

Personal Details

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Executive Summary

I began my career as an R&D scientist specializing in infrared and Raman spectroscopy and X-ray powder diffraction. After completing an MSc in Analytical Chemistry, I moved into pharmaceutical analysis and progressively broader roles spanning laboratory management, regulatory compliance, lecturing, sales support, commercial development, marketing, leadership and consultancy work.

I bring extensive experience in regulated laboratories, with particular expertise in analytical instrument qualification, data integrity and compliance. Drawing on scientific and regulatory intelligence, including FDA inspection findings and emerging compliance trends, I develop evidence-based consultancy, content and training to help organizations understand requirements and apply them in practice.

My approach combines technical expertise with strategic thinking, mentoring and change management. I adapt to different team and project needs, helping manage workloads, milestones and team dynamics while keeping technical detail aligned with wider organizational goals. Over 20 years of international work have strengthened my communication and cross-cultural collaboration skills across all organizational levels.

Qualifications / Training

Subject	Level	Training Organization	Date
Neuro Linguistic Programming (<i>NLP</i>)	• Practitioner • Master Practitioner	The Northern School of NLP, UK (and other NLP training organizations / courses)	2002-04
Analytical Chemistry	MSc	Birkbeck College, University of London MSc Thesis – Chemometric Modeling of FT-IR and Raman Spectra of Macroreticular Polystyrene Beads	1987-89
Chemistry	BSc	The University of Bradford Final Year Specialism and Project – Raman Spectroscopy	1981-85

- Additional Training Includes:**
- ◇ **Coaching for Better Results** – Julian Russell, Executive Coach, PPD Learning 2004
 - ◇ **Crossing the Chasm** - 3-day workshop with Michael Eckhardt, Chasm Director, 2021
 - ◇ **Data Integrity Level 1 (*Current FDA Data Integrity Perspectives*)** – Monica Cahilly# 2012
 - ◇ **Data Integrity Level 2 (*Critical Thinking and Advanced Auditing*)** - Monica Cahilly# 2014
 - ◇ **Data Integrity Level 3 (*Train the Trainer*)** - Monica Cahilly (#GMQA) 2017
 - ◇ **Data Integrity Level 4 (*Forensic Data Integrity Review*)** – Peter Baker (Live Oak) 2019
 - ◇ **Data Integrity (*Conducting Data Integrity Investigations*)** - Peter Baker (Live Oak) 2021
 - ◇ **Develop Outstanding Teams** - Simon Horton & Alex Marshall (2006, PDP Learning)
 - ◇ **How to Run a Knowledge Café** - Dave Gurteen, for facilitation training (2009, Ark)
 - ◇ **ISO 9001 Internal Auditing** - for PerkinElmer UK OneSource® ISO Accreditation (2010, BSI)
 - ◇ **ISPE Conferences and Events** - UK CoP, Annual, and International ISPE Events
 - ◇ **Kepner Tregoe Training** - GSK Management Training (1997)
 - ◇ **Operations Management** - Institute of Management Diploma / NVQ 5 - (1994-1995)

Most Recent Roles

Owner and Director <i>(current role)</i>	Compliance2425 Ltd. High Wycombe, Buckinghamshire, UK (2024 – Present) Strategic Laboratory Compliance Consultancy <i>(Remote and on-site)</i> <i>(Regulatory Intelligence, Data Integrity, and Analytical Instrument Qualification (AIQ))</i> Leveraging my 40+ years' analytical and regulatory compliance experience & knowledge through consulting activities to help laboratories in regulated industries be compliant through:
Advancing <i>(With stakeholders)</i>	Analytical Instrument Qualification (AIQ). Provide expert consultancy in analytical instrument qualification and wider laboratory compliance & remediation. Actively monitor signal sources for regulatory trends, non-compliance findings and updates to key regulatory references such as USP <1058>. Integrate this knowledge into providing support to industry and regulators.
Leveraging <i>(A high profile)</i>	A High Compliance Profile with Industry and Regulators. Develop and maintaining a high compliance profile through GAMP, Linked In and publications.
Collaborate <i>(Pharmacopeias, FDA, & other sources)</i>	With Compliance Thought Leaders. From Pharmacopeias to FDA and other regulators, exploring opportunities to educate, network and collaborate. Develop tools for compliance data analysis and trends monitoring.
Orca1 <i>(Develop, support and collaborate)</i>	Advisor and Consultant for the Orca1.di software platform. This advanced AI driven Regulatory Intelligence tool provides simple access to high value regulatory intelligence data and insights <i>(for Pharmaceutical and Medical Devices)</i> . Reach out to discuss your regulatory intelligence needs - I can demonstrate the platform.
Analysis of <i>(Turning data into knowledge)</i>	Regulatory Data (from Orca1 and Public Domain), to identify insights and key trends for sharing with customers, influencers, and industry compliance leaders.
+	Part-Time Lecturer – Greenwich University <i>(Pharmaceutical Science Courses)</i>
+	ISPE GAMP UK CoP Chair <i>(from January 2027)</i>
Compliance Marketing Product Manager	Agilent Technologies Remote Worker <i>(UK Office, Stockport)</i> (2016 - 2024) Agilent CrossLab Group - Laboratory Instrument Compliance Services <i>(Consultancy, CSV, and Analytical Instrument Qualification (AIQ))</i> Helped drive sustained double-digit growth in Agilent's compliance services through targeted marketing initiatives and sales training through:
Creating <i>(Marketing)</i>	Targeted content: presentations, training, white papers, technical notes, brochures, case studies, flyers, videos, and updating Agilent Compliance Web Pages.
Engaging <i>(Stakeholders)</i>	With Regulatory Contacts. Customers, influencers, regulators, marketing teams and different divisions across Agilent <i>(sharing, collaborating, and training)</i> .
Leveraging <i>(Subscription Access)</i>	Regulatory Intelligence (subscription access): to identify laboratory compliance changes, trends, opportunities and identify key non-compliance findings to leverage across Agilent. Design Regulatory Findings into compliance marketing content.
Training <i>(Sales Chanells)</i>	Sales Teams in features, benefits and competitive advantages of the Agilent Compliance Engine (ACE) and digital instrument qualification services. Recruitment, training and mentoring of regional compliance consultants.
Other Activities:	- Coordinate collateral updates - Data integrity trainer - Lead content labelling evaluation - Proposing new marketing documents - Socialize draft marketing for feedback - Supported regional compliance specialists in China, India, Europe, Singapore and USA

Additional Career Profile

Agilent Technologies **Remote Worker** (*Home office, UK Office in Stockport*). **(2014 – 2016)**

Global Strategic Compliance Specialist

- Identify & target international conferences to present at
- Monitor regulatory trends and FDA non-compliance findings

This global role extended the success of my European work to an international level. I gave educational compliance “*thought leadership*” presentations at conferences including ISPE, KENX, RQA, and Agilent events around the world.

Agilent Technologies **Remote Worker** (*Home office, UK Office in , Stockport*). **(2011 – 2014)**

European Compliance Specialist

- Customize equipment qualification plans (*EQPs*)
- Train sales, support sales growth, facilitate EQP implementation

Customization of Agilent Equipment Qualification Plans (*EQPs*) quickly progressed into sales support, sales training and business growth roles. Deep customer compliance discussions to accelerate migration / successful implementation.

Perkin Elmer **OneSource®**, Seer Green, Buckinghamshire, UK **(2006 – 2011)**

European Validation Manager

- Co-Chaired AAPS workshop – first review of USP <1058> (*2010*)
- Qualification protocols and bespoke customer OneSource® QMS

Supported the growth of OneSource® services across Europe, leveraging consultancy and laboratory compliance expertise to implement an integrated, single-point service contract & compliance services for laboratory instruments.

Greenwich University **Medway Campus, Chatham, UK[#]** **(2006)**

Consultant Lecturer

Working in teams, students covered Technology Transfer, problem solving / decision making (Kepner Tregoe), communication (& 1:1 Belbin profiling).

Invited by the University of Greenwich to deliver Pharmaceutical Technology Transfer workshops to final-year BSc Pharmaceutical Sciences students, after closure of Terasolutions Ltd.

Tera Solutions Ltd **Middle Farm, Cumdivock, Dalston, Carlisle, UK** **(2002 – 2005)**

Owner and Director

- Consultant lecturer at Greenwich University[#] (*Technology Transfer*)
- UK sales agent for Ecochem (*Czech ISO 17025 Accredited Lab.*)

I founded Tera Solutions Ltd to leverage my pharmaceutical, analytical and management experience. I reached out to companies about ISO 17025 analytical services and “*filtered*” discussions for potential consultancy opportunities.

GlaxoSmithKline **Quality Assurance, North Lonsdale Road, Ulverston, UK** **(2000 – 2002)**

Quality Operations Manager

- Harmonization of Analytical Practices (*GSK CAP committee*)
- Lean Lab (*six sigma*), 50 % reduction in cycle times

Led a 72-person Quality Assurance laboratory through significant organizational change and downsizing, driven by generic competition. Facilitated 50 % Test Time reduction (*Lean Six Sigma*), corporate projects and union discussions.

GlaxoSmithKline **Quality Assurance, North Lonsdale Road, Ulverston, UK** **(1989 – 2000)**

QA Analyst (*Analytical Dev.*)
HPLC Lab Leader & NPIA
QA Team Manager Role(s)

- Analytical method development, validation and transfer
- Implemented “***Just-In-Time***” batch release of critical site material
- Setup and commissioned new Testing Lab in NPIA
- QA Year 2000 – Laboratory implementation manager

I held several positions with increasing people, budget and technical responsibilities. I was promoted to run the HPLC Lab in Quality Assurance (*QA*), set up a new lab in New Product Introduction (*NPIA*) to provide direct analytical support for site API transfers and projects, and then Team Management roles in QA (*intermediates, then Shifts*).

SmithKlineBeecham **Physical Organic Chemistry, The Frythe, Welwyn, UK** **(1985 – 1989)**

Scientist (*in Drug Discovery*)

- **FT-IR** - Applied to research studies and structural identification
- **MSc Thesis** - Chemometric modeling of bile acid sequestrants

Applied FT-IR to support site drug discovery research projects, investigate lipid–drug interactions, and record / interpreted spectra for structural identification of novel compounds prior to biological activity screening.

Critical Competencies

- **Analytical Science** Experienced analytical scientist, skilled in analytical method development, validation and transfer. Strong background in QC, laboratory management, defining analytical strategies for process improvement / R&D projects and robust regulatory audit defense. Expertise in a broad range of spectroscopic, chromatographic and physical techniques. Specialist expertise in FT-IR and pharmacopeia requirements.
- **Communication** Visual and creative thinker skilled at simplifying complex information and communicating it clearly through writing, presentations and training. Combines scientific, operational, marketing and consultancy experience with strong adaptability and self-awareness.
- **Problem Solving** Strong problem-solving and critical-thinking skills, combining structured analysis, such as Kepner Tregoe and active listening. I apply intuitive facilitation from my NLP training to identify root causes and develop effective solutions.
- **Team Working** My experience in teamworking, Belbin team-role profiling and workshop design helps me adapt effectively to complex, global teams. I use Belbin, NLP and communication tools to understand team dynamics and tailor my approach to the situation. This helps teams work together effectively and stay focused on critical milestones and project outcomes.
- **Winning Support** I collaborate, share knowledge, help and mentor others. I build extended networks of contacts as I work, research information, and develop my own learning. This approach helps me sponsor change and enables me to gain support from others.

USP Experience

As a laboratory manager, I provided justification for all use of alternative analytical procedures to USP (*and Ph. Eur.*) monograph testing.

I was a Member of the USP Nominating Committee for the Council of Experts for 2025-2030 cycle, and attended the 2025 USP Convention in Washington DC (*May 2025*)

Additional Experience Dimensions

This section includes elements of “functional” experience related to roles held during my career.

Subject	Dimension
Business	• Budget, cost and asset management, due diligence, growth targets and KPI monitoring
Computer Systems	• Word, PowerPoint, & Excel. Software / LIMS evaluation and system change control
Critical Thinking	• Strong analytical skills, combining problem solving, situation analysis and NLP
Project Management	• Coordinated, planned and managed a range of projects with tight deadlines
Quality Management	• Interpreting and applying ISO 9001, 17025, ASTM and Pharmaceutical Regulations
Regulatory	• Inspection Fronting (<i>cGMP</i>) and preparation (<i>customer, FDA, MHRA... Etc.</i>)
Training	• Designed and delivered compliance workshops and experience-based learning
Validation	• Validated procedures, methods, software, and qualified Lab equipment

ISPE Membership Activity

My professional membership focus is the International Society for Pharmaceutical Engineering (*ISPE*). Earlier in my career, I held Chartered Chemist (*CChem*) and Chartered Scientist (*CSci*) designations and was a Member of the Royal Society of Chemistry (*MRSC*) and the Chartered Management Institute (*MCI*).

ISPE GAMP UK Community of Practice Steering Committee (*CoP*)

- **Member:** 2014-2024
- **Co-Chair:** 2025-2026
- **Chair** (*From January 2027*)

Written Publications and Documentation

Experienced in authoring and reviewing technical content, with expertise in laboratory compliance, policy, regulatory trends, SOPs and analytical best practice. I have written and contributed to many articles and publications, including FDA non-compliance findings and GAMP® Good Practice Guides, supporting industry knowledge transfer and communication of regulatory and technical requirements.

Examples of Documents and Publications Reviewed *(with Acknowledgement)*

1. **Analytical Quality Control Group Guide on Analytical Instrument Qualification**, Dr Christopher Burgess and Dr. R.D. McDowall, ECA Analytical Quality Control Group, Jan. 2025. [Link](#)
2. **Do We Qualify or Validate a Spectrometer?**, Mahboubeh Lotfinia and Dr. R.D. McDowall, Spectroscopy, Vol. 39, Issue 8, 6th Jan. 2025. [Link](#)
3. **Ingenious Ways to Manipulate Peak Integration?**, Dr. R.D. McDowall, LC-GC International, Vol. 1, Issue 2, 1st Feb. 2024. [Link](#)

Examples of Recent Publications

1. **Darwin Awards for Regulatory Non-Compliance**, Paul Smith, Dr. R.D. McDowall, Monika Andraos and Mahboubeh Lotfinia *(in Preparation – at external review stage)*.
2. **The Museum of Analytical Antiquities**, Paul Smith and Dr. R.D. McDowall, Technology Networks, 25th Nov. 2024. [Link](#)
3. **Are You Sure You Understand USP <621>?**, Paul Smith and Dr. R. D. McDowall, LC-GC International, 16th Sep. 2024. [Link](#)
4. **What Does Performance Qualification Mean for Infrared Instruments**, Paul Smith and Dr. R. D. McDowall, Spectroscopy, Vol. 35, Issue 4, 1st Apr. 2020 [Link](#)
5. **GAMP Good Practice Guide: Computerized GCP Systems & Data**, 2nd Edition, Data Integrity Section
6. **Analysis of FDA Infrared 483 Citations: Have You a Data Integrity Problem?**, Paul Smith and Dr. R. D. McDowall, Spectroscopy, Vol. 34, Issue 9, 1st Sep. 2019, [Link](#)
7. **Data Integrity and USP <1058>: Part 1 of 3 – Specifications and Suppliers**, Paul Smith and Dr. R. D. McDowall, LCGC Europe, Vol. 31, Issue 7, 1st Jul. 2018, [Link](#)
8. **Data Integrity and USP <1058>: Part 2 of 3 – OQ Supervision and Execution**, Paul Smith and Dr. R. D. McDowall, LCGC Europe, Vol. 31, Issue 9, 1st Sep. 2018 [Link](#)
9. **Data Integrity and USP <1058>: Part 3 of 3 – Monitoring and Requalification**, Paul Smith and Dr. R. D. McDowall, LCGC Europe, Vol. 32, Issue 1, 1st Jan., 2019 [Link](#)

Presentations & Compliance Events

My international experience includes close collaboration with colleagues across multiple global regions, working across geographic, language and cultural differences. At GSK, I represented Active Pharmaceutical Ingredients (API) sites when I served on the Compendium of Analytical Procedures (CAP) committee, contributing to the global harmonization of analytical procedures across the newly formed GSK. I supported technology transfer from R&D to API sites and participated in multi-site compliance projects, including (Y2K), LIMS and CDS upgrade projects.

I regularly present internationally at conferences, compliance seminars, workshops, training events and webinars, and deliver educational sessions at customer sites. The presentation subjects I am most frequently asked to deliver include comparisons of approaches, trends, news and different perspectives on include:

- **Analytical Instrument Qualification**
- **Data Integrity**
- **Preparing for a Regulatory Inspection**
- **Regulatory Trends and Inspection Findings**

Example Workshops / Presentations for Regulatory Authorities:

1. **Malaysia** (NPRA) **Full Day Agilent Compliance Seminar** (7 different presentations by me) at National Pharmaceutical Regulatory Agency (NPRA) Headquarters, Malaysia, 15th Aug. 2018
2. **India** (Range of Indian Authorities) **Compliance Checkpoints for Analytical Instruments in Pharma and Biotech Industries**, Training Course for GLP QA Professionals, Jul. 2012 (event shared with US FDA)
3. **Ireland** (then IMB) **HPLC Compliance**, Workshop Presentation at IMB training day in Dublin, 14th Jan. 2014
4. **USA** (FDA) **Development of a Trace Cross-Contamination Analysis Strategy**, Presentation to FDA at the Bethesda Site to support Safe Medical Limit for GSK Ulverston cross-contamination analysis, Nov. 1997

Recent Webinar Examples:

1. **The Pharmaceutical Inspection Cooperation Schema (PIC/S), Regulatory and Laboratory Implications for NMPA Membership of PIC/S**, Agilent China Webinar, Paul Smith & Justin Fang, 23rd Aug. 2024
2. **Are Your Perpetuating Your Data Integrity Problems?**, Paul Smith and R.D. McDowall, 24th May 2022, Redica Systems: [YouTube Link](#)
3. **Regulatory 101 - Core Elements of Laboratory Compliance**, 8th May 2015, Live Agilent Webinar (Europe, Asia and USA – 3 different time zones): [Link to PDF](#) (electronic recording no longer on-line)
4. **Gain Insights into Compliance Trends and Better Prepare for FDA Audits**, 8th Oct. 2018, LC-GC: [YouTube Link](#)

Examples of UK Presentations / Workshops:

1. **Regulatory Updates**, Each ISPE UK GAMP Community of Practice (CoP) Meeting (2 events per year)
 2. **Confused by Data Integrity Guidance?**, ISPE UK CoP, 1st May 2018, GSK Stevenage, [Link to PDF](#)
 3. **Deconstructing UKAS to Develop Effective Compliance Strategies**, Nov. 2014, Agilent Seminar
 4. **The Role of the Analytical Laboratory in Technology Transfer**, Visiongain Conference, 13th Dec. 2010
 5. **Why is the Lean Lab so Popular**, GSK Global Manufacturing and Supply Conference, 24th May 2002
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Overseas Compliance Events and Presentations

I have given face-to-face presentations in many parts of the world, which typically combine educational compliance seminars with customer visits and on-site events. I optimize presentations to the regulatory requirements, inspection findings and trends relevant to each country or region, designing in language and translation requirements. Many countries have been visited multiple times and include:

Asia-Pacific (APAC) Region:

- Australia
- China
- India
- Malaysia
- Singapore
- South Korea
- Thailand

In the European Region

- Austria
- Belgium
- Czech Republic
- Denmark
- Finland
- France
- Germany
- Hungary
- Ireland
- Italy
- Malta
- Netherlands
- Norway
- Spain
- Sweden
- UK

In the Americas Region

- Mexico
- Puerto Rico
- USA

Note: A more detailed list of publications, seminars & compliance events can be provided