

# MSc REGULATORY AFFAIRS

MEDICINES / MEDICAL DEVICES



## PROSPECTUS

## ABOUT US

The **Organisation for Professionals in Regulatory Affairs** has been running the TOPRA **MSc Regulatory Affairs** more than 25 years, and has been working in partnership with the **University of Hertfordshire** to offer this well-respected programme since 2013.

TOPRA and UH are pleased to announce the new MSc programme which offers **two pathways – Medicines and Medical Devices** – offering a much expanded curriculum and greater flexibility for students.

The new programme has been validated by UH, which has a strong track record in Life and Medical Sciences. It has developed a Pharmaceutical Science programme in collaboration with a range of local and national companies, from small biotech companies to multinational pharmaceutical giants.

TOPRA is the professional membership organisation for individuals working in healthcare regulatory affairs. TOPRA works with members internationally to enable and promote excellence across the healthcare regulatory profession.

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## ABOUT THE MSc

# MSc REGULATORY AFFAIRS MEDICINES/MEDICAL DEVICES

The **TOPRA MSc Regulatory Affairs** programme is designed for regulatory professionals who have already gained first-hand experience of regulatory affairs and wish to increase the breadth and/or depth of their knowledge.

It is a part-time flexible programme that is continually adapted to meet the ever-changing demands of the regulatory healthcare environment. Students can choose from 22 modules to ensure the overall programme is tailored to consolidate their own professional practice and provides development opportunities particularly for those who are at the stage of **consolidating** or **driving** their career (see page 52).

The MSc RA programme is unique in that all content is designed, structured and delivered by senior regulatory professionals from both industry and regulatory bodies, which means it always covers the most up-to-date and relevant issues facing regulatory professionals in their everyday practice. This also ensures all graduates have an in-depth knowledge and appreciation of various subjects directly relevant to them. The modules provide regulatory knowledge as well as the skills required to be a highly effective regulatory professional, such as leadership, strategic thinking, management and negotiation.

The MSc RA programme has been updated and revalidated by the University of Hertfordshire to include two pathways: **Regulatory Affairs (Medicines)** and **Regulatory Affairs (Medical Devices)**. Students on either pathway have the opportunity to take up to two modules from the other pathway – enabling greater flexibility to broaden their regulatory expertise across specialties.



**TOPRA 2020**  
CHANGE | CHALLENGE | FUTURE

**INVESTING FOR THE FUTURE**  
TOPRA is committed to providing regulatory professionals with continuing education opportunities in order to deliver better, safer healthcare for patients. The new updated MSc RA is a key element of our TOPRA 2020 initiative.



**EXCELLENCE**  
Developing regulatory excellence

“I would recommend the regulatory MSc to other colleagues, because it gives an overview of the different areas within regulatory in a short period of time. With this comes confidence dealing with different situations and, as we all know, no two days are the same in regulatory life”



## WHAT'S INVOLVED

### ENTRY REQUIREMENTS

The normal entry requirements for the programme are a BSc (Hons) – normally a minimum classification of 2:2 – in an appropriate scientific discipline (or equivalent qualification from a recognised educational institution) and the candidate must be able to demonstrate that they have sufficient regulatory experience to benefit from the programme.

However, candidates with limited regulatory affairs experience or who have experience but do not have a degree may be considered – contact [mscadmin@topra.org](mailto:mscadmin@topra.org) to discuss your individual circumstances.

An IELTS (International English Language Testing System) certificate 6.5 overall (with no individual component below 6.0) will normally be required for applicants whose first language is not English. The Course Director and the Collaborative Partnership Leader may consider the candidate's proficiency has been proven by their regulatory work output in English and/or through working and living in the UK or in a company that only communicates in English.

The programme is subject to the university's Principles, Policies and Regulations for the Admission of Students to Undergraduate and Taught Postgraduate Programmes (in UPR SA03), along with associated procedures. These will take account of university policy and guidelines for assessing accredited prior certificated learning (APCL) and accredited prior experiential learning (APEL).

### COURSE STRUCTURE

The MSc RA programme is offered in part-time mode taking 1-6 years, depending on the final award (see below).

Students may join the programme at the start of any of the scheduled modules as the programme does not follow a traditional semester entry format. Modules run on a three-year cycle with a total of five medicines modules, including the Overview of EU Regulatory Affairs (Module 0), which runs twice a year, and four medical devices modules taking place each year (see page 4).

Students for either the Medicines or Medical Device pathway can take up to two modules from the other pathway to allow great flexibility in tailoring their qualification.

Students not wishing to commit to the full MSc are able to register for a postgraduate diploma (requires eight modules), or a postgraduate certificate (requires four modules). Students registering for the postgraduate certificate may take any four modules from either the Medicines or Medical Device pathways. Any student who has registered for the PG Dip or PG Cert can transfer onto the full MSc programme (see page 4).

## MEDICINES PATHWAYS

MODULE 0	Overview of EU Regulatory Affairs
MODULE 1	Strategic Planning in Regulatory Affairs
MODULE 2	Regulatory Strategy for a New Active Substance: Nonclinical Development
MODULE 3	Regulatory Requirements for a New Active Substance: Quality
MODULE 4	Regulatory Strategy for a New Active Substance: Global Clinical Development
MODULE 5	Regulatory Strategy for a New Active Substance: Global Clinical Development
MODULE 6	Regulatory Strategy: From Development to the Market Place
MODULE 7	Regulatory Strategy for Established Active Substances
MODULE 8	Data for Abridged Applications and Specialised Products
MODULE 9	Registration of Biological, Biotechnology and Advanced Therapy Products
MODULE 10	Leadership and Strategic Management in Regulatory Affairs
MODULE 11	The US Regulatory Environment
MODULE 12	Data Management and Digitalisation in Regulatory Affairs

## MEDICAL DEVICES PATHWAYS

MODULE 13	Principles of Medical Device Regulatory Affairs
MODULE 14	Design, Development and Certification of Medical Devices
MODULE 15	Clinical Evaluation of Medical Devices
MODULE 16	Post Market Surveillance and Vigilance for Medical Devices
MODULE 17	Regulatory Strategy in the Post Market Phase
MODULE 18	Drug-device Combinations and Other Technologies
MODULE 19	Regulation of In vitro Diagnostic Medical Devices
MODULE 20	Regulation of Electrical, Electronic and Software Devices
MODULE 21	US Regulation of Medical Devices

## WHAT'S INVOLVED

### ASSESSMENTS

Following each module the student must complete coursework assignments related to the module topic. The coursework is assessed at defined times during the academic year in which the modules are undertaken (see table below for **timings of the modules**).

Submission dates for the course journals and assignments are given at each individual module. A maximum period of three months is allowed for completion of the coursework.

Students are required to satisfy the examiners with respect to the coursework prepared for each module undertaken. Should a candidate fail to satisfy the Board of Examiners, coursework may be resubmitted within a timeframe stipulated by the Board.

### DISSERTATION

Following successful completion of eight modules, students must submit a research-based MSc dissertation (Module 22) of 18,000–20,000 words to achieve the MSc award (see page 50).

### MODULE SCHEDULES

Students can take plan when to take particular modules from the table below.

	Jan–Feb	Mar–Apr	May–Jul	Sept–Oct	Nov–Dec
2017	9, 19	0, 1	3, 13, 14	2	0, 4, 15
2018	5, 12	0, 6, 16	7, 13, 17	11, 18	0, 8
2019	10, 19	0, 9	1, 13, 20	2, 21	0, 3, 12
2020	4, 14	0, 5	6, 13, 15	7, 16	0, 11, 17
2021	8, 18	0, 10	9, 13, 19	1, 20	0, 2, 21
2022	3, 12	0, 4	5, 13, 14	6, 15	0, 7, 16
2023	8, 17	0, 11	10, 13, 18	9, 19	0, 1, 20
2024	2, 21	0, 3	4, 12, 13	5, 14	0, 6, 15
2025	7, 16	0, 11	8, 13, 17	10, 18	0, 9, 19

### AWARDS

› The award of an MSc requires 180 credit points\* passed at Level 7 including the dissertation.

› The award of a Pg Dip requires 120 credit points passed at Level 7.

› The award of a Pg Cert requires 60 credit points passed at Level 7.

#### MSc Regulatory Affairs (Medicines)

› Compulsory – dissertation

› Students must pass at least 6 modules from modules 0–12

› Students may take up to 2 modules from modules 13–21

#### Pg Dip Regulatory Affairs (Medicines)

› Students must pass at least 6 modules from modules 0–12

› Students may take up to 2 modules from modules 13–21

#### MSc Regulatory Affairs (Medical Devices)

› Compulsory – dissertation

› Students must pass at least 6 modules from modules 10, 13–21

› Students may take up to 2 modules from modules 0–12

#### Pg Dip Regulatory Affairs (Medical Devices)

› Compulsory – dissertation

› Students must pass at least 6 modules from modules 10, 13–21

› Students may take up to 2 modules from modules 0–12

#### PG Cert Regulatory Affairs

› Students must pass at least 4 modules from modules 0–21.

## WHY DO AN MSc WITH TOPRA?

TOPRA is committed to supporting regulatory professionals to perform at the highest level – and does this via a wide range of professional development activities. TOPRA's postgraduate programme – which offers postgraduate qualifications from Certificate to PhD – has been developed *by* regulatory professionals *for* regulatory professionals. All module leaders are practising experts in their field offering up-to-date, tailored courses in a wide range of regulatory specialties.

This updated flexible **MSc RA (Pharmaceutical/Medical Devices)** enables students to build a postgraduate qualification to drive their future career. Students benefit from the best of both worlds – by being aligned with a global professional body with the support of the **University of Hertfordshire**, a world-class academic institution.

### ACADEMIC RESOURCES

All TOPRA's MSc students have access not only to the UH library, but to the Royal Pharmaceutical Society Library and other academic libraries (access arranged via TOPRA), as well as to SCONUL ([www.access.sconul.ac.uk](http://www.access.sconul.ac.uk)) which allows borrowing facilities for part-time, distance and placement students.

Students also have access to StudyNet, UH's MLE (managed learning environment), in order to access to all information relevant to their studies and communicate with other students via a discussion forum. StudyNet thus provides a vital link between teaching staff and students.

### SUPPORT MECHANISMS

At their first module, all students attend a mandatory tutorial meeting and from then onwards they can contact the Course Director (and Dissertation Academic Adviser for Dissertation student support) via telephone and email.

Each student is encouraged to use Personal Development Planning (PDP) which is a process of recording and reflecting on their skills and experience which will to help plan their personal, educational, and career development. Both TOPRA and UH are on hand to offer access to careers advice.

The university offers a professional counselling support service, equal opportunities advice, and disability services (contact TOPRA or UH for details).

Some students may be eligible for a UK Government postgraduate loan. Please see the government's website Postgraduate Loans for further information.



## MODULE 0

### OVERVIEW OF EU REGULATORY AFFAIRS

To provide a brief overview of the many aspects of regulation of medicines in Europe, enabling attendees to understand the legislative framework and practical aspects of EU pharmaceutical regulatory affairs.

#### CONTENT

This module is designed for regulatory professionals to develop and deepen their understanding of all aspects of regulatory operations in the EU, and the role of the regulatory affairs function. It will allow them to examine the regulatory requirements imposed on drug development, the processes of preparing regulatory documentation for clinical trial authorisation and marketing authorisation.

## LEARNING OUTCOMES

### KNOWLEDGE AND UNDERSTANDING

#### Successful students will typically:

- › Demonstrate a conceptual understanding of the regulatory requirements: EU directives and legislation; regulatory authorisation and associated documentation for marketing submissions to evaluate current developments critically
- › Display a comprehensive understanding of the EU regulatory aspects of drug development
- › Possess a systematic understanding of knowledge, and a critical awareness of the regulatory environment and procedures governing regulatory approval of clinical trials in the EU and regulatory marketing authorisation in the context of drug development.

### SKILLS AND ATTRIBUTES

#### Successful students will typically:

- › Demonstrate the ability to critically analyse the legal documentation and guideline considerations of EU regulatory affairs
- › Deal with complex issues both systematically and creatively, make sound judgements in the absence of complete data, and communicate their conclusions clearly to specialist and non-specialist audiences in relation to obtaining regulatory authorisation
- › Critically appraise and evaluate communications from regulatory bodies and research publications.

## MODULE 1

### STRATEGIC PLANNING IN REGULATORY AFFAIRS

To enable students to understand the practical and strategic aspects of global regulatory affairs, helping them develop sufficient knowledge and skills to provide advice to their companies and contribute to regulatory strategy.

#### CONTENT

This module is designed to develop and deepen students' understanding of all aspects of the management of global regulatory operations and strategic planning. It enables them to examine the strategic regulatory options for planning global drug development programmes, the interactions between the companies and the regulatory agencies, the processes of preparing strategic regulatory documentation for gaining marketing authorisation and commercialisation of a product.

“You can pick the different modules you want to study. This flexibility is useful as you can choose ones you do not have experience with to broaden your knowledge”

## LEARNING OUTCOMES

#### KNOWLEDGE AND UNDERSTANDING

##### Successful students will typically:

- › Demonstrate a systematic understanding of knowledge in, and a critical awareness of the theory and practice of global strategic planning strategies as they relate to obtaining regulatory marketing authorisation and pricing negotiations
- › Display critical knowledge of the regulatory requirements, global legislation, regulatory authorisation and associated documentation for planning drug development programmes
- › Demonstrate an in-depth conceptual understanding of strategic plans for the regulatory approval of drug development programmes.

#### SKILLS AND ATTRIBUTES

##### Successful students will typically:

- › Critically appraise and evaluate communications from regulatory bodies and research publications for the management of regulatory affairs and strategic planning in drug development
- › Demonstrate the ability to critically analyse the legal documentation and regulatory consideration of drug development
- › Deal with complex issues both systematically and creatively, make sound judgements in the absence of complete data, and communicate their conclusions clearly to specialist and non-specialist audiences regarding planning regulatory strategies for drug development programmes for regulatory authorisation and marketing approval.



## MODULE 2

# REGULATORY STRATEGY FOR A NEW ACTIVE SUBSTANCE: NONCLINICAL DEVELOPMENT

To enable students to understand the practical and legislative requirements for the nonclinical phase of global drug development. It explores regulatory issues that are likely to arise and provides advice and discussion around solutions to such situations.

## CONTENT

This module is designed to develop and deepen regulatory professionals' understanding of all aspects of the nonclinical development for a new active substance. It enables them to examine the nonclinical regulatory requirements imposed on drug development, the processes of preparing documentation for the nonclinical dossier, including considerations for the nonclinical study reports and summaries.

## LEARNING OUTCOMES

### KNOWLEDGE AND UNDERSTANDING

#### Successful students will typically:

- › Develop a systematic understanding and a critical awareness of the practical aspects of nonclinical development, types and design of nonclinical safety studies and pharmacokinetic requirements in the context of the nonclinical research phase of drug development
- › Demonstrate a comprehensive understanding of the nonclinical regulatory requirements, nonclinical guidelines and other requirements for running nonclinical drug safety studies
- › Have a conceptual understanding of the legal and ethical aspects of nonclinical research and the importance of critical evaluation of the study designs and data generated during research on medicinal products.

### SKILLS AND ATTRIBUTES

#### Successful students will typically:

- › Demonstrate the ability to critically analyse the nonclinical regulatory documentation and guidelines for the nonclinical part of drug development.
- › Deal with complex issues both systematically and creatively, make sound judgements in the absence of complete data, and communicate their conclusions clearly to specialist and non-specialist audiences
- › Critically appraise and evaluate communications from regulatory bodies and research publications covering the nonclinical data.



## MODULE 3

### REGULATORY REQUIREMENTS FOR A NEW ACTIVE SUBSTANCE: QUALITY

To enable students to understand quality data requirements in the pharmaceutical regulatory environment so they can address practical regulatory questions in this area and offer advice to colleagues.

#### CONTENT

This module is designed for regulatory professionals to develop and deepen their understanding of all aspects of the regulation of chemistry and pharmacy data. It will allow them to examine the regulatory requirements imposed on preparing chemistry and pharmacy data, the processes of preparing chemistry and pharmacy documentation such as the Common Technical Document, IMPDs and INDs.

“Doing the MSc gives you confidence to deal with a large amount of information, become familiar with where to go to get information about different regulations etc, and summarise information quickly”

## LEARNING OUTCOMES

#### KNOWLEDGE AND UNDERSTANDING

##### Successful students will typically:

- › Display a systematic understanding of chemistry and pharmacy data requirements with the knowledge to interpret them during development of a new chemical active substance
- › Possess a comprehensive understanding of good manufacturing processes in formulation and the validation requirements in the context of drug development
- › Demonstrate conceptual understanding of the legal and regulatory requirements for the development of a new active substance including EU clinical directives, global legislation and guidelines to evaluate critically current research.

#### SKILLS AND ATTRIBUTES

##### Successful students will typically:

- › Demonstrate the ability to critically analyse the legal documentation and regulatory considerations for the chemistry and pharmacy data required for developing the specifications for the drug product
- › Deal with complex issues both systematically and creatively, make sound judgements in the absence of complete data, and communicate their conclusions clearly to specialist and non-specialist audiences
- › Critically appraise and evaluate communications from regulatory bodies and research publications covering chemistry and pharmacy data.



## REGULATORY STRATEGY FOR A NEW ACTIVE SUBSTANCE: GLOBAL CLINICAL DEVELOPMENT

To enable students to understand and develop regulatory strategies for all aspects of global clinical research, as well as addressing practical regulatory issues in this area.

### CONTENT

This module is designed for regulatory professionals to develop and deepen their understanding of all aspects of the regulation of global clinical development. It allows them to examine the regulatory requirements imposed on clinical development; the processes of preparing documentation for clinical study reports and regulatory overview summary documents; and strategic considerations for the running of international clinical trial programmes.

### KNOWLEDGE AND UNDERSTANDING

#### Successful students will typically:

- › Possess a systematic understanding and critical awareness of the regulations and international directives pertaining to clinical development of a new medicine
- › Show a critical awareness of the clinical programme strategies, which can be employed during development and registration of a new medicine, and exhibit effective regulatory leadership throughout clinical development and the registration of a new medicine
- › Display a comprehensive understanding of the EU legislation on the different aspects of clinical development, and of the procedures and regulatory requirements for clinical trial reports, clinical overview and summary documents for optimal product labelling
- › Evaluate methodologies and develop critiques of the medical, statistical, economic and operational aspects of clinical trial programmes.

### SKILLS AND ATTRIBUTES

#### Successful students will typically:

- › Demonstrate the ability to critically analyse the legal documentation relating to global operational clinical trial programme considerations of clinical research
- › Deal with complex issues both systematically and creatively, make sound judgements in the absence of complete data, and communicate their conclusions clearly to specialist and non-specialist audiences
- › Critically appraise and evaluate global clinical research communications from regulatory bodies and research publications.



## MODULE 5

# REGULATORY CONTROL OF CLINICAL OPERATIONS

To enable students to consider and evaluate practical regulatory aspects of global clinical research; and explore and critically debate the regulatory issues likely to arise during clinical programmes in order to be able to provide effective advice on such situations.

## CONTENT

This module is designed for regulatory professionals to develop and deepen their understanding of all aspects of the regulation of clinical operations. It will allow them to examine the regulatory requirements imposed on clinical research, the processes of preparing documentation for clinical trial authorisation and the ethical and legal considerations. In particular, the module will impart the ability to critically appraise actions and report recommendations on the appropriateness of strategies in clinical research.

## LEARNING OUTCOMES

### KNOWLEDGE AND UNDERSTANDING

#### **Successful students will typically:**

- › Develop a systematic understanding and a critical awareness of the practical aspects of good clinical practice (GCP), good manufacturing practice (GMP), ISO 14155 and pharmacovigilance in the context of clinical research
- › Critically evaluate the current regulatory requirements, EU clinical directives/regulations, clinical trial authorisation and associated documentation for both pharmaceuticals and devices
- › Demonstrate in-depth knowledge and comprehensive understanding of the legal and ethical aspects of clinical research and importation of medicinal products/medical devices.

### SKILLS AND ATTRIBUTES

#### **Successful students will typically:**

- › Demonstrate the ability to critically analyse the legal documentation and ethical considerations of clinical research
- › Deal with complex issues both systematically and creatively, make sound judgements in the absence of complete data, and communicate their conclusions clearly to specialist and non-specialist audiences
- › Critically appraise and evaluate communications from regulatory bodies and research publications.

## MODULE 6

### REGULATORY STRATEGY: FROM DEVELOPMENT TO THE MARKET PLACE

To enable students to consider and evaluate practical regulatory aspects of regulatory strategy for commercialising products and maintaining the brand from development stages to registration and throughout the product lifecycle; and explore and critically debate the regulatory issues likely to arise before and during commercialisation of products in order to be able to provide effective advice as necessary.

#### CONTENT

This module enables regulatory professionals to develop and deepen their understanding of all aspects of the regulatory strategic issues related to defining and shaping the brand, protecting and maintaining brand awareness throughout the product lifecycle. It allows them to examine the regulatory requirements imposed on commercial medicinal products.

“Nice to get to deliberate (in the case studies) with colleagues from different companies and agencies. Different opinions were circulated and I learned a lot from this exercise”

## LEARNING OUTCOMES

#### KNOWLEDGE AND UNDERSTANDING

##### Successful students will typically:

- › Have a conceptual understanding that enables them to evaluate critically the different strategic approaches to product lifecycle management and drug development
- › Possess a critical knowledge of the regulatory requirements, directives and international requirements for commercialising products and maintaining the brand
- › Demonstrate an in-depth knowledge and critical awareness of the legal and ethical aspects of lifecycle management of medicinal products.

#### SKILLS AND ATTRIBUTES

##### Successful students will typically:

- › Demonstrate the ability to critically analyse the legal documentation considerations of maintaining and managing the brand through lifecycle management, including advertising and promotion, changing legal status and safety reporting
- › Select and examine appropriate methods of communication of complex data regarding commercialised products for dissemination to both non-regulatory experts and regulatory experts, including the SmPC (summary of product characteristics) data
- › Critically appraise and evaluate communications from regulatory bodies and research publications regarding commercialised medicinal products.



## MODULE 7

# REGULATORY STRATEGY FOR ESTABLISHED ACTIVE SUBSTANCES

To enable students to consider and evaluate practical aspects of regulatory strategy for established active substances; and explore and critically debate the regulatory issues likely to arise for established active substances in order to be able to provide effective advice.

## CONTENT

This module enables regulatory professionals to develop and deepen their understanding of all aspects of the regulations and the strategic issues to be considered in relation to medicines containing established active substances, including line extensions, generics and the relevant aspects for over-the-counter (OTC) products. It allows them to examine the regulatory requirements imposed on established active substances.

## LEARNING OUTCOMES

### KNOWLEDGE AND UNDERSTANDING

#### **Successful students will typically:**

- › Display systematic understanding and critical awareness of the strategies for approval of established active substances in the context of abridged applications and OTC products
- › Have a critical understanding of the regulatory requirements, directives and associated documentation associated with established active substance approval
- › Demonstrate a conceptual understanding of the legal requirements for approval of established medicinal products as OTC products in order to evaluate critically the current research and advanced scholarship in the discipline.

### SKILLS AND ATTRIBUTES

#### **Successful students will typically:**

- › Demonstrate the ability to critically analyse the legal documentation and regulatory considerations of established active substances
- › Deal with complex issues both systematically and creatively, make sound judgements in the absence of complete data, and communicate their conclusions clearly to specialist and non-specialist audiences regarding established active substances
- › Critically appraise and evaluate communications from regulatory bodies and research publications regarding established active substances.

## MODULE 8

# DATA FOR ABRIDGED APPLICATIONS AND SPECIALISED PRODUCTS

To enable students to consider and evaluate practical aspects of regulatory strategy for abridged applications and specialised products; and explore and critically debate the regulatory issues likely to arise for abridged applications and specialised products in order to provide effective advice in this area.

## CONTENT

This module enables regulatory professionals to develop and deepen their understanding of all aspects of the regulation, the issues and the diversity of abridged applications. It also outlines the data requirements for a variety of different new dosage forms and new indications. The data requirements for certain specialised products are also covered. It allows students to examine the regulatory requirements imposed on abridged applications and specialised products.

“Very good course to give an insight into data requirements for abridged applications and specialised products”

## LEARNING OUTCOMES

### KNOWLEDGE AND UNDERSTANDING

#### Successful students will typically:

- › Develop a systematic understanding of knowledge, and a critical awareness of the legal requirements for development and marketing of established active substances in the context of abridged applications and specialised products
- › Have a conceptual understanding of the processes and strategies to comply with the regulatory requirements, directives, and associated documentation with the strategy for abridged applications and specialised products that enables them to evaluate critically current research and advanced scholarship in the discipline
- › Be able to identify, evaluate and connect the chemical/pharmaceutical, nonclinical and clinical data required for abridged applications and specialised products.

### SKILLS AND ATTRIBUTES

#### Successful students will typically:

- › Demonstrate the ability to critically analyse the legal documentation and regulatory considerations of abridged applications and specialised products
- › Deal with complex issues both systematically and creatively, make sound judgements in the absence of complete data, and communicate their conclusions clearly to specialist and non-specialist audiences regarding abridged applications and specialised products
- › Critically appraise and evaluate communications from regulatory bodies and research publications regarding abridged applications and specialised products.



## MODULE 9

# REGISTRATION OF BIOLOGICAL, BIOTECHNOLOGY AND ADVANCED THERAPY PRODUCTS

To enable students to consider and evaluate practical aspects of regulatory strategy for biological, biotechnology and advanced therapy products; and explore and critically debate the regulatory issues likely to arise for biological, biotechnology and advanced therapy products in order to provide effective advice on such situations.

## CONTENT

This module enables regulatory professionals to develop and deepen their understanding of all aspects of the regulation of the issues of the scientific principles underpinning development of biological/biotechnology products and how the inherent complexities impact on regulation. It also considers the data requirements for biological, biotechnology and advanced therapy products and allows students to examine the regulatory requirements imposed on biological, biotechnology and advanced therapy products.

## LEARNING OUTCOMES

### KNOWLEDGE AND UNDERSTANDING

#### **Successful students will typically:**

- › Display a systematic understanding of knowledge, and a critical awareness of the unique nature and strategies for development of biological, biotechnology and advanced therapy products
- › Possess a comprehensive understanding of the regulatory requirements and associated documentation with the licensing of biological, biotechnology and advanced therapy products
- › Demonstrate a conceptual understanding of the legal and pharmaceutical requirements that define the regulatory strategy for biological, biotechnology and advanced therapy products.

### SKILLS AND ATTRIBUTES

#### **Successful students will typically:**

- › Deal with complex issues both systematically and creatively, make sound judgements in the absence of complete data, and communicate their conclusions clearly to specialist and non-specialist audiences regarding biological, biotechnology and advanced therapy products
- › Demonstrate the ability to critically analyse the legal documentation and regulatory considerations of biological, biotechnology and advanced therapy products
- › Critically appraise and evaluate communications from regulatory bodies and research publications regarding biological, biotechnology and advanced therapy products.

## LEADERSHIP AND STRATEGIC MANAGEMENT IN REGULATORY AFFAIRS

To enable students to consider and evaluate practical aspects of leadership and management required to run a successful regulatory affairs department, which is responsible for the regulatory strategy for product development, maintenance and commercialisation. It allows them to explore and critically debate the management issues likely to arise in running a successful regulatory affairs department in order to be a key contact for main stakeholders and bring competitive advantage to the company.

### CONTENT

This module enables regulatory professionals to develop and deepen their understanding of all aspects of the management and leadership skills needed to run a successful regulatory affairs department in order to bring competitive advantage to the company and the main stakeholders.

### KNOWLEDGE AND UNDERSTANDING

#### Successful students will typically:

- › Develop a systematic understanding and critical awareness of the practical management aspects of running a regulatory affairs department responsible for product development, maintenance and commercialisation
- › Demonstrate a critical knowledge of how to liaise and collaborate with other departments to ensure the appropriate documentation used in development, maintenance and commercialisation of healthcare products is in place
- › Possess a comprehensive understanding of the legal requirements and management theory governing regulatory strategies for product development, maintenance and commercialisation.

### SKILLS AND ATTRIBUTES

#### Successful students will typically:

- › Demonstrate the ability to understand the management and leadership skills required to run a regulatory affairs department as a manager, a leader or a member of the team
- › Deal with complex issues both systematically and creatively, make sound management judgements in the absence of complete data, and communicate their conclusions clearly to specialist and non-specialist audiences, including working with other departments
- › Critically appraise and evaluate communications from regulations, guidelines, research and other publications regarding the management of a regulatory affairs department.

## THE US REGULATORY ENVIRONMENT

To enable students to consider and evaluate practical regulatory aspects of regulatory affairs in the US; and explore and critically debate the regulatory issues likely to arise during drug development in order to be able to provide effective advice on the regulatory affairs activities involved with drug development in the US.

### CONTENT

This module enables regulatory professionals to develop and deepen their understanding of all aspects of regulatory operations in the US. Its purpose is to provide students with an understanding of the regulatory environment in the US in order to place these global influences in perspective.

### KNOWLEDGE AND UNDERSTANDING

#### Successful students will typically:

- › Possess a systematic understanding and critical awareness of the regulatory environment and procedures governing regulatory approval of clinical trials in the US and regulatory marketing approval in the context of drug development
- › Demonstrate a conceptual understanding of the regulatory requirements, FDA requirements, regulatory authorisation and associated documentation for marketing submissions
- › Display originality in the application of knowledge of the US regulatory aspects of drug development to critically evaluate current research in the discipline.

### SKILLS AND ATTRIBUTES

#### Successful students will typically:

- › Demonstrate the ability to critically analyse the legal documentation for US drug development
- › Critically appraise and evaluate communications from regulatory bodies (such as the FDA) and critically evaluate research publications
- › Deal with complex issues related to the US regulatory authorisation, both systematically and creatively, make sound judgements in the absence of complete data, and communicate their conclusions clearly to specialist and non-specialist audiences.





## MODULE 12

# DATA MANAGEMENT AND DIGITALISATION IN REGULATORY AFFAIRS

To enable students to understand the theoretical background to data management, document management, electronic submissions, eCompliance, regulatory information management and the new Identification of Medicinal Products (IDMP) requirements, and find solutions to practical problems in this area; and deal with large volumes of data and different data – from nonclinical to post-market pharmacovigilance.

## CONTENT

Data management has always been a key part of regulatory affairs from nonclinical data to post-market pharmacovigilance – and the amount of data and the complexity of the data analysis is increasing. This module covers data management in daily regulatory affairs work; digitisation; EMA telematics strategy; eCTD; EMA's collaboration strategy; archiving of documents; CSV; regulatory information management; regulatory intelligence and knowledge management; IDMP; and big data approaches to RA.

## LEARNING OUTCOMES

### KNOWLEDGE AND UNDERSTANDING

#### Successful students will typically:

- › Be able to explain the importance of data, document and information management and critically evaluate the IDMP requirements
- › Demonstrate a critical understanding of the processes and requirements necessary for completing an eCTD (electronic common technical document)
- › Demonstrate a conceptual understanding of data and document management in daily regulatory affairs work and identify issues with electronic compliance.

### SKILLS AND ATTRIBUTES

#### Successful students will typically:

- › Be able to make recommendations about regulatory information management and IDMP strategies
- › Manage documents and data in an effective and efficient way
- › Critically analyse data and documentation strategies and processes
- › Critically appraise regulatory processes and documentation
- › Be able to explain the basis for electronic regulatory submissions.

## PRINCIPLES OF MEDICAL DEVICE REGULATORY AFFAIRS

To enable students to understand the legislative framework for the regulation of devices in Europe and beyond; understand the practical aspects of regulatory strategy for medical devices and be able to answer questions in this area; and have an appreciation of the overall regulatory pathway and key requirements to market a medical device product in the EU.

### CONTENT

This module enables regulatory professionals to develop and deepen their understanding of all aspects of regulation and strategic issues to be considered in relation to medical devices, including strategic advice on the application of the EU medical device legislation to enable products to be CE-marked.

“Good to have notified  
body, competent  
authority and industry  
representatives”

### KNOWLEDGE AND UNDERSTANDING

#### Successful students will typically:

- › Demonstrate a conceptual understanding of the strategies for development and marketing of medical device products so they can be critiqued and alternative hypotheses developed
- › Demonstrate a critical knowledge of the legal and other aspects of the regulatory strategy for medical device products
- › Possess a systematic understanding and critical awareness of the regulatory requirements of directives, regulations and associated documentation relating to medical device products, with particular emphasis on EU regulatory procedures.

### SKILLS AND ATTRIBUTES

#### Successful students will typically:

- › Deal with complex issues both systematically and creatively, make sound judgements in the absence of complete data, and communicate their conclusions clearly to specialist and non-specialist audiences
- › Demonstrate the ability to critically analyse the legal documentation and regulatory considerations of medical devices
- › Critically appraise and evaluate communications from regulatory bodies and research publications regarding medical devices.

## DESIGN, DEVELOPMENT AND CERTIFICATION OF MEDICAL DEVICES

To enable students to demonstrate an understanding of the development, manufacturing and GxP (good practice) requirements for product development so that they can provide appropriate advice on the key regulatory issues affecting the design and manufacturing of medical devices; and to understand the importance and concepts of risk management and the ways in which risk is managed from the design stage onwards.

### CONTENT

The module covers control of design and development; input and output requirements and the required documentation using example devices. It also looks at the impact of materials choice, design, verification, validation and certification of medical devices as well as the applicable legislation, regulatory standards, guidance and other documents (including GxP). Other topics include: packaging and labelling (including unique device identification); biocompatibility and toxicology, risk management (including ISO 14971 and feedback of PMS data); and additive manufacturing and sterilisation.

### KNOWLEDGE AND UNDERSTANDING

#### Successful students will typically:

- › Be able to critically evaluate the design of a device including the materials it is made from
- › Demonstrate critical understanding of the safety and performance of devices using applicable product standards for the EU and other global markets
- › Critically evaluate the principles and practice of risk management as set out in ISO 14971 to a level where they can apply it to a complex medical device
- › Be able to create and appraise the documents required to apply for certification of medical devices for the EU and other global markets.

### SKILLS AND ATTRIBUTES

#### Successful students will typically:

- › Give appropriate advice to the medical device team on key regulatory issues affecting the design, development and manufacturing of devices
- › Produce the necessary technical documentation within project timeframes
- › Critically appraise and evaluate communications from competent authorities, notified bodies and research publications covering the design, development and certification of medical devices globally.

# CLINICAL EVALUATION OF MEDICAL DEVICES

To enable students to understand the broad scope of clinical investigation and the regulatory processes required with the alternative routes to demonstrate regulatory compliance.

## CONTENT

The module provides an overview of the clinical research paradigm for medical devices and the key underlying ethical and statistical methodology; core regulatory requirements that relate to the appropriate performance of devices; analysis of the place clinical evaluation plays in risk analysis and risk management during device development and manufacture; an understanding of the requirements for ethics committee approval and institutional review board (IRB) approval; knowledge of notification and pre-approval requirements; systematic review in clinical investigation; an understanding of the health technology appraisal systems and reimbursement on clinical evaluation.

### KNOWLEDGE AND UNDERSTANDING

#### Successful students will typically:

- › Be able to critically evaluate existing literature and assess the need for clinical evaluation
- › Critically evaluate the methodology and conduct of clinical research
- › Appraise the factors that influence the quality of clinical evaluation
- › Demonstrate a systematic understanding and critical awareness of the regulatory requirements, directives and associated documentation relating to the clinical evaluation of medical devices.

### SKILLS AND ATTRIBUTES

#### Successful students will typically:

- › Demonstrate the ability to critically analyse the legal documentation relating to clinical evaluation of devices
- › Deal with complex issues both systematically and creatively, make sound judgements in the absence of complete data, and communicate their conclusions clearly to non-specialist audiences
- › Critically appraise and evaluate communications from regulatory bodies and stakeholders relating to the conduct of clinical research.

## POST MARKET SURVEILLANCE AND VIGILANCE FOR MEDICAL DEVICES

To enable students to define the terminology and explain the concepts of vigilance and post market surveillance (PMS), and their practical applications and integration into the lifecycle of a medical device. The focus is on meeting European requirements.

### CONTENT

The module covers EU requirements for PMS, including recalls and vigilance, as well as the role of competent authorities (CAs), notified bodies (NBs), manufacturers and other economic operators in this area; and relevant guidance documents. It also includes key elements of proactive PMS; the role of the person responsible for regulatory compliance; tailoring PMS systems to specific products, including drug-device combinations and IVDs; and the requirements of EN ISO13485, the quality management standard for medical devices.

### KNOWLEDGE AND UNDERSTANDING

#### Successful students will typically:

- › Critically evaluate the requirements and guidance for PMS
- › Critically evaluate the requirements and guidance for vigilance
- › Possess a systematic understanding and critical awareness of the European requirements including legislation, guidance and associated documentation relating to surveillance and vigilance for medical devices.

### SKILLS AND ATTRIBUTES

#### Successful students will typically:

- › Critically appraise a PMS system and make recommendations on the implementation of a PMS system
- › Be able to make recommendations about vigilance procedures
- › Demonstrate the ability to critically analyse the legal requirements relating to surveillance and vigilance
- › Critically appraise and evaluate communications from competent authorities, notified bodies, economic operators and other stakeholders relating to the conduct of surveillance and vigilance.

# REGULATORY STRATEGY IN THE POST MARKET PHASE

To enable students to provide regulatory affairs insight into the strategic issues affecting the commercial and regulatory maintenance of a medical device throughout its lifecycle, with focus on post-launch activities and future pressures.

## CONTENT

This module enables professionals to develop and deepen their understanding of a variety of topics of importance to the maintenance of the commercial and regulatory health of their company's medical devices once they have been successfully placed on the market. Topics include advertising, data protection and privacy, patents and IP, health technology assessment (HTA) and reimbursement, environmental legislation and standards, relationships with distributors, own-branders, authorised representatives, trade association and regulatory bodies, product supply and logistics, product liability law, unannounced audits and good regulatory practice.

### KNOWLEDGE AND UNDERSTANDING

#### **Successful students will typically:**

- › Demonstrate a critical understanding of the factors required to maximise the success of a medical device
- › Understand the importance of intellectual property, data protection and product liability and judge when legal advice is required
- › Demonstrate a critical understanding of HTA and reimbursement
- › Critically evaluate the application of environmental legislation and standards to medical devices.

### SKILLS AND ATTRIBUTES

#### **Successful students will typically:**

- › Demonstrate the ability to critically analyse the legal, regulatory and quasi-regulatory requirements applying to medical devices
- › Deal with complex issues both systematically and creatively, make sound judgements in the absence of complete data, and communicate their conclusions clearly to specialist and non-specialist audiences
- › Apply good regulatory practice particularly when interacting with regulatory bodies, including critically appraising communications
- › Make recommendations on how to prepare for unannounced audits.

## DRUG-DEVICE COMBINATIONS AND OTHER TECHNOLOGIES

To enable students to consider and evaluate the practical quality and regulatory aspects of drug-device combinations and medical devices manufactured by innovative manufacturing techniques. To explore and critically debate the quality and regulatory issues likely to arise from the manufacturing of medical devices with such techniques, in order to be able provide effective management and advice about placing combination products on the market.

### CONTENT

Aimed at regulatory professionals interested or working with medical devices manufactured with innovative/non-traditional processes and/or falling within the classification of drug-device, combination and/or borderline products. It covers: application of legislation, directives, guidelines; interpretation and classification of documents and regulatory requirements revolving around medical devices manufactured with innovative/non-traditional processes, including drug-device, combination and borderline products. It also includes: PMS, vigilance, notified body/competent authority, special requirements for clinical evaluation and testing, risk analysis and management.

### KNOWLEDGE AND UNDERSTANDING

#### Successful students will typically:

- › Understand and be able to manage successfully the application of regulatory requirements and relevant legislation, including required documentation for the purpose of placing medical devices and drug-device combination products on the market
- › Critically analyse the further requirements related to innovative manufacturing processes and recommend strategies for development and marketing of medical devices manufactured with innovative/non-traditional processes
- › Demonstrate critical understanding of issues related to requirements dictated by applicable legislation over and above the medical device regulations
- › Judge appropriate regulatory strategies for drug-device combination and borderline products.

### SKILLS AND ATTRIBUTES

#### Successful students will typically:

- › Demonstrate the ability to interpret, analyse and put into practice current legislation applicable to MDs manufactured with innovative/non-traditional processes
- › Make sound judgements of complex issues and deliver strategic solutions and conclusions that can realistically be applied in practice
- › Critically appraise and evaluate communications from regulatory bodies and research publications regarding medical devices manufactured with innovative/non-traditional processes.

## REGULATION OF IN VITRO DIAGNOSTICS MEDICAL DEVICES

To ensure that students have a clear understanding of the regulatory framework and requirements relating to the placing of *in vitro* diagnostic medical device products on the market in the EU with additional reference to regulatory requirements in other jurisdictions.

### CONTENT

The module covers the current and upcoming regulatory environment in the EU and other jurisdictions, such as Japan, China and Brazil. It includes: definitions, classification, standards and conformity assessment; clinical evaluation and notified body involvement; quality management systems; technical documentation and requirements for performance data; risk management; labelling and product information; traceability, post-market surveillance and vigilance; registration requirements; and other relevant legislation. Strategic issues and developing technologies are also considered.

### KNOWLEDGE AND UNDERSTANDING

#### Successful students will typically:

- › Demonstrate a critical understanding of the regulatory environment in the EU and the legislative framework, and the legislative framework in other territories and critically evaluate how these compare to the EU
- › Critically evaluate the challenges involved in conducting clinical evidence studies using IVD products, by considering the differences between these products and other medical devices in the design and production of clinical data
- › Demonstrate a critical understanding of quality system requirements associated with the manufacture and supply of IVDs
- › Demonstrate a critical understanding of the different stakeholder roles involved in manufacturing, supply and regulation of IVDs.

### SKILLS AND ATTRIBUTES

#### Successful students will typically:

- › Be able to recommend development strategies for IVD products to meet global requirements
- › Explain the regulatory requirements for vigilance and post-market surveillance for IVDs and be able to make recommendations about the implementation of a surveillance strategy
- › Explain the regulatory requirements for the development of an IVD medical device and be able to guide the preparation of the IVD technical documentation needed for CE marking
- › Critically appraise and evaluate communications from regulatory bodies and research publications regarding IVDs.



## REGULATION OF ELECTRICAL, ELECTRONIC AND SOFTWARE DEVICES

To enable students to understand the practical and strategic regulatory issues relating to the development, maintenance and marketing of active devices (which includes electrical, electronic and software); and to explore and critically debate the commercial implications and the impact of the regulations on product stakeholders.

### CONTENT

The module covers the legislative requirements for electrical, electronic and software devices as well as the current guidance available. The practical considerations of designing, developing or gaining approval for these devices will be discussed. In particular the regulation and approval of software devices is particularly challenging with limited guidance available and very few experienced professionals, the challenges and hurdles will be explored as well as some potential solutions and areas in which more guidance is needed.

### KNOWLEDGE AND UNDERSTANDING

#### Successful students will typically:

- › Demonstrate a systematic knowledge and critical awareness of the theory and practice of active devices regulation
- › Be able to determine and justify which classification an active medical device falls into and identify the relevant conformity assessment procedure
- › Critically evaluate the regulations and their impact on development, maintenance and marketing of active devices
- › Understand the importance and content of key medical electrical equipment and systems safety standards
- › Possess a comprehensive understanding of the unique issues relating to active devices and their use.

### SKILLS AND ATTRIBUTES

#### Successful students will typically:

- › Demonstrate the ability to critically analyse the legal documentation and regulatory considerations for active devices
- › Deal with complex issues both systematically and creatively, make sound judgements in the absence of complete data, and communicate their conclusions clearly to non-specialist and specialist audiences
- › Critically appraise and evaluate communications from regulatory bodies and research publications covering active devices.

## US REGULATION OF MEDICAL DEVICES

To provide students with a comprehensive understanding of US regulatory procedures for medical devices, enabling them to make recommendations on regulatory strategy for the US market. The module will provide them with an understanding of a globally important market in addition to the knowledge of the EU that the rest of the course provides.

### CONTENT

The course includes: US Food, Drug and Cosmetics Act; structure and mission of the FDA; device classification in the US; pre-market notification; pre-market approval; establishment registration; device listing; quality system regulation; labelling; medical device reporting; FDA audits and enforcement; combination products; key differences to the EU system.

### KNOWLEDGE AND UNDERSTANDING

#### Successful students will typically:

- › Understand the global importance of the US medical devices market and the history and context of medical device regulation in the US
- › Demonstrate a critical understanding of US medical devices regulation, processes and procedures
- › Critically evaluate the different routes into the US medical devices market and the regulatory requirements and processes for each
- › Evaluate the differences and similarities between the regulation of medical devices in the US and EU.

### SKILLS AND ATTRIBUTES

#### Successful students will typically:

- › Be able to make recommendations about entering the US medical devices market and a suitable strategy for doing so. This will include the ability to apply product jurisdiction, device classification criteria and identify relevant regulatory pathways and requirements
- › Make sound judgements in the absence of complete data and communicate their conclusions effectively
- › Critically appraise and evaluate communications relating to medical devices from US regulatory bodies and research publications.

## DISSERTATION

The dissertation project will be an analysis of an issue related to the student's professional discipline. It will require the student to explore critically the relevant literature and regulations and conduct a systematic investigation into a practice or professional issue developing new insights and perspectives related to the topic of choice.

It aims to enable students to complete a substantial piece of work which demands the use of appropriate methods of inquiry and skills to critically evaluate a practice issue or policy related to the discipline of study – as well as define and evaluate alternative perspectives for addressing a particular practice issue.

**Students will be supported by a Dissertation Academic Adviser who will be able to provide advice on:**

- › Use of methods appropriate to theoretical investigation
- › Review of advance literature, searching and utilising evidence to investigate an issue in their practice
- › Strategic project management including setting context, the process of planning and directing activities to achieve goals
- › Critical appraisal skills including critical analysis, synthesis and application to practice
- › Refining academic writing skills including integrating text from a variety of sources and selecting and shaping information in to a clearly written and well organised thesis.

“Completing the MSc RA has offered me the opportunity to expand my job responsibilities into new areas after completing relevant modules. It has helped me create an excellent network within the pharmaceutical industry, both by meeting other regulatory professionals and by interacting with industry experts while completing my dissertation research.”

## CAREER PATHWAYS

### DEVELOP YOUR CAREER WITH TOPRA

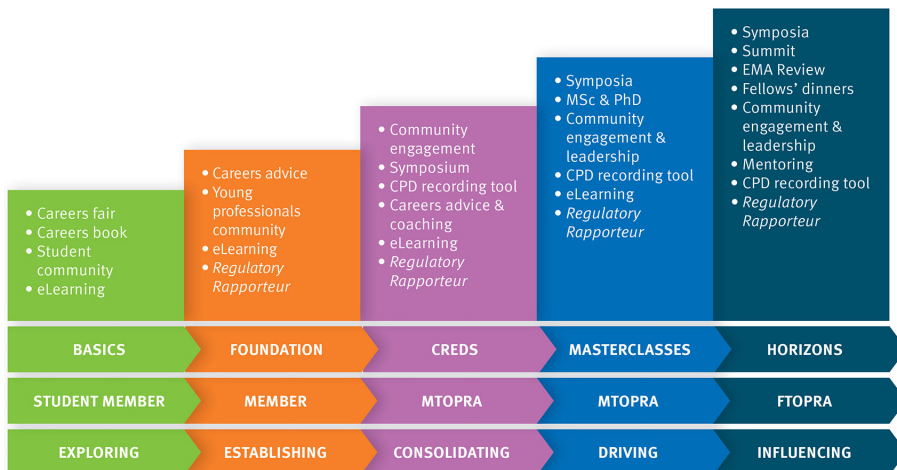
TOPRA is the professional body exclusively for individuals engaged in regulatory affairs and regulatory science in healthcare. Our members work in industry, agency and support companies, in pharmaceuticals, medical devices and veterinary medicine.

We provide a continuing professional development (CPD) programme and encourage all members to identify their learning needs as mapped against our competency framework, which reflects a range of practice levels. Individuals are encouraged to meet those learning needs by whatever means are most suitable – from courses to mentoring to reading. Members can record their learning in their online TOPRA CPD record, which contributes to achieving MTOPRA status and will help form the basis of achieving Chartered Scientist status from the Science Council via TOPRA.

TOPRA's postgraduate programmes have seen hundreds of regulatory professionals achieve a worthwhile qualification – from certificate, to diploma or MSc Regulatory Affairs (Medicines/ Medical Devices).

Sound research is the driver for any scientific sector – and regulatory science is no different. TOPRA now offers an opportunity to study at PhD level and contribute to the body of regulatory knowledge.

TOPRA's educational and CPD programmes enable all regulatory professionals to perform to the highest level through all stages of their careers – from student to thought leader.



## CASE STUDIES



**Margarita Christen, MSc RA**  
Associate Regulatory Integration  
Elanco

I have just finished the TOPRA MSc in Regulatory Affairs. I chose TOPRA because of their level of professionalism and I stayed because from the beginning I learned and accomplished so much. All thanks to the kind support of the team and the warm long-lasting friendships there made.

I highly recommend it, noting that no matter the level or degree of knowledge in the field that one might have, there is always that extra step in learning that will help us reach our professional and personal goals. That is what TOPRA means for me.



**Alex Cook, PhD, MSc RA, MTOPRA**  
Global Regulatory Affairs Manager  
PRA Health Sciences

I opted for the TOPRA MSc as a new challenge after taking the introduction to regulatory affairs course at the start of my regulatory career. The quality of teaching on the course was excellent and it gave the opportunity to network with people from different backgrounds and areas of regulatory affairs.

The TOPRA MSc gave me a through grounding in all areas of regulatory and I often refer back to it during the course of my daily work. It also gave me the opportunity to travel to Berlin and the Czech Republic!

The MSc reminded me that studying is hard when you have a full-time job and are not a full-time PhD student on a studentship, but after completing all 8 modules as well as my dissertation I am very glad I did the full MSc. The TOPRA MSc gave me a through grounding in all areas of regulatory and I often refer back to it during the course of my daily work.

***[www.topra.org/newmsc](http://www.topra.org/newmsc)***



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