NSF Health Sciences Pharmaceutical Public Courses

NSF.ORG

Improving human and planet health is the mission of NSF

Businesses, regulators, and consumers all look to NSF to facilitate the development of public health standards and to provide services that help protect food, water, consumer products, and the earth's environment.

Health Sciences Training Solutions

NSF offers training and consultancy services for leading organizations in the health care industries. Our client-focused solutions offer timely, real-world global knowledge from regulatory and quality experts who recognize the needs of our learners and the issues they face.

Pharmaceutical Training

NSF provides regulatory and quality pharmaceutical training courses and professional qualifications rooted in industry best practices, real-world experience, and regulator insights. Our interactive training helps you meet international requirements at every stage of the product lifecycle.

Choose from instructor-led and online, self-paced pharmaceutical training courses created by our team of leading global experts, or work with NSF to incorporate your company's business operations, policies, procedures, brand, and messaging into our training offerings.

Our Staff of Experts

Our global pharmaceutical experts ensure content is up to date, highly interactive and designed with the learner in mind. These courses offer one-of-a-kind training developed by experts and former regulators from around the globe.

For more information about training solutions and incorporating your company's business operations, policies, procedures, brand, and messaging into our training offerings call +44 (0) 1751 434 807 or email pharmacourses@nsf.org.

NSF Health Sciences Pharmaceutical eLearning & Public Courses

Public Courses

Pharmaceutical Law and Administration 6
Medicinal Chemistry and Therapeutics 7
Formulation and Processing 8
Pharmaceutical Microbiology 9
Active Substances and Excipients 10
Mathematics and Statistics 11
Analysis and Testing 12
Pharmaceutical Packaging 14
Pharmaceutical Quality Systems 15
Practical Module 16
Investigational Medicinal Products 17
The Role and Professional Duties of the QP 18
Advanced Equipment Qualification and Process Validation 19
A-Z of Sterile Products Manufacture 21
Certificate in Pharmaceutical Quality 22
GMP for Biological and Biotechnology Products 24
GMP for Clinical Trials Manufacture and Supply 25
GMP PQS Lead Auditor (CQI & IRCA Certified Training) 26
Pharmaceutical GMP 27
Pharmaceutical Legislation Update Subscription Service 28
Quality Risk Management 29
Responsible Person and Good Distribution Practice 30

eLearning Courses

Adverse Events and Product Quality Complaints – A Guide for Employees 35
Analysis and Testing 35
Change Control Overview 35
Cleaning Qualification 35
Combination Products GMP and Regulatory Overview 35
Computerised Systems Validation 35
Data Integrity: Overview and Documentation Completion, Review and Approval 35
Data Integrity: Beyond the Basics 35
Data Integrity: Management Requirements 36
Deviation Investigations and CAPA 36
General Drug or Pharmaceutical cGMP and Quality Systems Programme 36
GMP Refresher Training 36
Good Distribution Practices 36
GxP Inspection Management Lifecycle 36
GxP Refresher Training: ICH Q8, Q9 and Q10 36
Interface of GMP with GCP Quality Management Systems 37
Microbiology: The Basics 37
Pharmaceutical Microbiology 37
Process Validation and Equipment Qualification 37
Self-Inspections – How to Make Them Add Value to Your Organisation 37
SOP Writing and Revision 37
Sterile Manufacturing Practices 37
Certificate in Pharmaceutical Manufacturing 38

Pharmaceutical Qualified Person Training Overview

Our pharmaceutical Qualified Person (QP) training program provides MSc-level training with an industrial perspective that not only exceeds the requirements of the UK QP Study Guide, but also provides a context to help decision-making and help you survive as a QP.

NSF offers pharmaceutical Qualified Person training in conjunction with the University of Strathclyde in Scotland, one of the premier universities for pharmaceutical education in the UK. This blend of academic excellence and sound industry-based experience sets our QP training apart from the other providers and ensures an unparalleled success rate. The course consists of 12 modules and meets the requirements for theoretical training as detailed in the latest Qualified Person Study Guide. All of our QP training modules are RSC approved.

The modules provide practical, face-to-face or virtual tuition in master's degree-level detail to prepare candidates for the challenging and ever-growing role of acting as a QP in today's pharmaceutical industry. This course uniquely focuses on the knowledge and practical decision-making exercises necessary to build skills and confidence for the QP role. Sufficient time and depth are provided to grow QPs to be the best they can be and to prepare the candidates for the role ahead, not just the assessment process.

Not everyone attends our QP modules because they want to become a QP. Many use the training to develop as technical managers in other areas of pharmaceutical manufacture and control. Others attend as part of their continuing professional development. The syllabus is seen by many as essential skills training for all technical leaders, managers and supervisors working in the industry supporting product realization and release.

Our QP courses:

- Pharmaceutical Law and Administration
- Medicinal Chemistry and Therapeutics
- Formulation and Processing
- Pharmaceutical Microbiology
- Active Substances and Excipients
- Mathematics and Statistics
- Analysis and Testing
- Pharmaceutical Packaging
- Pharmaceutical Quality Systems
- Practical Module
- Investigational Medicinal Products
- The Role and Professional Duties of the QP

For more information contact qppharma@nsf.org

https://www.nsf.org/training/series/pharmaceutical-qualified-person-training-overview


3PT

Pharmaceutical Law and Administration

University of Strathclyde Glasgow

ROYAL SOCIETY OF CHEMISTRY | APPROVED TRAINING

Pharmaceutical law and administration are key foundation knowledge requirements for all QPs. This course provides comprehensive coverage of the medicinal product legislation in both the EU and UK. The course meets the requirements of the UK QP Study Guide and also provides comprehensive coverage of EU legislation for EU QPs.

Our highly interactive training course provides aspiring QPs, and other pharmaceutical quality professionals, the EU and UK pharmaceutical legislation understanding needed to carry out their duties with skill and authority and to ensure compliance with relevant laws.

This course covers:

- Pharmaceutical legislation in the UK, Europe and the US
- Regulations and guidance that dictate how we must work on a daily basis
- Why these laws exist and how they come into being
- Roles and responsibilities of regulatory agencies
- The key role that QPs and pharmaceutical quality professionals must play to ensure compliance with international legislation in the interest of patient safety

Key Learning Objectives

On completion of this course, you will know and understand:

- Why we have medicines laws and what they seek to achieve
- UK mechanisms for controlling medicinal products
- European mechanisms for controlling medicinal products
- An overview of US legislation for controlling drug products
- International harmonization activities of ICH and PIC/S

For more information and registration details, please visit:

https://www.nsf.org/training/series/pharmaceutical-law-administration

Medicinal Chemistry and Therapeutics

University of Strathclyde Glasgow

ROYAL SOCIETY OF CHEMISTRY | APPROVED TRAINING

The medicinal chemistry and therapeutics training course is essential knowledge for QPs and those working with pharmaceuticals. This intensive course provides an understanding of the technical terminology, demystifying reference material from patient information leaflets to data sheets.

If you work in the industry, it is vital that you understand the impact of your products on your patients, the good they do and the harm they can cause.

Key Learning Objectives

On completion of this medicinal chemistry and therapeutics training course, you will know and understand:

- How the body works (from cells to key physiology) and what goes wrong
- Major therapeutic areas: central nervous system, heart, respiratory tract, inflammatory disease and gastrointestinal tract
- Drug therapy: receptors, autonomic nervous system and other drug targets
- Cleaning and risk-based cross-contamination avoidance
- In addition, there are opportunities to discuss your products with expert tutors from one of the top schools of pharmacy in the UK and hear presentations on currently marketed products

For more information and registration details, please visit:

https://www.nsf.org/training/series/medicinal-chemistry-therapeutics

Formulation and Processing

University of Strathclyde Glasgow

ROYAL SOCIETY OF CHEMISTRY | APPROVED TRAINING

It is important that the Qualified Person understands the principles of formulation and processing to ensure that informed certification and release decisions are made.

This intensive, interactive pharmaceutical formulation and processing course allows aspiring Qualified Persons and other pharmaceutical professionals to understand the key quality requirements when manufacturing products and is delivered in two parts:

Part 1 **Non-sterile products** (capsules, liquids, topical medicines and inhalation products)

Part 2 **Sterile products**

We teach you the important formulation requirements for each of these product types and how those requirements influence the performance of the medicine in the body. We also teach you the key processing steps in the production of these dosage forms, as well as critical quality attributes and critical process parameters. We also cover what can go wrong during the processing of medicinal products and the potential consequences to the safety, quality and efficacy of the medicine.

Once a new chemical entity has proved its potential in clinical studies, the challenge becomes formulating the compound into an effective medicine and manufacturing that medicine reliably so that safety, quality and efficacy are assured.

Key Learning Objectives

On completion of this course, you will know and understand:

- The principles of drug design and formulation and the impact of even minor modifications on bioavailability/bioequivalence
- The various processes involved in the manufacture of major dosage forms, e.g. tablets, capsules, oral liquids, topical liquids, creams and ointments, sterile products and inhalation products
- The Good Manufacturing Practice (GMP) issues and challenges for the QP to enable informed release decisions
- How to apply the knowledge to:
  - Risk management
  - Risk assessment
  - Problem solving and decision-making
  - Auditing
- The principles of technology transfer and process validation

For more information and registration details, please visit:

https://www.nsf.org/training/series/pharmaceutical-formulation-processing

Pharmaceutical Microbiology

University of Strathclyde Glasgow

ROYAL SOCIETY OF CHEMISTRY | APPROVED TRAINING

This highly interactive, pharmaceutical microbiology course is designed to provide the aspiring Qualified Person and pharmaceutical professionals with the knowledge and understanding they need to assess microbiological risks in the pharmaceutical manufacturing environment. Learn how to assist in the design and implementation of comprehensive microbiological control strategies and how to make informed decisions when microbiological problems occur.

Microbiological contamination of products and processes continues to be a major concern to the industry and its regulators. The potential impact of such contamination can be catastrophic. Put simply, microbial contamination can kill your patients and your business. This pharmaceutical microbiology course is designed to provide both non-biologists and microbiologist with the knowledge, confidence and decision-making risk assessment skills to prevent this from happening.

Key Learning Objectives

On completion of this pharmaceutical microbiology course you will know and understand:

- The basic characteristics of all microorganisms found in your premises (how they get there and how to remove them)
- Microbiological methods
- How to sample, isolate and identify these organisms
- How to prevent contamination of your products and processes using risk management and assessment tools and techniques
- The interpretation of data
- QP decision-making
- How to satisfy the regulator and protect your patient

For more information and registration details, please visit:

https://www.nsf.org/training/series/pharmaceutical-microbiology

Active Substances and Excipients

University of Strathclyde Glasgow

ROYAL SOCIETY OF CHEMISTRY | APPROVED TRAINING

This Active Substances (AS) and Excipients training course gives a unique insight into the regulatory expectations associated with producing both chemically synthesized and biological/biotech ASs. The course also provides insight and expertise on managing global AS supply chains, vendor quality assurance and "how to audit" AS facilities. We summarise the key steps in identifying and removing impurities, including information on the impact of potential nitrosamine formation. During the course we will also visit Active Substance manufacturing facilities to see how the theoretical requirements are implemented in real life.

Key Learning Objectives

As AS supply chains become ever more diverse and cost pressures more acute, the pharma manager needs a keen appreciation of risk factors, design, control and monitoring of AS sources. This course allows delegates to differentiate between natural variation and risk across a range of AS processes, indicating the most appropriate and proportionate actions to take to mitigate any areas of concern.

You will be provided with an overview of the EU and US regulatory framework surrounding active substance and excipient manufacturing process and be given practical guidance on the key responsibilities of the Qualified Person when approving a GMP declaration.

You will also learn:

- How to meet EU and US Regulatory requirements and GMP guidance
- The major differences between chemical synthesis and bioprocesses; and contrasting both against drug product formulation
- How to manage change of AS source
- How to audit and provide QA oversight of excipients and Active Substances
- The course will also allow you to make informed decisions when faced with a range of GMP non-conformances during AS production

For more information and registration details, please visit:

https://www.nsf.org/training/series/active-substances-excipients

Mathematics and Statistics

There are many training courses on statistics and statistical analysis, but very few that focus specifically on the application of these techniques to pharmaceutical manufacture and control. This course does.

Taught by statisticians and pharmaceutical industry professionals, our course is designed to meet the needs of the aspiring Qualified Person (QP) and other pharmaceutical professionals. The highly participative training teaches you how to use statistical techniques to assess and monitor:

- The reliability and accuracy of data you generate
- The capability and reliability of the processes you work with every day

The pharmaceutical industry has historically underutilized the same statistical data analysis techniques many other industries have extensively used to drive product and process improvement. Even today, the pharmaceutical industry could still be characterized as data rich but information poor.

The provision of useful information is essential. That is why we created this pharmaceutical mathematics and statistics training course.

Recent developments in global Good Manufacturing Practice (GMP) guidelines are urging pharmaceuticals to catch up with other industries by placing greater emphasis on the trending of data. This applies to EU and US requirements for ongoing process verification as part of process validation, product quality reviews, ICH Q10 and more. The ability to analyze and trend data is now an essential survival skill. This pharmaceutical training course shows you how to do this simply and effectively.

Key Learning Objectives

At the end of this course, you will understand how to:

- Assess the reliability and accuracy of data and information arising from samples taken from a population, using techniques such as:
  - Basic statistics: mean, standard deviation, etc.
  - Histograms
  - Box plots
  - Confidence intervals
- Monitor and detect adverse trends before a process goes out of control, using:
  - Control charts: Shewhart, mean and range, cumulative sum control chart (CUSUM) and attribute charts
  - Linear regression
- Assess the capability and reliability of a process
- Use and know the limitations of acceptance testing using ISO 2859
- Compare results using:
  - T-tests
  - Analysis of variance (ANOVA)
- Interpret the interaction of process parameters via experimental design and multivariate analysis
- Maintain regulatory compliance

For more information and registration details, please visit:

https://www.nsf.org/training/series/mathematics-statistics

Analysis and Testing

University of Strathclyde Glasgow

ROYAL SOCIETY OF CHEMISTRY | APPROVED TRAINING

This highly focused, intensive course is taught by leading scientists and former quality control (QC) managers. It is designed to provide the aspiring Qualified Person or pharmaceutical quality professional with the knowledge and understanding they need to perform their duties with skill and competence when interacting with QC laboratories.

During our pharmaceutical analysis training course, we explain the strengths and limitations of analysis and specific analytical methods. You learn how to apply the principles of quality management and Good Manufacturing Practice (GMP) to the testing environment in a pragmatic, effective way. We also advise you on data integrity and how to ensure that your laboratories are compliant.

Virtually all critical patient and business decisions made by QPs and other quality professionals are in some way based on data provided by an analytical laboratory. Therefore, it is of paramount importance that this data is accurate and reliable. In recent years, data integrity has become a very hot topic. Hence, it is essential that decision makers understand the basis of the analytical techniques used and their respective strengths and weaknesses.

This course seeks to provide a foundation of knowledge which enables QPs and others to judge analytical data, ask relevant questions to aid interpretation and know when to call for additional data/advice. This knowledge is also essential when auditing laboratories.

Key Learning Objectives

On completion of this pharmaceutical analysis and testing course, you will know and understand:

- The essential components of a laboratory management system that can ensure data integrity
- The philosophy and principles of pharmaceutical analysis
- The basis for commonly used analytical techniques
- How to provide acting and trainee QPs with sufficient understanding of pharmaceutical analysis that enables them to have effective dialogue with the laboratories providing them with data

For more information and registration details, please visit:

https://www.nsf.org/training/series/analysis-testing

Pharmaceutical Packaging

Why are packaging related errors still one of the greatest causes of recalls?

This highly interactive training course is designed to answer that question. It provides aspiring Qualified Persons and other pharmaceutical professionals with the knowledge and understanding they need to manage, oversee, control or audit all aspects of packaging activities. Topics range from the regulatory requirements for packaging and control of packaging components to the design of packaging lines/process and distribution of medicines.

Take ideas for improvement back to your workplace. Our QP pharmaceutical packaging course covers all important aspects of the packing process and their associated Good Manufacturing Practice (GMP) and pharmaceutical quality system (PQS) challenges. This includes selection of suitable materials, pack design, pack security and design/control of packing processes. From starting components to patient, our course provides a detailed review of the supply chain so you can design your ideal packaging department that is ready for inspection.

Key Learning Objectives

On completion of this QP pharmaceutical packaging course, you will know and understand:

- The QP study guide expectations for packaging
- Background on different packaging materials and their selection, uses, control and impact on product stability
- Packaging design considerations to protect both the product and the patient including labelling, anti-counterfeiting, tamper evidence and serialization
- Regulatory aspects of packaging design, usability and stability programmes
- Supply chain management from supplier selection to contract manufacturing organizations (CMOs), distributors, storage, transportation and the patient
- Packaging operations and their risks and control
- New changes and challenges to packaging
- Packaging issues impacting QP and quality assurance (QA) decisions

For more information and registration details, please visit:

https://www.nsf.org/training/series/pharmaceutical-packaging

Pharmaceutical Quality Systems

Do more than just reduce costs. Learn how to simplify systems and add value to your company. In this intensive, highly interactive course you learn the essential elements of an effective, compliant and modern pharmaceutical quality system (PQS). We show you how to implement, monitor and manage a quality system that meets the needs of all major international regulatory agencies.

As QPs and quality professionals, you cannot certify or release products and stay in business unless your PQS is under control. A vast majority of adverse inspection findings relate to the PQS. Our course helps you decide if yours is effective, fit for purpose and working well or if not, you will learn what to do.

The quality of your products depends on the quality of your people and the effectiveness of the PQS. A properly functioning PQS should be a business management system that drives continuous improvement and cost savings.

Attend this course if you want to:

- Learn how to do more with less
- Simplify your PQS to improve speed and flexibility

Pharmaceutical quality systems training is for anyone who monitors all or part of a PQS. In addition to providing invaluable oversight to senior leaders, this course meets the requirements of Annex 16 and other key EudraLex chapters and annexes

Key Learning Objectives

On completion of this pharmaceutical quality systems training course you will know and understand:

- What is a PQS and what is in a PQS
- Industry norms and best practices
- QP decisions
- How the PQS is applied throughout the lifecycle of a medicinal product
- How to demonstrate to inspectors and management that the PQS is effective
- The impact of culture on the PQS

For more information and registration details, please visit:

https://www.nsf.org/training/series/pharmaceutical-quality-systems

QP Practical Module

University of Strathclyde Glasgow

ROYAL SOCIETY OF CHEMISTRY | APPROVED TRAINING

In an ever-changing pharma world, it is a challenge for QPs and prospective QPs to gain a functional understanding of the equipment and processes used to manufacture and test today's dosage forms. This Royal Society of Chemistry approved course provides hands-on experience to trainee QPs wishing to gain a better understanding of what really happens in manufacturing and testing. As part of your practical QP training, you'll gain knowledge from industry and academic experts and solve real-life QP problems.

Key Learning Objectives

On completion of this course, you will:

- Have experienced totally practical, hands-on lab-based training at one of the top schools of pharmacy in the UK
- Understand the "why" behind key pharma industry processes
- Become closer to products than is possible in a Good Manufacturing Practice (GMP) environment
- Grasp the impact of starting materials and risk-based supplier management programs
- Gain a practical understanding of sterile products, tablets, continuous processing and analysis

For more information and registration details, please visit:

https://www.nsf.org/training/series/practical-module

Investigational Medicinal Products

University of Strathclyde Glasgow

ROYAL SOCIETY OF CHEMISTRY | APPROVED TRAINING

As a QP or quality assurance professional working in this challenging area, are you aware of the current and planned changes around the manufacture of investigational medicinal products (IMPs)? This highly interactive IMP training course makes sure you are up to date.

Our course focuses on the quality systems and the Good Manufacturing Practice (GMP)/Good Clinical Practice (GCP) interface from the QP or quality leader's perspective. More specifically, the QP's duties and challenges in protecting trials, volunteers and patients. Led by former IMP expert inspectors, QPs and current consultants, this course adds value to QPs, auditors and those working in clinical trial supply.

Key Learning Objectives

On completion of our IMP training course you will know and understand:

- The regulations and requirements for the IMP QP, as well as upcoming changes
- The requirements of the IMP module in the UK QP study guide
- What regulators and inspectors look for
- Where to focus audits of IMP operations on behalf of a QP
- QP duties around IMPs and the GMPs relevant to IMPs

For more information and registration details, please visit:

https://www.nsf.org/training/series/investigational-medicinal-products

The Role and Professional Duties of the QP

University of Strathclyde Glasgow

ROYAL SOCIETY OF CHEMISTRY | APPROVED TRAINING

This intensive, interactive training course provides aspiring QPs and other pharmaceutical quality professionals the knowledge and understanding they need to perform the legal duties of the QP. Further, it teaches attendees how the QP must work with others to ensure that those duties and responsibilities are performed in the best interests of the company, the patient and society.

This course also helps you to understand what the QP must do themselves and what can/must be delegated to others. We provide advice on how the QP should work in tandem with professionals in other departments and stress the non-technical people skills that are essential to be a good QP.

When certifying medicinal products, it is of paramount importance that a QP has the ability to look at the broad issues of managing quality and to approach these issues in a cohesive way when making decisions to release or reject. Throughout the course you'll have the opportunity to test your skills via interactive release or reject scenarios.

Key Learning Objectives

On completion of this course, you will know and understand:

- The QP's legal and professional duties in detail and the Code of Practice of the QP
- How the QP must work with others to ensure that those duties and responsibilities are performed in the best interests of the company, the patient and society
- What the QP must do themselves and what can/should be delegated to others
- Proposed and recently implemented legislation and guidance
- The interpersonal skills essential to be a good QP

For more information and registration details, please visit:

https://www.nsf.org/training/series/role-professional-duties-qp

Advanced Equipment Qualification and Process Validation

This highly participative process validation training course is designed to ensure that you understand the current EU and FDA requirements for the design, execution, assessment and reporting of equipment qualification and process validation studies.

Our tutors are internationally recognized experts in the field and can help you efficiently perform equipment qualification and pharmaceutical validation studies that meet the needs of regulators in the US and Europe.

For example, the 2011 FDA Guidance on Process Validation and the 2015 EU Good Manufacturing Practice (GMP) Annex 15 introduced a new approach to equipment/facility/utility qualification and process validation. This course provides a demonstration of the practical application of the science- and risk-based approach to qualification and validation that meets these dramatically revised regulations.

We explain how facility/utility/equipment qualification and process validation must link to patients' needs and regulatory requirements, using tools such as risk management, statistical data analysis and change management to efficiently accomplish this. Our course shows you how to efficiently plan, design, execute and document qualification/validation activities to new and existing processes with beneficial results.

Key Learning Objectives

On completion of this course you will know and understand:

- The modern concept of facility/utility/equipment qualification and process validation and introduced regulatory expectations
- How to gain process understanding and how this links to effective process validation
- The key components expected for effective facility/utility/equipment qualification and process validation:
  - Facility design and qualification of equipment and utilities
  - Process performance qualification
  - Change management
- The tools and techniques that can increase the efficiency and effectiveness of facility/utility/equipment qualification and process validation:
  - Risk management tools
  - Statistical tools, e.g. process capability, design of experiments (DoE), etc.

For more information and registration details, please visit:

https://www.nsf.org/training/series/equipment-qualification-process-validation


NSF
Speaker

A-Z of Sterile Products Manufacture

ROYAL SOCIETY OF CHEMISTRY | APPROVED TRAINING

From Aseptic practices to Z values and everything in between!

This highly participative and popular training course teaches you about key scientific, technical and regulatory challenges associated with Good Manufacturing Practice (GMP) of sterile product manufacturing. Whether you need to meet EU, FDA or any other regulatory agency's needs, this course gives you the knowledge, skills and tools to succeed.

A pharma product administered parenterally bypasses the body's natural defense mechanisms. Consequently, any quality defect could potentially cause serious harm to the end user. Linking everything you do to providing a safe and effective formulation to the end user is critical. This course concentrates on how product quality is assured via practical and interactive review of the science and compliance behind sterile products manufacturing.

This course has been revised in line with the revisions to EudraLex Volume 4, Annex 1.

Key Learning Objectives

Completion of this sterile products training course will enable you to:

- Describe a typical sterile production process and the facility, equipment and utilities associated with sterile product manufacture
- Know what aspects require detailed definition, validation and ongoing monitoring
- Know the typical failure modes and how to determine most probable root cause and mitigation strategies
- Understand how the key attributes of a sterile product impact:
  - The pharmaceutical quality system
  - The organization
  - The management oversight process
  - Risk management and mitigation
  - The end user or patient

For more information and registration details, please visit:

https://www.nsf.org/training/series/a-z-sterile-products-manufacture

Certificate in Pharmaceutical Quality

Certificate in Pharmaceutical Quality is based upon the US FDA's six systems approach to quality. This program is designed for professionals working in pharmaceutical operations, including quality departments.

There are nine virtual instructor-led courses in total, and to be awarded a Certificate in Pharmaceutical Quality trainees need to take one course from each system.

Quality Systems

On completion of this course, you will know and understand:

- What is a Quality System and what is in a Quality System
- How the Quality System is applied throughout the lifecycle of a drug substance and drug product
- How to demonstrate to inspectors and management that the Quality System is effective
- The impact of culture on the Quality System

Laboratory Controls-Chemistry

On completion of this course, you will know and understand:

- The essential components of a laboratory management system that can ensure data integrity
- The basis and limitations for commonly used analytical techniques
- The interpretation of data including out of specification and out of trend results
- Stability testing requirements
- Laboratory controls are critical to the decision-making of the Quality Unit as they form a critical part of the data to help with batch release decisions

Laboratory Controls-Microbiology

On completion of this course, you will know and understand:

- The characteristics of microorganisms
- Microbiological methods
- How to sample, isolate and identify microorganisms
- Development of environmental monitoring and contamination control strategies

Production Systems-Sterile Drug Products

On completion of this course, you will know and understand:

- Design, qualification and operation of cleanrooms
- Pharmaceutical water systems
- Methods of sterilization and aseptic processing
- Formulation considerations
- Major processing methods
- Critical process steps
- Risk-based decision-making
- Key GMP requirements, including sterility assurance and contamination control

Production Systems-Non-Sterile Drug Products

On completion of this course, you will know and understand:

- Pre-formulation issues and product development
- Routes of administration
- Non-sterile dosage forms: Tablets, capsules, inhalation products, liquids, creams and ointments
- Major processing methods
- Formulation challenges for each route of administration
- Critical process steps
- Key GMP requirements and investigating deviations

Production Systems-Biological Drug Products

On completion of this course, you will know and understand:

- The key design, controls and monitors associated with the common biotech process steps
- The basic science and typical process controls associated with producing a high quality biological or biotech drug substance
- An introduction to how quality is assured across the bioprocess and the insights/limitation of QC testing
- A summary of hot topics including regulatory censure, GMP observations and trends
- Guidance on the key concerns when acting as QA/ production/technical services professional in this field
- The critical requirements of cGMPs alongside a range of bioprocesses

Facilities and Equipment

On completion of this course, you will know and understand:

- The principles of design of a drug product facility
- cGMP as it relates to engineering activities, such as calibration and maintenance
- The modern concept of facility/utility/equipment qualification and process validation and introduced regulatory expectations
- How to gain process understanding and how this links to effective process validation
- The key components expected for effective facility/ utility/equipment qualification and process validation
- Facility design and qualification of equipment and utilities
- Process performance qualification
- Change management

Drug Substances and Vendor Management

On completion of this course, you will know and understand:

- The requirements in ICH Q7 for the GMP of Drug Substances
- How to meet US Regulatory requirements and GMP guidance
- The major differences between chemical synthesis and bioprocesses
- How to manage change of Drug Substance source
- Vendor management of Drug Substance supply chains

Packaging and Labelling

On completion of this course, you will know and understand:

- Background on different packaging materials and their selection, uses control and impact on product stability
- Packaging design considerations to protect both the product and the patient including labelling, anti-counterfeiting, tamper evidence and serialization
- Packaging operations and their risks and control
- Typical packaging issues impacting the Quality Unit's decision-making

For more information and registration details, please visit:

https://www.nsf.org/training/area/health-sciences-training-solutions/pharmaceutical/certificate-pharmaceutical-quality

GMP for Biological and Biotechnology Products

This course details the rules and interpretation of GMP for biopharma products and discusses issues and challenges with seasoned NSF experts.

The course provides insights on how to interpret and deploy the requirements of both the US cGMP and EudraLex Volume 4 (particularly Annex 2). It covers the cGMP requirements for each key process step especially concerning process development, validation, control, auditing, effective quality assurance (QA) and quality control (QC).

Key Learning Objectives

On completion of this course, you will know and understand:

- The common stages in the mammalian and bacterial bioproduction processes
- How to verify the effectiveness of each bioprocess stage via online and offline monitoring and testing
- The critical challenges associated with bioprocessing in terms of vulnerability, risk assessment and process control
- How to design the pharma quality system around the requirements of the biomolecule

Our biotech training helps you learn how to:

- Identify the key differences in bioprocessing compared to chemical synthesis of small molecule drug substances
- Feel confident in making the right decisions at the right time with the right information when faced with the common challenges or GMP deviations associated with bioprocessing of drug substances
- Identify what should appear in batch documentation associated with the key bioprocessing steps
- Generate a risk-based, targeted audit agenda, and be aware of the requirements in the EudraLex GMP Volume 4, Annex 2
- You will also become better equipped at adding value to commissioning, qualification, validation, production, operational QA and GMP auditing on-site and across fragmented global supply chains

For more information and registration details, please visit:

https://www.nsf.org/training/series/gmp-biological-biotechnology-products

GMP for Clinical Trials Manufacture and Supply

ROYAL SOCIETY OF CHEMISTRY | APPROVED TRAINING

Keeping up with the changing legislation for clinical trials provides challenges for all those working with investigational medicinal products. This highly interactive training course teaches you all you need to know about international GMP regulations and requirements for the manufacture, control, storage and distribution of medicines to be used in clinical trials manufacture.

Using practical exercises, our clinical trial GMP training tutors help you to gain a better understanding of the ever-changing world of clinical supply and its legislation. Our tutors are a combination of ex MHRA inspectors and current IMP QPs, and teach you simple and pragmatic ways of working designed to help you better meet the needs of the regulators.

Key Learning Objectives

On completion of this course, you will know and understand:

- The legislation and guidance around clinical trials and what is changing
- The interpretation of GMPs suitable for clinical trials
- The phases in clinical trials and how requirements change
- Auditing and control of clinical trial operations
- The areas of interface between GMP and GCP requirements and how these should be managed
- Clinical batch releases

For more information and registration details, please visit:

https://www.nsf.org/training/series/gmp-clinical-trials-manufacture-supply

GMP PQS Lead Auditor

(CQI & IRCA Certified Training)

CQI | IRCA

CERTIFIED COURSE

Gain the skills and tools that have taken many experienced auditors decades to develop in this CQI and IRCA certified training GMP PQS Lead Auditor course. Learn how to perform better audits and have the opportunity to become a Certified GMP Pharmaceutical Quality Systems Lead Auditor. Designed and developed by ex-MHRA inspectors and industry experts, and taught by highly experienced pharmaceutical auditors and former regulatory agency inspectors, this intensive, pharmaceutical lead auditor training course provides you the knowledge, understanding, skills and confidence to audit all aspects of pharmaceutical manufacture and control.

This course is designed for auditors assessing:

- Manufacturing operations
- Contract manufacturing organizations
- API suppliers
- Excipient suppliers
- Packing component suppliers
- Service providers

Built around personal practice, our curriculum follows the auditing guidance of ISO 19011, and includes a virtual audit of a facility that manufactures a range of dosage forms. You'll plan and prepare audits of the supplier and your own supplier audit system with exercises in teamwork planning, preparation, performance and addressing who, why and how we audit. You'll also be provided PQS and observations to find and classify, as well as the opportunity to practice an opening and close-out meeting. Further, you will be assigned a personal tutor to address any questions you may have.

This course meets the training requirements for CQI and IRCA (www.quality.org) and is intended for individuals from a range of pharmaceutical backgrounds including QPs, quality assurance professionals, self-inspectors from QA and operations teams, virtual companies and quality unit staff. Many companies now require their auditors to be trained through the NSF certified lead auditor course.

Successful completion, along with the relevant experience, can lead to CQI and IRCA GMP PQS lead auditor certification.

Key Learning Objectives

This course provides auditors with the knowledge, skills and tools to:

- Understand the GMP context for pharmaceutical quality system lead auditors
- Plan, conduct, report and follow up an audit of a GMP PQS
- Provide guidance for auditors of suppliers, contractors, CMO service providers, outsourced activities and self-inspectors
- Develop QPs and those auditing on behalf of QPs
- Drive continuous improvement of systems and processes
- Drive continuous improvement of auditors and audit systems

For more information and registration details, please visit:

https://www.nsf.org/training/series/gmp-pqs-lead-auditor

Pharmaceutical GMP

Whether you're just starting in the industry or an experienced staff member, this highly interactive GMP pharmaceutical training course will teach you how to apply pharmaceutical GMP in your workplace and keep you up to date with industry requirements.

Covering important sections of the ever-changing EudraLex Volume 4, you will leave with a thorough understanding of the essentials of GMP. You will be able to identify up-to-the-minute information on new and existing pharmaceutical GMP initiatives and regulations.

The course provides an excellent opportunity to share your GMP questions with experienced industry experts and get practical advice first-hand.

Key Learning Objectives

On completion of this course, you will be able to:

- Explain the origin and reasons for GMP
- Apply the practical interpretation of GMP expectations and best practices
- Identify EudraLex and PIC/S expectations

For more information and registration details, please visit:

https://www.nsf.org/training/series/pharmaceutical-gmp

Pharmaceutical Legislation Update Subscription Service

ROYAL SOCIETY OF CHEMISTRY | APPROVED TRAINING

Pharmaceutical legislation and regulatory authority guidance are continually changing. These changes, and their interpretation, can have significant implications for companies. Many changes require detailed planning to implement and failure to do so can result in serious compliance problems.

This pharmaceutical regulatory training provides you with 12 months of updates on changes to legislation and guidance that have the potential to impact the manufacture and distribution of medicinal/drug products. A full update for the past year and a summary of what is new each quarter will be provided in February, May, September, and late November. Your subscription will start with the next available update.

The updates are provided as recordings through NSF's online LMS portal and can be viewed at a time convenient to you. We will create an account for you on our LMS and you will receive an enrolment email giving you a link to access the material. There will also be an opportunity for Q&A with our expert through a live two-hour virtual meeting each quarter.

This training provides essential information for Qualified Persons and other quality professionals employed by organizations that manufacture or distribute medicinal/drug products.

Key Learning Objectives

To understand and discuss the current interpretation of recently implemented and proposed changes to legislation and guidance which have the potential to impact the manufacture and distribution of medicinal products. This includes changes from:

- EU medicines legislation: Directives and regulations
- EU GMP guidance
- The impacts of Brexit on biopharmaceutical processes and supply chains across the EU and the UK
- ICH guidance
- US drug legislation and FDA guidance
- UK medicines legislation and MHRA requirements and processes

For more information and registration details, please visit:

https://www.nsf.org/training/series/pharmaceutical-legislation-update-subscription

Quality Risk Management

Updated to reflect the 2023 Revision 1 of ICH Q9, this interactive training course provides you with a thorough understanding of quality risk management as set out in ICH Q9. We explore the full extent of the approach and practice the most commonly used tools and techniques to improve your decision-making skills, and better protect your company and your patients by addressing both proactive and reactive risk management.

We show you how to take a structured, risk-based approach to quality management to enable a science- and data-based approach toward the business, enabling a detailed process understanding to establish control strategies. We explore the best practice approaches including risk perspectives and incorporating risk in the pharmaceutical quality system.

We start with underlying facilitation methods and tools such as flowcharts, process mapping, and cause and effect diagrams (also called Ishikawa or fishbone diagrams). We then consider the statistical tools that enable effective data assessment, aid in determining the significance of the data set(s) and facilitate more reliable decision-making, including control charts to turn data into information.

We introduce the less frequently used tools and their applicability, and explore real-life scenarios and case studies using the most commonly used techniques of failure mode effect analysis (FMEA) and Hazard Analysis and Critical Control Point (HACCP).

ICH Q9 is essential for our industry. Managers with responsibility for managing risk should attend this course to ensure they are equipped to assess a variety of risks and make decisions on priorities and mitigating actions. The course helps participants realize it is not possible to do everything. It will also provide the tools to help make the right decisions to ensure resources are spent on the most important activities. These tools can then be utilized directly in participants' own companies.

Key Learning Objectives

By the end of this training, you will:

- Understand how to apply ICH Q9 routinely and in times of crisis in the workplace
- Learn how and when to use the supporting facilitation and statistical tools
- Learn decision-making tools such as FMEA and HACCP

For more information and registration details, please visit:

https://www.nsf.org/training/series/quality-risk-management

Responsible Person and Good Distribution Practice

Cogent Gold Standard Approved Training

Learn how to become a Responsible Person (RP), the duties and responsibilities of an RP and the role of the RPi (Responsible Person (import).

Supported and recognized by the MHRA, NSF's Responsible Person and Good Distribution Practice course meets the Cogent Gold Standard competencies for the role of the Responsible Person in Medicinal Products and the accompanying standard. After successful completion of our Gold Standard RP and Good Distribution Practice (GDP) training and assessment, you will receive a certificate from Cogent Skills featuring the MHRA logo.

This GDP and Responsible Person training course provides you with a thorough understanding of the regulatory requirements for operating within a storage and distribution center for materials or medicinal products in the pharmaceutical industry.

It will also give a practical understanding of the systems and processes required to be implemented to ensure that your operation is compliant and delivers product that is safe and efficacious in an efficient manner.

This course is suitable for all levels of personnel involved in the handling and storage of medicines and pharmaceutical materials, from those working for multi-national companies distributing product worldwide to small independent warehouses wholesaling medicines.

Key Learning Objectives

By the end of this GDP and Responsible Person training course, you will:

- Have both the technical and behavioral skills required to be an RP/RPi
- Have knowledge of legislative requirements for the storage and distribution of excipients, active substances and medicinal products
- Know the fundamental elements of good distribution and storage practices
- Know practical examples and best practices of how to implement key systems
- Have a wider network of professionals working in distribution

For more information and registration details, please visit:

https://www.nsf.org/training/series/good-distribution-practices-responsible-person

Interested in Training Your Team?

Professional training is essential in developing the expertise of your team and in helping ensure smooth operations.

Wherever you are in the world, our team of professional training consultants and regulatory and quality subject matter experts can provide solutions to your training needs to address your unique requirements.

We provide training in one of three ways, depending on your organization's needs, timing and budget:

- Live instructor-led training: in-person or virtual
- Online eLearning: self-paced, on-demand access to digital content
- Blended approach: self-paced learning combined with instructor-led training

Choose Courses That Are Ready to Use or Designed Around Specific Requirements

Your needs may be a perfect fit for courses already in our catalog that you could begin using today. Or you may have specialized needs that call for content tailored to your organization. We can help you with:

- Off-the-shelf training: Choose from our wide selection of regulatory, compliance and quality courses. We'll confirm with you that the content satisfies your needs and expectations.
- Customized training: We can customize an off-the-shelf course so that it's consistent with your operations, policies and procedures, brand and messaging, products and services. In addition, we can use scenarios, examples and team works that are relevant to you.

If none of our listed courses fit your needs, we can develop a completely new training course that's specific to your regulatory environment, procedures, language(s) and more. Contact us on pharmacourses@nsf.org to discuss your needs.

Auditor

Auditing QC Laboratories
GMP Audits and Self-Inspections
Internal Auditor

GXP

Certified Investigator
Data Integrity
Deviation and CAPA Management
Deviation Investigations and CAPA
Documentation Simplification
GMP for Clinical Trials Manufacture and Supply
Good Clinical Practice
Good Distribution Practices
Good Pharmacovigilance Practice
Pharmaceutical GMP
Quality Risk Management
Responsible Person and Good Distribution Practice
Supplier Quality Management

Qualification and Validation

Cleaning Validation
Equipment Qualification and Process Validation
Introduction to Validation Training

Qualified Person

Active Substances and Excipients Training
Analysis and Testing
Formulation and Processing
Investigational Medicinal Products
Mathematics and Statistics
Medicinal Chemistry and Therapeutics
Pharmaceutical Law and Administration
Pharmaceutical Microbiology
Pharmaceutical Packaging
Pharmaceutical Quality Systems
Practical
Role and Professional Duties of the QP

Quality Systems

Certified Investigator
Changing GMP Behaviors
Data Integrity
Deviation and CAPA Management
Documentation Simplification
Human Performance: Beyond Human Error
Pharmaceutical Quality Systems
Quality Risk Management
Responsible Person and Good Distribution Practice
Supplier Quality Management

Regulatory

Pharmaceutical Law and Administration
Pharmaceutical Legislation Update Subscription Service
Regulatory Affairs for QA: Marketing Authorizations
Regulatory Affairs for QA: Variations

Sterile and Biotech

Advanced Therapy Medicinal Products
A-Z of Sterile Product Manufacture
Cleaning Validation
Contamination Control Strategy
Formulation and Processing
GMP for Biological and Biotechnology Products
Introduction to Advanced Therapy Medicinal Products
Pharmaceutical Microbiology
Quality Risk Management for Sterile Products

Other Technical Training

Active Substances and Excipients Training
Analysis and Testing
GMP for Clinical Trials Manufacture and Supply
Investigational Medicinal Products
Mathematics and Statistics
Medicinal Chemistry and Therapeutics
Pharmaceutical Packaging
Statistical Process Control
Statistical Testing

Self-Paced eLearning

Explore and learn at your own pace with self-paced eLearning – a flexible and convenient way to enhance your skills.

Adverse Events and Product Quality Complaints – A Guide for Employees

The purpose of this course is to provide an introduction to Pharmacovigilance and why it is required to monitor the detection, assessment and prevention of adverse events, adverse reactions and side effects of medicinal products post marketing.

https://nsfpharmabiotech.trainingfolks.com/store/1221828-adverse-events-and-product-quality-complaints-a-guide-for-employees

Analysis and Testing

This course provides comprehensive instruction on Analysis and Testing in pharmaceutical manufacturing. This course utilizes real-world scenarios, embedded video and audio content to instruct on the practical application of these requirements.

https://nsfpharmabiotech.trainingfolks.com/store/3421913-analysis-and-testing

Change Control Overview

This course provides an overview of the requirements of a change control process. The change control system provides a systematic approach to managing all GxP changes made to a product or system. The review and approval of changes prior to their implementation allows us to ensure that no unnecessary changes are made and the proposal is risk assessed to determine if there will be an impact to product safety, quality, efficacy, ultimately to ensure that the patient is not harmed by any changes made.

https://nsfpharmabiotech.trainingfolks.com/store/3625329-change-control-overview

Cleaning Qualification

This course of four chapters will give you a sound basis of the regulatory requirements expected of a good pharmaceutical cleaning process, how to calculate limits and their justification. The pros and cons of various cleaning methods and how to approach them. Finally, how to plan and approach a validation exercise with specific cleaning acceptance criteria.

https://nsfpharmabiotech.trainingfolks.com/store/463111-cleaning-qualification

Combination Products GMP and Regulatory Overview

This course provides an overview of the US and EU regulatory framework relative to combination products. This course will discuss the primary mode of action (PMOA), key stakeholders, and Drug-Device Combination (DDC) product requirements as well as a brief discussion of the regulatory framework for jurisdictions beyond the US and EU.

https://nsfpharmabiotech.trainingfolks.com/store/3706076-combination-products-gmp-and-regulatory-overview-1-5-hours

Computerised Systems Validation

The purpose of this course is to provide an overview of current good CSV practice along with some practical advice about how to achieve good outcomes in a cost-effective and resource-efficient way.

https://nsfpharmabiotech.trainingfolks.com/store/2939446-computerised-systems-validation

Data Integrity: Overview and Documentation Completion, Review and Approval

Problems with data integrity continue to lead to vigorous regulatory actions. Such issues can be prevented with a thorough knowledge and understanding of the regulators' requirements. This eLearning course (module 1 of our Data Integrity series) is aimed at anyone working in the Pharmaceutical Industry and is designed to provide an overview of what is meant by data integrity, what needs to be considered during documentation completion, review and approval and how to keep your data complete, consistent and accurate throughout the data lifecycle.

https://nsfpharmabiotech.trainingfolks.com/store/665216-course-1-data-integrity-overview-and-documentation-completion-review-and-approval

Data Integrity: Beyond the Basics

This module (module 2) will build on the key messages of module 1 and go beyond the basics. It will look at some more specialised or particular aspects of this topic which has such wide ranging impact. This course consolidates knowledge and experience of 11 years' work from an ex MHRA Inspector. Management and the Quality Unit need to have a deeper understanding of Data Integrity to give them the confidence to get involved and this module is designed to highlight the known weaknesses in company systems.

https://nsfpharmabiotech.trainingfolks.com/store/806440-course-2-data-integrity-beyond-the-basics

Data Integrity: Management Requirements

Data Integrity Module 1, Basics of Data Integrity addressed what everyone needs to know for this essential topic. Module 2 went beyond the basics focusing on the technical details for subjects such as auditing and computer systems management. In this third module we build on your essential knowledge to understand what the Senior Management should ensure is in place, in use and effective.

https://nsfpharmabiotech.trainingfolks.com/store/855628-course-3-data-integrity-management-requirements

Deviation Investigations and CAPA

This course provides an overview of the requirements of a deviation investigation and CAPA process. It defines the key features of the system, as well as the lifecycle of the deviation investigation steps: Defining the problem, Conducting a risk assessment, Collecting and analysing data, Conducting root cause analysis, Developing and implementing CAPA's, Final impact assessment/ Deviation closure and Conducting effectiveness checks.

https://nsfpharmabiotech.trainingfolks.com/store/2602957-deviation-investigations-and-capa

General Drug or Pharmaceutical cGMP and Quality Systems Programme

This comprehensive programme is presented in three modules, each between 1 and 2.5 hours in duration. The course covers the history of GMP and outlines the concepts of Pharmaceutical Quality Systems and GMPs, followed by intermediate and advanced topics describing the elements of the quality system in detail.

https://nsfpharmabiotech.trainingfolks.com/store/3421915-general-drug-or-pharmaceutical-cgmp-and-quality-systems-programme

GMP Refresher Training

This course provides important GMP Refresher Training required for all individuals involved in the manufacture and supply of medicinal products. It provides a reminder of the different regulatory organisations globally that are responsible for defining Good Manufacturing Practice requirements, as well as updated and draft guidance documents from PIC/S, ICH and FDA. It also provides detail on the significant changes to Annex 1 implemented in August 2023. It highlights the most frequent inspection findings against cGMP from both the FDA and MHRA, as well as a reminder of the Golden Rules of GMP.

https://nsfpharmabiotech.trainingfolks.com/store/3625704-gmp-refresher-training-2024

Good Distribution Practices

The purpose of this course is to provide an overview of current Good Distribution Practices (GDP) and the fundamental requirements for a wholesale distribution authorisation holder and why GDP is so important in the provision of safe, efficacious medicines to our patients.

https://nsfpharmabiotech.trainingfolks.com/store/3773668-good-distribution-practices

GxP Inspection Management Lifecycle

This training course covers the GxP Inspection Management Lifecycle. It is suitable for staff wanting to understand more about GCP, PV, GMP and GDP regulatory inspections from planning, conduct and responding to inspection findings.

https://nsfpharmabiotech.trainingfolks.com/store/391534-gxp-inspection-management-lifecycle

GxP Refresher Training: ICH Q8, Q9 and Q10

This course provides an overview of ICH Q8 Pharmaceutical Development, ICH Q9 Quality Risk Management (QRM) and ICH Q10 Pharmaceutical Quality System (PQS). It summarises the key principles and benefits that accrue with the effective and collective implementation of ICH Q8, 9 and 10.

https://nsfpharmabiotech.trainingfolks.com/store/2811534-gxp-refresher-training-ich-q8-q9-and-q10

Interface of GMP with GCP Quality Management Systems

This course session provides an overview of the interface of GMP with GCP Quality Management Systems. The four chapters will provide you with an understanding of the similarities and differences between GCP and GMP.

https://nsfpharmabiotech.trainingfolks.com/store/2731821-interface-of-gmp-with-gcp-quality-management-systems-2022

Microbiology: The Basics

This introductory course (which is divided into 3 chapters) is ideal for staff in operational and support areas – production, engineering, QC, QA, validation and technical, as well as those new to the pharmaceutical industry and/or microbiology. We cover the real meaning of microbiology in operations and why it matters. You'll learn the risks associated with microbes and how to eliminate or control them so that the patient is protected. You will be able to apply your knowledge from this session in your daily work.

https://nsfpharmabiotech.trainingfolks.com/store/3243117-microbiology-the-basics

Pharmaceutical Microbiology

This course provides comprehensive instruction on Pharmaceutical Microbiology in pharmaceutical manufacturing. It covers introductory topics, such as microbiological problems in pharmaceutical manufacturing, microorganisms and how they grow. Intermediate topics cover identifying and counting microorganisms, pyrogens, microbiological evaluation of raw materials, contamination and spoilage, preservation, antibiotics, and good disinfection practices. The advanced topics covered are sterilization methods, sterility testing, cleanroom validation, environmental monitoring and microbiological risk assessment.

https://nsfpharmabiotech.trainingfolks.com/store/3718217-pharmaceutical-microbiology

Process Validation and Equipment Qualification

This course provides comprehensive instruction on the Process Validation and Equipment Qualification in pharmaceutical manufacturing. Completing the three modules will provide learners with a holistic view of validation encompassing pre-validation studies, process development, and process evaluation, emphasizing modern approaches that apply principles of QbD, PAT, and ongoing quality risk management (QRM).

https://nsfpharmabiotech.trainingfolks.com/store/3415063-process-validation-and-equipment-qualification

Self-Inspections – How to Make Them Add Value to Your Organisation

Why do you conduct Self-Inspections and why are they important to your organisation? This course provides an overview of the key elements in each stage of the Self-Inspection process, outlining where it fits into the overall audit pyramid.

https://nsfpharmabiotech.trainingfolks.com/store/3175164-self-inspections-how-to-make-them-add-value-to-your-organisation

SOP Writing and Revision

This course revisits the core purpose of SOPs, which is so often forgotten in many companies. It will provide useful guidance on how to write, implement and maintain your SOPs within your Sites' documentation hierarchy.

https://nsfpharmabiotech.trainingfolks.com/store/427083-sop-writing-and-revision

Sterile Manufacturing Practices

This course provides comprehensive instruction on Sterile Manufacturing Practices in pharmaceutical manufacturing. It utilizes real-world scenarios, embedded video and audio content to instruct on the practical application of these requirements.

https://nsfpharmabiotech.trainingfolks.com/store/3722045-sterile-manufacturing-practices

For more information and registration details, please visit:

https://nsfpharmabiotech.trainingfolks.com/store

Certificate in Pharmaceutical Manufacturing

The Certificate in Pharmaceutical Manufacturing program brings together five eLearning courses that meet the educational needs for a professional involved in the manufacture of medicines for the pharmaceutical sector.

The courses can be taken individually or purchased at a specially priced bundle rate.
They are:

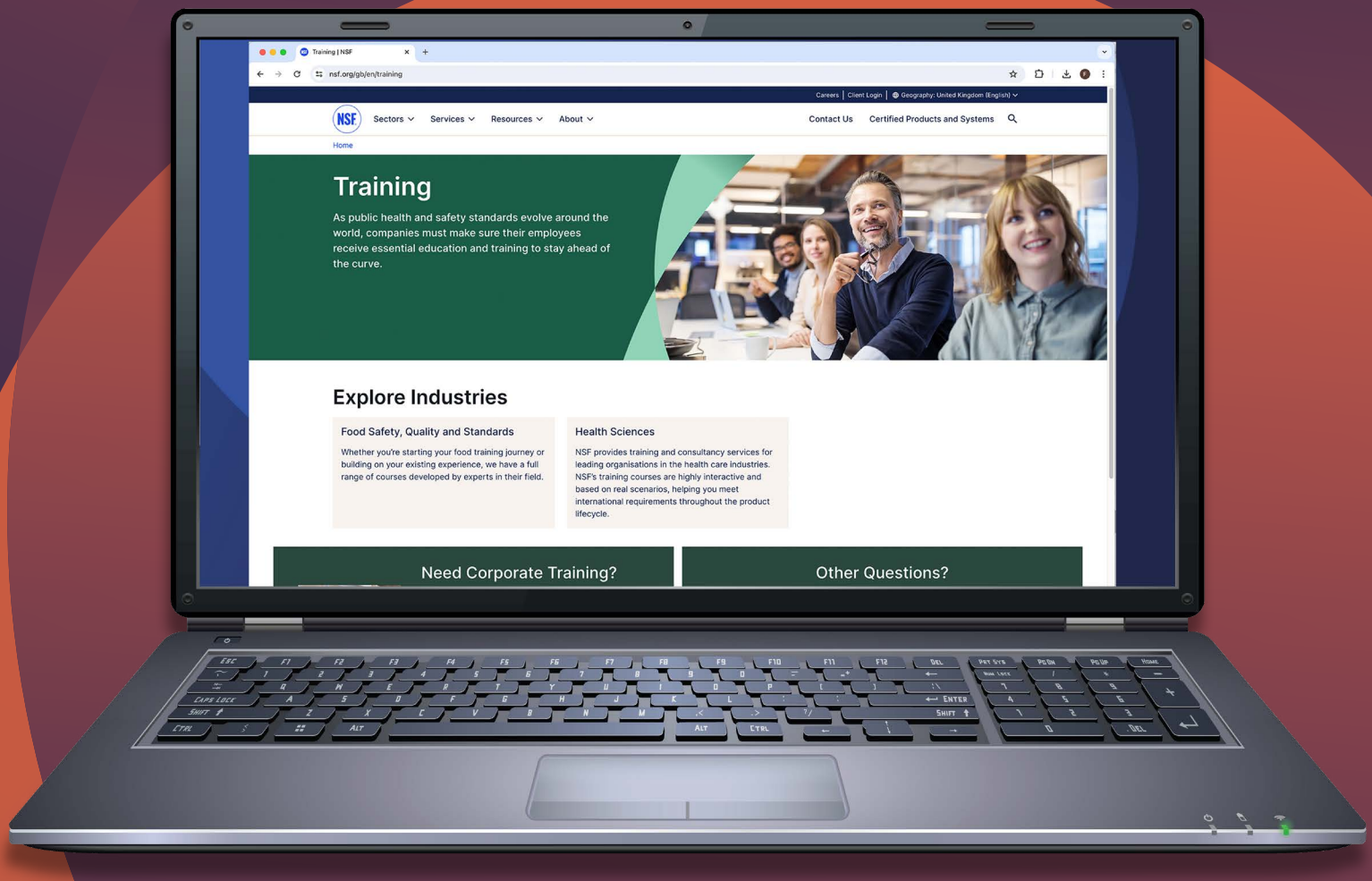
- Analysis and Testing
- General Drug or Pharmaceutical cGMP and Quality Systems
- Process Validation and Equipment Qualification
- Pharmaceutical Microbiology
- Sterile Manufacturing Practices

Each course contains engaging knowledge checks and concludes with a final competency assessment and course completion certificate.

This training provides you with a total of 26 hours of engaging eLearning content utilizing real-world scenarios, embedded video, and audio to instruct on the practical application of the topics listed.

For more information and registration details, please visit:

https://www.nsf.org/training/area/health-sciences-training-solutions/pharmaceutical/certificate-pharmaceutical-manufacturing-online-course-series



NSF Health Sciences Pharmaceutical Public Courses

Check out our full listing of course offerings today at nsf.org/training

Contact Us
Visit www.nsf.org/training or email pharmacourses@nsf.org

NSF Health Sciences
T +44 (0) 1751 434 807
Follow us on LinkedIn