EU Regulations and the role of the Qualified Person (QP)

The supply of medicinal products to the European Union requires that every batch of a medicinal product is formally certified by a "Qualified Person" (QP). This applies equally to batches manufactured inside and outside the EU. The QP is a formal and legal position and forms a unique role in the manufacture of medicinal products. The relationship between the QP and all actors in the supply chain is an important consideration for pharmaceutical companies.

about the course

This course looks at the evolution of the QP role in the European Pharmaceutical Manufacturing Industry. It covers how and why the QP role was defined. It also explains the responsibilities of the QP within the Quality Management System and how this system in European Pharmaceutical Manufacturing Companies differs from the rest of the world.

Course Duration is 1 Day.

course content

- Legal framework of QP role
- Transitional arrangements
- Educational requirements and experience necessary for a QP
- QP behavior
- Responsibilities of a QP
- Where a QP fits into a Pharmaceutical Manufacturing Company
- Interactions between QP and non-European Pharmaceutical Companies
- Contract QPs vs full-time employees
- Real life examples of difficult issues experienced by QP

who should attend

Quality, Production and Regulatory personnel in pharmaceutical companies who interact with QPs in Europe. The course aims to explain the QP role and inherent responsibilities. This will give non-European companies the ability to develop their relationship with European companies and their QPs, to streamline the introduction of medicinal products to the European market, either manufactured inside or outside of Europe.

about the presenters

Mary Wallace

Mary obtained QP status in 1986 by derogation and has had over 30 years' experience of QP release, QMS and regulatory requirements in the pharmaceutical industry. Her experience has been gained over a wide range of medicinal products including solid dose pharmaceuticals, sterile medicinal products, parenteral nutrition and API production. Mary was instrumental in setting up and establishing the Diploma in Pharmaceutical Manufacturing Technology (QP course) in the School of Pharmacy, TCD, Dublin where she was Course Coordinator for 10 years. Before leaving TCD in 2000, she introduced and set up the first annual QP forum in 1999, which has been successfully running since, growing in popularity every year. Mary has been working as a Senior Consultant with EUPS since November 2014.

Stan O'Neill

After qualifying as a Pharmacist, Stan spent over five years working in the pharmaceutical industry in Regulatory Affairs, Marketing and Quality Assurance (QP) and then joined the Irish Medicines Board (now the HPRA) for a period of ten years. In his capacity as a Senior Inspector, he performed GMP inspections throughout the world, criminal investigations in Ireland, represented Ireland at European level for the negotiation of standards of inspection for medicinal products and trained Inspectors and Enforcement Officers at Irish, European and International levels.

what else should I know

Course Fee: $1000 per person
Location: Shirley Ryan AbilityLab, Chicago, IL,USA
Date: 28 November 2018

The course fee includes all course material, lunch and refreshments. Please note that this course may also be organized on an in-house basis. The program can be tailored to site specific needs, technologies and regulatory requirements, please contact us for further information.

how to apply

Applications can be made online at **www.gxp.ie** or by emailing **training@gxp.ie**

gxp training www.gxp.ie

about gxp training

GXP Training was set up to harness the expertise within The Compliance Group, EUPS and its wider network to develop and deliver a suite of Training Courses in the GxP environment.

As well as providing professional and focus scheduled courses that will provide cost effective ways to meet training needs within the industry, all course will be available for in-house training, should this be the customers preferred route.

the compliance group gxp training eups