

Ian R. Francis

Curriculum Vitae

Employment History

Novartis Pharma AG

2012 - 2025

Global Drug Development IT

- ***Information Security & Risk Manager***
- ***Global Quality Manager for Technical Research and Development IT***

Key Achievements:

- **EMA Inspection Lead:** Acted as the primary point of contact during a regulatory inspection by the Danish Medicines Agency on behalf of EMA (with Swiss Medic and FDA observers). The inspection was heavily focussed on validation of key clinical management systems used for trials critical to a Marketing Authorisation Approval (MAA), with a CSV specialist as part of the inspection team (*Ib Alstrup*). Despite challenging questions from the inspectors, the inspection was successful leading to a recommendation for Marketing Authorisation Approval by the EMA.
- **Promoting digital/automated validation processes:** In the role of system owner for key quality management systems (eQMS, Documentum D2, HP/Microfocus ALM), I have championed the move away from stand-alone documents and paper-based testing, to modern digital tools. Moving requirements out of traditional Office documents into a lifecycle management tool (ALM) greatly increases efficiency, and compliance, by ensuring traceability/coverage.
- **Establishing risk-based CSV:** Previous risk-based approaches did not provide clarity or value to end users, resulting in a checklist based mentality. I revised the approach entirely, but still within the GAMP framework parameters, provided clarity on the purpose and objectives of a true risk-based approach to CSV.

Responsibilities and Experience

As Domain Quality Manager for TRD, work closely with the IT Solution Groups and the Business QA, taking the role of Project QM in major projects, managing the validation of a wide variety of GxP relevant IT solutions. Examples include:

- Real-time integration Broker: an ESB-type solution to interface SAP and clinical trial management systems.
- NIRT: A custom in-house IRT solution
- Argus: SAE/Safety management system
- Drug-2-Patient: Custom solution for Clinical trial product tracking tool to support recalls.
- iRelease: Custom solution for release of clinical batches for distribution

- ⇒ Act as the domain ISEC Officer.
- ⇒ As the Risk Manager for Global Drug Development IT, manage the GDD IT Function risk register and report to the global IT leadership team.
- ⇒ Manage compliance for Crown Jewel assets within Global Drug Development.
- ⇒ Practical experience applying GAMP 5 and Computer Systems Validation within GxP (FDA/EMA) regulated environments.
- ⇒ Provide expert knowledge in the improvement and implementation of related areas of the global Quality Management System.
- ⇒ Acts as leader in the development, maintenance, and application of the Global IT Security & Compliance Framework within Global Drug Development IT Domain.

- ⇒ Acts as leader in providing guidance on the application of other governing frameworks, notably Computerised Systems Validation (GAMP), GxP/ERES compliance, quality management, and related IT Compliance topics (e.g. GDPR).
- ⇒ Acts as thought leader, driving innovation and improvement in IT Quality processes and solution development
- ⇒ Coaching and mentoring Quality and IT personnel in IT compliance and quality to support projects and services
- ⇒ Approve critical project deliverables (Classification, Validation Plan, Test Plan, Validation Report) across all regulated projects within the TRD domain.
- ⇒ Perform Tollgate Reviews (audits) for projects within Domain
- ⇒ Knowledge/experience in CSA (Computer Software Assurance) and related processes / documentation.
- ⇒ Knowledge and practical experience in applying GxP Guidelines; 21 CFR - Parts: 11, 210, 211, 820-QSR; Eudralex Annex 11- ERES, OECD and ICH Guidelines.
- ⇒ Experience validating and qualifying applications for different business areas as Supply Chain, Manufacturing, Labs, Regulatory, ITSM (IT Service Management) and Quality Systems, among others.
- ⇒ Experience developing validation documentation and testing protocols (IQ/OQ/PQ/UAT) within various SDLC phases, and processing documentation using an Electronic Testing System.
- ⇒ System Owner for global HP/Microfocus ALM and Documentum systems.
- ⇒ Experience in inspection readiness, inspections support and establishing action plans based on observations/findings after inspections.
- ⇒ Experience with regulatory agencies (e.g., FDA, EMA) presenting/explaining CSV documentation and processes, sharing details about IT GxP processes and establishing actions plans for any observation or recommendation.
- ⇒ Experience using Microsoft Office software, as well as application of technical writing best practices and principles. Experience writing, reviewing, and approving procedures and compliance documentation.
- ⇒ Experience validating document management, quality management, and test management systems.
- ⇒ Expert user of Microsoft Office suite (Word, Excel, PowerPoint, Visio, Project, Access) to deliver content and value.

BIOP AG

2010 - 2011

Principle Consultant, Life Sciences

In this role I provided Quality management, validation and compliance consultancy services for our 2 main clients (Novartis and Roche, see below). Additionally, I managed the internal Quality Management System and SOPs, validation of our Clinical Data Management Solution, and provided internal training on CSV and audit readiness.

2010 - 2011 Novartis, Basel, Switzerland

Role: Project Quality Manager

Computer System Quality Management

- ⇒ Managed Project and Operational Quality and Compliance for a variety of computerised systems including Clinical Dossier Publishing system, electronic Document Management system and a high performance Statistical Computing environment.
- ⇒ The role was broad in scope, involving managing GxP relevant development projects from the perspectives of IT quality, compliance with regulatory expectation, internal procedures and IT best practices, requiring pragmatic implementation solutions.
- ⇒ Strategic support within Novartis Pharma Development IT to enhance existing quality management systems and project methodologies to incorporate Risk-Based approaches, Agile techniques and Electronic Test Management.

2010 Roche, Basel, Switzerland

Role: Validation Manager

Validation support for European ERP system implementation

A continuation of the project started in 2006-2007, Roche were deploying their successful core solution across the EMEA region. Primary responsibility for compliance and validation of the Global Lot Tracing system implementation; a cross-system solution to globally collect batch tracing data to support batch recall, ePedigree and similar business functions.

Senior Consultant, Life Sciences Group, UK & Switzerland

In this role I provided quality management, validation and compliance consultancy services to many Life Science companies across Europe and North America. Below is a summary of some of these roles and locations:

2008-2010 Novartis, Basel, Switzerland**Role: Project Quality Manager**

- Worked within the existing Quality Management System and templates to define a risk-based Validation approach appropriate to the business needs.
- Provided Quality Management for key Clinical and support systems, including the Global Statistical and Programming system and the global electronic document management system used by the Development IT group.
- Championed the use of electronic test management tools (HP ALM) to streamline the testing process.

2007 Kyphon SARM, Neuchâtel, Switzerland**Role: Validation Manager**

- Validation manager within the deployment team for Oracle e-Business Suite
- Enhanced the QMS with validation policies.
- Managed user requirements and trained users and consultants on validation fundamentals.

2006-2007 F. Hoffman-La Roche, Basel, Switzerland**Role: Validation Analyst**

- Provided validation support for an ERP system implementation across 8 countries.
- Developed and maintained a database for managing over 5000 user requirements and 3000 test scripts.

2005-2006 Dales Pharmaceuticals, Skipton, UK**Role: Validation Manager**

- Led compliance and validation for the ERP (Oracle e-Business Suite).
- Delivered validation plans, qualification protocols, and governance procedures.

2005-2006 Zenosis, London, UK**Role: CSV Consultant**

- Validated a new Learning Management System and provided compliance guidance.

2005 American Red Cross, Washington DC, USA**Role: Qualification Manager**

- Managed IT infrastructure qualification for Medical Device (510K) applications.

2004 Sanofi Aventis, Paris, France**Role: Validation Analyst**

- Reviewed ERP system test case documents for quality and compliance, and managed traceability to specifications.

2004 OSI Pharmaceuticals, New York, USA**Role: Qualification Manager**

- Gap analysis of infrastructure processes and procedures.
- Delivery of key procedures to provide the IT group with documented best-practice processes.
- Training and support in applying concepts of qualification to the existing IT infrastructure, generating system qualification guidelines.

2004 Novartis Consumer Health, North America**Role: Qualification Analyst**

- Supported ERP implementation with IT infrastructure validation and reporting.

2004 Mylan Pharmaceuticals, Morgantown, USA**Role: Validation Manager**

- Delivered training on the SAP validation lifecycle, with an emphasis on a risk-based approach.

2003-2004 American Red Cross, Washington DC, USA**Role: Qualification Manager**

- Reviewed technologies and contributed to the validation master plan.

2003 Novopharm, Toronto, Canada**Role: Validation Analyst**

- Developed test scripts for LIMS implementation and advised on documentation compliance.

2003-2005 Fako İlaçları, Istanbul, Turkey**Role: Validation Manager**

- ERP Implementation - developed a comprehensive Quality Management System, covering all aspects of the system development lifecycle, such as

Change Management, Document Management, Software Design and Coding Standards, etc.

- Managed system lifecycle documentation for the implementation and operations

2002 Colorcon, Philadelphia, USA

Role: CSV Auditor/assessor

- Data center and associated infrastructure assessment. Assessment report and recommendations for remediation delivered.

GlaxoSmithKline

1995 - 2002

Role: Global Compliance & Validation Analyst

Role: LIMS Project Business Analyst

Role: Senior Laboratory Analyst (Primary Quality Assurance)

Cyanamid UK

1993 - 1994

Role: Analytical Technician (Pilot Plant)

Publications

Marc Schwartz, Frank Harrell, Jr., Anthony Rossini and Ian Francis, *R: Regulatory Compliance and Validation Issues; A Guidance Document for the Use of R in Regulated Clinical Trial Environments*, The R Foundation (<http://www.r-project.org/foundation/>), 2008

Ian Francis, *Data Privacy - Our Compliance Blind Spot*, ISPE (<https://www.ispe.org/data-privacy-compliance-blind-spot>) 2017 (Requires ISPE Login)

Professional Qualifications

BSc. (Hons.) Applied Chemistry

University of Portsmouth, Hampshire

Diploma in Industrial Studies

University of Portsmouth, Hampshire

Position Applied For:

The Role

We are looking for a motivated Quality Associate to join our European Quality & Compliance team, based in Basel. This role will play an integral part in advancing and maintaining our GDP/GMP documentation standards, ensuring inspection readiness, and driving process improvements across our quality systems.

Key Responsibilities

Manage, maintain, and continuously improve GDP and GMP documentation systems (SOPs, batch records, master documentation) to ensure full compliance with global Quality standards.

Build or update documentation processes and workflows, collaborating across Quality, Regulatory Affairs, Laboratory and Manufacturing teams.

Support audit and inspection readiness by preparing documentation, coordinating evidence generation, and responding to corrective/preventive actions.

Participate in continuous improvement initiatives: identify gaps, implement corrective actions, and contribute to training and competency programmes.

Work in a cross-functional, multilingual environment, liaising with local operations and global stakeholders.

Candidate Profile – Requirements

Proven experience in a regulated environment (pharmaceutical, biotech, laboratory) with responsibility for GDP and/or GMP documentation.

Demonstrated ability to build or refine documentation processes (for example: authoring SOPs, work instructions, documentation workflows, change control).

Background in Quality Assurance, Regulatory Affairs or Laboratory operations is highly desirable.

Fluent in English and the local language.

Strong interpersonal, collaboration and communication skills. Comfortable working on-site.