APPENDIX 2

Curriculum Vitae

Dr Peter H. Gough

Hon. DSc, MSc, CSci, CChem, FRSC, FCQI, CQP

Recognised Areas of Expertise

- Pharmaceutical Laws and Guidance
- The role and responsibilities of the European Qualified Person (QP)
- Pharmaceutical analysis and testing; particularly Good Control Laboratory Practice (GCLP) and the handling of out of specification (OOS) results
- The design and application of pharmaceutical quality management systems
- Quality risk management and its application within the quality by design (QbD) framework
- Statistical process control and the integration of statistical thinking within the quality management system
- Manufacture and control of oral solid dosage forms
- Hosting and Preparing for Regulatory Authority GMP Inspections (EU & FDA)

Current Employment

Executive Director at NSF Health Sciences which includes, but is not limited to, the following responsibilities:

- Management of the NSF Health Sciences business, as part of the Executive team
- NSF Health Sciences UK office infrastructure
- Keeping all NSF Health Sciences consultants up to date with legislative changes
- To act as a consultant for NSF Health Sciences in the areas of recognised expertise given above.

Responsible for the development and management of the following NSF Health Sciences courses:

- Pharmaceutical Legislation Updates
- Modern Approaches to Pharmaceutical Validation
- Analytical Method Validation
- Investigating OOS Results
- On-going Stability Testing
- Implementing Quality by Design
- The Role and Responsibilities of the QP
- Maths and Statistics
- Analysing and Trending Data to drive improvement
- Quality Risk Management
- Pharmaceutical Law and Administration
- Pharmaceutical Analysis and Testing
- Quality Aspects of the CTD

Involvement with Professional Associations/Societies

- A Chartered Chemist and a Fellow of the Royal Society of Chemistry (RSC). A former the Chairman of the Royal Society of Chemistry's Qualified Person Assessor panel
- A Fellow of the Chartered Quality Institute (CQI) and a Chartered Quality Professional. An Honorary Life Member and a former chairman of the CQI's Pharmaceutical Quality Group
- A member of the Parenteral Drug Association (PDA)
- A member of the International Society for Pharmaceutical Engineering (ISPE)

Career History

A chemist with a Master's degree in analytical chemistry with over 40 years' experience of pharmaceutical manufacture, control and quality management. Eligible to act as a Qualified Person within the EU since 1984. Awarded an honorary Doctor of Science degree in 2016 by Kingston University, London, for services to pharmaceutical quality management.

A 30-year career working for Eli Lilly that encompassed the following roles:

- Head of Analytical Services
- Production supervisor for penicillin solid dose products
- Head of API production
- Head of Quality Assurance

- Project leader for quality improvement projects
- Senior Quality Consultant in the Global Quality Systems division

This has provided a broad experience, with quality control laboratories, the manufacture of solid dosage forms and active pharmaceutical ingredients as well as extensive experience of defining pharmaceutical quality systems at both the site and global levels.

Has always been a passionate advocate of the application of statistical tools and techniques to provide understanding and control of manufacturing and business processes.

Has extensive experience with preparation and hosting of GMP inspections by Regulatory Authorities; particularly those performed by UK MHRA and on behalf of EMA.

An experienced GMP auditor of API producers, sold dose manufacturing, analytical laboratories and suppliers to the pharmaceutical industry.

Experience in the filling of medicinal gases gained whilst acting as a QP for a medicinal gas company for over 10 years.

A former member of the European Federation of Pharmaceutical Industries and Associations (EFPIA) Manufacturing and GMP ad hoc group. He was an EFPIA delegate to the ICH GMP Workshop in 2003 that led to the ICH Q8, 9 and 10 guidelines and was subsequently the EFPIA topic leader on the ICH Expert Working Group that prepared the ICH Q9 guideline on Quality Risk Management. Peter was given the “Leveraging Collaboration Award” by the US FDA for his contributions to the ICH Q9, Quality Risk Management, "Briefing Pack".

Has remained close to the development of the ‘Quality by Design’ (QbD) concept as it has evolved since 2003 and continues to provide education and consultancy in these principles.

He is an Honorary Lecturer in GMP and Pharmaceutical Quality Management at the University of Strathclyde.

A regular speaker at industry meetings organised by PDA, ISPE, RSC, DIA and FIP.

Numerous articles published in professional journals, such as Industrial Pharmacist, GMP Review, etc. and has been quoted in others, such as the Gold Sheet.