WTQ WakeUp to Quality with Charlie Wakeham

Charlie Wakeham: Consultant Résumé (Curriculum Vitae)

charlie.wakeham@wakeuptoquality.com linkedin.com/in/charliewakeham

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

- ISPE Qualified Instructor (GAMP courses) 2023
- 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.

★ **International Society of Pharmaceutical Engineering 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 APAC 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.

★ **Renowned speaker** at industry conferences worldwide

★ **Contributing Author or Co-Lead** to ten ISPE GAMP 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