CUSTOMIZED ON-SITE TRAINING

EDUCATION FOR THE PHARMACEUTICAL AND BIOTECH INDUSTRIES

Over the last 30 years, NSF International has become the leader in providing customized educational courses. Our courses change the way people think and, in doing so, provide an immediate return on investment. All of our educational programs are designed to improve the performance of individuals as well as their company.

All of our educational programs can be customized and presented at your own site. In fact, over half of our programs are conducted at our clients' locations.

The benefits of courses presented on-site include:

Reduced costs: Travel and hotel costs disappear. You also control course duration and attendee costs. Optimum attendance to maintain high levels of interaction is 10-25, although we are flexible to meet your exact needs.

Less stress and time away from home and the office: We come to you!

Privacy and confidentiality: We can discuss the challenges you and your colleagues are facing in total confidence and under your own confidentiality agreement.

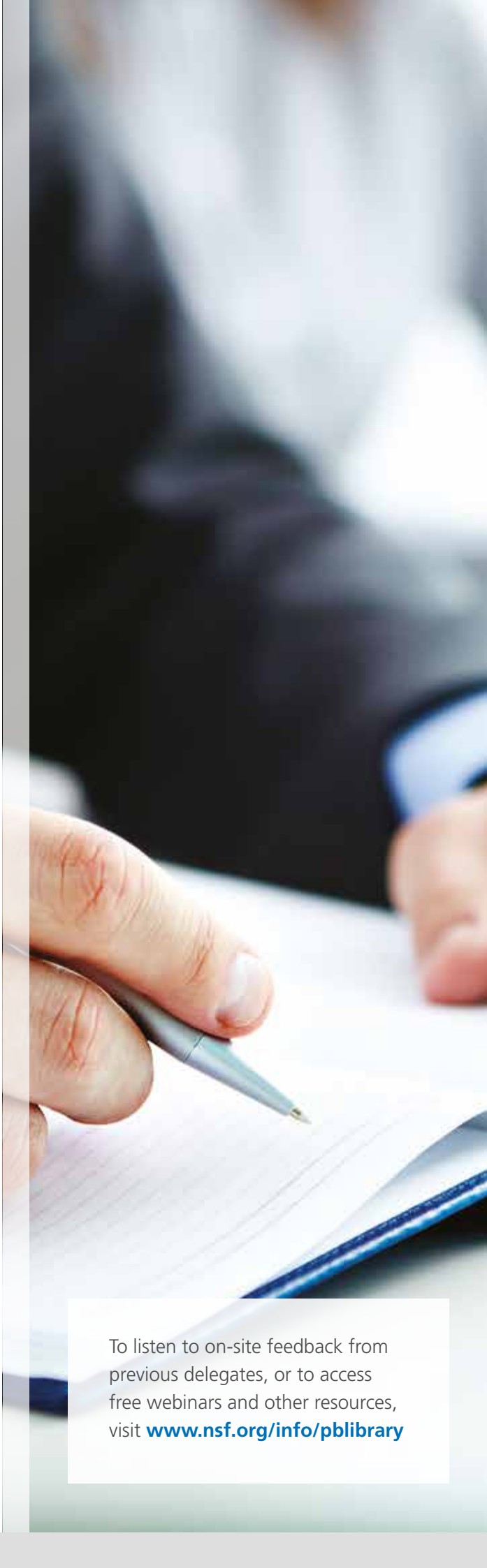
Full customization: Course content is designed to meet the needs of your products and processes, your systems and procedures, and your challenges and problems. Our experts work with you in advance to make sure the content, including case studies and problem solving exercises, meets your exact needs and requirements.

Local language: In addition to English, we have the capability to present selected courses in German, French, Italian and Mandarin.

Changing behaviors and improving performance: All of our courses (public and on-site) provide the skills and motivation you need to make a real difference. The advantage of an on-site course is that you have more people available to make a difference. A large group of highly motivated change agents can make a real impact on your company's performance.

Customized support: Following every course, you will have access to our subject matter experts to provide additional support and guidance. You will also have free access to our library of webinars, videos and white papers.

Check our extensive course listings at
www.nsf.org/info/pharma-training



To listen to on-site feedback from previous delegates, or to access free webinars and other resources, visit **www.nsf.org/info/pblibrary**

Here are some of our most successful on-site courses. For more information or if you have a specific request, please email pharmamail@nsf.org or call +44 (0) 1751 432 999.

LEADERSHIP, QUALITY CULTURE AND IMPROVING GMP BEHAVIORS

These courses will help you motivate your people to do more with less and do it better:

- Quality Culture: How to create a culture that improves profit and compliance
- Changing GMP Behaviors: A simple five-step process
- Quality Systems – Best Industry Practices: Find out what the best companies do
- How to Change Quality Habits: Getting people to do the right thing, automatically
- Training Effectiveness: How to improve your training

CONTINUOUS IMPROVEMENT, ERROR REDUCTION AND SIMPLIFICATION

If you suffer from high levels of deviations, quality incidents, human error or over-complexity, these courses will transform your productivity and reduce risk:

- Human Error – Causes and Prevention: Five-steps to improving human reliability
- Advanced Problem Solving: Taking your root cause investigations to another level
- The Art and Science of Simplification: How to remove deadly complexity
- The Analysis and Trending of Data: Using your data to drive improvement

CASE STUDY – USA COMPANY RESTRUCTURE

Problem: A client had invested in a major company reorganization, which resulted in many problems including a demotivated and less-skilled workforce, poor decision making and investigation, poor QA/QP support across the organization, and issues with self-inspection and regulatory inspection outcomes.

Solution: NSF met with the leadership team and designed a customized program of modular on-site training, based on our QP syllabus. Topics included pharmaceutical law and the role of the QP, quality culture and other QMS-specific subjects. We provided real-life scenarios and problem-solving exercises to ensure a clear common body of technical knowledge across the board.

Result: We left the company with over 120 staff trained, including those from QA, QC, engineering, manufacturing and senior management. The company's quality culture was enhanced and continuous improvement working groups were established. Our client is still rolling out and fine-tuning the training to smaller groups to ensure a brighter future for the organization.

WHAT PEOPLE ARE SAYING

The course is very interesting and engaging. The use of motivation, ability and habit to cultivate quality habits is rather powerful.

Changing Quality Habits, Singapore

As a new employee, this course gives great value. The behaviors and practices I have learned will help me work effectively towards reducing errors and preventing the recurrence of errors, and have a positive feedback effect on fellow colleagues.

Human Error Prevention, Denmark

CASE STUDY – USA AND EUROPE MODULAR TRAINING PROGRAM

Problem: NSF International was approached by a global pharmaceutical company who wished to embed quality thinking into all aspects of their business. This was a proactive initiative with the aim of creating a quality culture across the organization.

Solution: We provided a series of ten four or five day modules that were delivered within the same month at locations in the USA and Europe. The modules were:

1. Pharmaceutical Law
2. Investigational Medicinal Products
3. Quality Management Systems
4. Statistical Tools and Techniques for Quality
5. Microbiology
6. Small Molecule API and Products
7. Biotech API and Products
8. Packaging
9. Pharmaceutical Analysis
10. Sterile Products Manufacturing

Result: Over an eight year period we delivered training to over 400 people from a variety of backgrounds, working in many different roles in the organization; from QA/QC, production, engineering, regulatory, pack design, etc. Many of the graduates from this program went on to hold senior leadership positions within the organization, which continues to thrive and employ NSF to deliver transformational education across their global network.

QUALITY SYSTEMS, GMP AND SELF-INSPECTIONS

Our unique certified auditor course is world-class, and our pharmaceutical GMP course is the most popular course in Europe. If you want your quality system to improve productivity and your competitive edge, look no further:

- The A-Z of Quality Management Systems
- Pharmaceutical GMP: How to excel at doing the basics
- Deviation and CAPA Systems: How to prevent repeat incidents – five easy steps
- Good Documentation Practices: How to create documents people can use
- The Cost of Poor Quality: Improving margin by reducing waste
- EU GMP Requirements for Clinical Supplies Manufacture
- Effective Pharmaceutical Audits and Self-Inspections: Certified auditor course
- Product Quality Review: Using data to drive continuous improvement
- Change Control – Best Industry Practices: How to simplify your change control system
- Rapid Change Control: How to manage change simply and quickly
- Process Validation: The modern approach
- Batch Manufacturing Records: How to simplify and improve

WHAT PEOPLE ARE SAYING

The exercises are excellent. They get everyone engaged, talking and learning.

Analysis & Testing, USA

Excellent course at a good pace to give a very good broad overview.

Healthcare Training, UK

★★★★½

ON-SITE TRAINING COURSE ATTENDEES OVER THE LAST YEAR RATED THE OVERALL QUALITY OF OUR COURSES AS 4.5 OUT OF 5 STARS.

REGULATORY COMPLIANCE, INSPECTIONS AND DATA INTEGRITY

Staying in business means staying in regulatory compliance. We provide a pragmatic, economical, science-based approach to compliance. We don't believe in "blind" compliance; we believe in compliance that puts the patient first:

- EU and FDA Inspections Readiness: How to succeed on the day
- Regulatory Crisis Management – Best Industry Practices: What to do when things go wrong
- Data Integrity: How to manage and prevent data integrity issues
- Regulatory Update: What new regulations are coming and how to interpret them
- Pharmaceutical Law: A no-nonsense, practical interpretation of pharmaceutical regulations
- How to Audit – Data Integrity

CASE STUDY – UK PROCESS VALIDATION

Problem: A company that had run an on-site GMP training course with NSF International asked us to run a one-day process validation course focused on the requirements of Annex 15, which spearheaded a sharper approach to validation and resulted in a gap in staff knowledge. To ensure all staff had an overview of the changed regulatory requirements and the latest tools and technology available in the pharmaceutical industry, the client wanted a customized course to meet their needs and address key weak areas.

Solution: NSF provided a customized on-site training course on process validation. This consisted of 14 specific sessions covering an introduction to modern validation in the EU, a detailed explanation of the three stages of validation from initial development through to sustaining quality over the product lifecycle, validation planning and validation steps, and important tools such as quality risk management.

Teamwork activities fostered creativity and learning, ensuring staff were working together towards a common goal, and an open forum was included to address any outstanding issues and questions.

Result: Fifteen employees were educated on process validation and the requirements of Annex 15 and now know exactly what is required of them. The improved knowledge has added value to the business; applying the learned concepts to new and existing processes has ensured a real return on investment for the company and resulted in safer products for patients.

PLANT, UTILITIES AND LABORATORIES

To improve your productivity you need to get the most out of your fixed assets. From reliability-centered maintenance of plants and equipment, to removing bottlenecks in the QC lab, we have you covered. These courses provide what you need for optimization, without compromising compliance:

- The A-Z of Pharmaceutical Water Systems: Everything you ever wanted to know
- Pharmaceutical Packaging: Minimizing risk in this high-risk area
- Good Control Laboratory Practice
- Out of Specification Investigations: Best industry and regulatory practices
- Ongoing Stability: Regulatory and best-in-class practices
- How to Audit – QC Chemical Laboratories
- Analyzing and Trending Data: Using your data to drive improvement
- Equipment, Facility and Utility Qualification
- Cleaning Validation: How to satisfy the regulators and best-in-class practices

CASE STUDY – INDIA GOOD DOCUMENTATION PRACTICES AND DATA INTEGRITY

Problem: An Indian pharmaceutical company needed help with good documentation practices (GDP), over-complicated documents and understanding the complete requirements of data integrity. The company wanted to make sure that its data was accurate, consistent and complete and that employees knew what was required of them. It wanted to prevent future catastrophic and costly data integrity issues.

Solution: We provided a three-day on-site training course on GDP and data integrity, customized to company requirements. This intensive course covered documentation issues, data integrity controls, data governance systems and the implications for management, how to drive out complexity, data integrity audits, assessments and how to handle data integrity issues once identified. Teamwork exercises were incorporated throughout.

Result: We left the company with 40 employees educated on the importance of maintaining and assuring data integrity across the product lifecycle. The company was able to drive out complexity and drastically simplify its documentation system, making it easier to understand what's essential and what's not.

STERILE PRODUCTS, BIOTECH AND CONTAMINATION CONTROL

Sterile products are high value and high risk and more stringently regulated than any other medicines. This unique collection of courses provides you with what you need to make sterile products safely and efficiently. You will receive the most up-to-date understanding of the technologies involved and an understanding of the regulatory requirements. You will also find out what you must do when things go wrong. Environmental monitoring failure? Media fill failure? Biological indicator failure? HVAC failure? Problems with visual inspection? We cover them all… and more:

- Good Autoclave Practices: The control and management of your autoclaves
- The A-Z of Sterile Products Manufacturing
- GMP for Biological and Biotechnology Products
- Techniques for Effective Failure Investigation for Sterile Products
- Cleaning Validation: Science-based, pragmatic, pure and simple
- Pharmaceutical Microbiology for the Non-Biologists: Demystifying the "black art"
- Risk-Based Approach to Environmental Monitoring: Getting the most from your environmental monitoring program
- How to Audit – Bulk Biotech Operations
- How to Audit – Sterile Products Manufacture
- Pharmaceutical Microbiology: The interpretation and risk assessment of micro data
- Contamination Control: How to protect your products and processes

RISK MANAGEMENT AND RISK-BASED DECISION MAKING

The best companies manage risk better than their competitors. They recognize there is no such thing as zero risk and that the more risk averse you are, the GREATER the risk to your business and your patients. If you want to make better risk-based decisions, and understand best-in-class practices for risk management, the following courses are for you:

- Risk Management: Best industry practices
- Risk-Based Decision Making for Quality Professionals and QPs: How to make the right decisions

WHAT PEOPLE ARE SAYING

Course was very beneficial and gave greater oversight on dry substance and dry production manufacture. This will help me to do my job.

GMP for Biological and Biotechnology Products, Ireland

Engaging course with enthusiastic presenters with good anecdotal evidence and overall knowledge.

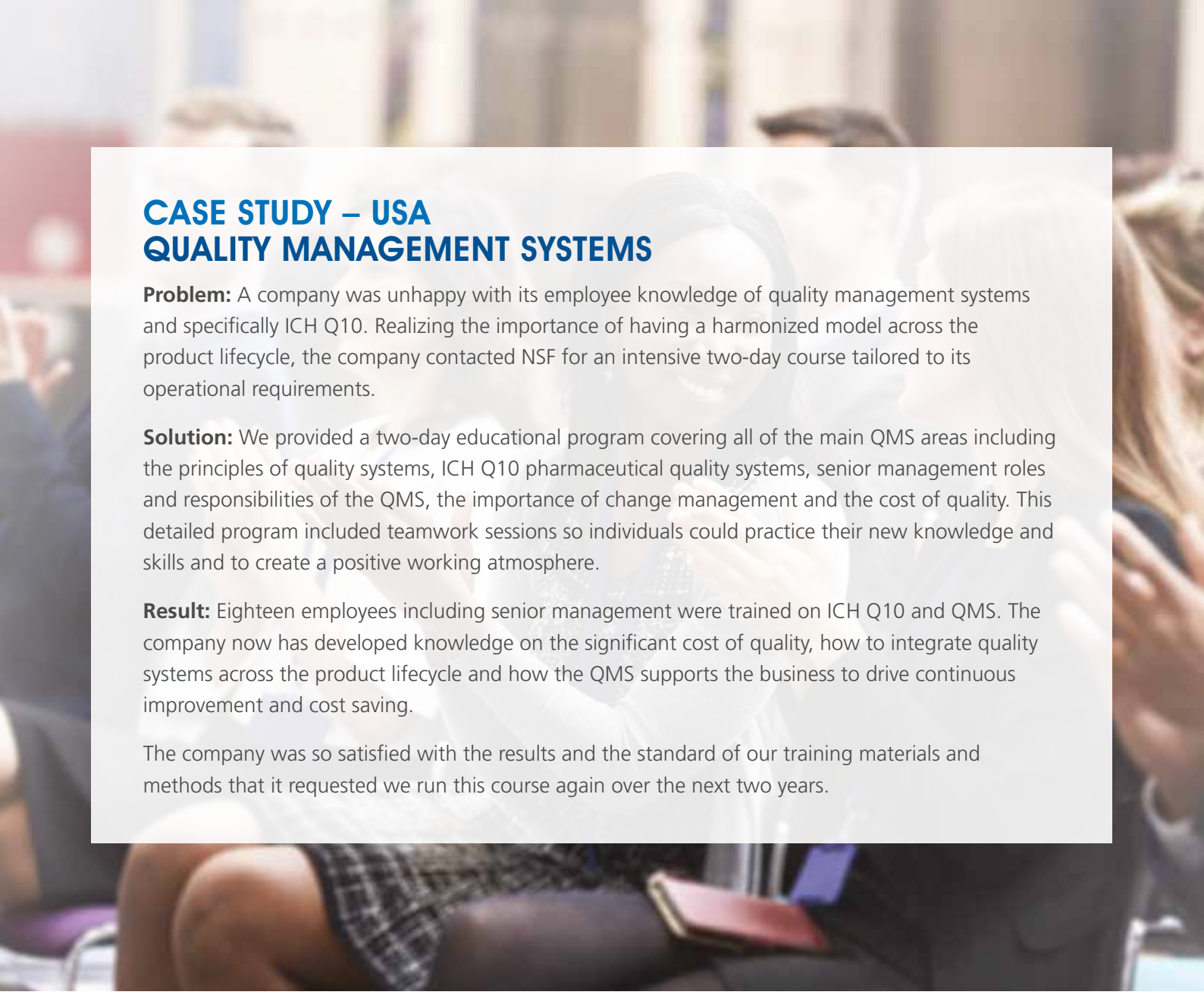
Modern Approaches to Qualification, Process Validation and Cleaning Validation, UK

I had many a-ha moments during this training. The examples presented were very useful and interesting.

Quality Risk Management in Action, Denmark

Impressed with experience of the trainer – this was the key factor in making the training successful.

Risk-Based Decision Making in Sterile Products Manufacture, UK



CASE STUDY – USA
QUALITY MANAGEMENT SYSTEMS

Problem: A company was unhappy with its employee knowledge of quality management systems and specifically ICH Q10. Realizing the importance of having a harmonized model across the product lifecycle, the company contacted NSF for an intensive two-day course tailored to its operational requirements.

Solution: We provided a two-day educational program covering all of the main QMS areas including the principles of quality systems, ICH Q10 pharmaceutical quality systems, senior management roles and responsibilities of the QMS, the importance of change management and the cost of quality. This detailed program included teamwork sessions so individuals could practice their new knowledge and skills and to create a positive working atmosphere.

Result: Eighteen employees including senior management were trained on ICH Q10 and QMS. The company now has developed knowledge on the significant cost of quality, how to integrate quality systems across the product lifecycle and how the QMS supports the business to drive continuous improvement and cost saving.

The company was so satisfied with the results and the standard of our training materials and methods that it requested we run this course again over the next two years.

CONTACT US

For more information, visit **www.nsfpharmabiotech.org**, contact **pharmamail@nsf.org** or call **+44 (0) 1751 432 999**.

NSF INTERNATIONAL | PHARMA BIOTECH
The Georgian House, 22/24 West End,
Kirkbymoorside, York, UK YO62 6AF
T +44 (0) 1751 432 999
F +44 (0) 1751 432 450
E pharmamail@nsf.org
www.nsfpharmabiotech.org

LPH-418-0317