Personal Details

Paul Andrew Smith

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Executive Summary

I started as a R&D scientist *(infrared and Raman spectroscopist)* – where my strong interest in FT-IR and spectroscopic techniques comes from. After my MSc *(Analytical Chemistry)*, I broadened my experience by moving into primary pharmaceutical analysis. My work has covered regulatory trends, commercial activity and compliance thought leadership from my consultancy, management, lecturing, sales support, marketing and leadership roles.

I have been involved in instrument qualification / compliance throughout my career and helping laboratories be compliant is a passion. My consultancy work builds on my qualification expertise, my compliance thought leadership activity and my data integrity training. The success of my Agilent work was based on me leveraging scientific and regulatory knowledge when presenting, creating content and developing training. I include non-compliance findings in my work *(e.g. presentations, training and writing)*. An essential part of this involves focusing on regulatory intelligence data and closely monitoring trends. I network, collaborate and explore ways to harmonize and simplify laboratory compliance requirements *(e.g. USP <1058> evolution vs GAMP® evolution)*.

I thrive where my work includes a balance of people, technical and strategic components. I make time to mentor people because it drives growth through supportive leadership, facilitates change and is rewarding. In my teamwork, I monitor workload, project milestones and team dynamics, leveraging my NLP training to enhance my communication and maintain my flexibility. My cross-cultural consultancy, Agilent and PerkinElmer work required me to simultaneously focus on attention to detail, while working towards strategic objectives.

Qualifications/Training

Subject	Level	Training Organization	Date
Chemistry	**BSc**	The University of Bradford Final Year Specialism and Project – Raman Spectroscopic Studies	**81-85**
Analytical Chemistry	**MSc**	Birkbeck College, University of London MSc Thesis – Chemometric Modeling of FT-IR and Raman Spectra of Macroreticular Polystyrene Beads	**87-89**
Neuro Linguistic Programming *(NLP)*	• **Practitioner** • **Master Practitioner**	The Northern School of NLP, UK *(and other NLP training organizations)*	**02-04**

Additional Training

◊ **Coverdale Leadership Training -** GSK Management Training (Jan. 1999)
◊ **Critical Thinking -** Monica Cahilly (GMQA) & Peter Baker (LiveOak): 2012-2021
◊ **Crossing the Chasm -** 3-day workshop with Michael Eckhardt, Chasm Director, 2021
◊ **Data Integrity Certification -** Monica Cahilly (GMQA) & Peter Baker (LiveOak): 2012-2021
◊ **Develop Outstanding Teams -** Simon Horton & Alex Marshall (2006, PDP Learning)
◊ **How to Run a Knowledge Café -** Dave Gurteen, for facilitation training (2009, Ark)
◊ **ISPE Conferences and Events -** UK CoP, Annual, and International ISPE Events
◊ **Kepner Tregoe Training -** GSK Management Training (March 1997)
◊ **Operations Management** - Diploma / NVQ 5 - Institute of Management (1994-1995)

Most Recent Roles

Owner and Director *(current role)*	**Compliance2425 Ltd.** **High Wycombe, Buckinghamshire, UK (2024 – Present)** **Strategic Laboratory Compliance Consultancy** *(Remote and on-site)* *(Regulatory Intelligence, Data Integrity and Analytical Instrument Qualification (AIQ))* Leveraging my 40 years' analytical and regulatory compliance experience & knowledge through consulting activities to help laboratories in regulated industries be compliant through:
Driving *(With Stakeholders)*	**Strategy and Harmonization of Analytical Instrument Qualification.** Monitor, support and drive updates to USP <1058> and the GAMP® **Good Practice Guide: GxP Compliant Laboratory Computerized Systems** *(2nd Edition)*. Provide gap analysis, strategic advice, training and support. I continue to monitor developments, maintaining my contribution to the historical evolution of both documents.
Maintaining *(A high profile)*	**Strong Relationships with Industry Thought Leaders**, by continuing to exchange "*regulatory intelligence*", providing advice and support for trusted contacts. Maintaining a high Linked In compliance network profile.
Monitoring *(Pharmacopeias, FDA, & other sources)*	**Public Domain Regulatory Data**. From Pharmacopeias to FDA, Google alerts and other public regulatory sources. Develop and maintain tools for compliance data analysis and trends *(as a backup to Orac1 – maintaining independent monitoring).*
Selling *(Leveraging Regulatory Intelligence Data)*	**Licensed Access to the Orca1.di Regulatory Intelligence** software platform. This powerful AI driven platform ensures easy access to high value regulatory intelligence data and insights. Search, trend and visualize data with a few mouse clicks. Enhance supplier or materials risk evaluation, prepare for audits with inspector profiles. Access FDA EIRs and 483s. Powerful search & analysis of regulatory data for pharmaceutical and medical device companies. I am an Orca1 Evangelist.
Sharing Information	**With** customers, influencers and industry compliance leaders. I proactively explore collaboration opportunities across my network to support compliance and trust.

Compliance Marketing Product Manager	**Agilent Technologies** **Remote Worker** *(UK Office, Stockport)* **(2016 - 2024)** **Agilent CrossLab Group - Laboratory Instrument Compliance Services** *(Consultancy, CSV and Analytical Instrument Qualification (AIQ) - 8 Years, 1 Month)* Lead Marketing role in promoting Agilent compliance services through:
Creating *(Brochures / flyers)*	**Targeted content**: presentations, training, white papers, technical notes, brochures, case studies, flyers, videos, and updating Agilent Compliance Web Pages.
Engaging *(Stakeholders)*	**With Regulatory Contacts**. From customers, influencers, functional groups, divisions to marketing teams across Agilent *(sharing, collaborating and training)*.
Leveraging *(Redica)*	**Subscription Access** to search for and identify laboratory compliance changes, trends and non-compliance examples. Share and design into Marketing content.
Networking *(With stakeholders)*	**To Proactively Share Regulatory Data**. Develop insights and share compliance data with stakeholders, network influencers and across Agilent and industry.
Other Activities:	• Coordinate agency collateral changes • Data integrity trainer • Keep a strong presence in GAMP® • Lead content labelling evaluation • Monitor PIC/S membership and updates • Socialize draft collateral for feedback

Additional Career Profile

Global Compliance Specialist & Thought Leader

Agilent Technologies

Drive compliance awareness through thought leadership.

Remote Worker *(UK Office, Stockport).* **(2014 – 2016)**

- Compliance thought leadership *(articles & presentations)*
- Identify & target opportunities to educate and present
- Monitor FDA trends & non-compliance findings
- Represent Agilent at international conferences

European Compliance Specialist

Agilent Technologies

Technical sales support for Agilent qualification services.

(For Agilent ACE)

Remote Worker *(UK Office, Stockport).* **(2011 – 2014)**

- Customize equipment qualification plans *(EQPs)*
- Facilitate implementation, answer customer questions
- Support evolution of USP <1058> and GAMP®

European Validation Manager

Perkin Elmer

OneSource® Services

Compliance development.

OneSource®, Seer Green, Bucks., UK **(2006 – 2011)**

- Co-Chaired AAPS workshop on USP <1058> *(2010)*
- Designed & wrote customer OneSource® QMS suites
- Trained and supervised engineers in Lab compliance
- Wrote qualification and validation protocols

Consultant Lecturer

Greenwich University

Final Year BSc Pharmaceutical Science Students

Medway Campus, Chatham, UK **(2006)**

Technology transfer in the pharmaceutical industry[#]
(Experienced based learning: Working in teams, problem solving, facilitation, communication and decision making. 1:1 profiling)

Owner And Director

Tera Solutions Ltd

Management Consultancy

Middle Farm, Cumdivock, Dalston, UK **(2002 – 2005)**

- Analytical science consultancy & data interpretation
- Consultant lecturer[#] *(Quality and Technology Transfer)*
- UK sales agent for Czech ISO 17025 Accredited Lab.

 # Greenwich University, Medway Campus, Chatham, UK.

Quality Operations Manager

GlaxoSmithKline

API Manufacturing

Leadership of busy Quality Assurance Lab. (70 + people) through uncertainty and change.

QA, North Lonsdale Road, Ulverston, UK **(2000 – 2002)**

- Defined Lab policy, approved SOP's & procedures
- Fronted Lab regulatory inspections *(e.g., FDA, MHRA)*
- Global GSK CAP committee member *(Harmonization)*
- Lean Lab *(six sigma),* 50 % reduction in cycle times
- LIMS & CDS upgrade projects *(supporting 7 UK sites)*

Analyst, Section Head, Project Analyst, Team Manager Role(s)

GlaxoSmithKline

API Manufacturing

I held several positions across Quality Assurance *(QA)* and New Product Introduction *(NPIA)*, with increasing people, project and technical responsibilities.

QA, North Lonsdale Road, Ulverston, UK **(1989 –2000)**

- Analytical method *(development, validation & transfer)*
- JIT usage decisions/batch release *(intermediate products)*
- Managed teams, HPLC (9 staff), QC / Shifts (11 & 24)
- Presented to FDA on trace cross-contamination
- Production secondment – Bioprocess commissioning
- Setup and commissioned new Testing Lab in NPIA
- Software validation (FT-IR) & change *(HPLC LIMS)*
- Year 2000 – Lab implementation manager

Scientist

SmithKlineBeecham

Drug Discovery

Vibrational Spectroscopist.

POC, The Frythe, Welwyn, UK **(1985 – 1989)**

- Structural Identification - interpreted FT-IR spectra of novel drug compounds. FT-IR Research Studies
- MSc Thesis - Chemometric modeling of insoluble polymer spectra and physical properties

Critical Competencies

- **Analytical Science** — I have developed, validated and transferred a range of analytical methods, defined analytical strategies to support projects, for budgets, project needs and decisions based on the data. I am experienced in a wide range of analytical techniques, which include, for example, FT-IR, Fluorescence, Raman, NIR, UV-Visible, GC, GC-MS, HPLC, HPLC-MS, TLC, Dissolution, KF, Melting Point and reaction monitoring.
- **Analytical Communication** — I am a visual, creative and conceptual thinker. I absorb information quickly and can simplify / re-structure it to improve understanding. I use this skill when presenting, writing, training and creating marketing content. My written skills were developed as a scientist & operations manager and refined further in my consultancy. My NLP training has enhanced my self-awareness, flexibility and listening skills.
- **Problem Solving** — I am a natural problem solver, and I have been strongly involved in investigating problems and applying "***critical thinking***" throughout my career. I filter facts & information with the non-verbal communication of others, to build ***"problem specifications"***. This approach uses a blend of structured techniques *(e.g., Kepner Tregoe)*, with intuitive facilitation and strong listening skills.
- **Team Working** — My team working experience, 1:1 Belbin and cross-team profiling work enables me to be flexible when working in complex, virtual, global teams and matrix organizations. I adapt my approach to the situational needs *(team, workload and team dynamics)*, to help ensure delivery of 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 justified alternative analytical methodology to USP monograph testing *(equivalent, ICH validated).* As a consultant, my USP activity is proactive, monitoring Pharmacopeial Forum (PF) and publicizing changes. I have been particularly involved in evolution of USP <1058>, co-Charing the 2010 New Orleans AAPS round table discussion of USP <1058>, nominating Dr. R.D. McDowall *(to represent European)*. **Member of the Nominating Committee for the Council of Experts for 2025-2030**.

Additional Experience Dimensions

Area	Dimension
Analytical Science	• Analysed needs *(project / customer)*, developed and validated analytical methods
Budget	• Capital budgets *(to £300k)* and monitored revenue budgets *(to £2.7 million)*
Computer Systems	• Word, PowerPoint and Excel. New software evaluation and system change control
Management	• Delegating, prioritising, problem solving / decision making *(Kepner Tregoe)*
People Management	• Remote, direct and virtual. Recruited, mentored, motivated and lead people
Regulatory	• Inspection fronting *(cGMP)* and preparation *(e.g. Customer, FDA & MHRA...Etc.)*
Statistics	• Chemometrics, TQM, Lean Sigma, Experimental Design Techniques and QbD
Team Working	• Profiled teams *(using Belbin, VAK and NLP)* for team selection / or coaching
Validation	• Validated procedures, methods, software, and qualified Lab equipment.

Professional Membership

ISPE Membership *(299279)*
Deputy Chair - UK ISPE GAMP Community of Practice *(CoP)* Steering Committee

Publications and Documentation

I have written and reviewed many Lab compliance related articles and content. These cover different analytical compliance subjects and often include analysis of non-compliance findings. I contribute to GAMP® good practice guides and support knowledge sharing. Example publications are listed below:

Examples of Documents and Publications Reviewed *(Acknowledgement)*

1. **Are You Ready for the Latest Data Integrity Guidance? Part 1: Scope, Data Governance, and Paper Records**, Dr. R.D. McDowall, Spectroscopy, Vol. 36, Issue 11, 1st Nov. 2021. Link
2. **Ingenious Ways to Manipulate Peak Integration?**, Dr. R.D. McDowall, LC-GC International, Vol. 1, Issue 2, 1st Feb. 2024. Link
3. **Do We Qualify or Validate a Spectrometer?**, Mahboubeh Lotfinia and Dr. R.D. McDowall, Spectroscopy, Vol. 39, Issue 8, 6th Jan. 2025. Link
4. **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

Examples of Publications

1. **Trends in Analytical Instrument Qualification**, International Labmate, 5th Nov, 2008 Link
2. **20th Anniversary Special Feature – Validation and Qualification**, Pharmaceutical Technology Europe, 1st Dec., 2008 Link
3. **Use of RFID Asset Management Systems for Monitoring Analytical Instrumentation**, Paul Smith & Ralph M. Dioguardi, Pharmaceutical Technology, 1st Sep. 2010, Link
4. **FT-IR Identification: the Expertise Required to Ensure Compliance**, Pharmaceutical Technology Europe, Paul Smith, Jerry Sellers, Vol. 23, Issue 9, 1st Sep. 2011, Link
5. **GAMP Good Practice Guide: GxP Compliant Laboratory Computerized Systems 2nd Edition**, October 2012, ISBN: 9781936379507 *(developed through a SIG - special interest group)*
6. **Strategies for Successful Analytical Technology Transfer**, International Pharmaceutical Industry (IPI), Vol. 5, Issue 4, 2013 Link
7. **Harmonizing USP <1058> and GAMP for Analytical Instrument Qualification**, Pharmaceutical Engineering, Jan./Feb. 2014, Link *(see article for list of authors)*
8. **Data Integrity in the Analytical Laboratory**, Pharmaceutical Technology, Vol. 38, Issue 5, 2nd May 2014, Link
9. **Life Cycle Risk Assessment of HPLC Instruments**, Paul Smith and Dr. R.D. McDowall, LCGC Europe, Vol. 28, Issue 2, 1st Feb. 2015, Link
10. **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
11. **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
12. **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
13. **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
14. **GAMP Good Practice Guide: Computerized GCP Systems & Data**, 2nd Edition, Data Integrity Section,
15. **What Does Performance Qualification Mean for Infrared Instruments**, Paul Smith and Dr. R. D. McDowall, Spectroscopy, Vol. 35, Issue 4, 1st Apr. 2020 Link
16. **Are You Sure You Understand USP <621>?**, Paul Smith and Dr. R. D. McDowall, LC-GC International, 16th Sep. 2024. Link
17. **The Museum of Analytical Antiquities**, Paul Smith and Dr. R.D. McDowall, Technology Networks, 25th Nov. 2024. Link

Presentations and Compliance Events

My international experience includes close collaboration across geographical regions and different cultures throughout Europe and the world. I was part of the GSK "**Compendium of Analytical Procedures**" *(CAP)* committee *(global harmonization of analytical procedures)*. Additionally, I was involved with technology transfer *(from R&D to API sites)*, and year 2000 multi-site projects *(e.g. LIMS and CDS Upgrades)*.

As a compliance thought leader, I have frequently travelled to many parts of the world to present at conferences, compliance seminars, run workshops, training events, webinars and to give educational seminars at customer sites, covering a range of compliance subjects, non-compliance findings and trends. Commonly requested presentation subjects include analytical instrument qualification, audit preparation, data integrity, FDA findings / regulatory trends and analytical quality by design *(AQbD)*. I value presenting & sharing knowledge.

Example Workshops / Presentations for Regulatory Authorities -:

1. **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
2. **Ireland** *(then IMB)* **HPLC Compliance**, Workshop Presentation at IMB training day in Dublin, 14th Jan. 2014
3. **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)*
4. **Malaysia** *(NPRA)* **Full Day Agilent Compliance Seminar** *(7 Presentations by me)* at National Pharmaceutical Regulatory Agency (NPRA) Headquarters, Malaysia, 15th Aug. 2018

Example Webinars:

1. **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)*
2. **Hot Topic of the Season: USP Spectroscopy**, 20th Aug. 2015, Live Agilent Webinar *(Europe, Asia and USA)*.
3. **Gain Insights into Compliance Trends and Better Prepare for FDA Audits**, 8th Oct. 2018, LC-GC: YouTube Link
4. **Impact of the Pandemic on Regulatory Trends**, 26th Aug. 2020, Redica Systems *(not available on-line)*
5. **Data Integrity for Dissolution Laboratories**, Dissolution Discussion Group (DDG), 12th Aug. 2021
6. **Are Your Perpetuating Your Data Integrity Problems?**, Paul Smith and R.D. McDowall, 24th May 2022, Redica Systems: YouTube Link
7. **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.

Example UK Presentations / Workshops:

1. **Why is the Lean Lab so Popular**, GSK Global Manufacturing and Supply Conference, 24th May 2002. *(as GSK)*
2. **The Compliance and Regulatory Requirements of HPLC Training – and How to Satisfy Them**, PerkinElmer User Meeting, 19th May 2004 *(as Terasolutions)*
3. **Outsourced laboratory compliance and qualification services**, 3rd Annual Contract Manufacturing Conference, London, 18th Nov. 2009 *#(as PerkinElmer)*
4. **The Role of the Analytical Laboratory in Technology Transfer**, Visiongain Conference, 13th Dec. 2010 #
5. **Deconstructing UKAS to Develop Effective Compliance Strategies**, Nov. 2014, Agilent Seminar
6. **Confused by Data Integrity Guidance?**, ISPE UK Community of Practice *(CoP)*, 1st May 2018, GSK Stevenage, Link to PDF *(as Agilent)*
7. **Regulatory News and Intelligence Updates**, Each ISPE UK GAMP CoP Meeting *(2 per year)*
8. **Evolving Guidance on Laboratory Instruments**, Workshop at ISPE UK GAMP CoP, 24th Nov. 2024, GSK Stevenage *(as Compliance2425)*

Presentations and Compliance Events

I have given face to face presentations in Australia, China, Europe, India, Israel, Malaysia, Malta, Mexico, Puerto Rico, South Korea, Russian Federation, Thailand and the USA.

Presentations given in a particular country are updated to include the regulatory requirements and non-compliance findings / trends appropriate for that country / region. This is possible because I have access to regulatory intelligence data and through the development of tools to facilitate the analysis. Where presentations are in the public domain, PDF copies can be made available – otherwise, they remain the intellectual property of the organization I worked for at the time. The international presentations below are from my work at Agilent. *Note: After Covid 19 Pandemic, most presentations I gave were on-line.*

Example Overseas Presentations / Workshops:

1. **Israel** – **Trends in Laboratory Instrument Qualification**, Agilent Distributor Compliance Seminar, Tel Aviv, Paul Smith and Dr. R. D. McDowall, 29th Nov. 2011
2. **Poland** – **Preparing Your Laboratory for a Regulatory Audit**, Agilent Distributor Compliance Seminar, 13th Mar. 2012
3. **Hungary** – **How the Agilent Compliance Engine (ACE) 2.0 Supports Laboratory Compliance**, Agilent Distributor Customer Compliance Seminar, 8th May 2012
4. **Sweeden** – **Trends in Laboratory Instrument Qualification and FDA Warning Letters**, Agilent Compliance Seminar, Stockholm, 17th Oct. 2012
5. **Austria** – **Trends in Laboratory Instrument Qualification**, Agilent Compliance Seminar, Vienna, 16th Dec. 2012
6. **Denmark – Laboratory Audit Preparation**, Agilent Compliance Seminar, Copenhagen, 27th May 2014
7. **Russian Federation - GMP Deficiencies: FDA Warning Letters – How can we learn from these?** Agilent Compliance Seminar, Moscow, Nov. 2014.
8. **Malta** – **Laboratory Compliance Update and Agilent ACE**, Agilent Distributor Workshop, Valetta, 14th Nov. 2014
9. **Thailand** – **Laboratory Compliance by Design**, Agilent Compliance Seminar, Bangkok, 10th Mar. 2015
10. **India** – **Data Integrity – An Update on Regulatory Focus and Observations**, Agilent Compliance Seminar, Chennai, May 2015
11. **South Korea - Strategic QbD for the Analytical Laboratory**, Agilent Compliance Seminar, Seoul, Sep. 2015
12. **China** – **Quality of Laboratory Instrument Performance**, ISPE Annual Conference, Beijing, 21st Apr. 2015
13. **Germany** – **Insight from Regulatory Action**, Agilent Compliance Seminar, Frankfurt, 17th Jan. 2016
14. **Spain** – **Laboratory Instrument Qualification Workship**, Agilent Compliance Seminar, Madrid, 5th Apr. 2016
15. **France** – **Insights from Regulatory Action**, Agilent Compliance Seminar, Paris, 20th Mar. 2016
16. **Singapore** – **Leveraging Laboratory Asset Data to Make Informed Laboratory Decisions**, ISPE Annual Meeting, 28th Aug. 2016
17. **Italy** – **Systems Compliance – An Instrument Suppliers Perspective**, Agilent Compliance Seminar, Rome, 15th Mar. 2017
18. **Ireland** – **Data Integrity: From Guidance Papers to Practical Interpretation**, RQA Meeting, Dublin, 11th Oct. 2018
19. **Puerto Rico** – **Regulatory Trends – FDA Action and How to Leverage the New FDA Compliance Dashboards**, Agilent Compliance Seminar, San Juan, 28th May 2019
20. **USA** – **Analytical Instrument Qualification – A Continuum of Requirements**, Agilent Compliance Seminar, Salt Lake City, 5th Jun. 2019