days and is structured around lectures, case studies and discussion groups conducted in English. Lecturers are drawn from the industry, regulatory authorities and academia.

In most modules emphasis is given to discussion of European regulatory requirements and to practical problems involved in meeting them. Where appropriate, comparisons are made with the regulatory requirements of other major markets.

Thirteen Modules Relating to the Pharmaceutical Industry are Offered:

0. Overview of EU Regulatory Affairs
1. Strategic Planning in Regulatory Affairs
2. Regulatory Strategy for a New Active Substance: Preclinical Development
3. Regulatory Requirements for a New Active Substance: Chemistry and Pharmacy
4. Regulatory Strategy for a New Active Substance: Global Clinical Development
5. Regulatory Control of Clinical Operations
6. Regulatory Strategy: The Market Place
7. Regulatory Strategy for Established Active Substances
8. Data Requirements for Abridged Applications and Specialised Products
9. Registration of Biological, Biotechnology and Advanced Therapy Products
10. Optimising the contribution of Regulatory Affairs to Product Development, Maintenance and Commercialisation
11. The US Regulatory Environment
12. Medical Device Regulatory Affairs

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Module Schedule

The schedule for the modules over the next seven academic years is detailed below.

	Sept/Oct	Nov/Dec	Jan/Feb	Mar/Apr	May/June
2010/2011	4	0, 5	6	12	0, 7
2011/2012	11	0*, 8	10	9	0*, 1
2012/2013	2	0*, 3	4	5	0*, 6
2013/2014	12	0*, 7	11	8	0*, 10

Specific dates for the current academic year are published on the TOPRA website and in the module booking form.

The syllabuses for the modules are described later. A degree of flexibility both in the specific content of individual modules and the number of modules offered is maintained in order that they can be updated to keep abreast of regulatory requirements and to meet the changing needs of the regulatory professional.

0 Dates to be confirmed*



Modules

Work to be Undertaken

Module

Following each module the student must complete a course journal and written assignments related to the module topic. The course work is assessed at defined time points during the academic year in which the modules are undertaken. Submission dates for the course journals and assignments are given at each individual module.

A maximum period of four months is allowed for completion of course work.

MSc Dissertation

Following successful completion of 8 modules, students may submit a research-based MSc dissertation of 18,000 – 20,000 words. This must be completed within five years of first registration for the course. In exceptional circumstances (see Student Handbook) time extensions to this five year period may be granted subject to approval by the University of Wales.

Failed Candidates

Students are required to satisfy the examiners with respect to the course journal and written assignments prepared for each module undertaken. They must also satisfy the examiners with respect to the MSc dissertation.

Should a candidate fail to satisfy the Board of Examiners, course work may be resubmitted within a time-frame stipulated by the Board of Examiners.

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Modules

Summary of Syllabuses for Each Module

The MSc course is designed for Regulatory Affairs Professionals working in the pharmaceutical industry. To operate successfully, Regulatory Affairs Professionals require a thorough understanding of Regulatory Affairs in all its aspects and the ability to apply the knowledge in a strategic way.

The programme of individual modules was developed to provide the wide knowledge base necessary to fulfil the Regulatory Affairs function. The syllabus encompasses major aspects of pharmaceutical legislation, scientific principles and commercial practice underpinning the role of Regulatory Affairs.

Module 0 provides an overview of regulatory affairs in the EU. Module 1 represents a platform for understanding pharmaceutical legislation and industry issues necessary for optimising the contribution of the regulatory function to development of strategic product management in both large and small companies. Modules 2, 3 and 4 concentrate on critical evaluation of scientific issues and implications for drug development in the three areas of data required for product registration, ie. chemistry and pharmacy, preclinical and clinical. Appreciation of the regulatory, legal and practical obligations in conducting clinical research and successful marketing are considered in Modules 5 and 6 respectively. Critical issues for registration of new dosage forms containing established active substances and other abridged registration applications are assessed from a procedural perspective in Module 7 and from the perspective of data requirements in Module 8.

In addition to the basic programme provided by Modules 1 to 8, modules on more specialised topics are included. Currently these cover the following topics:

- specific product types of major regulatory importance such as biological and biotechnological products, Advanced Therapy products, and medical devices (Modules 9 and 12)
- special features of operating in the major pharmaceutical market of the USA (Module 11)
- optimising the management function of Regulatory Affairs to fulfil its crucial role in drug development throughout the product lifecycle (Module 10)

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Aim:

The purpose of this Module is to provide an understanding of EU drug development and the role of Regulatory Affairs. Identifying the different functions involved in the product development process, their inter-dependencies together with a legislative overview.

Overview of EU Regulatory Affairs

Learning outcomes

- Have an understanding of the Regulatory function and the EU environment
- Will understand the need for Marketing authorisation, applications, science, content and structure
- Will recognise the importance of EU Regulatory procedures
- Identify post authorisation activities
- Have an understanding of some of the Specialist Areas, for example; Medical Device Technology, Biotechnology Products, Abridged Applications, Referrals, Orphan Drugs, Advertising, Paediatric Development.

Outline of Module topics:

The Regulatory Function and the EU Environment

- The role and importance of the Regulatory Affairs function and how it fits into the product development process
- The EU regulatory environment, the organisations involved and how legislation is developed.

The Marketing Authorisation Application, Science, Content and Structure:

- The importance of Good Manufacturing and Clinical Practice
- The need for pharmacology, pharmacokinetic and toxicology data
- Clinical development and the conduct of clinical trials
- The content and structure of marketing authorisation applications in the common technical format

- The importance of Product Information; SmPC's, labelling and leaflets
- How to be ready for electronic submissions and eCTD.

EU Regulatory Procedures

- The Centralised procedure
- The theory and practical reality of the decentralised and mutual recognition procedures
- How to choose and use the procedures
- The importance of scientific advice.

Post Authorisation Activities

- Aspects of a successful life-cycle management
- The requirements and procedures for variations and renewals
- The importance of pharmacovigilance and risk management.

Links to other Modules

- Provides a foundation overview to the other modules



Module 1

Aim:

As a Regulatory Affairs Professional progresses in his/her career, aspects of project management and strategic planning become more important. Individuals need to develop the ability to anticipate problems, analyse complex situations, and offer the optimal strategy in order to achieve marketing approvals worldwide in a timely manner.

Strategic Planning in Regulatory Affairs

Learning outcomes

- Students will determine the global regulatory strategies and development programmes required to achieve marketing authorisation approval in Europe, North America, Japan, and beyond.
- Students will assess and discuss the commercial implications of regulatory approval and pricing negotiations.
- Students will analyse regulatory issues relating to in and out licensing of products.
- Students will define the interactions between the company and the Regulatory Agencies.

Outline of Module topics:

- Strategic planning in the pharmaceutical industry
- Regulatory strategies for successful pan-European registration
- Regulatory strategy for the USA
- Regulatory strategy for Japan
- Regulatory strategy for the emerging markets (Far East, Africa, Latin America)
- Micro, small and medium-sized enterprises (SMEs)
- Commercial licensing of products and regulatory considerations
- Introduction to trademarks and patents
- Regulatory strategies and company interactions with Regulatory Agencies
- Pharmaco-economics – Pricing and reimbursement
- Electronic Common Technical Document submissions
- Relationship between Regulatory Affairs and other pharmaceutical company functions

Links to other Modules

- Module 10 complements this Module in providing additional information on electronic submissions/IT support, regulatory intelligence and politics of regulation.
- Module 6 covers further interactions between regulatory affairs and business/commercial functions.

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Aim:

The purpose of this Module is to provide students with an understanding of the key requirements and submissions strategies associated with the preclinical development process in order to enable them to provide effective regulatory leadership within their organisations throughout the preclinical development.

Regulatory Strategy for a New Active Substance: Preclinical Development

Learning outcomes

- Students will describe the research processes used to identify and select new candidate compounds.
- Students will analyse the types and designs of preclinical safety studies required to successfully develop a new product. In addition, they will assess the regulatory acceptability of preclinical development programmes. They will determine the format and content as well as submission strategy for such information.
- Students will interpret pharmacokinetic principles and how these are applied to link the preclinical and clinical components of pharmaceutical development.
- Students will recognise the differing types of preclinical reports and summaries required through development to filing.
- Students will understand the Regulatory Authorities' views of the preclinical dossier.

Outline of Module topics:

- The real cost of a new active substance – an insight into trends that lead to rising development costs in the pharmaceutical industry
- The identification of a candidate product and the planning of its development
- The methodology of preclinical testing
- Designing and interpreting data from key safety studies (pharmacology, toxicology, mutagenicity, carcinogenicity and reproduction toxicology) including Good Laboratory Practice
- An introduction to pharmacokinetics and toxicokinetics and how these data are applied during development
- The key regulatory requirements and guidelines covering safety pharmacology, toxicology, mutagenicity, carcinogenicity and reproduction toxicity testing
- The role of the Regulatory Affairs department throughout the preclinical phase to filing and life-cycle management
- The Regulatory Authorities' view of the preclinical dossier
- The structure, content and focus of key preclinical components of the regulatory submissions including IMPD, IND, NDA, MAA and CTD

Links to other Modules

- Module 3 covers the progression of clinical trials in relation to the toxicity programme.
- Module 9 covers the preclinical requirements for biotech/biological products.
- Module 8 covers the toxicological data that may be needed for line extensions of marketed products.

Module 3

Aim:

The purpose of this Module is to provide students with an understanding of the chemistry and pharmacy development programme to enable them to provide effective advice on the suitability of the chemistry and pharmacy programmes from a regulatory perspective.

Regulatory Requirements for a New Chemical Active Substance: Chemistry and Pharmacy

Learning outcomes

- Students will identify the drug substance requirements: nomenclature, description, synthesis, development chemistry, quality control during synthesis, stability.
- Students will define the drug product requirements: formulation and pharmaceutical development, dissolution testing, bioequivalence of different dosage forms used in clinical trials, manufacture, GMP, process validation, specifications and routine tests, analytical method development, packaging and stability.
- Students will recognise the importance of analytical validation.
- Students will recognise the differences between the chemical and pharmaceutical aspects of clinical trial and marketing authorisation applications.
- Students will define the formatting of the chemistry and pharmacy documentation as per the requirements of the Common Technical Document.
- Students will understand the Regulatory Authorities' views of the chemistry and pharmacy dossier.

Outline of Module topics:

- The role of chemistry and pharmacy in the overall drug development programme.
- The chemistry and pharmacy dossier: format and structure in the EU and US. Module 3 of the Common Technical Document.
- Drug Master Files and Certificates of Suitability.
- Nomenclature and characterisation of drug substances.
- Analytical methods and validation.
- Manufacture and in-process controls of drug substances.
- Pharmaceutical development and manufacture of the drug product.
- Relevance of bioequivalence and bioavailability in formulation development.
- Quality control during the manufacture of the dosage form.
- Development of specifications for the drug substance and drug product.
- Stability requirements of drug substances and drug products.
- Chemistry and pharmacy section of clinical trials applications (IMPD/IND).
- Good Manufacturing Practice and its applications to the drug substance and drug product. Risk management.
- The role of the Qualified Person.
- Pharmaceutical Expert Reports versus the Quality Overall Summary and their relationship to the Common Technical Document.
- Packaging requirements of drug substances and drug products.
- Environmental impact assessment.
- View of the Regulatory Authorities: common deficiencies and major concerns.

Links to other Modules

- Module 2 covers preclinical aspects of the regulatory strategy for a new active substance.
- Module 8 covers data requirements for abridged applications and specialist products.
- Module 11 covers specific requirements for New Drug Applications in the US.

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Aim:

The purpose of this Module is to enable students to provide effective regulatory leadership within their organisations throughout the clinical development and the registration of a new medicine.

Regulatory Strategy for a New Active Substance: Global Clinical Development

Learning outcomes

- Students will differentiate between types of clinical study design and identify the pros and cons of each within the context of global regulatory requirements.
- Students will evaluate the medical, statistical, economic and operational principles underpinning the successful conduct of a clinical trial programme.
- Students will identify the activities required to ensure that data suitable for a product registration are derived from the clinical studies programme.
- Students will determine the strategic role of clinical study reports and summaries in obtaining an optimal product label.
- Students will understand the Regulatory Authorities' views of the clinical dossier.

Outline of Module topics:

- Designing the clinical programme: strategy for global development; the clinical trial programme; core protocol, pivotal studies, dose-finding, special studies, trial designs, patient numbers; statistical input (intention to treat, efficacy populations); pharmacoeconomics, pharmacogenomics
- Getting the trial underway: Clinical Trial Application strategy, special populations (paediatric, elderly, organ impairment), preclinical requirements, territories (trial locations: disease prevalence, patient populations, medical expertise), clinical trial registries
- Keeping the programme going: timescales, project management and costs
- Health Authorities – Your Partner in Drug Development: understanding and interpreting regulatory guidelines for a global drug development, seeking and implementing scientific advice
- Ensuring the right outcome: writing and evaluating clinical reports and summaries, risk/benefit evaluation, risk management, the target product profile and optimal product labelling
- Evaluating the data at the Regulatory Authorities: philosophies and assessment techniques, common faults in clinical registration packages, achieving a Global Clinical Programme and dossier

Links to other Modules

- Module 5 complements this Module, covering the practical regulatory issues associated with running clinical studies.



Module 5

Aim:

The purpose of this Module is to provide students with an understanding of the practical regulatory aspects of global clinical research, to enable them to provide effective advice on the regulatory issues likely to arise during clinical programmes.

Regulatory Control of Clinical Operations

Learning outcomes

- Students will understand the practical aspects of Good Clinical Practice and how it supports clinical research.
- Students will be able to identify the regulatory requirements for clinical research in major markets, understand the importance of the EU Clinical Trial Directive and the requirements and practicalities of preparing the required clinical trial applications and associated documentation.
- Students will gain an insight into the complexities and requirements of pharmacovigilance in clinical research.
- Students will be able to understand the management of clinical trial supplies.
- Students will be able to understand the requirements of Good Manufacturing Practice, authorisation and importation of investigational medicinal products.
- Students will be able to understand clinical trial reporting, the management of the data, data auditing and the practicalities of Good Clinical Practice inspections.
- Students will gain an appreciation of the legal and ethical aspects of clinical research, including insurance, indemnity and the role of the ethics committees and safety boards.

Outline of Module topics:

- Investigational Medicinal Product Dossier (IMPD), Investigational New Drug (IND) and other clinical dossier requirements including the progression of clinical trials in relation to the toxicity programme.
- Ethics Committees and Safety Boards.
- Clinical trial labelling, supplies management and Good Manufacturing Practice requirements
- Pharmacovigilance of clinical trials.
- Clinical trial reports.
- Data management.
- Good Clinical Practice – Inspections, data auditing and the Declaration of Helsinki.
- Compassionate use/extended access.
- The legal aspects of clinical trials.

Links to other Modules

- Module 4 complements this Module, covering the needs of global clinical development and effective advice on the suitability of clinical programmes from a regulatory perspective.

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Module 6

Aim:

The purpose of this Module is to provide students with an understanding of the strategic issues related to protecting and maintaining brand awareness throughout the product life.

Regulatory Strategy: The Market Place

Learning outcomes

- Students will recognise the needs of marketing colleagues in commercialising products and maintaining brand awareness through the development of new dosage forms, indications and switching of legal status.
- Students will demonstrate how the marketing life of a product can be optimised by use of patents and supplementary protection certificates and their role as regulatory professionals in maintaining the edge that such protection might offer.
- Students will evaluate the role of the Regulatory Affairs group in optimising the regulatory strategy in a manner which is sympathetic to the needs of pricing and reimbursement committees, such that any commercial advantages may be gained.
- Students will illustrate the importance of the SmPC as a means of communication with prescribers and as the basis for advertising and patient information.
- Students will identify the international constraints on the promotion of pharmaceutical products and OTC medicines.
- Students will define the responsibilities and requirements for keeping the licence current with respect to the reporting of adverse drug reactions.
- Students will differentiate the internal and external activities and interactions associated with issues management.

Outline of Module topics:

- The Needs of the Market: what is the market place, what does marketing want from regulatory, maintaining/extending brand awareness
- Intellectual Property, patents, trademarks, product naming, copyrights, supplementary protection certificates
- Demonstrating Value: pricing and reimbursement policies, pharmacoeconomics, formularies, NICE
- Getting the Foundations Right: the importance of SmPC statements, links to advertising, patient information, public assessment reports, Freedom of Information/Transparency
- Advertising and Controls of POMs and OTCs: EU, USA, Direct to Consumer (DTC) advertising
- Life Cycle Management: data and marketing exclusivity, line extensions, new indications and dosage forms, influence of generics
- Issues Management
- OTC Switching

Links to other Modules

- Module 1 covers the relationship between regulatory strategy and pricing, and reimbursement considerations.
- Module 7 complements this Module, covering regulatory strategies for submissions for established active substances.



Module 7

Aim:

The purpose of this Module is to enable students to study and understand the strategic issues to be considered in relation to medicines containing established active substances, including line extensions, generics and OTC products.

Regulatory Strategy for Established Active Substances

Learning outcomes

- Students will distinguish between the types of abridged applications possible in the EU and identify situations when the use of each of these is appropriate.
- Students will design and evaluate strategies for submissions in EU markets for products containing established active substances.
- Students will compare the routes to approval in the USA for products containing established active substances, sufficient to provide regulatory leadership to colleagues in this market.

Outline of Module topics:

- The commercial importance of abridged applications
- The type and range of abridged applications in Europe
- The legal background to abridged applications including data protection, marketing exclusivity and patent protection
- Options for abridged applications, and use of the different regulatory procedures
- Strategy for abridged applications including implications for harmonisation of the SmPC
- Processing of abridged applications by the Regulatory Authorities
- Particular issues for products containing well-established active ingredients, generic and over-the-counter (OTC) products
- Routes to approval of products containing established active ingredients in the USA

Links to other Modules

- Module 8 is designed to complement this Module by covering data requirements and specialised products.
- Module 9 provides more detail on biosimilar products
- Module 11 provides more detail on regulation of established active substances in the USA.

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Aim:

The purpose of this Module is to provide an understanding of the diversity of abridged applications, and to outline the data requirements for a variety of different new dosage forms and new indications. The Module also covers consideration of the data requirements for certain specialised products.

Data Requirements for Abridged Applications and Specialised Products

Learning outcomes

- Students will identify the chemical/ pharmaceutical, preclinical and clinical data required for line extensions taking into account the interaction between the various parts of a dossier.
- Students will define the requirements for bridging data in various situations.
- Students will examine the data requirements for line extensions, generic applications and for specialised products.
- Students will evaluate the data requirements for Supplemental Applications in the USA.

Outline of Module topics:

- Discussion of various types of abridged applications including new routes of administration, new dosage forms and new indications
- Chemical and pharmaceutical requirements for abridged applications including Drug Master Files and Comparability Protocols
- Bioequivalence
- Small-molecule generics
- Data requirements for biosimilar products
- Preclinical requirements for abridged applications
- Clinical data requirements for line extensions
- Discussion of particular product categories such as novel delivery systems, sustained release products, fixed-dose combination products and inhalation products
- Requirements for drug/device combinations
- Radiopharmaceuticals
- Blood products
- Herbal medicines

Links to other Modules

- Module 7 covers regulatory strategy for submissions for established active substances.
- Module 2 covers preclinical aspects of the regulatory strategy for a new active substance.
- Module 3 covers the regulatory requirements for chemistry and pharmacy for a new active substance.



Aim:

The purpose of this Module is to enable students to study and understand the scientific principles underpinning development of biological/ biotechnology products and how the inherent complexities impact on regulation.

Registration of Biological, Biotechnology and Advanced Therapy Products

Learning outcomes

- Students will discriminate between a biological and a chemical entity and will recognise and interpret the complex nature of biological/biotechnology products.
- Students will appraise the quality issues specific to biologicals, for example potential virus contamination, assay by bioassay.
- Students will analyse the implications of change in production process on product and the concept of comparability.
- Students will differentiate between classes of biological products such as vaccines, monoclonal antibodies and gene therapy and the data requirements specific to these products.

Outline of Module topics:

- What is a biological? How are they regulated?
- Characterisation and quality control
- Implications for change in process on product development
- Preclinical requirements
- Clinical development of biotech products
- New technologies, for example gene therapy, and how they are regulated
- Biosimilar products

Links to other Modules

- Module 1 covers global regulatory strategy.
- Modules 2-5 cover quality, safety and efficacy aspects of the regulatory strategy for a new active substance.

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Aim:

The aim of this Module is to provide students with an understanding of the skills needed to run a successful Regulatory Affairs department in order to optimise the contribution that Regulatory Affairs can make to the development, maintenance and commercialisation of products. In addition, the importance of liaison and collaboration with other key departments will be addressed, together with an introduction to the influencing and negotiation skills needed for effective teamwork.

Optimising the Contribution of Regulatory Affairs to Product Development, Maintenance and Commercialisation

Learning outcomes

- Students will review examples of policies and processes needed to run a Regulatory Affairs department.
- Students will identify and apply recruitment and training objectives in Regulatory Affairs.
- Students will examine tools such as regulatory intelligence and IT that are available to help manage a department.
- Students will categorise the key departments with whom Regulatory Affairs need to work co-operatively.
- Students will establish how they can maximise the contribution they make to product development, maintenance and commercialisation by working in collaboration and negotiating appropriately with other departments.
- Students will evaluate the necessity of project/portfolio management and decision analysis.

Outline of Module topics:

- Building a Regulatory Department
- Training for a Regulatory Department
- IT support
- Regulatory intelligence
- Collaboration with Pharmacovigilance, Marketing, Quality Control
- Introduction to negotiation skills
- Business planning, budgeting and registration fees
- The politics of regulation (influencing and lobbying)
- Product development plans and Regulatory project planning
- Decision analysis and portfolio management

Links to other Modules

- Module 1 complements this Module, covering aspects of project management, development strategies, regulatory procedures and the commercial implications of drug development.



Module 11

Aim:

The USA is the largest single country market for pharmaceutical products in the world. As such, the regulatory requirements of the US Food and Drug Administration have a major influence on the design of pharmaceutical development programmes aimed at achieving successful registration in both the USA and globally. This influence impacts to some extent on all Regulatory Affairs Professionals, whether directly involved with the USA or not. The purpose of this Module is to provide students with an understanding of the regulatory environment in the USA in order to place these global influences in perspective.

The US Regulatory Environment

Learning outcomes

- Students will examine the legal basis of pharmaceutical regulations in the USA and how the FDA operates within the legal framework.
- Students will differentiate the format and content of IND, NDA, BLA, ANDA and SNDA submissions, and examine the practical issues associated with these applications.
- Students will analyse FDA approaches to specific product types such as OTC products and orphan drugs.
- Students will assess the impact of US Regulatory Affairs on the global development and regulatory strategy for pharmaceuticals.

Outline of Module topics:

- History of drug regulation in the USA
- The legal basis of Regulatory Affairs in the USA
- Recent legislation (PDUFA and FDAAA).
- The IND
- The NDA and BLA
- The ANDA
- The SNDA
- OTC products
- Orphan drugs
- Fast track approvals
- Adverse event reporting
- Labelling, advertising and advertising controls
- Communicating with FDA

Links to other Modules

- Module 1 covers global regulatory strategy.
- Module 4 and 5 cover the global clinical development programme.
- Module 7 and 8 cover regulatory strategies and data requirements for abridged applications.
- Module 9 covers global strategies for biotechnology products.

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Module 12

Aim:

To provide students with a good appreciation of the regulatory control of medical devices particularly within the European Union. After participation in the Module, students should be able to provide strategic advice on the application of the medical device directives to enable products to be CE-Marked and on key international legislation.

Medical Device Regulatory Affairs

Learning outcomes

- Students will distinguish the routes to Conformity Assessment in the EU.
- Students will assess the role of the Competent Authorities and the Notified Bodies.
- Students will define the requirements of post-market surveillance and vigilance, and the role that risk management plays throughout the lifecycle of a device.
- Students will identify the documentation requirements for CE-Marking and the application of Harmonised Standards.
- Students will compare how medical devices are regulated in other markets and examine related international activities such as the Global Harmonisation Task Force.
- Students will interpret the requirements of clinical evaluation, how to initiate a clinical study and the ever increasing impact of Health Technology Assessment.

Outline of Module topics:

- The New Approach legislative environment in the European Union and the medical devices directives
- Conformity Assessment procedures
- Clinical evaluation
- Essential Requirements and Standards
- Risk-based classification system
- Post-market surveillance including vigilance
- Risk analysis and risk management
- The role of the Competent Authority and the Notified Body
- Medical device legislation in other markets and the Global Harmonisation Task Force
- Labelling for medical devices
- Devices containing drugs and borderline products
- *In-vitro* diagnostics

Links to other Modules

- Module 1 covers global regulatory strategy.
- Module 4 and 5 cover the global clinical development programme.
- Module 7 and 8 cover regulatory strategies and data requirements for abridged applications.
- Module 9 covers global strategies for biotechnology products.



Some questions answered

1. Who is eligible to register for the MSc?

In order to maintain and maximise the high standards set by the MSc course it is important to ensure that potential candidates are sufficiently qualified to contribute to and gain from the learning opportunities offered. It is important to note that the course offers the greatest benefit to regulatory specialists committed to a career in Regulatory Affairs.

Please refer to the 'Entry Requirements' on page 4 for further details.

2. If a student wishes to register does s/he have to decide at the beginning which eight modules to attend?

No, but in order to guarantee a place it is helpful if a student decides which modules to take before the start of each academic year.

3. Does the student have to commence the course with Module 1?

No, the student may commence the course with any module. The order of selection is the student's own personal choice. The first day of the first module attended is the official start date for students enrolled on the course.

4. Do students have to study for the full MSc or can modules be undertaken on a single, free-standing basis?

While priority is given to registered students, participants may be accepted onto one or more modules if space permits. There are no formal entry requirements for non students, however delegates should be sufficiently experienced to be able to contribute appropriately. This is a suitable option for personnel wishing to increase their knowledge of specific areas of Regulatory Affairs, without the need to pursue the additional studies required to pass the MSc.

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Some questions answered (*continued*)

5. If a student takes a few modules on a free-standing basis and then decides to take the MSc, can his/her previous modules contribute?

The student should preferably decide before undertaking a module whether or not it will contribute towards the MSc. Sometimes a student takes his/her initial module as a non-MSc student and then decides to register for the MSc. In such a case the initial module may count towards the MSc provided s/he makes an application immediately following the module.

6. What does an MSc student have to do?

- Attend eight modules.
- Follow up each module with private study and prepare a course journal and written assignments related to the subject of each module.
- Complete an additional MSc dissertation of 18,000 – 20,000 words. The topic is the student's choice, but subject to the approval of the Course Director and Examiners.
- Give a short oral presentation of the dissertation to an audience of Regulatory Affairs Professionals.

7. How much work does a student really have to do?

The student must be prepared to work hard! At the modules, the student will be provided with a great deal of information that will offer guidance. As with any postgraduate course it is then up to the student to find further information so as to develop a wide-ranging breadth of knowledge and an information base. Students are expected to prepare appropriately for each module and, for each module, to complete the course journal and written assignments. This independent work should take at least an additional 80 hours per module. The course journal is prepared by collecting and analysing reference material relevant to the subject of the module, eg. pertinent guidelines or published references. Also, two written assignments must be completed, one from a choice of three questions and the other being a compulsory problem-based analysis.

The student's ability to build up an information base in the form of a course journal is assessed for each module; the student must demonstrate that s/he understands the significance of the information gathered, analyses and relates it to areas of drug development or industrial practice. Understanding, interpretation and presentation of facts and arguments are tested by preparation of the written assignments. By the time the student has participated in the module, researched the topic and satisfactorily completed the written assignments, an in-depth knowledge of the subject of the module should have been acquired.

The percentage of marks awarded for each element, course journal, written assignments and dissertation is detailed in the Students Handbook, available on request from the TOPRA office.



Some questions answered *(continued)*

8. What type of work is involved in preparing an MSc dissertation?

The MSc dissertation is a research-based dissertation. The selection of a topic involves thinking of a regulatory-related subject that can be researched with the aim, like all research, of answering questions. The regulatory field has many open questions. For example: is the non-clinical testing carried out on biotechnology products suitable to identify the potential risks? Answering this question could involve finding out from the public domain (scientific and industrial literature, product information available on request eg. SBA, EPAR), or investigation of the student's own company's research, what testing has been done on a range of approved products (The Research). Then this information should be analysed (comparing the testing between products, with guidelines, with clinical use, with non-biotechnology products); the findings discussed and conclusions drawn. (Note: This outline is provided to demonstrate how research can be applied to regulatory topics rather than the laboratory situation. It is not formal guidance).

Students preparing to undertake the dissertation will be briefed further during their studies and asked to send in a research proposal to the Course Director, using the required application form (Student Handbook).

Details required include proposed title, research aims, methods and analysis, together with details of a proposed supervisor. On the basis of information supplied, the Examiners and Course Director will determine if the proposal is acceptable or needs revision.

9. What else should a student consider before embarking on the course?

Studying for the MSc in Regulatory Affairs requires a considerable commitment from the student and his/her employer. The amount of studying required in addition to attendance at the modules is described in this brochure. This information should help you decide if the course is the right one for you.

The Student Handbook should be read before attending the initial module as it gives full details of the regulations governing the course together with relevant practical information. All students receive a copy of the handbook when they are admitted to the course.

For full details of how the modules contribute to the MSc, any other information concerning registration for the course or an individual module, please contact the TOPRA office on: +44 (0)20 7510 2560 or visit the TOPRA website on: www.topra.org



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