ADDRESSING THE SHORTAGE OF QPs IN THE PHARMA INDUSTRY

by Lynne Byers

The role of a Qualified Person (QP) is to assess and certify batches of medicinal products to be released to the market or used in a clinical trial. As part of this role, a QP has a legal responsibility to ensure that every batch of a medicinal product released onto the market complies with its clinical trial or marketing authorisation and has been made according to good manufacturing practices. Therefore, the role of the QP is central to the pharmaceutical industry and the development of new medicines.

However, despite the UK pharmaceutical sector employing over 60,000 people, there are only 350 QPs in the UK, which is a stark shortage of those required to take on the role. Unless this shortage is addressed, there is likely to be a huge limitation on the industry's ability to perform clinical trials of new medicines in the UK and globally, in addition to the routine supply of commercial products..

Here are three ways the pharmaceutical industry can tackle the shortage of QPs.

POSITION THE ROLE OF A QP AS AN ASPIRATIONAL CAREER

The biggest challenge of becoming a QP is becoming well rounded and knowledgeable in all dosage forms and all the different manufacturing types. However, becoming a QP can be incredibly rewarding, not only financially – salaries for QPs in the UK generally begin at about £50,000 per year and move upwards of £70,000-£100,000 – but also personally.

Richard Tarrant was instrumental in the rollout of the AstraZeneca vaccine for COVID-19 as the QP responsible for signing off on the first batch of vaccines to go into clinical trials. "The role of a QP is incredibly rewarding, and I am proud to have played a role in the UK's response to the COVID-19 pandemic," said Tarrant. "The process of signing off on a batch of vaccines to be sent for clinical trials is thorough, and as the person responsible, I needed to ensure that while we were desperate to roll out a vaccine to fight COVID-19, I was not putting anyone at risk."

ADDRESS THE SKILL SHORTAGE

The pharmaceutical industry as a whole is facing a huge talent shortage, with careers in the industry demanding higher levels of skills. This is also true for those looking to take on the role of a QP. In the UK, people who apply for QP status tend to already to have at least five years of industry experience, placing an age limit on those who can apply to become a QP.

There is also a need to dial up global training capabilities to address the skill shortage. The COVID-19 pandemic has been a catalyst in virtual learning, with educational and training courses having to become digital practically overnight. This can be hugely beneficial to QP training programmes, which previously were time extensive and took place face-to-face. At NSF we offer our QP training courses both in person and virtually to allow overseas prospective QPs access to our courses. The other benefit of delivering virtual QP courses is that several companies have brought the training in-house, and this has enabled them to train cohorts of staff, increasing the companies' pipeline of QPs.

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ENCOURAGE RETRAINING

It is well understood that being a QP is not an easy job, and having the right soft skills as well as technical knowledge is important to success. It is here that mid-career workers in the pharmaceutical industry can thrive as QPs, having already built the necessary experience and skills within the sector. The industry needs to work with these employees to encourage them to retrain as QPs in order to keep the trainee pipeline full.

NSF'S TRAINING OFFERING

Since 1990, NSF has been running an approved QP training programme both in the UK and globally in conjunction with the University of Strathclyde. The NSF QP training programme is approved by the Royal Society of Chemistry as suitable for its members' continuing professional development. The intensive, interactive training course provides aspiring QPs with the knowledge and understanding they need to perform the legal duties of a QP. Further, it teaches attendees how a 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.

When certifying medicinal products, it is of paramount importance that a QP can look at the broad issues of managing quality and approach these issues in a cohesive way when making decisions to release or reject. Aspiring QPs will have the opportunity to test their skills via interactive release-or-reject scenarios throughout the 13-module course.

Additionally, last year the Royal Society of Chemistry, the Royal Pharmaceutical Society and the Royal Society of Biology – otherwise known as the Joint Professional Bodies – completed a review of the QP Study Guide, making changes to take Brexit and the new UK-EU Trade and Cooperation Agreement into account. This was the first time the QP Study Guide had been updated since 2018, and NSF led the way for the industry, updating its health science training programmes to reflect the necessary changes with immediate effect.

Richard Tarrant was trained by NSF and said of the course, "NSF supported me throughout my QP training, delivering industry-leading courses and a dedicated tutor who provided help and advice in getting through the process successfully. Since becoming a QP, I have enjoyed being part of the alumni and attending ongoing training, which is vital for keeping me up to date with the ever-changing regulatory landscape. Not only does NSF equip you with the training and skills you need to become a Qualified Person, but it also creates a support network of other QPs that is vital to this challenging line of work."

ABOUT THE AUTHOR

Lynne Byers has extensive pharmaceutical manufacturing management and QA experience spanning more than 35 years, gained working for major international pharmaceutical manufacturers as well as the MHRA. She joined NSF in 2017 as the Global Managing Director, Pharmaceuticals and Dietary Supplements Consulting. Ms. Byers is eligible to act as a Qualified Person and was a QP assessor on behalf of the Royal Society of Chemistry from 1999 to 2004. During her tenure with the MHRA she was responsible for agreeing to QPs being named and removed from manufacturing authorisations.

To find out more about NSF health science training visit **www.nsf.org/info/qptraining.**

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E pharmamail@nsf.org | **www.nsfpharmabiotech.org** | **www.nsf.org**

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