

MSc/PgDip/Pgcert Medical Device Quality Assurance and Regulatory Affairs

Part-time

Course Description

The QA/RA environment is becoming increasingly complex and recent EU legislation advocates placing qualified QA/RA professionals in strategic roles. This course is a unique modular training programme that will enhance the credentials of QA/RA professionals to fill these roles.

The course consists of eight modules completed over one to four years and is carefully designed in line with the requirements of the revised European medical device regulations (Directive 93/42/EEC and the Active Implantable Medical Device Directive 90/385/EC).

The course is delivered by internationally recognised medical device experts who are involved in all areas of medical devices. Our tutors are QP eligible with backgrounds in industry or at notified or standard bodies. They support you throughout the course, including a short work-based research project appropriate to your industry. At the end of the course you will understand:

- > Medical device regulatory frameworks
- > Risk management processes and their interaction with design and development
- > Clinical and performance evaluation
- > How to analyse, evaluate and prepare documentation for a regulatory submission
- > Quality system management requirements for the design, manufacture, use and post-market surveillance of medical device production and supply
- > Regulatory requirements for managing a medical device placed on the market, post-market surveillance and vigilance, and links between quality management systems feedback, clinical follow-up and vigilance decision making activities
- > The roles and responsibilities of regulatory and technical authorities
- > Communication methods to agree on a regulatory affairs strategy prior to and during the conformity assessment process

Course Content

Medical Device Regulatory Frameworks

1. Critically evaluate the legal and operational basis of the European CE marking approach, including the structure and purpose of the medical devices directives
2. Evaluate the concept of a medical device to:
 - a. Determine whether a product falls within the EU Directives definition
 - b. Determine which directive it falls under (90/385 EEC, 93/42 EEC or 98/79/EC)
3. Demonstrate understanding of the product lifecycle and its relationship to medical device regulations, and describe the role of regulatory affairs in pre-market development and post-market activities
4. Evaluate whether a device has complex and/or borderline features (e.g. PPE, drugs, animal tissues, etc.) which may lead to more complex conformity assessment routes

Medical Device Risk Management Design, Development and Product Validation

1. Evaluate regulations when creating a medical device product development plan
2. Determine the product-specific validation and verification methods required to ensure that design requirements can be achieved
3. Critically analyse the essential criteria required to develop a design history file
4. Apply the risk management process to a medical device product lifecycle

Medical Device Clinical Evaluation

1. Critically assess the directive requirements for clinical evaluations and investigations of medical devices and in-vitro diagnostic medical devices
2. Interpret the relevant Commission, competent authority and NBMED guidance documents on clinical evaluation and investigation
3. Explain how clinical evaluation forms part of the design and risk management processes and distinguish between the different methods of carrying out a clinical evaluation including their costs and benefits
4. Evaluate the elements of planning and managing a clinical investigation, and design performance evaluation studies for in-vitro diagnostic products

Medical Device Conformity Assessment-Preparing & Managing Technical Documentation

1. Critically analyse the medical device directive requirements for technical documentation
2. Evaluate the benefits of using information technology to manage product technical information within an organisation
3. Determine what data is required to ensure compliance with essential safety and performance requirements
4. Integrate the documentation requirements from the Global Harmonization Task Force (GHTF) guidance on Summary Technical Document (STED) documentation to create an effective summary document

Medical Device Conformity Assessment-Implementing and Managing Quality Management System Processes

1. Critically evaluate the fundamentals and concepts of a process within a quality management system
2. Demonstrate the typical organisational processes involved in medical device manufacturing
3. Assess the need for quality management system requirements and documentation, and critically process validation to product development
4. Explain and demonstrate the need for good manufacturing practices within medical devices

Medical Device Post-Market Surveillance and Vigilance

1. Critically analyse the directive requirements for post-market surveillance (PMS)
2. Create a PMS process, and implement and manage a market notification or product recall process
3. Apply the directive requirements for adverse incident reporting (Vigilance) and evaluate the relevant considerations when deciding whether to initiate a market notification or recall
4. Integrate effective feedback within an organisation using PMS and Vigilance data

Working With Competent Authorities, Notified Bodies and Other Regulatory Stakeholders

1. Demonstrate an in-depth knowledge of stakeholders within Europe with respect to medical devices, including relevant expert, specialist and scientific committees, working groups and notified bodies
2. Understand the process for development, consultation and implementation of new or modified EU regulations and guidance sufficiently to take part if necessary
3. Develop well thought-out strategies for staying up to date with changing EU and national regulatory decisions, emerging guidance and scientific opinion
4. Critically appraise the role of industry and trade associations, and identify those most relevant to your product area

Research Project in Practice

1. Critically review the literature relevant to the area of study
2. Develop technical and problem solving skills related to the project
3. Deliver an agreed programme of technical work
4. Critically analyse and communicate the aim, methodology and results of the research, verbally and in a written report, to a scientific audience

Entry Requirements

Each student must be working in the medical device or any associated industry as a large proportion of the course is based on practical examples.

Non-native speakers need to be proficient in English, typically shown by an IELTS score of 6.0 with a minimum of 5.5 in all skills or equivalent. If your English language skill is currently below IELTS 6.0, we recommend a Sheffield Hallam University pre-session English course.

Attendance

Part-time

PgCert Typically two years in duration. You will be required to successfully complete any four modules and associated assessments.

PgDip Typically four years in duration. You will be required to successfully complete all eight modules and associated assessments.

MSc Once you have successfully completed the PgDip, you are entitled to enrol onto the MSc which would typically take a year to complete.

All courses start in September and enrollment ends August 31.

Assessment

A variety of methods are used to assess study including written exams, case studies, oral presentations, student portfolios and project plans.

Fees

Home, EU and International Students

2014/2015 & 2015/2016 academic year

Part-time

PgCert - Typically £7,000 (includes University registration fee)

Previous studies may exempt you from some course modules.

Instalment options are available and you may qualify for a discount from the overall course fee.

For further information on fees and funding, please contact us on eudevices@nsf.org or +44 1142 541270.

PgDip - Typically £14,000 (includes University registration fee)

Previous studies may exempt you from some course modules.

Instalment options are available and you may qualify for a discount from the overall course fee.

For further information on fees and funding, please contact us on eudevices@nsf.org or +44 1142 541270.

MSc – For information on fees and funding, please contact us on eudevices@nsf.org or +44 1142 541270.

How to Apply

To enroll, please email eudevices@nsf.org or ring +44 1142 541270.

Contact Us

For further information contact our Medical Devices team at the Advanced Manufacturing Park, Sheffield, S60 5WG, phone +44 1142 541270 or email eudevices@nsf.org.

More Course Information Available at <http://www.nsf.org/services/by-industry/medical-devices/medical-devices-training>



Use your smartphone to scan the QR-code and visit the online course entry.