

Medical Technology Regulatory Affairs

MSc/PgDip/PgCert

Part-time

In today's competitive and highly regulated healthcare environment, it is essential for companies to bring new products to the market quickly – and to keep them on the market. Excellence in managing regulatory issues is therefore a key strategic advantage to healthcare companies.

Regulatory affairs professionals play an important part in co-ordinating scientific endeavour with regulatory demands throughout the life of a product.

Cranfield's MSc – in collaboration with TOPRA – provides, for the first time, a recognised way to formalise your skills in the field. The course combines TOPRA's long-standing experience and expertise with Cranfield's strong academic reputation and its links to industry.

Focus on your career

Through a collaboration between Cranfield Health and The Organisation for Professionals in Regulatory Affairs (TOPRA) this unique MSc provides graduate professionals working in healthcare regulatory affairs or related areas, with an advanced theoretical understanding of the processes and practices central to medical device regulatory affairs.

This formal qualification is the ideal way to demonstrate your existing skills to employers and peers, and to enhance your career in regulatory affairs by developing increasing levels of competence and professionalism. It is the 'gold standard' in the field.

For students with a specific interest who do not wish to complete the full MSc course, individual modules may be attended as stand-alone three-day short courses.

Benefit from practical experience

The research project, an integral part of the course, gives you the chance to apply the skills, knowledge and understanding acquired during the taught phase of the course to a practical problem in regulatory affairs.

The project normally takes place in your company. It benefits both you and your employer by enabling you to develop skills

in independent research, to contribute to your company's knowledge, and to overcome real challenges in the regulatory affairs field.

Skills and learning outcomes

Cranfield's Medical Technology Regulatory Affairs MSc presents a broad view of the regulatory affairs role. At the same time it provides a detailed insight into current and proposed EU legislation.

The programme will help you develop a set of transferable skills that will directly meet the requirements of your current or future employer including information technology, written and verbal communications skills, team-working, independent research skills, data analysis and critical thinking.

Why Cranfield?

Cranfield University is a wholly postgraduate university with an international community and a global reputation for inspirational teaching and research, industrial-scale facilities and superior links with industry and commerce.

In partnership with



THE ORGANISATION
FOR PROFESSIONALS IN
REGULATORY AFFAIRS



Course details

Duration: The course is available on a part-time basis only. You may take up to a maximum of five years to complete the course.

Start date: The start date is flexible: you can enrol at any time throughout the year.

Entry requirements: 1st or 2nd class UK honours degree, or equivalent, in a science, business or management subject, preferably with experience in a relevant role within the healthcare industry. Membership of TOPRA would be beneficial.

Contact details

For further details and application forms please contact the Enquiries Office on:

T: +44 (0)1234 758008 or
E: enquiries.health@cranfield.ac.uk

Students choose Cranfield for:

- new dedicated facilities as part of a £35 million University investment
- excellent employment prospects – 93% of our students secure relevant employment within six months of graduation
- superb personal support and contact with academics – we have the top staff-to-student ratio in the UK*
- exciting personal research projects that can be carried out in industry or academia
- a totally up-to-date and relevant syllabus

Benefit from our links with industry

Cranfield has joined forces with TOPRA, The Organisation for Professionals in Regulatory Affairs. The combined strengths of both institutions ensure the credibility and strong reputation of this unique MSc.

TOPRA is a non-profit, non-political, membership organisation which seeks to advance the status of the regulatory profession through education and provision of information. Current membership is drawn from industry, the regulatory agencies and the consultancy community, from all sectors including medical technologies, biotech, borderline products and pharmaceuticals and from over 40 countries.

TOPRA's involvement in this MSc ensures its relevance and currency in the field. You will be taught by a team comprising a combination of leading University staff and external practitioners. In addition, those attending the course come from a variety of companies. This mix ensures ample networking opportunities and a valuable exchange of knowledge.

Module outline

The MSc course is based on eight compulsory modules plus a research project. Taught module assessment is by course journal, case study and written assignments, and the research project by thesis and oral presentation. The pass mark is 50%.

The PgDip requires students to attend and pass all eight modules and to submit a dissertation rather than a thesis. The PgCert requires students to attend and pass five modules without a requirement to submit a dissertation or thesis.

Modules

Modules are delivered in up to four three-day sessions per year.

- Principles of European Medical Technology Regulatory Affairs
- Design, Development and Testing of Medical Technology
- Clinical Evaluation of Medical Technology
- Management of Regulatory Affairs and its Contribution to the Medical Product Lifecycle
- Medical Device Vigilance, Post-Market Surveillance (PMS) and Risk Management
- Regulation of Drug-Device Combinations and Other Medical Technology Products
- US Regulation of Medical Technology
- Regulatory Strategy in the Market Place

For those students who do not wish to complete the full MSc course, individual modules may be attended as stand-alone three-day short courses. Please enquire for more details.

Structure

- Assessed taught modules 50%
- Individual research project 50%

Who should apply?

The course is specifically designed for industry professionals working within healthcare regulatory affairs or related areas. Please see Entry requirements for more information.



*Times Higher –
QS World University rankings 2008.