What's Included in the Module Fees
- 12 customized reference books covering all course notes, with no further background reading required
- Exams for benchmarking or postgraduate study
- Certificates of attendance
- Visits
- Daytime conference facilities
- Lunch and refreshments
- Course dinner
Special bed and breakfast rates are available for NSF delegates (not included in course fees)

Discounts Available
- 20% for second delegate attending same module from same company
- 50% for third and subsequent delegates attending same module from same company
- 50% for NHS and Regulatory Authorities
- Discounts also available, at the discretion of the course leaders, for self-funding individuals and for certain charities

Additional Benefits
For delegates attending all 12 QP modules, a 50% reduction in course fees for recommended additional courses including...
- GMP for Biological and Biotechnology Products
- Effective Pharmaceutical Audits and Self-Inspections (An IRCA Certified Pharmaceutical QMS Auditor/Lead Auditor Course)
- Risk-Based Decision Making for Quality Professionals and QPs
- Risk-Based Decision Making in Sterile Products Manufacture
- For delegates paying for all modules in advance, a discount of 15% off the total cost will be applied (candidates paying in advance will be excluded from the multiple delegate discounts available)
- Other rewards and discounts are available. Please talk to Stella Pearson-Smith, QP Administrator, for current offers.

How to Reserve a Place
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Online Reservation
Provisional and firm bookings can be made via our website www.nsf.org/info/pharma-training

For further information on module content, to arrange a free gap analysis or to talk to the course leaders, for self-funding individuals and for certain charities, please contact Stella Pearson-Smith, QP Administrator, at QPpharma@nsf.org or call +44 (0) 1751 432 999.
We have been running Qualified Person (QP) training courses since 1990 and they are generally considered to be the best available – our QPs are very highly regarded within the industry and their status is recognised by many other countries including Austria, Belgium, Denmark, Hungary, Ireland, Jordan, Malta, The Netherlands, Norway and Switzerland.

Did you know? We have an exceptionally high first-time pass rate for our trainee QPs who have been successful at QP interview. For those who are not successful we will continue to offer free ongoing support including free repeat courses as required and extra viva practices. Along with support from their sponsors, this will help guarantee that all our trainees achieve QP eligibility.

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

The Aspiring QP and Technical Professional

What We Offer Core QPs
(designates taking four or more modules)
> A personal assigned tutor available throughout the program
> Individual training advice
> Support for delegates and sponsors
> New technical, essential skills training
  + Presentation techniques
  + Assertiveness
  + Rapid learning techniques
  + Conflict management
> 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

What We Offer – The Course
> 12 modules over 21 months
> More than meets the requirements of the UK QP Study Guide and 2001/82 EC, 2001/83 EC
> Essential CPD for all, not only QPs
> New technical, essential skills training
> Support for delegates and sponsors
> Ongoing access to NSF and its consultants
> CPD
> Alumni organization of experienced fellow QPs sharing the same training
> Sponsor/tutor meetings on modules
> Viva prep sessions including scenario tutorials and decision making
> Review of application form
> Revision interview
> Alumni organization of experienced fellow QPs sharing the same training
> CPD
> Ongoing access to NSF and its consultants

What We Offer You
> Help in formulating your own training and experience plan
> Use of the unique gap analysis tool
> Greatest opportunity for success
> Unusual networking opportunity
> Complete, detailed training and reference materials

What We Offer – The Course
> Unequalled training for highly experienced industrial experts and experienced QPs
> Supported by lecturers from one of the country’s top Schools of Pharmacy
> Uniquely, you have the time required to learn and thoroughly understand:
  ✔ The knowledge
  ✔ The skills
  ✔ The role
> Highly interactive, face-to-face education
> Training to do the job, not just pass an exam
> Flexible courses start and stop to suit you
> Postgraduate qualifications as necessary from Postgraduate Certificate to MSc

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Add your name to the NSF roll of honour
– all these people have trained with us

Nigel Adams • Gareth Adiam • Stuart Allen • Paul Anderson • Richard Angwin • Kate Barker • Lynda Baker • Suzanne Bell • Justin Barry • Cathy Bateman • Daniel Bell • David Belshaw • Christine Bennett • Neil Bennett • Dale Billingsley • Sonia Bradford • Lynn Bryan • Philip Bulton • Samantha Clack • Robert Clarke • Neil Connor • Peter Connock • Roy Cowell • Bruce Cuthbertson • Kris Davé • Faith Daykin • Martin Dearden • Peter Deegan • Karam Dhillon • Robert Dilks • Elaine Dymond • David Earl • Sam Elcomb • Grant Elliott • Clare Embley • Elizabeth Evans • Marcus Evans • Karl Fry • Richard Funnel • Maynell Ghili • Amanda Hall • Johan Havinga • Paul Henly • Nick Hill • Nigel Holcombe • Judith Hoodless • Mark Hughes • Sandra Ilesley • Ronald Imhoff • Mike Irving • Ian Jackson • Sukhinder Jaffar • Hazel James • Phil Jenkinson • John Johnson • Adam Jones • Janline Jonkman • Julian Kay • Tony Kem • Mark Kind • Boudy König • Sheila Lachot • Bob Lambert • Trevor Lees • Fraser Leslie • Brian Lewis • Debbie Lloyd • Alison Lockett • Tony Loeffen • Veronica Lothian • Martin Lush • Karen Lynch • Fiona MacIntyre • Tony Mayhall • Grame McBurney • Robert McConnell • Thomas McHale • Fiona McKeen • Wallace McRobert • Kim Morwood • Stephen Moss • Derek Murphy • Shirley Mulch • Anneka Nederbragt • Deborah Nugent • Russell Nugent • Paul O’Connor • Brendan O’Dorman • Tony Osborne • David Palmer • Philip Parry • Zen Pawlack • Andrew Pentelow • Anna Pickering • Ian Founder • Martinie Powell • Nick Precious • David Preston • David Price • Neil Raw • Annie Rietveld • Mike Roberts • Daniel Robinson • Richard Rogers • David Ross • Michael Rowe • Monika Souler • John Seeger • Jane Shaw • Stephen Simpson • Cite Sims • Richard Smalley • Robert Smith • Scott Smith • Andrew Spencer • Martin Spencer • Peter Stancliffe • Wendy Steele • Paul Stockbridge • Paul Thomas • Emma Thomson • Bill Thorne • Mandy Torgoose • Pamela Turner • Lena Vägberg • Piet Van Rens • Maria Vincent • Jessica Walker • Neil Wayman • Gordon Whittle • Richard Wilford • Richard Wilkins • Sam Williamson • Kevin Wilson • Christopher Woodage • Paul Wright • Jane Williams • Gareth Naylor • Mark Girdwood • David Ling • Alan Mayo • Mukesh Patel • Rachel Mizzi • Nick Branch • Mark Stephon • Leonor Arebola • Hernal Patel • Emily Rumsey • Jennifer Watson • Catherine Kay • James Muller • Daniel Pilkington • Peter Gannon • Joanne Lewis • Matthew Jaynes • Chris Miller • Gillian Morris • Colin Newbould • John O’Neill • Christine Perkins • Angela Hoskins • Jenni Newcombe • Vicky Bauch • Jane Colman • Mark Dignham • Bruce Vernon • Trevor Clarke • Derrick Jones • Simon Tanner • Tim Dickinson • Treedd Edwards • Meriom Lindsay • Mark Hilton • Helen Brannan • Ruth Buchanan • Tony Pinney • Dawn Harrison • Kate Kraehl • Breda Quinn • Ronnie O’Connell • Stephen Davenport • Dru Homer • Neil Smith • Ed Teco • Claire Pierce • Barbara D’wyer • Cecile Begat • Jordan Costello • Trevor Watson • Robert Clayton • John Tognarella • Philip Millward • Justin Ahern • Colin Chambers • Kathryn Rooney • Amanda Race • Rachel Evans • Nigel Morton • Richard Brown • Shawn Murtough • Ian Birch • Claire Montgomery • Gify George • Jonathan Dormer • David Jamieson • Stefan Verstegen • Peter Kendrick • Chris Forest • James Culyer • John Horry • Chris Hinds • Maria Adesida • Jack Beattle • Donna McKenna • Richard Brown • Stephen Clarke • Philip Davies • Nigel Chesterton • Jonathan Bradshaw • Sarah Gardiner • Shaun Barford • David Thomson • Azhar Salahudeen • Claire Trumper • Jason Morris • Phil Cryan • Eurym Roberts • Stephan Croft • Leen van de Water • Jacqueline Barry • David Franks • Hazel Pitt • Linden Stead • Adam McMennan • Laura Matthys • Jasbir Rattu • Atia Hasnain • Stephen Swan • Rachael Hill • Set Yong • Pauline Johnstone • Lee Heading • Abdul Ghafoor • Maxine Shaw • Lana Morrison • Peter Mollison • Akbar Kulasi • Kate Smith • Philip Rose • Paul Gomm • Helen O’Shea • Richard Gore • David Cross • Arthur Stevenson • Adam Elliott • Clare Myott • Robert Scott • Lynsey Niblett • Anne Moore • Caroline Gibbs • Tony James • Steve Evans • Julia Hocking • Jill O’Mullane • David Harvey

Reserve your place: web: www.nsf.org/info/pharma-training

RELEVANT FIRST DEGREE OR EQUIVALENT QUALIFICATION in BIOLOGY, CHEMISTRY or PHARMACY

JOINS PROFESSIONAL BODY (“Member” status minimum)

UNDERTAKES:
(1) Appropriate practical experience and
(2) Supplementary educational study through NSF QP training

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

QPs in Europe
Increasingly the NSF QP course is attended by non-UK European delegates. National requirements for QP training and education may differ and many European individuals attend for the following reasons:
> To gain an MSc to meet educational requirements
> To obtain CPD to meet knowledge requirements
> To access the best training for quality leaders in the pharmaceutical industry

Contact us for further information:
Mike Halliday,
Vice President, NSF Health Sciences, Pharma Biotech Consulting (mikehalliday@nsf.org)
or
Stella Pearson-Smith,
QP Administrator (StellaPearsonSmith@nsf.org).
Our syllabus more than meets the requirements of the QP study guide. Examples of topics include:

**MODULE 1**
**PHARMACEUTICAL LAW & ADMINISTRATION**
- European medicines legislation
- United Kingdom medicines legislation
- Other relevant legislation
- Licensing and inspection
- Standards and guidelines
- Qualified Person administration issues

**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 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

**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

Reserve your place:  web: www.nsf.org/info/pharma-training
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

MODULE 9
QUALITY MANAGEMENT SYSTEMS
- Principles and philosophy
- Designing an effective QMS
- Interpersonal skills
- QMS and supply chain control
- QMS and continuous improvement

MODULE 10
PRACTICAL MODULE
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
- Critical Control Points
- 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

Join our Alumni Family
2016 marks the tenth annual NSF QP Alumni meeting. This ongoing support network for the NSF QPs provides invaluable CPD for the busy QP and a lifelong support after the course is completed.
Postgraduate Certificate, Diploma or MSc in Pharmaceutical Quality and Good Manufacturing Practice

While each module is a stand-alone course, increasingly delegates are taking all modules with NSF and aiming for postgraduate qualifications.

Background
Recognition in the industry and by your peers is always an important incentive to both the individual and the company. NSF Pharma Biotech offers, for those taking Qualified Person (QP) training, an opportunity to gain postgraduate qualifications, depending on how much time you can afford to put in.

The Benefits of Attending all Modules
> Linked consistent education with practice in QP decision making skills throughout
> Linked training to do the QP job, not just pass a Viva
> Reinforcement of key messages
> Access to discounts for MSc
> Benchmarking exams to confirm progress
> Access to discounted additional courses essential to the QP
> Enhanced networking
> 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 2

Certificate
For the quality professional who is looking to gain a further qualification or just recognition in their profession. You will need to complete three NSF Pharma Biotech foundation modules and three modules of your own choice, and perform satisfactorily in the assessments for each, 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, i.e. 21 months.

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. Candidates will be required to satisfy the Board of Examiners in a presentation of their project dissertation and in an oral examination. Projects shall normally be submitted within six months of completing the Diploma course.

Exemptions and Rewards
> Diploma/MSc candidates can apply for one exemption for a module covering a topic of existing expertise. However, for those taking all 12 modules, NSF Pharma Biotech will pay £1500 towards the University of Strathclyde Diploma/MSc fees
> Candidates who achieve an MSc will be invited to attend NSF Pharma Biotech’s annual one-day QP Continuing Professional Development 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, MSc and any other details please contact Dr Chris Prior at c.b.prior@strath.ac.uk

Reserve your place today  web: www.nsf.org/info/pharma-training telephone: +44 (0) 1751 432999 email: QPpharma@nsf.org
Now RSC Approved Training

Qualified Person & Professional Development Training

With Opportunity for Postgraduate Qualification

The right people. The right solution. The first time.™

www.nsfpharmabiotech.org

email QPpharma@nsf.org
tel +44 (0) 1751 432 999
fax +44 (0) 1751 432 450
post The Georgian House, 22-24 West End, Kirkbymoorside, York, UK, YO62 6AF

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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 Quality Management Systems ✔ ✔ ▲
Module 10 Practical Module ✔ ✔ ✔
Module 11 Investigational Medicinal Products ✔ ✔ ▲
Module 12 The Role & Professional Duties of the QP ✔ ✔ ▲

Three compulsory foundation modules (✔) plus three of choice (▲) for Certificate

Module assessments (for modules taken) ✔ ✔ ✔

Composite course written exam ✔ ✔ ✔

Paper I ✔ ✔
Paper II NA ✔
MSc Project NA NA ▲

The information contained in this brochure is correct at the time of printing and is published in good faith. We reserve the right to make any changes which may become necessary.
### Module Content

The NSF Health Sciences QP course is designed to meet the requirements of the UK Study Guide.

Each module is designed as a stand-alone course, so although the modules are numbered, it is not necessary to study them in sequential order. We also offer repeats of some modules to offer you maximum flexibility.

Ask us about our free gap analysis service— we can help you determine which modules would be of benefit to you and whether your experience or existing qualifications will qualify for an exemption from certain areas of study.

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### Module 1

**PHARMACEUTICAL LAW & ADMINISTRATION**

**Subject Sessions**
- Medicines Law – An Introduction
- EU Law – An Overview
- Global GMP Legislation
- Legislation in the EU Affecting Clinical Trials
- The Role and Duties of the Qualified Person
- The EU Marketing Authorization Application
- Format, Content – CTD
- Marketing Authorization – Routes and Variations
- The Non-Clinical Dossier/Toxicology
- Medicines Legislation: Authorizations for Manufacturing, Importing and Wholesale Dealing
- Medical Devices Legislation
- Route to Becoming a QP and Eligibility (UK and related Member States)
- Adverse Licensing

### Module 2

**MEDICINAL CHEMISTRY & THERAPEUTICS**

**Subject Sessions**
- Introduction to Physiological Processes
- Transmission Across a Synapse: Signal Transmission in the Nervous System
- Autonomic Nervous System
- Introduction to Drug Action
- Introduction to Central Neurotransmitter Systems
- Parkinson's Disease
- Schizophrenia and Antipsychotics
- Depression and Antidepressants
- Anatomy & Physiology: Heart & Lungs
- Nervous System
- Anxiety and Anxiolytics
- Introduction to the Heart and Cardiovascular System
- Cardiovascular Disease (Heart Attack)
- Diabetes and the Use of Insulin
- Gastrointestinal Disorders and Their Treatment
- Inflammation
- Anti-Inflammatory Drugs
- Use of Drugs in Surgery
- Contamination Control and Cleaning Validation – Regulations and Guidelines

### Module 3a

**FORMULATION AND PROCESSING, PART 1**

**Subject Sessions**
- Course Introduction and Objectives to Formulation and Processing
- Introduction to the Chemical Functional Groups
- Absorption, Distribution, Metabolism and Elimination
- Workshop – Physicochemical Properties of Drugs
- Preformulation Issues
- Pharmacokinetics and Concepts of Bioavailability and Bioequivalence
- Oral Liquids
- The Oral Route of Administration

### Module 3b

**FORMULATION AND PROCESSING, PART 2**

**Subject Sessions**
- Fundamentals of Solid Dose Formulations
- Teamwork: Powder Flow Properties
- Capsules
- GMP Issues for Solid Dose Manufacture
- Teamwork: Facility Design
- Blending and Granulation
- Teamwork: Blending and Granulation
- Tablet Compression
- Teamwork: Compression
- Tablet Process Controls
- Tablet Coating
- Teamwork: Coating
- An Ex Inspector’s View of Solid Dose Manufacture
- Teamwork: Create a Control Strategy for a QP in a Solid Dose Facility
- QP Issues for Solid Dose and Capsules
- QP Issues for Oral Liquids
- Teamwork: Oral Liquids, Facility Design
- Teamwork: Capsules – Oral Liquids Liquids, Creams, Ointments – Processing and GMP Issues
- Teamwork: LCO QP Issues

### Module 4

**PHARMACEUTICAL MICROBIOLOGY**

**Subject Sessions**
- Microorganisms – The What, Why & How
- Growing Microorganisms
- Counting Microorganisms – Methods of Enumeration
- Rapid Microbiological Methods – An Overview
- The Pharmaceutical Manufacturing Environment – Where can Microorganisms Exist?
- Identification of Microorganisms
- Microbiological Analysis of Water
- Pyrogens and Pyrogen Testing
- Microbiological Evaluation of Raw Materials and Non-Sterile Products
- The Reality – Microbiological Contamination and Spoilage of Pharmaceuticals
- Principles of Preservation
- Preservation Efficacy Testing
- Antibiotics
- Assessment of Antimicrobial Activity
- Good Disinfection Practice
- Sterilization – Principles and Methods
- Sterilization by Filtration
- Biovalidation of Sterilization

### Module 5

**ACTIVE PHARMACEUTICAL INGREDIENTS**

**Subject Sessions**
- Course Introduction and Objectives
- Overview of Chemical Synthesis and a Typical Bioprocess
- Qualify Factors for APIs (Including Biologicals)
- Regulatory Control of APIs
- Teamwork: The Responsibilities for QP API Declarations
- Introduction to EudraLex Vol 4 Part II
- Teamwork: Treasure Hunt from EudraLex Vol 4 Part II
- The Application of GMP to API Manufacture, According to EudraLex Vol 4 Part II
- Teamwork: Pharmacopeial Monographs and APIs
- Facilities for APIs
- Teamwork: Facilities for APIs
- GMP Utilities Used in API Manufacturing including Water, Gases and Effluent Removal/Treatment
- API Impurities and Common API Purification Techniques
- Teamwork: Site Tours and Discussion Groups
- An Introduction to Biological and Bioprocesses
- GMP for Biopharmaceuticals
- Teamwork: Why Bioprocessing is Different to Chemical Synthesis
- Premises for Biopharmaceutical Manufacturing
- Teamwork: Site Tours and Discussion Groups
- Overview of Key Steps in a Typical Bioprocess
- GMFs and Quality Assurance for Excipients

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**Reserve your place today:**
- [web: www.nsf.org/info/pharma-training](http://www.nsf.org/info/pharma-training)
- [tel: +44 (0) 1751 432999](tel:+44%20(0)%201751%20432999)
- [email: QPharma@nsf.org](mailto:QPharma@nsf.org)
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### Module 6: Mathematics & Statistics

**Subject Sessions**
- Summarizing and Visualizing Data (Histograms, Probability Curves and Box Plots)
- Confidence in Your Means and Proportions
- Statistical Process Control – Control Charts
- Statistical Process Controls – Cusum Charts
- Attribute Control Charts for Count Data and Other Useful Charts
- Statistical Process Control – Fishbone Diagrams and Pareto Charts
- Conflict Management
- Statistical Process Control – Process Capability
- Six Sigma ‘Real World’ Experiences using Control Charts
- ISO2869 (BS6001, Mil. Std.) Inspection by Attributes
- Statistical Testing – Two Groups (t-test)
- Statistical Testing – Three, or more, samples (ANOVA)
- Statistical Testing – Outliers ( Dixon’s test)
- Regression Analysis (includes 3 short teamworks)
- QbD and Chemometrics
- Experimental Design and Taguchi
- Multivariate Analysis

### Module 7: Analysis & Testing

**Subject Sessions**
- The Analytical Laboratory (GCLP)
- Sampling and Sample Management
- The Role and intent of Pharmacopeial Monographs
- Analytical Methods (Documentation, Validation and Transfer)
- Suspect Analytical Results (OOS, OOT and Atypical Results)
- The Analytical Toolbox ‘Classical Methods, KF, Electrochemical etc
- Physico-chemical Testings of Solid Dosage Forms (Hardness, Friability, Dissolution)
- Spectroscopy – Introduction
- UV/Visible Spectroscopy
- Atomic Spectroscopy – Trace Metal Analysis
- Infra-Red Spectroscopy (IR) and Near Infra-Red (NIR)
- Raman Spectroscopy
- Introduction to Chromatography
- Thin Layer Chromatography
- High-Performance (Pressure) Liquid Chromatography (HPLC)
- Factors Affecting HPLC Performance
- Gas Chromatography
- Capillary Electrophoresis (CE) and Size Exclusion Chromatography (SEC)
- Integration – Converting Signals to Analytical Results
- ELISA, PCE and SDS Page
- Pharmacognosy
- Analysis of ‘Large’ Molecules
- Mass Spectrometry (MS)
- Nuclear Magnetic Resonance (NMR)
- Stability Testing
- Equipment Qualification and Maintenance
- Water Testing: TOC and Conductivity
- Container-Closure Systems
- Labeling Regulations
- Design of Packaging Components
- PPM Supplier Considerations
- Delegate Presentations
- Auditing to PS 8000 (including checklist/aide mémoire)
- Incoming Goods Sampling,
- Specifications and Sampling Plans
- Automated Safety Systems
- Delegate Presentations
- Packaging GMPs, the 5Ps
- Teamwork: Facility Design Exercise
- Teamwork: QMS for Packing
- Inspection Processes
- Teamwork: Inspection Exercise
- Teamwork: Line Clearance, Where are the risks?
- Teamwork: Line Clearance, How do we combat risks?
- Teamwork: Line Clearance
- Serialization
- Good Distribution Practice
- Visit to Distributor
- QP Concerns, Interests on Wholesaler Pharmacy Visits
- Presentation Proposals for Department Designs, QMS, BPR and Line Clearance
- Feedback on week to date, key messages
- Controlled Temperature Storage and Distribution
- QP Life in Packing
- Anti Counterfeiting
- Group Work: Design an Audit Aide Mémoire to Auditing Packing Departments
- Teamwork: Find it Exercise in ICH Q10
- ICH Q9 Quality Risk Management
- Teamwork: Risk Management and QMS
- Senior Management Roles and Responsibilities with regard to the QMS
- Senior Management Roles and Responsibilities – Aide Mémoire
- Teamwork: Senior Management Commitment to Quality
- People
- Teamwork: Training and Development of People
- Documentation and Records
- Data Integrity
- Introduction to Change Control – Planned Changes
- Teamwork: Change Control
- Supply Chain Management
- Teamwork: The Quality Management of Materials
- Introduction to GDP
- Teamwork: GDP
- Teamwork: Design Criteria
- Production
- Production Aide Mémoire
- Teamwork: Production and QA
- Facilities, Equipment and Services Management
- Validation and Qualification Systems
- Batch Release System
- Teamwork: Release Scenarios: To Release or Not?
- Teamwork: QP Relationships
- Laboratory Control Systems
- Teamwork: Deviation Management
- Teamwork: Audits Audits and Self-Inspections
- Teamwork: Evaluation

### Module 8: Pharmaceutical Packaging

**Subject Sessions**
- Introduction and Objectives
- Teamwork: Introduction to Material Packs
- Overview of Materials
- Stability Testing
- Teamwork: Stability
- Introduction to GDP
- Teamwork: The Quality Management of Materials
- Introduction to ICH Q8, Q9 and Q10
- Teamwork: Production and QA
- Facilities, Equipment and Services Management
- Validation and Qualification Systems
- Batch Release System
- Teamwork: Release Scenarios: To Release or Not?
- Teamwork: QP Relationships
- Laboratory Control Systems
- Teamwork: Deviation Management
- Teamwork: Audits Audits and Self-Inspections
- Teamwork: Evaluation

### Module 9: Quality Management Systems

**Subject Sessions**
- Teamwork: Principles of QA and QMS – Overview
- Integration of Quality Systems Across Product Lifecycle
- Teamwork: Quality Management System Elements
- Teamwork: Find it Exercise in ICH Q10
- ICH Q9 Quality Risk Management
- Teamwork: Risk Management and QMS
- Senior Management Roles and Responsibilities with regard to the QMS
- Senior Management Roles and Responsibilities – Aide Mémoire
- Teamwork: Senior Management Commitment to Quality
- People
- Teamwork: Training and Development of People
- Documentation and Records
- Data Integrity
- Introduction to Change Control – Planned Changes
- Teamwork: Change Control
- Supply Chain Management
- Teamwork: The Quality Management of Materials
- Introduction to GDP
- Teamwork: GDP
- Teamwork: Design Criteria
- Production
- Production Aide Mémoire
- Teamwork: Production and QA
- Facilities, Equipment and Services Management
- Validation and Qualification Systems
- Batch Release System
- Teamwork: Release Scenarios: To Release or Not?
- Teamwork: QP Relationships
- Laboratory Control Systems
- Teamwork: Deviation Management
- Teamwork: Audits Audits and Self-Inspections
- Teamwork: Evaluation

### Module 10: Practical Module

**Subject Sessions**
- Sterile Products
- Formulation and Processing
- Analysis and Preformulation
- Biologics
- Total Product Life Cycle
- Teamwork: Principles of QA and QMS – Overview
- Integration of Quality Systems Across Product Lifecycle
- Teamwork: Quality Management System Elements
- Teamwork: Find it Exercise in ICH Q10
- ICH Q9 Quality Risk Management
- Teamwork: Risk Management and QMS
- Senior Management Roles and Responsibilities with regard to the QMS
- Senior Management Roles and Responsibilities – Aide Mémoire
- Teamwork: Senior Management Commitment to Quality
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- Introduction to Change Control – Planned Changes
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- Teamwork: The Quality Management of Materials
- Introduction to GDP
- Teamwork: GDP
- Teamwork: Design Criteria
- Production
- Production Aide Mémoire
- Teamwork: Production and QA
- Facilities, Equipment and Services Management
- Validation and Qualification Systems
- Batch Release System
- Teamwork: Release Scenarios: To Release or Not?
- Teamwork: QP Relationships
- Laboratory Control Systems
- Teamwork: Deviation Management
- Teamwork: Audits Audits and Self-Inspections
- Teamwork: Evaluation

### Module 11: Investigational Medicinal Products

**Subject Sessions**
- Scene Setting: What is a Clinical Trial?
- Teamwork: What I Want to Know is...
- Legislation in the EU Affecting Clinical Trials
- Appendices: Directive 2001/20/EC
- Directive 2003/94/EC
- Directive 2005/25/EC
- Key Differences between EU and US Approach to Clinical Trials
- Teamwork: Key Differences between EU & USA
- Teamwork: Key Differences between Commercial and Clinical Manufacture
- Specific EU GMP Guidance – Annex 13 Appendix: EudraLex Volume 4 Annex 13 – Investigational Medicinal Products
- GCP and GMP Interface Areas
- The Role of the EU QP for IMPs
- Introduction to ICH Q8, Q9 and Q10 and Validation
- Essentials of a Quality Management System in the Development of Medicines (ICH Q10) + reference paper
- Specific Documentation in Clinical Trials
- QP Declaration Template
- Effective Management of Starting Materials Including Comparators + Extract from EudraLex Volume 4 Part 2
- Teamwork: QP Batch Release Scenarios
- GMP Issues for Clinical Trial Manufacturing
- Practical Implications of Importation of Clinical Supplies
- Teamwork: Importation
- Testing and Specifications
- GMP Issues in Clinical Trial Packaging Operations
- The View from a contract Clinical Trials Packager
- Interactive Voice Response Systems (IVRS)
- QP Batch Release Scenarios
- Teamwork: Tic Tac Exercise
- Cleaning Validation and Verification
- Teamwork: Cleaning
- Contractual Relationships and Technical Agreements
- Current Inspection Issues
- Q&A with MHRA Inspector & Panel
- Teamwork: Audit Observations or more QP Batch Release Scenarios
- Distribution of Clinical Supplies
- What’s New in CTs?

### Module 12: Role & Professional Duties of the QP

**Subject Sessions**
- The Legal Duties of the Qualified Person
- Batch Certification by the QP – Annex 16
- What Gives a QP Confidence?
- Risk-Based Decision Making for the QP
- The QP Application Process
- My Journey through the QP Viva Process
- Education and Training of QPs
- The Relationship Between the QP and Regulatory Authorities
- EU and UK Legislation and Guidelines: An Update
- Human Error
- Leading with Influence
- The QP: What it is like in Real Life
- The Role of the IMP QP
- The Qualified Person: Code of Practice
- The QP as a Change Agent
- Keeping Up-to-Date

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**Reserve your place today:**

web: [www.nsf.org/info/pharma-training](http://www.nsf.org/info/pharma-training)

tel: +44 (0) 1751 432999

e-mail: QPpharma@nsf.org
Module 6: Mathematics & Statistics

Subject Sessions
- Summarizing and Visualizing Data (Histograms, Probability Curves and Box Plots)
- Confidence in Your Means and Proportions
- Statistical Process Control – Control Charts
- Statistical Process Controls – Cusum Charts
- Attribute Control Charts for Count Data and Other Useful Charts
- Statistical Process Control – Fishbone Diagrams and Pareto Charts
- Conflict Management
- Statistical Process Control – Process Capability
- Six Sigma
- ‘Real World’ Experiences using Control Charts
- ISO2869 (BS6001, Mil. Std.) Inspection by Attributes
- Statistical Testing – Two Groups (t-test)
- Statistical Testing – Three, or more, samples (ANOVA)
- Statistical Testing – Outliers ( Dixon’s test)
- Regression Analysis (includes 3 short teamwork)
- QbD and Chemometrics
- Experimental Design and Taguchi
- Multivariate Analysis

Module 7: Analysis & Testing

Subject Sessions
- The Analytical Laboratory (GCLP)
- Sampling and Sample Management
- The Role and Intent of Pharmacopeial Monographs
- Analytical Methods (Documentation, Validation and Transfer)
- Suspect Analytical Results (OOS, OOT and Atypical Results)
- The Analytical Toolbox ‘Classical Methods, KF, Electrochemical etc
- Physico-chemical Testings of Solid Dosage Forms (Hardness, Friability, Dissolution)
- Spectroscopy – Introduction
- UV/Visible Spectroscopy
- Atomic Spectroscopy – Trace Metal Analysis
- Infra-Red Spectroscopy (IR) and Near Infra-Red (NIR)
- Raman Spectroscopy
- Introduction to Chromatography
- Thin Layer Chromatography
- High-Performance (Pressure) Liquid Chromatography (HPLC)
- Factors Affecting HPLC Performance
- Gas Chromatography
- Capillary Electrophoresis (CE) and Size Exclusion Chromatography (SEC)
- Integration – Converting Signals to Analytical Results
- ELISA, PCE and SDS Page
- Pharmacognosy
- Analysis of ‘Large’ Molecules
- Mass Spectrometry (MS)
- Nuclear Magnetic Resonance (NMR)
- Stability Testing
- Equipment Qualification and Maintenance
- Water Testing: TOC and Conductivity
- Container-Closure Systems
- Labeling Regulations
- Design of Packaging Components
- PPM Supplier Considerations
- Delegate Presentations
- Auditing to PS 8000 (including checklist/aide mémoire)
- Incoming Goods Sampling, Specifications and Sampling Plans
- Automated Safety Systems
- Delegate Presentations
- Packaging GMPs, the SPs
- Teamwork: Facility Design Exercise
- Teamwork: QMS for Packing
- Inspection Processes
- Teamwork: Inspection Exercise
- Teamwork: Line Clearance, Where are the risks?
- Teamwork: Line Clearance, How do we combat risks?
- Teamwork: Line Clearance
- Serialization
- Good Distribution Practice
- Visit to Distributor
- QP Concerns, Interests on Wholesaler Pharmacy Visits
- Presentation Proposals for Department Designs, QMS, BPR and Line Clearance
- Feedback on week to date, key messages
- Controlled Temperature Storage and Distribution
- QP Life in Packing
- Anti Counterfeiting
- Group Work: Design an Audit Aide Mémoire to Auditing Packing Departments
- Teamwork: Find it Exercise in ICH Q10
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Module 8: Pharmacological Packaging

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- Teamwork: Introduction to Material Packs
- Overview of Materials
- Stability Testing
- Teamwork: Stability

Module 9: Quality Management Systems

Subject Sessions
- Teamwork: Principles of QA and QMS – Overview
- Integration of Quality Systems Across Product Lifecycle
- Teamwork: Quality Management System Elements

Module 10: Practical Module

Subject Sessions
- Sterile Products
- Formulation and Processing
- Analysis and Preformulation
- Biologics

Module 11: Investigational Medicinal Products

Subject Sessions
- Scene Setting: What is a Clinical Trial?
- Teamwork: What I Want to Know is…
- Legislation in the EU Affecting Clinical Trials
- Appendices: Directive 2001/20/EC
- Directive 2003/94/EC
- Directive 2005/28/EC
- Key Differences between EU and US Approach to Clinical Trials
- Teamwork: Key Differences between EU & USA
- Teamwork: Key Differences between Commercial and Clinical Manufacture
- Specific EU GMP Guidance – Annex 13
- Appendices: EudraLex Volume 4 Annex 13
- Investigation of Medicinal Products
- GCP and GMP Interface Areas
- The Role of the EU QP for IMPs
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- Teamwork: Importation
- Testing and Specifications
- GMP Issues in Clinical Trial Packaging Operations
- The View from a contract Clinical Trials Packager
- Interactive Voice Response Systems (IVRS)
- QP Batch Release Scenarios
Prospective QPs – Gap Analysis Service

If you’re considering training as a QP, you will need to plan your study program and make sure you have the knowledge and experience required by the UK Study Guide. Depending on your own individual circumstances, it may not be necessary for you to attend every module.

We are happy to help you assess your needs by providing a gap analysis based on an evaluation of your CV, and/or we can provide our unique self-assessment tool which helps you to carry out your own gap analysis. 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.

Some requirements can be addressed by self-study or work experience, and others will require formal study. We are always available to discuss your requirements and answer any questions you may have.

There is no charge for this service. Contact our QP Course Administrator at QPpharma@nsf.org for more information.
Qualified Person Training – Provisional Module Booking

When you have established which modules you need to attend, we can hold provisional places for you without obligation. Planning your training program in this way ensures that you will receive relevant pre-course reminders and information.

Remember also that delegates who sign up for a minimum of four QP modules with us will be assigned a personal tutor, who will be on hand throughout your training to offer guidance and support.

Please indicate below which modules you’re interested in and return the form to our QP Course Administrator at QPpharma@nsf.org. We will then make provisional bookings for you to make sure you don’t miss your preferred dates.

Your Details

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email QPpharma@nsf.org
tel +44 (0) 1751 432 999
tax +44 (0) 1751 432 450
post The Georgian House, 22-24 West End, Kirkbymoorside, York, UK, YO62 6AF
# Qualified Person Training

**October 2016 to July 2018**

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**Recommended Training (not part of QP Syllabus)**

- Pharmaceutical GMP Audits and Self-Inspections
- Risk-Based Decision Making for Quality Professionals and QPs
- GMP for Biological and Biotechnology Products
QP Module Planner

We acknowledge that it isn’t always easy to fit training around your work schedule. To help you with this, we run repeats of certain QP modules. There are also some courses from our main public training program which provide suitable alternatives to the QP modules indicated.

**KEY**

- **Series Modules** – our scheduled program of Modules 1-12
- **‘Repeat’ Modules** – additional dates to give you extra flexibility
- **Available Training** – courses from our public training program which provide you with similar knowledge related to the QP module*

*For specific details or further advice contact Stella Pearson-Smith (QPpharma@nsf.org)

The information contained in this brochure is correct at the time of printing and is published in good faith. We reserve the right to make any changes which may become necessary.
The Experience of QP Training with NSF Health Sciences

See what some former delegates have to say – they’re people who see it from your perspective. Read on to get a flavor of how it feels to be part of the NSF QP program.

James Culyer, Bard Pharmaceuticals

The reason for choosing NSF was quite simply that there was no choice. As a company we had a long-standing relationship with NSF; all 7 of the site QPs had studied and qualified with them, including my manager and the Quality Director himself. The relationship spanned many years and had become a two-way process, with many of our QPs routinely involved in delivering material and sharing experiences as industry presenters at NSF’s many and varied training courses. There was a deep trust in the abilities of both parties to deliver exactly what was needed and the thought of going elsewhere for QP training with no understanding of the capabilities, knowledge of the course materials, and no experience of the approach taken was not even entertained. To reiterate, NSF was quite simply the first and only choice.

I needn’t have worried; the courses themselves are extremely informative and quite simply great fun. The atmosphere is relaxed and informal and the speakers experts in their respective fields. Many hints and tips for survival were gladly given; how to handle the revision workload, how to survive the exams, how to get the most out of the courses – basically, all the essentials!

Also, from the very first morning of the first course you start the networking process, and that is just a formal way of saying you start making new friends. And that is one of the best things about the NSF approach to QP development, the huge emphasis on networking; practically every aspect of the course – the training techniques, the venues, the ‘extra-curricular’ activities – are all based around encouraging you to build a broad and long-lasting network of contacts that will serve you through the viva process and beyond, throughout the rest of your career.

The other great thing about the NSF QP courses is the personal tutor system. Once you sign up for at least four of the QP modules you are automatically assigned a personal tutor. This will be one of the NSF team members actively involved in the QP training courses, and they will inevitably have acted as a QP at some point in their career. They remain an ever-present source of information and guidance right up to the point you sit, and hopefully pass, your viva.

In the months leading up to the viva process NSF offers one further service, the mock viva. The extremely gruelling three hour session serves to identify the gaps you have that need filling, your ability to put yourself across in a viva experience, and the overall manner in which you present yourself and approach the various different types of viva questions and scenarios. I remember my own mock viva very well, and remember how helpful it was in focussing my revision topics leading up to the real thing a few short weeks later.

So overall I don’t think you can do better than to choose NSF as the training provider for the QP program. Their focus is 100% on getting you through, successfully, first time. The structure of the courses and course material, the social aspects of the modules, the emphasis on networking, the tutoring and mentoring, and all in all the supportive nature of the service they provide gives you the best chance possible. All you need to do is turn up on the day and pass the thing!

Shawn Murtough, Penn Pharmaceuticals

NSF provides first-class training services that will greatly assist any prospective candidate in their quest for eligibility to act as a Qualified Person.

The structure of the program allows candidates to join and leave at any point, which provides flexibility in meeting your training needs against a busy work schedule. The content revisits key themes on different modules to ensure a thorough understanding of how certain aspects interlink between the different modules. The style of teaching and learning that NSF promote is interactive, meaning that core messages are first delivered by traditional methods and then emphasised through teamwork sessions which greatly assist full understanding and comprehension.

NSF training always takes place in high quality venues, with the trainers being recognised as industry experts. I would have no hesitation in recommending NSF as the leading training provider in respect of the QP study guide.
Leen van de Water, Pannoc

For me the Qualified Person training at NSF was not just the only possible way to become a QP in Belgium. I’m still the only non-pharmacist as a QP in Belgium at the moment. It was a one out of a thousand opportunity.

Not only did I gain a lot of theoretical and practical knowledge about the different pillars of a pharmaceutical company: pharmaceutical legislation, formulating, processing, APIs, analysing and testing, packaging, the quality management system… for me the opportunity to network, get in touch with new people, and talk about problems and solutions was as important as the knowledge.

Also the opportunity to develop the necessary soft skills for a QP was important, and it definitely brought my English to a higher level.

The Qualified Person training of 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.

I hope a lot of Belgians follow my footsteps to become a QP via the NSF training as a non-pharmacist.

Ian Birch, Roche Pharma

NSF provided me with the most comprehensive QP training I could have hoped for. I can understand why the training is held in such high regard, as the tutors’ delivery, experience and importantly, their focus on personal development, is exceptional.

The environment in which the course is run allowed me to develop a strong and effective network with other quality professionals, which you can’t put a price on!

NSF are an example of ‘best in class’ and I believe their approach to training produces quality professionals that can draw on experience from all areas of the industry.

David Franks, Reckitt Benckiser Pharmaceuticals

Why did I choose NSF?
NSF are renowned through the UK (and beyond) industry as leaders in training QPs.

From the first module you will know that a friendly, relaxed (but intense!) training course will meet your expectations.

The training is structured in a way that you get to apply your knowledge in scenario-based break-out sessions, and you get to work with a network of quality professionals, which I personally have taken out of the classroom and into my workplace.

If I could offer any words of advice, experience or wisdom to a new starter on the course, what would I say?
Use the training materials and gain a network with fellow delegates. Find the time during and after the course to build up that network. It will get you success beyond the viva.

Make use of your tutor as much as possible. My personal tutor was very knowledgeable of my company and former delegates and personnel, which really helped in understanding about my company’s dosage forms. She was a great help and really encouraged me throughout the course. She was available when I needed her, in and outside of normal hours. She was the shoulder to cry on and the boot up the backside when it was needed!

What have I enjoyed most about the training course?
The course tutors have made the course successful by presenting it in a way that builds up from the foundations to a level that will give you the confidence you need to become a QP. The optional evening sessions also help with the soft skills needed in the role. I enjoyed this the most, as it not only made filling in the QP application easy, it has given me the knowledge and self-belief to perform the QP duties after I passed the viva.

Leen van de Water, Pannoc

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Also the opportunity to develop the necessary soft skills for a QP was important, and it definitely brought my English to a higher level.

The Qualified Person training of 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.

I hope a lot of Belgians follow my footsteps to become a QP via the NSF training as a non-pharmacist.

Ian Birch, Roche Pharma

NSF provided me with the most comprehensive QP training I could have hoped for. I can understand why the training is held in such high regard, as the tutors’ delivery, experience and importantly, their focus on personal development, is exceptional.

The environment in which the course is run allowed me to develop a strong and effective network with other quality professionals, which you can’t put a price on!

NSF are an example of ‘best in class’ and I believe their approach to training produces quality professionals that can draw on experience from all areas of the industry.

David Franks, Reckitt Benckiser Pharmaceuticals

Why did I choose NSF?
NSF are renowned through the UK (and beyond) industry as leaders in training QPs.

From the first module you will know that a friendly, relaxed (but intense!) training course will meet your expectations.

The training is structured in a way that you get to apply your knowledge in scenario-based break-out sessions, and you get to work with a network of quality professionals, which I personally have taken out of the classroom and into my workplace.

If I could offer any words of advice, experience or wisdom to a new starter on the course, what would I say?
Use the training materials and gain a network with fellow delegates. Find the time during and after the course to build up that network. It will get you success beyond the viva.

Make use of your tutor as much as possible. My personal tutor was very knowledgeable of my company and former delegates and personnel, which really helped in understanding about my company’s dosage forms. She was a great help and really encouraged me throughout the course. She was available when I needed her, in and outside of normal hours. She was the shoulder to cry on and the boot up the backside when it was needed!

What have I enjoyed most about the training course?
The course tutors have made the course successful by presenting it in a way that builds up from the foundations to a level that will give you the confidence you need to become a QP. The optional evening sessions also help with the soft skills needed in the role. I enjoyed this the most, as it not only made filling in the QP application easy, it has given me the knowledge and self-belief to perform the QP duties after I passed the viva.

Leen van de Water, Pannoc

For me the Qualified Person training at NSF was not just the only possible way to become a QP in Belgium. I’m still the only non-pharmacist as a QP in Belgium at the moment. It was a one out of a thousand opportunity.

Not only did I gain a lot of theoretical and practical knowledge about the different pillars of a pharmaceutical company: pharmaceutical legislation, formulating, processing, APIs, analysing and testing, packaging, the quality management system… for me the opportunity to network, get in touch with new people, and talk about problems and solutions was as important as the knowledge.

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Prospective QPs Typical Questions Asked

<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do I need to attend all the modules?</td>
<td>No, unless you wish to aim for the Postgraduate Diploma or MSc, modules can be selected as required.</td>
</tr>
<tr>
<td>How can I decide which modules to attend?</td>
<td>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.</td>
</tr>
<tr>
<td>How long does the course take?</td>
<td>This depends on how many modules the delegates wish to attend and where these fall in the series. A full series typically takes 18 months but some delegates prefer to spread the course over 2 series. Flexibility is the name of the game!</td>
</tr>
<tr>
<td>How do I enrol for the Postgraduate Certificate?</td>
<td>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 direct with the delegate. The requirements for the Certificate are…</td>
</tr>
<tr>
<td></td>
<td>&gt; attend 3 foundation modules and 3 of choice, perform satisfactorily in the module assessments, sit the Certificate exam at the University</td>
</tr>
<tr>
<td>How do I enrol for the Postgraduate Diploma/MSc?</td>
<td>The University of Strathclyde coordinates their qualification directly with the delegate. Typically the requirements for the Diploma are…</td>
</tr>
<tr>
<td></td>
<td>&gt; attend all modules, perform satisfactorily in the module assessments, sit the Diploma exams at the University</td>
</tr>
<tr>
<td></td>
<td>The MSc requires the above plus a workplace thesis/project, approved by the Course Director at the University.</td>
</tr>
<tr>
<td>Do all modules cost the same?</td>
<td>No, some are 5 days in duration and some are 4 days. In addition different venues (such as the practical module in Glasgow) can impact on the course costs.</td>
</tr>
<tr>
<td>Once the series is finished do I still have use of your advice and consultancy?</td>
<td>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.</td>
</tr>
<tr>
<td>What is the success rate of your delegates at viva?</td>
<td>Information to date shows a pass rate of 96% for delegates we have trained.</td>
</tr>
</tbody>
</table>
**I’ve heard about the Personal Tutor System, what is it?**

Delegates who attend 4 or more modules are classed as “core” delegates. This brings additional benefits to the delegate…

- 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 6-8 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.

**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 continuing professional development.

**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.
### Qualified Person Training Course Fees

**October 2016 to July 2018**

<table>
<thead>
<tr>
<th>No</th>
<th>Title</th>
<th>Days</th>
<th>Fee £</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Pharmaceutical Law &amp; Administration</td>
<td>5 days</td>
<td>3395</td>
</tr>
<tr>
<td>2</td>
<td>Medicinal Chemistry &amp; Therapeutics</td>
<td>5 days</td>
<td>3395</td>
</tr>
<tr>
<td>3a</td>
<td>Pharmaceutical Formulation &amp; Processing, Part 1</td>
<td>5 days</td>
<td>3395</td>
</tr>
<tr>
<td>3b</td>
<td>Pharmaceutical Formulation &amp; Processing, Part 2</td>
<td>5 days</td>
<td>3395</td>
</tr>
<tr>
<td>4</td>
<td>Pharmaceutical Microbiology</td>
<td>5 days</td>
<td>3395</td>
</tr>
<tr>
<td>5</td>
<td>Active Pharmaceutical Ingredients</td>
<td>4.5 days</td>
<td>2880</td>
</tr>
<tr>
<td>6</td>
<td>Mathematics &amp; Statistics</td>
<td>4 days</td>
<td>2750</td>
</tr>
<tr>
<td>7</td>
<td>Analysis &amp; Testing</td>
<td>5 days</td>
<td>3395</td>
</tr>
<tr>
<td>8</td>
<td>Pharmaceutical Packaging</td>
<td>5 days</td>
<td>3395</td>
</tr>
<tr>
<td>9</td>
<td>Quality Management Systems</td>
<td>5 days</td>
<td>3395</td>
</tr>
<tr>
<td>10</td>
<td>Practical</td>
<td>5 days</td>
<td>3575</td>
</tr>
<tr>
<td>11</td>
<td>Investigational Medicinal Products</td>
<td>4 days</td>
<td>2750</td>
</tr>
<tr>
<td>12</td>
<td>Role &amp; Professional Duties of the Qualified Person</td>
<td>4 days</td>
<td>2750</td>
</tr>
</tbody>
</table>

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Reserve your place today

visit [www.nsf.org/info/pharma-training](http://www.nsf.org/info/pharma-training), call us on +44 (0) 1751 432999 or email us at [QPpharma@nsf.org](mailto:QPpharma@nsf.org)
What’s Included in the Module Fees

Course fee includes tuition, full course documentation, any visits arranged, attendance certificate and assessments as well as attendance at our QP skills sessions. Daytime conference facilities, lunches, refreshments and the formal course dinner are always included. Hotel accommodation and other evening meals are not included, but we do have specially negotiated Bed and Breakfast rates with all of the hotels.

We know that we are in the fortunate position of being considered the premier provider of QP training. We also know that we are by no means the cheapest – although we like to think that you get what you pay for. Nonetheless, we appreciate that the pharmaceutical industry is going through a period of belt tightening and, whilst QP training represents a critical undertaking which will only be done once and so should be done right, we understand that budgets are not limitless.

We Would Like to Help by Offering the Following Discounts

> For companies sending more than one delegate from the same site to any of our modules, the second attendee will receive a 20% discount on the course fee; third and subsequent delegates receive a 50% discount

> 50% discount is available for Regulatory Authorities and UK National Health Service employees

> Discounts may be available at the discretion of the Executive Directors, on a case by case basis for self-funding individuals and to support charities

How to Reserve a Place

To provisionally reserve a place on the series, any individual modules or for further information please contact our QP Course Administrator at QPpharma@nsf.org.

Online Reservation

Provisional and firm bookings can be made via our website www.nsf.org/info/pharma-training

The information contained in this brochure is correct at the time of printing and is published in good faith. We reserve the right to make any changes which may become necessary.
We have been running Qualified Person (QP) training courses since 1990 and they are generally considered to be the best available – QPs are very highly regarded within the industry and their status is recognised by many countries including Austria, Belgium, Denmark, Hungary, Ireland, Jordan, Malta, The Netherlands, Norway, and Switzerland.

The Aspiring QP and Technical Professional

Choose your place: web: www.nsf.org/info/pharma-training

What We Offer You

1. Complete, detailed training and reference materials
2. What We Offer Core QPs
3. The role
4. The skills
5. The Aspiring QP and Technical Professional
6. Give you the time required to learn and train thoroughly
7. Help in formulating your own training and experience plan
8. Flexible courses start and stop to suit you
9. High-impact, face-to-face education
10. Supported by lecturers from one of the country's top schools
11. Unequalled training for highly experienced industrial experts and
12. Certificate to MSc
13. Revision interview
14. Assertiveness techniques
15. Presentation techniques
16. Decision making
17. Leadership

Additional Benefits

> 50% for NHS and Regulatory Authorities
> Discounts also available, at the discretion of the program

How to Reserve a Place

For further information on module content, to arrange a free gap analysis or to talk to someone about the process and eligibility, please contact Stella Pearson-Smith, QPpharma@nsf.org or call +44 (0) 1751 432 450.