

## Charlie Wakeham: Consultant Résumé (Curriculum Vitae)

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### Career Experience

**Director** 2024 - present  
WakeUp to Quality

- Resolving Quality and Compliance challenges in a GxP world through consultancy and training.

**Global Head of Quality and Compliance** 2023  
Magentus, Australia (formerly Citadel Health)

- Global responsibility for improving organizational quality, implementing project quality, and safeguarding data privacy to DPA/GDPR.

**APAC GxP Compliance Manager** 2013 – 2022  
Waters Corporation, Australia

- Delivering data integrity consultancy, CSV assistance, and periodic review services to regulated companies, and advising on their quality systems, working practices, SOPs and data governance.
- Implementing and managing validation services across Asia Pacific in support of GxP-regulated Waters Empower and NuGenesis customers.
- Guiding corporate product development teams on compliance and defining validation approaches for Software as a Service offerings.

**Project Engineer through to R&D Manager** 1997 – 2013  
Pall Life Sciences, UK (now Cytiva)

- Design (process, mechanical, software and hardware), development and validation of GxP-critical process control systems, laboratory computerized systems and single-use bioprocessing systems.
- QMS creation, maintenance, auditing and continual improvements.

### Qualifications, Affiliations, and Training

- Fellow of the Institute of Mechanical Engineers 2010 – 2020
- Chartered Engineer CEng (via Engineering Council) 2001 – 2020
- Member of the Institute of Mechanical Engineers 2000 – 2010
- Quality Management Systems Lead Auditor 2012
- Management of Risk and Uncertainty 2008
- Project Management APMP 2003
- Master of Science, Advanced Manufacturing (Distinction) 1997
- Bachelor of Engineering, Mechanical Engineering (2:1) 1996

### Highlights

★ **Subject matter expert** in computerized systems quality and data integrity. Extensive knowledge of GxP regulations, guidances and industry best practices.

★ **ISPE GAMP Activities:**

- **Chair** of ISPE GAMP Global Steering Committee
- **Chair** of ISPE GAMP South Asia Steering Committee
- **Leader** of ISPE GAMP Global CSA SIG
- **Member** of ISPE Guidance Documents Committee
- **Member** of ISPE Annual Meeting Planning Committee

★ **Experienced provider of training and consultancy** including delivering training to regulatory agencies.

★ **Frequent speaker** at industry conferences in Europe, USA and Asia Pacific.

★ **Contributing Author or Co-Lead** to nine ISPE GAMP Good Practice Guides.

★ **Awards received:**



Committee of the Year Award (GAMP Global Steering Committee), ISPE Annual Meeting 2022



Max Seales Yonker Member of the Year Award, ISPE Annual Meeting 2019



Committee of the Year Award (GAMP Data Integrity SIG Leadership Team), ISPE Annual Meeting 2017