



PETER GOUGH

NSF Vice President

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

AREAS OF EXPERTISE

TRAINING

Pharmaceutical law and administration
The Role of the Qualified Person
Pharmaceutical Quality Systems
Quality Risk Management
Good Control Laboratory Practice
Investigating Out of Specification results
Statistical Process Control

AUDITING

Quality Control Laboratories
Oral solid dose manufacturing
Pharmaceutical Quality Systems

CONSULTANCY

GMP and GDP compliance
Good Control Laboratory Practice
Preparation and hosting of GMP inspections
Oral solid dose manufacturing

KEY KNOWLEDGE AREAS

Pharmaceutical law and guidance
Good Manufacturing Practice (GMP)
The Role of the Qualified Person
Pharmaceutical Quality Systems
Quality Risk Management
Good Control Laboratory Practice
Investigating Out of Specification results
Product Quality Reviews
Chemical Analysis and Testing
Process Validation
Statistical Process Control
Solid dose manufacture
Chemical API manufacture

CONTACT

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EXPERIENCE

- > An analytical chemist with over 45 years' experience of pharmaceutical solid dose manufacture, quality control and quality management systems.
- > An expert in EU legislation and guidance on the manufacture and control of medicinal products.
- > A Qualified Person and a past chairman of the Royal Society of Chemistry's Qualified Person Assessor panel.
- > A former chairman of the U.K. Pharmaceutical Quality Group.
- > A former member of the European Federation of Pharmaceutical Industry Association's (EFPIA) Manufacturing and GMP ad hoc group and EFPIA topic leader on the ICH Expert Working Group that prepared the Q9 guideline on Quality Risk Management.
- > An Honorary Lecturer on pharmaceutical quality management and GMP at the University of Strathclyde.

KEY JOB ROLES

- > NSF Vice President, 2020 to date
- > NSF Executive Director, 2005 to 2019
- > Various roles at Eli Lilly and Company, 1974 to 2005
 - o Senior Quality Consultant in Global Quality Systems, 2002 to 2005
 - o Leader of quality improvement projects, 1999 to 2002
 - o Head of Quality Assurance and QP, 1989 to 1999
 - o Head of API manufacture, 1987 to 1989
 - o Supervisor of Penicillin product production, 1986 to 1987
 - o Head of Analytical Services, 1979 to 1986
 - o Analytical Supervisor, 1976 to 1979
 - o QC Analyst, 1974 to 1976

EDUCATION

- > Hon. DSc for services to pharmaceutical quality management, Kingston University, 2016
- > Fellow of Chartered Quality Institute and Chartered Quality Professional, 2008
- > Fellow of Royal Society of Chemistry, 2001
- > Fellow of the Institute of Quality Assurance, 1997
- > Eligible as EU Qualified Person, 1985
- > MSc Analytical Chemistry, Kingston University, 1981
- > Graduate of Royal Institute of Chemistry, Kingston University, 1979

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