



QUALIFIED PERSON AND CONTINUING PROFESSIONAL DEVELOPMENT TRAINING

WITH OPPORTUNITY FOR POSTGRADUATE QUALIFICATION



Scenario 1 - Could be the 'repeat' validation.

- Annex 1 - would need to revalidate.
- Batch size is not appropriate to support 10-100k batch size - consider ↑ size.
- Influenza - high risk patients, but high risk of not vaccinating.

Things to investigate:

- Any events during filling.
- Change controls
- Operator training
- What is the organism
- Any equipment failures.
- Are interventions representative?
- Review process



ROYAL SOCIETY
OF CHEMISTRY

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NSF International has been running highly interactive Qualified Person (QP) training courses since 1990. NSF trained QPs are highly regarded within the industry and their status is recognized by many countries including Austria, Belgium, Denmark, Hungary, Ireland, Jordan, Malta, the Netherlands, Norway and Switzerland.

Individuals also join us from Singapore, Australia and the USA for professional development and to gain an understanding of the role of the QP in other countries. Our broad attendee base combined with our expert tutors provides you with great networking opportunities and high-quality education.

I WANT TO BECOME A QP WHAT DOES NSF OFFER?

The course provides practical, face-to-face tuition in sufficient depth to prepare you fully for the challenges ahead. The fact is that you are more likely to become a QP with us than with any other training provider. Here's what's in it for you:

- > Free QP seminar to learn all about NSF and the QP training program
- > Flexible courses start and stop to suit you
- > Training to do the job and be the best QP you can be, not just pass an exam
- > Comprehensive course notes including reference materials/useful links all in one place
- > Support and guidance from world-class tutors and industry experts including University of Strathclyde academic experts
- > Exceptionally high pass rates of over 96 percent
- > Excellent networking opportunities allowing sharing of best practices
- > Speakers including MHRA, industry and joint professional body experts
- > Visits to a range of facilities including a pharmacy, a wholesale distributor and API facilities at no additional cost
- > Postgraduate qualifications as necessary from Postgraduate Certificate to MSc – see page 8 for more information

If you decide to take a qualifying number of modules to become a core QP, we also have a range of other benefits – see page 5.

WHAT PEOPLE ARE SAYING

I've loved every aspect of this course. I have unfortunately used other providers for most of my QP training and I'm completely blown away by the gulf in class between NSF and the others! Particularly the way the focus is on creating a 'team' of trainee QPs. I am glad I have managed to get on some of these courses.

Alistair Meek, Mentholatum, UK.

I'M FROM EUROPE AND WANT TO BECOME A QP WHAT DOES NSF OFFER?

Increasingly, NSF's QP course is attended by European delegates. Because national requirements for QP training and education differ, we offer a global QP training approach that allows you to:

- > Receive QP training covering all legislation for EU/UK
- > Get MSc level training – a requirement for QPs in several member states
- > Obtain continuing professional development (CPD) to meet knowledge requirements
- > Access the best training for quality leaders in the pharmaceutical industry

You can use our unique gap analysis/self-assessment tools to help build a customized, realistic training plan – see page 5 for more information on this.

WHAT PEOPLE ARE SAYING

As a QP candidate in the Netherlands who had to go through the UK viva process, my employer and I chose NSF because its QP program is well known in the Netherlands and we believe it is the most comprehensive. I followed a number of selected modules and they helped me enormously to reach the level of knowledge and confidence to tackle the challenging role of QP, particularly a QP for IMPs.

Minas Papadimitriou, Merus, Netherlands.

I'M A MANAGER/SPONSOR WHAT DOES NSF OFFER?

If you're a potential sponsor or manager looking to train a QP, rest assured that you're in capable hands. As well as the aforementioned benefits, here's what we can guarantee for you:

- > Free QP seminar for prospective QPs, managers and sponsors
- > Direct feedback, support and quality aftercare services
- > Benchmarking and exam updates
- > Visits to facilities to consolidate attendee knowledge and learning
- > Royal Society of Chemistry-approved training
- > QP selection process assistance – we will come to you and help you select the right individuals

WHAT PEOPLE ARE SAYING

As a QP sponsor who has successfully sponsored four trainee QPs through their training and viva, I would highly recommend the training and support provided by NSF. NSF ensures their service is unique and the tutors and the course administration team always go above and beyond to cater for each individual's needs. In addition to strong technical skills, QPs need to have equally strong leadership and influencing skills as well as being very resilient in complex situations. From my perspective, NSF provide both the technical and soft skills training in abundance and everyone I know who has completed this training has grown technically and as an individual.

Breda Quinn, RB, UK.

HOW NSF CAN HELP YOU ON THE JOURNEY TO BECOMING A QP

UK QP

UK Procedure to Become a Qualified Person Under the Permanent Provisions of European Council Directives 2001/82/EC and 2001/83/EC:	
NSF ADVICE	<ul style="list-style-type: none">• RELEVANT FIRST DEGREE OR EQUIVALENT QUALIFICATION IN BIOLOGY, CHEMISTRY OR PHARMACY• JOINS PROFESSIONAL BODY ("Member" status minimum)
NSF TRAINING	<ul style="list-style-type: none">• UNDERTAKES: (1) Appropriate practical experience and (2) Supplementary educational study through NSF QP training
NSF ONGOING SUPPORT/ADVICE	<ul style="list-style-type: none">• APPLIES TO PROFESSIONAL BODY FOR: (1) Suitability by assessment (2) Recognition of eligibility to be entered into the joint register• NOMINATED AS QP BY HOLDER OF MANUFACTURING AUTHORIZATION• LICENSING AUTHORITY OF MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY, DoH, ACCEPT NOMINATION• INDIVIDUAL MAY ACT AS A QUALIFIED PERSON FOR A LICENCE HOLDER

EUROPE QP

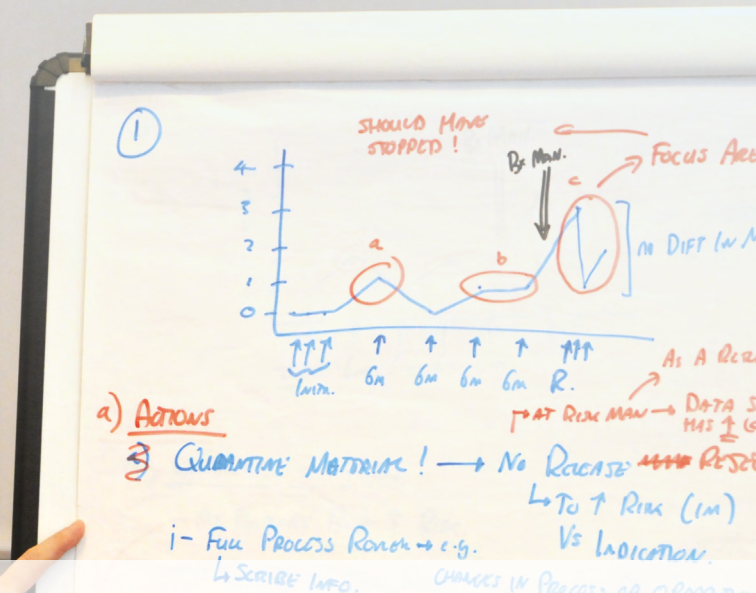
QP is a European qualification legally required in pharmaceutical manufacturing but for individuals outside the UK, local rules apply and we would always recommend that you discuss your own situation with your local authority. Some authorities require individuals to gain the Postgraduate Diploma/MSc in order to be accepted as a QP but please do make sure you get confirmation of your training plans before commencing with the training.

THINKING OF BECOMING A QP?

QP FREE SEMINARS

Whether you're planning your next career move, you're a potential sponsor or you're a manager looking to train a QP, join us and get the answers to all your questions. Hear from people who have been through the training and how it has changed their careers for good!

Visit www.nsf.org/info/qptraining for further details and for dates/locations.



We can help you with a gap analysis by evaluating your CV or by providing you with our unique self-assessment tool. We will then provide you with a written recommendation on which modules would be necessary or of professional benefit, with specific reference to your background.

Our gap analysis can also act as a comparison against your self-assessment to help you draw up a realistic training plan. We are always available to discuss your requirements and answer any questions. There is no charge for this service. Contact our QP course administrator at **QPpharma@nsf.org** for more information.

- > A personal assigned tutor available throughout the program
- > Individual training advice
- > Ongoing technical support for delegates and sponsors
- > Non-technical, essential skills training
 - Presentation techniques
 - Assertiveness
 - Rapid learning techniques
 - Conflict management
 - Coaching and mentoring
 - Leadership
 - Decision making
 - And others
- > Viva prep sessions including scenario tutorials and decision making
- > Review of application form
- > Revision interview
- > Sponsor/tutor meetings on modules
- > Alumni organization of experienced fellow QPs sharing the same training
- > CPD
- > Ongoing access to NSF and its consultants



TECHNICAL SYLLABUS

The full QP course for aspiring QP and technical professional:

- > Consists of 12 modules
- > More than meets the requirements of the UK QP Study Guide and 2001/82 EC, 2001/83 EC
- > Is essential CPD for all, not only QPs

Each module is designed as a stand-alone course, so it is not necessary to study them in sequential order. We also offer repeats of some modules for maximum flexibility. If work commitments or other obstacles arise during your training, we are flexible and will work with you on the best options available.

Our syllabus not only meets the requirements of the QP study guide, it provides a context to help decision making and help you survive as a QP. Examples of topics include:

MODULE 1

PHARMACEUTICAL LAW & ADMINISTRATION

- > European medicines legislation
- > UK medicines legislation
- > Other relevant legislation
- > Licensing and inspection
- > Standards and guidelines
- > QP administration issues



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MODULE 2

MEDICINAL CHEMISTRY & THERAPEUTICS

- > Functions of the body
- > Major disease states
- > Pharmacology
- > Implications of clinical knowledge for the QP

MODULE 3

PHARMACEUTICAL FORMULATION & PROCESSING

- > Dosage forms, routes of administration, biopharmaceutics
- > Formulation aspects
- > Manufacturing aspects and critical control points (CCP)

MODULE 4

PHARMACEUTICAL MICROBIOLOGY

- > Biology and biochemistry of microorganisms
- > Pyrogens
- > Antimicrobial compounds
- > Sterilization and disinfection
- > Microbiological aspects of quality water systems
- > Microbiological aspects of sterile pharmaceuticals manufacture

ON-SITE TRAINING

All our QP courses can be brought on-site, tailored to your specific needs and delivered at a time that suits you and your organization. For more information on this route, contact us via QPpharma@nsf.org.

MODULE 5

ACTIVE PHARMACEUTICAL INGREDIENTS

- > Regulatory aspects
- > Manufacturing processes and their influence on quality
- > Supplier quality assurance
- > Analysis
- > Bulk biologicals and biotech products

MODULE 6

MATHEMATICS & STATISTICS

- > Introduction
- > Use and application
- > Use of computers and software
- > Future trends

MODULE 7

ANALYSIS & TESTING

- > Philosophy and principles of analysis; GCLP
- > Stability
- > Physico-chemical properties of materials/ principal methods of analysis
- > Method validation
- > Industrial practice and standards

MODULE 8

PHARMACEUTICAL PACKAGING

- > Materials and components
- > Supplier auditing and component testing
- > The printing process
- > The packing process – ideal facility design
- > The route to the patient
- > QP decision making



Click here to find out more about QP training with NSF.

MODULE 9

PHARMACEUTICAL QUALITY SYSTEMS

- > Principles and philosophy
- > Designing an effective PQS
- > Interpersonal skills
- > PQS and supply chain control
- > PQS and continuous improvement

MODULE 10

PRACTICAL

This module provides an opportunity to manufacture and test a range of dosage forms. Each delegate will be able to obtain experience in the manufacture of a variety of dosage forms with consideration of:

- > Documentation required
- > Process parameters
- > CCP
- > In-process controls applicable
- > Concerns for the QP
- > End product testing

This includes oral solid dose, sterile, biotech and analytical hands-on experience. Additional experience is required for the UK QP application process.

MODULE 11

INVESTIGATIONAL MEDICINAL PRODUCTS

- > The regulatory framework for clinical trials, including latest changes
- > Clinical trial design
- > Levels of GMP and validation required
- > IMP

MODULE 12

THE ROLE & PROFESSIONAL DUTIES OF THE QUALIFIED PERSON

- > Duties and responsibilities of the QP
- > Role of the QP
- > Future trends
- > Interpersonal skills to do the job



POSTGRADUATE CERTIFICATE, DIPLOMA OR MSC IN PHARMACEUTICAL QUALITY AND GOOD MANUFACTURING PRACTICE

While each module is a stand-alone course, NSF offers an opportunity to gain postgraduate qualifications, depending on how much time you can afford to put in. The bulk of the work is done through attendance at the QP modules, especially for those looking to gain the Postgraduate Certificate and Diploma. Recognition in the industry and by your peers is an important incentive to both the individual and the company.

CERTIFICATE

The certificate option is ideal for the quality professional who is looking to gain a further qualification or recognition in their profession. You will need to complete three foundation modules and three modules of your own choice, and perform satisfactorily in all assessments, to be eligible to apply for the Postgraduate Certificate with the University of Strathclyde.

DIPLOMA

Delegates registered for the diploma qualification who perform satisfactorily in the module assessment procedures may then sit the course diploma examinations. If successful, they will be awarded the University Diploma in Pharmaceutical Quality and Good Manufacturing Practice. The duration of the study parallels the QP modules.

MSC

Holders of the diploma who have attained a suitably satisfactory result may proceed to the University of Strathclyde MSc in Pharmaceutical Quality and Good Manufacturing Practice by undertaking a supervised, industrially relevant project on a subject approved by the course director.



EXEMPTIONS AND REWARDS

- > Diploma/MSc candidates can apply for one exemption for a module covering a topic of existing expertise. For those taking all 12 modules, NSF will pay £1500 toward the University of Strathclyde MSc fee
- > Candidates who achieve an MSc will be entitled to attend NSF's annual one day Pharmaceutical Legislation Update course as our guest for life*
- > Delegates who gain UK QP status, or an MSc or diploma, will be entitled to apply for membership of the Chartered Quality Institute (CQI) to gain MCQI status
- > Registration with the University of Strathclyde confers student status and permits use of all student facilities

These postgraduate qualifications are awarded by the University of Strathclyde, which is regularly in the top ranks of schools of pharmacy in the UK.

**up to a maximum of ten free places per course*

FEES

For further information regarding the University fees for the Postgraduate Certificate, Diploma or MSc and for any other details, please contact QPpharma@nsf.org.



WHAT PEOPLE ARE SAYING

The Qualified Person training from NSF made me the QP I am today, with a backpack full of knowledge, skills and the necessary network to make the very important decision, to release or not to release. The opportunity to develop the necessary soft skills for a QP was also important. I hope a lot of Belgians follow my footsteps to become a QP via the NSF training as a non-pharmacist.

Leen van de Water, Pannoc, Belgium.

Despite there being no Australian requirement for formal QP qualifications, I have attended a number of UK-based QP modules due to a lack of such high-quality training locally. Given the similarity of European and Australian requirements I found the QP training provided by NSF to be both excellent value and directly relevant to the Australian quality/regulatory environment. The knowledge and experience of the tutors, offsite visits to view the practical application and the interactive nature of the training all made the long trip from Australia worthwhile.

Paul O'Shea, Servier Laboratories PTY, Australia.



		Certificate	Diploma	MSc
Module 1	Pharmaceutical Law & Administration	✓	✓	✓
Module 2	Medicinal Chemistry & Therapeutics	*	✓	✓
Module 3a	Pharmaceutical Formulation & Processing, Part 1	*	✓	✓
Module 3b	Pharmaceutical Formulation & Processing, Part 2	*	✓	✓
Module 4	Pharmaceutical Microbiology	*	✓	✓
Module 5	Active Pharmaceutical Ingredients	*	✓	✓
Module 6	Mathematics & Statistics	*	✓	✓
Module 7	Analysis & Testing	*	✓	✓
Module 8	Pharmaceutical Packaging	*	✓	✓
Module 9	Pharmaceutical Quality Systems	✓	✓	✓
Module 10	Practical	*	✓	✓
Module 11	Investigational Medicinal Products	*	✓	✓
Module 12	The Role & Professional Duties of the QP	✓	✓	✓
<i>Three compulsory foundation modules (✓) plus three of choice (*) for Certificate</i>				
Module assessments (for modules taken)		✓	✓	✓
Composite course written exam	Paper I	✓	✓	✓
	Paper II	NA	✓	✓
	MSc Project	NA	NA	✓

THE BENEFITS OF ATTENDING ALL MODULES

- > Linked, consistent education with practice in QP decision making skills
- > Linked training to do the QP job and become the best QP you can be, not just pass a viva
- > Benchmarking exams to confirm progress to delegates and sponsors
- > Access to discounts and discounted additional courses essential to the QP
- > Lifelong networking and support that delegates say makes a real difference
- > Access to CPD for the delegate and for the company
- > Sponsor support and sponsor/NSF tutor meetings
- > Plus the many other benefits of being a core delegate, as detailed on page 5

PROSPECTIVE QPS TYPICAL QUESTIONS ASKED

Do I need to attend all the modules?

No, unless you wish to aim for the Postgraduate Diploma or MSc, modules can be selected as required.

How can I decide which modules to attend?

Delegates are offered a free gap analysis with a course tutor. Guidance can be given during a face-to-face interview or remotely after providing a detailed CV for review.

How do I enrol for the Postgraduate Certificate?

Delegates should register their interest with their tutor and/or QP course administrator. The University of Strathclyde will be informed and will subsequently coordinate the qualification directly with the delegate. The requirements for the Certificate are...

- > Attend three foundation modules and three of choice, perform satisfactorily in the module assessments, sit the certificate exam at the University

How do I enrol for the Postgraduate Diploma/MSc?

The University of Strathclyde coordinates their qualification directly with the delegate. Typically, the requirements for the diploma are...

- > Attend all modules, perform satisfactorily in the module assessments, sit the diploma exams at the University

The MSc requires the above plus a workplace thesis/project, approved by the course director at the University.

Do all modules cost the same?

No, some are five days in duration and some are four days. In addition, different venues (such as the practical module in Glasgow) can impact on the course costs.

Once the series is finished do I still have use of your advice and consultancy?

Yes. Past delegates on our courses are always welcome to contact us with comments or queries for opinion or advice. This is a free service and we are always pleased to keep in touch with past delegates.

What is the success rate of your delegates at viva?

Information to date shows a pass rate of 96 percent for delegates we have trained.

I've heard about the personal tutor system, what is it?

Delegates taking a qualifying number of modules to become a core QP will also get these benefits...

- > Core delegates are assigned a personal tutor who offers support and guidance through regular meetings on modules regarding the application process and experience requirements for the viva
- > Core delegates are also offered a free revision interview six to eight weeks before their viva to assess the delegate's readiness for the viva
- > Review of the QP application form prior to submitting to the joint professional bodies

Is there an exam for each module?

Yes, the exams usually take place prior to the next module, on the Sunday evening at 18.30. Some modules however are assessed by dissertation and a deadline provided for submission.

Do I need a sponsor?

Yes. Ideally a QP and someone who knows you and your roles and responsibilities well. Someone who can provide you with ongoing support through your training. Your sponsor will be required to complete a sponsor's report to accompany your QP application form. NSF encourage sponsors to visit a module and meet the personal tutor to check on progress.

I don't want to be a QP but this looks like great training, can I attend?

Yes. Not everyone attending the modules is looking to become a QP. Many use the training to develop as technical managers or as part of their CPD.



Click here to hear from training delegates on how NSF training courses have impacted their careers and organizations.



CONTACT US

Due to high demand, provisional booking is recommended. To reserve a place on the series or any individual modules, or for further information, please contact QPpharma@nsf.org, visit www.nsf.org/info/qptraining or call +44 (0) 1751 432 999.



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