

a whitepaper from



NSF Health Sciences Qualified Person Training

NSF Health Sciences Qualified Person (QP) training provides practical, focused, face-to-face instruction from seasoned professionals and University lecturers who are acknowledged experts in their fields.

Our founder, David Begg, began QP training in 1990 when the QP Study Guide was being developed. David saw the need to educate beyond a minimum, to give QPs and other pharmaceutical professionals a syllabus of education that truly prepares them to work in our industry. This belief in education has been maintained over 23 years and 150+ courses, and has helped over 250 professionals gain QP status. The rigorous course can be used to gain postgraduate qualifications up to the MSc level. It has also been accepted by health authorities in several EU member states as sufficient training to allow non-pharmacists to become QPs.

The course acts as continuing professional development for quality professionals from other disciplines such as auditing, manufacturing, QC and engineering, as well as for existing and prospective QPs. It provides the

knowledge and practice QPs will need to face in their ever-demanding roles.

For more information on **NSF Health Sciences QP training in the EU**, visit <http://nsf-dba.com/pages/qp-training> or contact Stella Pearson-Smith in our UK office at sps@nsf-dba.com.

Whilst the legal requirements for the Qualified Person (QP) have been enshrined in EU legislation for over 30 years, several other regulatory agencies are now naming individuals for certain Quality related roles.

Despite the need for a QP not being a legal requirement in the USA, more and more firms are asking NSF Health Sciences to provide an in-house program to educate selected Quality and Technical Professionals, often globally, across their organization, to a standard similar to the EU QP. This has helped facilitate better decision making, staff development and retention of key people.

For more information on the options for **in-house Quality Professional Programs** contact Austin Caudle in our US office at acaudle@nsf.org.

The Route to QP Eligibility in the EU

In this article, James Culyer, a Supply Chain Assurance Manager at Bard Pharmaceuticals Ltd in the UK, provides an engaging personal account of his experience with NSF-DBA's QP program, from start to finish.



“The route to QP eligibility starts long before you make the conscious decision to send off the application form for that first QP module training course. It even starts long before most people know what a QP is; let alone what’s involved in becoming one. It actually starts when

you make the decision at some point in your career that you want to work in the pharmaceutical industry. You could argue that the route starts even earlier at the point when you choose your university degree course as chemistry, microbiology, pharmacy or other life science qualification.

I feel lucky in my own particular career route leading up to realizing I wanted to be a QP. I already had experience working in a QC laboratory in a steriles manufacturing facility and in validation roles at sterile injectables, non-sterile liquids, and oral solid dosage forms manufacturing sites. That gave me a strong foundation in different manufacturing techniques and

processes that was to prove invaluable to me both during the training and the viva process, and beyond in the real and chaotic world of the QP. When I finally approached the site Quality Director to discuss the possibility of becoming a QP, the decision was borne out of a strong desire for challenge – not just the challenge of the training and qualification process, but out of a desire for an ongoing career challenge. I wanted a position in the company that challenged me on a daily basis, where every day would be slightly different, and every problem complicated with a slightly different set of considerations to take into account. If you don't crave this kind of role, give up on the QP dream now!

Once the site Quality Director agreed to allow me to pursue my chosen career, I began the first module of NSF-DBA's QP program. My company had a long-standing relationship with NSF-DBA; with all seven of our site QPs having 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-DBA's many and varied training courses. There was a deep trust in the abilities of both parties to deliver exactly what was needed. The thought of going elsewhere for QP training was not even entertained. NSF-DBA was quite simply our first and only choice. From the time I applied, I had a full three weeks to mentally prepare myself before the start of the course. This involved talking to the existing site QPs and attempting to discover what on earth I had let myself in for. 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, which were the best clubs, bars and restaurants to go to, etc. Basically, all the essentials!

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 are experts in their respective fields. 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. As you progress through the

modules, you start to realize how important, and in fact essential, these new friends really are. They allow you to access a vast amount of industry experience and knowledge, provide the opportunity to visit and understand other manufacturing sites and review quality management systems, and give you the support of a large number of like-minded people who are going through exactly the same process. The huge emphasis on networking is one of the best things about the NSF-DBA approach to QP development. Practically every aspect of the course – the training techniques, the venues and the extracurricular activities – is based around encouraging you to build a broad and long-lasting network of contacts that will serve you both through the viva process and beyond throughout the rest of your career.

The other great thing about the NSF-DBA QP courses is the personal tutor system. Once you sign up for a certain number of the QP modules¹, you are assigned a personal tutor. This will be one of the NSF-DBA team members actively involved in the QP training courses, who will inevitably have acted as a QP at some point in his or her career. You meet with your assigned personal tutor during each module and spend a short period of time reviewing your progress and your next steps toward the viva process. Additionally, you can email or phone your personal tutor any time in between those meetings to ask for advice and guidance. Your tutor acts as an expert mentor for the QP qualification process, helping you identify your strengths and weaknesses, defining development needs and even providing opportunities or contacts within the industry to address those needs. This support becomes ever more important as you progress through the QP modules and start to complete your viva application form, which in itself serves as a gap analysis of your eligibility to act as a QP. The tutor remains 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-DBA offers one further service (free of charge), the mock viva. It takes place at the NSF-DBA offices in Kirkbymoorside² and serves as an invaluable preparedness check prior to submitting your

NSF Health Sciences Pharma Biotech

2001 Pennsylvania Avenue NW, Suite 950, Washington, DC 20006 USA
Tel: +1 (202) 822-1850 | USpharma@nsf.org | www.nsf.org/info/pharmabiotech

The Georgian House, 22/24 West End, Kirkbymoorside, York, UK YO62 6AF
Tel: +44(0)1751 432999 | Fax: +44(0)1751 432450 | EUpharma@nsf.org

application form. The extremely intense three- to three-and-half-hour session serves to identify the gaps you have that need filling, your ability to handle a very realistically simulated 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 focusing my revision topics leading up to the real thing a few short weeks later. All credit goes to my own two mock viva assessors, Mike Halliday and Peter Smith, who did an excellent job in the preparation for the day and in the execution of the process itself.

Overall, I don't think you can go wrong, or do better, than to choose NSF-DBA as the training provider for

the QP program. The focus is 100 percent 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 the overall supportive nature of the service they provide give you the best chance possible.

After you finish the course, QP Alumni meetings are available to keep you up-to-date (meetings count towards CPD) and give you an opportunity to reminisce with fellow students.”

¹ Attendance at four QP modules is required to become a 'core' QP delegate. For details of the benefits, please contact our QP Administrator, Stella Pearson-Smith, sps@nsf-dba.com

² Other locations available by arrangement

Copyright © 2013 NSF International.

This document is the property of NSF International and is for NSF International purposes only. Unless given prior approval from NSF, it shall not be reproduced, circulated or quoted, in whole or in part, outside of NSF, its committees and its members.

Cite as: NSF International. August 2013. NSF Health Sciences Qualified Person Training. NSF: Ann Arbor, MI.

NSF Health Sciences Pharma Biotech

2001 Pennsylvania Avenue NW, Suite 950, Washington, DC 20006 USA
Tel: +1 (202) 822-1850 | USpharma@nsf.org | www.nsf.org/info/pharmabiotech

The Georgian House, 22/24 West End, Kirkbymoorside, York, UK YO62 6AF
Tel: +44(0)1751 432999 | Fax: +44(0)1751 432450 | EUpharma@nsf.org