

Charlie Wakeham: Consultant Résumé (Curriculum Vitae)

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Career Experience

Director 2024 - present
WakeUp to Quality Pty Ltd

- 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 within a Clinical LIMS SaaS provider 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 activities, and periodic review services to regulated companies, and advising on their quality systems, working practices, SOPs, and data governance.
- Implementing and managing validation professional services across Asia Pacific in support of GxP-regulated Waters Empower CDS and NuGenesis LIMS/LES customers.
- Advising corporate product development teams on compliance requirements and defining validation approaches for SaaS 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 instrumentation and 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 validation, quality, and data integrity.
- ★ **ISPE GAMP® Leadership Roles:**
 - **Past Chair** of ISPE GAMP Global Community of Practice
 - **Past Chair** of ISPE GAMP South Asia CoP
 - **Leader** of ISPE GAMP Global CSA Special Interest Group
 - **Co-Chair** of ISPE GAMP Editorial Review Board
 - **Director** of ISPE Australasia Affiliate Board
 - **Member** of ISPE Guidance Documents Committee
 - **Member** of ISPE Annual Meeting Planning Committee
- ★ **Extensive knowledge** of GxP regulations, guidances, and industry best practices.
- ★ **Experienced provider of training and consultancy** including delivering training to regulatory agencies.
- ★ **Frequent speaker** at industry conferences worldwide
- ★ **Contributing Author or Co-Lead** to nine ISPE GAMP Good Practice Guides.
- ★ **Awards received:**
 -  Committee of the Year Award, ISPE Annual Meeting 2022
 -  Max Seales Yonker Member of the Year Award, ISPE Annual Meeting 2019
 -  Committee of the Year Award, ISPE Annual Meeting 2017