ELIQUENT
LIFE SCIENCES

OVERVIEW AND CAPABILITES

July 2024

The ELIQUENT Team

ELIQUENT Life Sciences is the powerful alliance of six global consultancies working as a collective, **coordinated Quality, Compliance and Regulatory team**.

This unprecedented assembly of experts enables a unique understanding of the life sciences industry and the unmatched expertise companies need when navigating today's evolving regulatory environment.

VALIDANT
ELIQUENT LIFE SCIENCES

Validant is a full-service life science consulting firm serving developers and manufacturers of pharmaceuticals, biologics, **medical devices,** and diagnostics worldwide. Validant provides strategy, execution, and ongoing support for a range of regulatory, compliance, and quality needs.

GREENLEAF HEALTH
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Greenleaf Health is a leading FDA regulatory consulting firm that provides strategic and technical guidance to pharmaceutical, biotechnology, and **medical device** companies researching, developing, and manufacturing innovative solutions to pressing global public health challenges.

DR DATAREVIVE
ELIQUENT LIFE SCIENCES

DataRevive is a regulatory consultancy firm that supports global pharma and biotech clients navigating to the regulatory approval pathway. DataRevive experts deliver CMC, preclinical, clinical, and GxP expertise to innovators seeking product approvals in major global markets.

ORIEL | STAT A MATRIX
ELIQUENT LIFE SCIENCES

Oriel Stat-A-Matrix is a global leader in training and consulting for business process improvement, **regulatory compliance, and quality management systems.** Oriel experts support regulatory compliance, product submissions, and processes improvements across the lifecycle.

IDEC
ELIQUENT LIFE SCIENCES

IDEC offers regionally specialized regulatory guidance and end-to-end product support for pharmaceutical innovators seeking approval in the **Japanese market.** IDEC experts specialize in product design, market strategy, commercialization, and product management strategies.

RAPPORT
ELIQUENT LIFE SCIENCES

RApport is a UK based regulatory consultancy supporting global life science innovators. RApport's specialized capabilities provide strategic and technical guidance to companies gaining and maintaining authorization for products in the European market.

Talent on Demand
Approach to GxP SME Support

RECENT EXAMPLES:

- Data Integrity/Lab Controls
- Sterility Assurance
- Annex 1 implementation
- Biosimilar Batch Certification
- Deviations improvement & backlog
- Inspection Readiness
- Organization Effectiveness
- Batch Record Review
- Quality Systems Design, Strategy and implementation
- Design Controls
- Risk Management/pFMEA

Strategy advisory
Access to thought leaders in Quality, Regulatory and Compliance

Tactical SME
Scale up options to critical projects & timelines

Monitoring
Ongoing support incl audits, training and reviews

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Full-Service Support

The combined achievements and substantial qualifications of the ELIQUENT team enables a **full-service engagement** that delivers **end-to-end support**. Together, we unlock regulatory excellence.

From the earliest phases of development, through regulatory submissions, to post-approval support, ELIQUENT's robust blend of technical skill and clinical expertise guide companies to approval and beyond.

With a global approach that includes both strategic direction and hands-on global support, ELIQUENT's customized PV services empower companies to operate with confidence.

ELIQUENT's team of highly specialized compliance experts build customized solutions that equip companies with best-in-class strategic support, technical expertise, and project-based solutions.

Our team of respected professionals and global experts bring an unmatched level of credibility and trust when interacting with regulators and guiding companies to remediation solutions.

ELIQUENT's customizable training programs equip teams and employees with the tools and skills to maintain regulatory processes and build a common culture of accountability.

Market Solutions

In the complex life sciences landscape, where innovation meets regulation, a trusted regulatory partner is paramount. No matter the **therapeutic area**, **modality** or **market**, our premier team of life science experts have the specialized skills to help.

Drugs & Biologics

ELIQUENT's team of experts provide strategic and technical guidance on drugs and biologics from product development to regulatory review and beyond post-market requirements.

Areas of expertise:

- Monoclonal Antibodies
- Enzyme Replacement Therapies
- Biosimilars
- Tissue-Based Therapies
- Vaccines

Devices & Diagnostics

Leverage our team's extensive experience as you navigate the process of bringing new devices and diagnostics to market and manufacturing them to quality standards.

Areas of expertise:

- Class I, II, and III devices
- Digital Health
- Molecular Diagnostics
- Immunoassays
- Laboratory Tests
- Companion Diagnostics

Advanced Therapies & CGT

Our team of regulatory and clinical experts apply their specialized skillset to move complex autologous or allogeneic therapies through the regulatory process into manufacturing and beyond.

Areas of expertise:

- Gene therapy
- Somatic cell therapy
- Tissue-engineered therapies
- Combined advanced therapies

Combination Products

Unlock the full potential of your combination product. ELIQUENT's supports companies developing combination products with expert guidance throughout the combination product lifecycle

Areas of expertise:

- Single-entity, co-packaged, and cross-labeled products
- Drug-coated devices
- Drug delivery systems
- Companion Diagnostics

Industry Due Diligence

ELIQUENT applies vast institutional knowledge to equip investors with the information needed to ensure life science transactions account for business objectives, regulatory risks, and the industry landscape

Areas of expertise:

- Product Development and Review
- Quality manufacturing
- Identification of Regulatory Risk

Global Solutions

Expertise beyond borders. ELIQUENT'S established and growing **global presence** spans the regulatory process and major markets. Our premier team of global regulatory experts support markets across the U.S., Europe, and Asia.

United States

ELIQUENT is a leading Food & Drug Administration (FDA) regulatory consulting firm that provides strategic and technical guidance to pharmaceutical, biotechnology, and medical device companies.

Our experts have shaped the landscape of FDA regulatory policy and strategy for decades. We bring this unrivaled knowledge and unique insight to our work with clients every day.

Europe

The ELIQUENT team applies their deep and diverse knowledge of European regulations to keep clients in lock-step with evolving global standards.

With decades of experience in the European market, our team understands the intricacies of the European Medicines Agency (EMA) and offers tailored solutions to ensure products meet and exceed the needs of our clients.

Asia: Japan & China

ELIQUENT offers regionally specialized solutions for the innovators across Asia. Our comprehensive solutions include:

JAPAN: Guidance to innovators seeking approval in Japan, the third-largest pharmaceutical market in the world.

CHINA: Customized solutions for Chinese innovators seeking authorization in the U.S. market.

Comprehensive Capabilities.

Unlocking regulatory excellence.

Comprehensive Capabilities

ELIQUENT is a trusted partner to global life science innovators. **Why?** Our unique platform goes beyond traditional consulting to deliver **end-to-end solutions**. No matter your pathway position, regulatory requirements, global market or therapeutic area – ELIQUENT's integrated solutions align with your regulatory goals to unlock success.

Regulatory Affairs — **Pharmacovigilance** — **Quality & Compliance** — **Remediation Solutions** — **Expert Training**

ELIQUENT LIFE SCIENCES

The convergence of unparalleled global experts working collaboratively to deliver integrated regulatory solutions.

Market Solutions

Guided by decades of regulatory and clinical experience, the ELIQUENT team delivers value to clients in the following markets:

- Drugs & Biologics
- Medical Devices & Diagnostics
- Advanced Therapies
- Combination Products
- Industry Investors

Pathway Solutions

As former regulators and industry leaders, our understanding of the product lifecycle is unrivaled. Clients turn to our team for objective guidance across the regulatory pathway, including:

- Nonclinical, Pre-Clinical & Clinical Support
- Regulatory Submissions
- Manufacturing & Distribution
- Post-market and Lifecycle Solutions

Global Solutions

ELIQUENT'S established and growing global presence spans the regulatory process and major markets. Our premier team of global regulatory experts support the following global markets:

- United States
- Europe
- Asia

Full-Service Support

Regulatory Affairs Solutions

Guided by decades of regulatory and clinical experience, and firmly grounded in the principles of public health, ELIQUENT's team of experts is unmatched. Clients count on us to provide objective advice and valuable insight throughout the product lifecycle. **ELIQUENT's full-service regulatory affairs solutions include:**

Pipeline Review & Optimization	Skilled evaluation and prioritization to effectively manage regulatory risk
Clinical Programs	Specialized guidance and strategic design of nonclinical, pre-clinical, and clinical programs
CMC Strategy	Risk-based design and effective implementation of phase-appropriate CMC solutions
Pathway Decisions	Expert support on product classifications, special designations, and expedited program pathways
Regulatory Meetings & Communications	Actionable strategies and insight for milestone meetings and regulatory communication
Regulatory Policy Guidance	Customized solutions to understand, implement, and comply with regulatory policies and programs
Marketing, Promotion & Labeling	Strategic direction on labeling requirements, promotional materials, and marketing programs
Lifecycle Support	Valuable expertise throughout the product lifecycle, including post-approval requirements and commitments

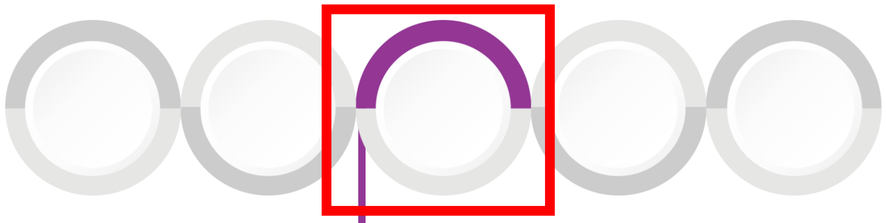
Full-Service Support

Pharmacovigilance Solutions

ELIQUENT's comprehensive capabilities are the gold-standard in pharmacovigilance. Our industry-recognize experts optimize practices to ensure consistency, compliance and operational efficiency, while aligning with evolving global demands. **ELIQUENT's full-service pharmacovigilance services include:**

Global Support	Trusted guidance when navigating and complying with global pharmacovigilance regulations
Adverse Event Reporting	Systematic identification, objective analysis, and strategic guidance responding to unintended occurrences
Regulatory Reporting	Technical skill and institutional knowledge of complex regulatory reporting obligations
Signal Detection	Expert development and implementation of detection processes, including reporting and risk communication
Risk Assessment & Management	Proactive identification, assessment and planning to manage potential risk and ensure regulatory compliance
Post-Marketing Surveillance	Established network experts to support commercial product safety systems and reporting functions
Risk Communications	Strategic development of communications plans to address emerging safety concerns and instill confidence in the market
Clinical Trials Safety Oversight	On-demand resources to support safety monitoring before and after regulatory approval

Full-Service Support

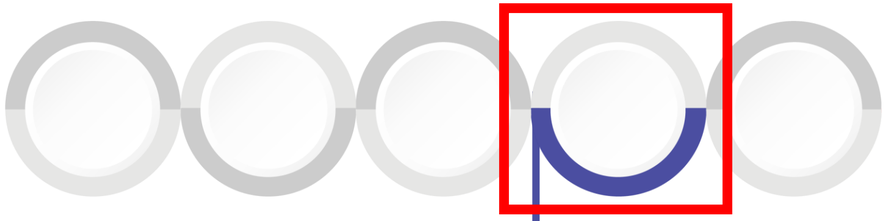


Quality & Compliance Solutions

A strong quality program is a cornerstone of regulatory success. With decades of experience and a track record of success, ELIQUENT is the industry leader in quality and compliance capabilities. Our team of unmatched experts guide companies to sustainable quality and regulatory excellence. **ELIQUENT full-service quality and compliance solutions include:**

Quality Systems	Objective evaluation and expert direction on quality system design, optimization & implementation
Inspectional Readiness	Customized strategies to prepare for inspections and align with regulatory expectations
Compliance & Enforcement Actions	Proven expertise when responding to regulatory compliance & enforcement actions
Supply Chain Optimization	Skilled support to evaluate and strengthen supply chain management practices
Good Clinical Practices	Risk-based methodology applied to the design and improvement of clinical quality systems
Laboratory Controls & Data Integrity Systems	Tailored solutions to ensure data integrity and manufacturing performance
Regulatory Meetings & Communications	Valuable guidance on regulatory communications, meetings, and correspondence
Consultation, Training & Regulatory Guidance	Strategic insight and actionable strategies spanning the product lifecycle

Full-Service Support



Remediation Solutions

ELIQUENT's team of respected professionals, along with a network of ready to deploy experts, work with companies to investigate, identify, resolve, and prevent both acute and systemic issues at regulated facilities. Together, we equip clients with the informed, objective guidance to detect and solve compliance problems earlier and more effectively. **ELIQUENT's full-service remediation solutions include:**

Compliance Assessments	Strategic and technical evaluations to identify areas of non-compliance & mitigate other potential risks
Rapid Response	Immediate deployment of compliance experts to provide valuable on-site support when time is of the essence
Customized Solutions	Actionable remediation plans to correct known problems, prevent future occurrences, and meet regulatory expectations
Comprehensive Communications	Valuable direction when interacting with and effectively responding to regulatory communications
Corrective Action Plans	Design and enable action plans that are both effective and sustainable for your business
Implementation Expertise	Tailored support to implement both acute and systemic improvements across facilities and product lines
On-Demand & On-Site	Skilled resources ready to support implementation plans, sustain compliance, and respond to evolving demands
Maintenance & Monitoring	Uphold the integrity of implemented practices with ongoing monitoring and maintenance
Third-Party Reporting	Trusted third-party reporting of progress against improvement commitments

Full-Service Support

Remediation Solutions

Regulatory Strategy Operation

- Regulatory and Clinical Strategy
- Lifecycle Management
- Product Gap Analysis & Remediation
- FDA/Agency Meeting Preparation
- IND, NDA/BLA, ANDA, IDE, 510(K), PMA Preparation
- Submissions & Publishing & eCTD
- CMC Strategy
- Advertising & Promotion
- Drug & Device Labeling
- Regulatory Affairs IT Systems
- Project Management
- Process Improvement & Implementation

Quality Systems Design ,Strategy, and Implementation

- Quality Systems Development
- Data Integrity
- Quality IT Systems
- Quality Remediation
- Management Controls
- Risk Management
- Design Controls
- Train and Qualify Staff
- New/Revised Standards & Regulations

Inspection Readiness and support

- Inspection Event Planning
- Inspection Readiness Culture SME
- Personnel Training & Interview Preparation
- Subject Matter Expert Support
- Post-Inspection Analysis

Health Authority Response & Remediation

- FDA/EMA/Health Authority Agency Intelligence
- Rapid Response to Inspections
- Remediation Support
- On-Site Remediation
- Project Management
- Coordination with Regulatory Counsel
- Third-Party Support

Auditing & Assessment

- Due Diligence
- Named Third-Party Oversight
- Internal Audits
- Authority Response
- Effectiveness Assessments
- Supplier Assessments

Lab Controls & Data Integrity

- Quality Control Operations Assessment
- Data Integrity Remediation
- Quality Control Organizational Assessment
- Interim Subject Matter Experts & Staffing

Interim Executive Leadership

- Consent Decree & Warning Letter Remediation Strategy
- Interim Executive Staffing
- Outsourcing Strategy

Interim Executive Leadership

- Leadership Mentoring
- Change Management
- Organizational Assessment
- Quality Goals and Metrics

Quality Operations Support

- Management Review
- Validation & Qualification
- Risk Management
- Laboratory Controls
- Batch Review
- Quality Engineering
- Exceptions
- Post Market Surveillance

Full-Service Support

Training Solutions

ELIQUENT experts provide in-person and remote training services to empower both leadership teams and employees with the skills and tools to create pragmatic problem-solving processes and maintain adherence to evolving regulatory, compliance, and quality standards.

Our training solutions equips internal teams to drive continual improvement and help build a common culture of accountability. **ELIQUENT's full-service training solutions include:**

In-person, virtual & on-demand	Training for teams, private groups, and individuals
Regulatory policies & procedures	Expert instruction on all aspects of regulatory programs across the product lifecycle
Quality Systems	Foundational and in-depth learning programs on quality management systems across the regulatory landscape
Inspectional readiness	Specialized programs to ensure readiness prior to regulatory inspections
Customized training programs	Flexible options to develop training programs on a variety of regulatory subjects

The ELIQUENT Difference

Redefining regulatory support.

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Case Studies

- ✓ CMO - ERP Software Selection
- ✓ CDMO - Data Integrity & IT Compliance Remediation Support
- ✓ Quality Transformation Initiative

Case In Point

Quality Transformation Initiative

CHALLENGE

A global pharmaceutical manufacturing site had **multiple product recalls and compliance issues** regarding its aseptic manufacturing site based in Europe.

SOLUTION

Validant deployed a quality transformation team of 7 consultants onsite in Europe to address, remediate and coach/mentor staff members on four core streams for their operations.

- ✓ People & Organization
- ✓ Process Robustness
- ✓ Equipment & Maintenance
- ✓ Quality Systems

The project composed of two phases (Phase 1 Assessment & Phase 2 Remediation) over an 11-month period working with both local and corporate leaders.

OUTCOME

- Addressed and **developed a compliance road map** for the site's operations.
- Enabled and supported the client in **remediating 175+ GMP** compliance/regulatory issues.
- **Educated the site's team** on regulations and best compliance practices for long-term success.
- **Successfully passed** a European Regulatory Inspection

Case In Point

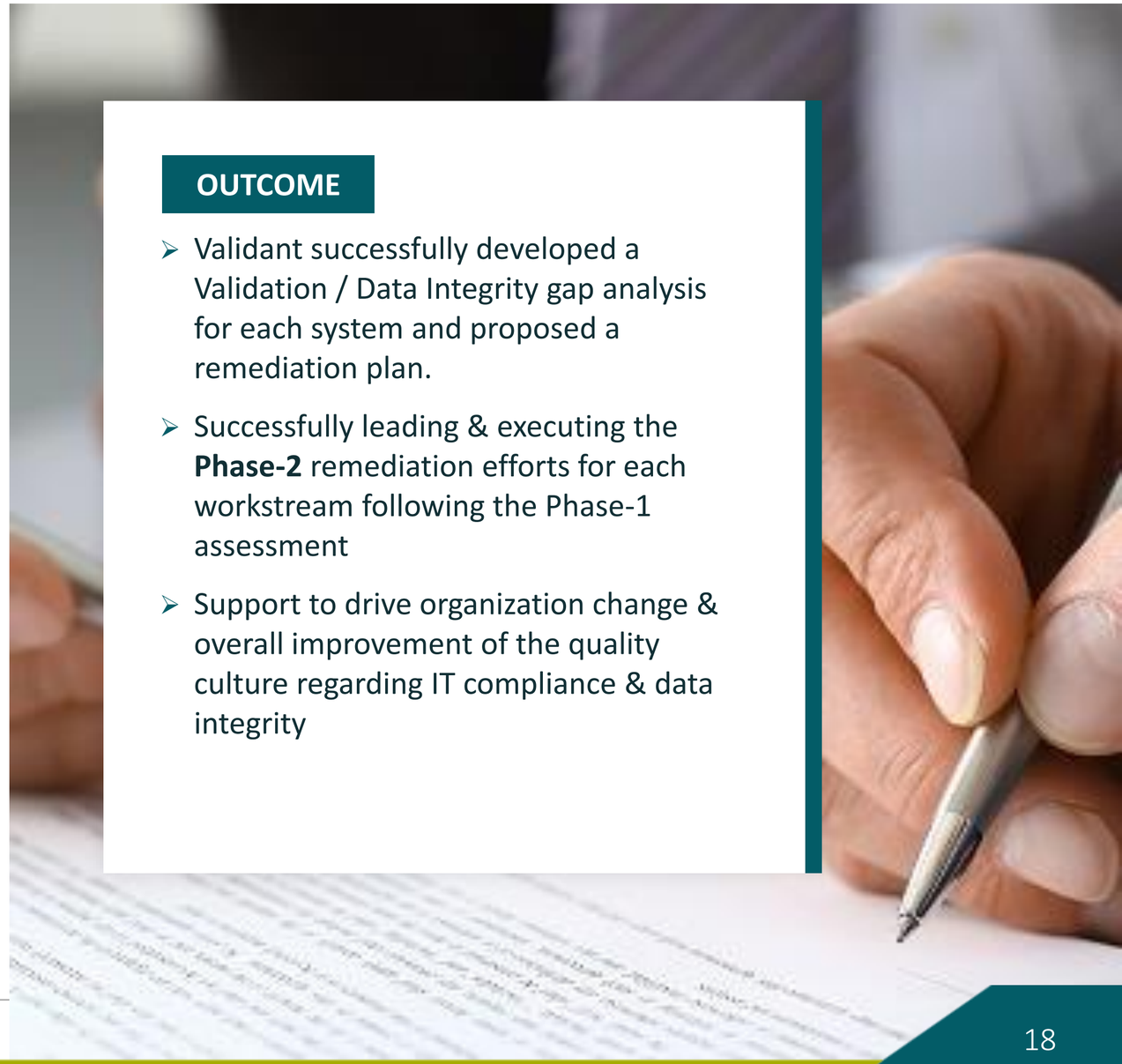
CDMO - Data Integrity & IT Compliance Remediation Support

CHALLENGE

The French company had a variety of GxP & CSV issues regarding the **IT infrastructure, BCP, Computerized Systems, Technology LifeCycle Management, Data Integrity, Governance & Organisation.**

SOLUTION

- ✓ Conducted **Phase-1** assessment (3 months), incl. 6 workshops (1-2 days) with over 15 users outlining critical/major/minor GxP issues
- ✓ Assessed a total of 55 systems (Lab apps, MS-Excel, Stand alone PC controlled equipment in MicroB, CellB, BioChem. etc. labs, QC & QA)
    - **Determine Data Integrity & CSV risk status of each system**
    - **Assess compliance to 21 CFR p11 / EU Annex 11**
    - **Review of:**
        - **Policies, SOPs, WI's, External Service Providers**
        - **Data Integrity Management controls**
        - **Security & Access controls**
        - **Change control of Roles & Responsibilities (RACI)**
        - **BCP**
        - **Technology LifeCycle Management**



OUTCOME

- Validant successfully developed a Validation / Data Integrity gap analysis for each system and proposed a remediation plan.
- Successfully leading & executing the **Phase-2** remediation efforts for each workstream following the Phase-1 assessment
- Support to drive organization change & overall improvement of the quality culture regarding IT compliance & data integrity

Case In Point

CMO - ERP Software Selection

CHALLENGE

The US company had multiple IT systems across Finance and Supply Chain, which were out of support and not compliant to GxP regulations i.e. Vendors out of business for some Inventory / procurement systems. As a result, there were major inefficiencies at a business process level requiring multiple work arounds / paper back up systems.
Major business risks / compliance risks associated with Data Integrity and business continuity for inventory systems

SOLUTION

- ✓ Review available analysis completed by the company
- ✓ Through discussions at Group and Site levels define high level system and business ERP requirements
- ✓ Identify potential Vendors and solutions in conjunction
- ✓ Issue a Request for Proposal to selected Vendors
- ✓ Review Vendor Responses
- ✓ Organize system demos for 2 target solutions (to be agreed)
- ✓ Support ERP selection decision making process with stakeholders.

OUTCOME

- ➢ Successufully supported the overall ERP selection process by identifying and shortlisting potential vendors within 4 months
- ➢ Ensured all compliance aspects were taking into consideration while meeting key operational needs
- ➢ Established a project budget and implementation strategy

Our thought leaders

European Partner Group

Kurt Moerck, Ph.D.

Partner: GxP Quality, Compliance and Regulatory Specialist

39+ years of experience within the pharmaceutical, medical device, and healthcare industry, including 30+ years' global experience at 3 of the largest worldwide pharmaceutical companies: SmithKline Beecham, Sanofi-Aventis, and Sandoz/Novartis, as well as Alcon Labs.

- ***Establishing and directing effective Audit and Compliance programs involved all sites in the USA, Europe, LATAM & Asia. Kurt also has extensive experience in the Quality and Compliance aspects of R&D operations, including Clinical Trials materials.***
- ***Vast experience in most dosage forms, including all forms of Drug Product (e.g. Steriles, Tablets, Ointments, etc.), Drug Substance, Biologicals/Biotech, Vaccines, Medical Devices, Combination Products, OTC Products Fractionated Plasma Products and Radiopharmaceuticals from both the quality and manufacturing perspective.***

Michael Ruck

Partner; IT Compliance/DI/CSV

30+ years of success across the bio & life sciences, and glass-technology industry, located in Germany, UK, Switzerland, Belgium, and now Ireland. Michael's broad areas of expertise include information technology strategy, governance, global operations in supply chain, manufacturing, quality & compliance management, shared services, and business process improvement.

- ***IT strategy, governance, and compliance;***
- ***global operations in supply chain, manufacturing, quality, shared services, and business process improvement;***
- ***transformational missions in both optimization of performance and growth of operating margins;***
- ***risk management and change/transformation management***

John O'Sullivan, Ph.D.

Partner: Quality Systems, GMP,GDP and Cold Chain

Quality Operations Leader with 40 years of diversified experience in the Pharmaceutical, Medical Device and Healthcare industries, including 20 years at Pfizer where he had quality oversight responsibility for all the company's manufacturing sites (APIs, Biotech drug substances, aseptic and solid oral dose finished products, medical devices) and distribution network.

- ***Quality oversight of global operations involved in the development, manufacture and distribution of drugs and medical devices.***
- ***Developing and deploying fit-for-purpose quality systems to achieve/maintain compliance with global (e.g. FDA, EMA) regulatory authority GMP/GDP requirements for APIs, drug substance and finished products (solid oral dose and aseptic)***
- ***Establishing and directing effective Audit and Compliance programs***
- ***Monitoring and enhancing manufacturing site Quality performance***
- ***Quality function organization, efficiency and effectiveness.***

Ann O'Connor

Partner: QA CMO Oversight, Combo Device, ex-HRPA

A pharmacist by background with over 35 years' experience in senior leadership roles in the Health Products Regulatory Authority (HPRA) and blue-chip multinational companies such as Grifols and Jazz Pharmaceuticals. Ltd. Specific specialisation in Governance, Quality and Regulatory Affairs and a history of providing global quality strategic direction and building high performing teams

Ann was a member of TOPRA Advisory Council from 2005 -2019 and was the winner of the TOPRA Communications award in 2011. She has also acted as a Preceptor for Pharmacy intern students and is a qualified Executive Coach.

- ***Regulatory inspection preparation & management,***
- ***cGMP/GMP compliance,***
- ***Process, systems, data integrity, training, deviations/investigations, due diligence.***

Executive Consultant & Partner, **John O'Sullivan**

John is an influential Quality Operations Leader with 40 years of diversified experience in the Pharmaceutical, Medical Device and Healthcare industries, including 20 years at Pfizer where he had quality oversight responsibility for all the company's manufacturing sites (APIs, Biotech drug substances, aseptic and solid oral dose finished products, medical devices) and distribution network. He has engaged with global regulatory agencies on quality policy and standards and has presented at several pharmaceutical conferences

John is based in Ireland and speaks English, French and Spanish.

ELQIUENT Life Sciences (VALIDANT) – Partner, Principal Executive Consultant (2022-Present)
United Parcel Services – Humanitarian support for vaccine distribution in Africa (2021-2022)
Pfizer Global Supply - Vice President, Quality Operations (2010- 2021)
Pfizer Global Supply – Various Quality leadership roles at site and regional level, covering product development, internal manufacturing, CMOs and Country Offices (1999-2010)
Baxter Healthcare - Quality Manager, Ireland Manufacturing (1991-1995) & Quality Director, Renal Division Europe (1995-1999)
Yves Rocher – Quality Manager Cork Manufacturing Site (1982-1991)

Projects
- Quality System development, implementation, assessment and enhancement
- Regulatory Agency inspection readiness, inspection performance/response and remediation
- Quality Culture development
- Deviation/CAPA enhancement

Extensive experience in:
- Quality oversight of global operations involved in the development, manufacture and distribution of drugs and medical devices
- Developing and deploying fit-for-purpose quality systems to achieve/maintain compliance with global (e.g. FDA, EMA) regulatory authority GMP/GDP requirements for APIs, drug substance and finished products (solid oral dose and aseptic)
- Establishing and directing effective Audit and Compliance programs
- Monitoring and enhancing manufacturing site Quality performance
- Quality function organization, efficiency and effectiveness.

Education:
B.Sc.Pharm University College, Dublin; Ph.D. Trinity College, Dublin; Certified Diploma in Accounting & Finance (*ACCA)*

Medical Device SME, **David Telling**

A Senior Quality & Regulatory Director for the Medical Device industry in Europe benefiting from more than 35 years' experience in various Quality roles, with the last 18 years in senior management positions within the MedTech environment.
Offering pragmatic Quality & Regulatory solutions to system development and remediation projects based upon a “can-do” approach.

ELIQUENT Life Sciences – Partner - Medical Device QA/RA
ELIQUENT Life Sciences – Multinational Pharmaceutical Manufacturer (United States) – Medical Device SME
ELIQUENT Life Sciences - Multinational Device Manufacturer (United Kingdom) – Acting Quality Director, Project Lead MDD Remediation
ELIQUENT Life Sciences – Multinational Device Manufacturer (United Kingdom) –Dutch Ophthalmic Research Center (Netherlands) – Acting Quality & Regulatory Director
Dutch Ophthalmic Research Center (Netherlands) – Project Lead FDA Readiness
Smith & Nephew (2004 – 2017) – VP Quality Assurance/Downstream Quality Director EU ANZ/UK & Germany Quality Director/UK Quality Director

Projects

- **Multinational Pharmaceutical Manufacturer (10 Months) –** Adoption of a Medical Device into the exiting Pharmaceutical QMS and subsequent preparation for initial and follow-up MDSAP Notified Body audits
- **Medical Device Manufacturer (12 Months)** - management of all quality processes including design control, Complaint Handling, Vigilance reporting, documentation, quality planning, CAPA and deviations Preparing & hosting Notified Body ISO13486:2016 & MDSAP audits (post remediation)
- **Medical Device Manufacturer (18 Months)** - Project Management of a significant MDD & MDSAP remediation project including recruitment / vetting of additional SME resources as necessary to achieve project goals including risk management, sterilization validation, procedural development, design file improvements and training. Writing and/or re-writing procedures where appropriate SME support not available.
- **Dutch Ophthalmic Research Center (10 Months)** - Management of all Quality & Regulatory processes including. validation, design control, Complaint Handling, Vigilance reporting, Global Product registrations and submissions. Preparing and hosting Notified Body ISO13486:2016 / MDSAP audits and FDA Inspections (US)
- **Dutch Ophthalmic Research Centre (15 Months)** - Project Management of a significant FDA readiness project including identification and secondment of internal staff to appropriate tasks. Reporting of project status to the Board of Directors.

Strengths include

- Pragmatism in cGMP Quality Assurance and/or Regulatory Affairs (FDA, MDD/MDR, MDSAP)
- Hosting regulator audits / inspections (Front-room / Back-room management)
- Harmonization of Quality systems across sites internationally.
- Management of Class III orthopedic devices (EU & FDA)

Education / Languages:

- Mechanical Engineering (Gloucestershire College)
- Multiple Quality training courses (Auditor / MDSAP / MDR / Validation)
- English (native) French (basic) German (minimal)

Executive IT GxP/DI/CSV SME, **Michael Ruck**

Michael is an accomplished senior executive and board member in international high profile leadership roles with more than 30 years of success across the Bio & Life-Sciences, and Glass-Technology industry, located in Germany, UK, Switzerland, Belgium, and now Ireland. Michael comes with broad areas of expertise include information technology strategy, governance, global operations in supply chain, manufacturing, quality & compliance management, shared services, and business process improvement. Fluent in both English and German.

ELIQUENT Life Sciences (Validant) – Partner & Principal Executive Consultant, IT/CSV/GAMP/Data Integrity/Supply Chain/Operations (2021-Present)
Johnson & Johnson – Global Head, Sr. Director, Technologies (2018-2020)
Janssen (J&J) - Global Head, Technology Strategy & Operations. (2012-2018)
Janssen (J&J)– WW VP, IT JSC Manufacturing, Sourcing, Tech Ops (2012-2016)

Extensive expertise in:
- IT strategy, Governance & Compliance.
- Global operations in supply chain, manufacturing, quality, shared services, and business process improvement.
- Transformational missions in both optimisation of performance & growth of operating margins.
- Risk Management and Change/Transformation management.

Areas of responsibility included:
- Design & delivery of the Technology Strategy
- Digital Roadmap – Design & deliverables incl. Data Architecture & supporting systems.
- Computer System Validation & Assurance (cGxP: US FDA 21 CFR p11; EU Annex 11), Data Integrity ("ALCOA+”)
- Due Diligence assessments, Audits, mitigation/remediation planning & execution.
- Digitalisation organisation/governance & compliance.
- Planning (RfI, RfP, RfQ) of ERP, MES, Historian, LIMS, WMS, PAT, DCS, SCADA for plants, labs, warehouses.
- Assessments & Audits in relation to Supply Chain, Manufacturing, Quality Management, OT & IT performance.
- Interim Operations, Organisational Change, Program & Project Management.

Education / Associations:
Michael has earned Bachelor of Science in Business Administration (IT/Computer Sciences) from the University of Applied Sciences, Pforzheim, Germany, and an LLM with Merit in Information Technology Law from the University of Edinburgh Law School.
Michael has a Diploma in General Management (Executive Program). Additionally, Michael is certified in Process Excellence/Six Sigma (Green Belt) and Computer System Validation (GAMP4).
Keynote speaker at international Bio-/Life-Sciences industry conferences, and a Visiting lecturer at the Hamburg University of Applied Sciences, Germany.

Executive Consultant & Partner, **Kurt Moerck**

Mr. Moerck is a bilingual (English/German) GMP Quality and Compliance professional with decades of global experience within the Pharmaceutical, Medical Device and Healthcare Industry, including over 30 years' spent with global industry leaders SmithKline Beecham, Sanofi-Aventis, Novartis/Sandoz, and Alcon Labs. Kurt is a USA citizen having lived and worked for the last 28 years in Europe and is now based in Germany.

Validant – Partner, Inspection Management and Compliance (2020-Present)
Novartis Global - Senior Advisor, Inspection Management and Compliance (2016-2018)
Sandoz International - Global Head, Inspection Management and Compliance Support, Global Quality Assurance. (2014-2016)
Sandoz International - Global Head, Audit and Compliance (2011-2014)
Sanofi Sandoz Aventis - Associate Vice President, Global Audit and Compliance, Industrial Quality and Compliance (2005-2011)
Aventis Pharma - Associate Vice President, Global Audit and Compliance, Industrial Quality and Compliance (1996-2004)

Projects

- Establishing and directing "Mock Inspection" activities
- Regulatory Agency Inspection Readiness Preparation and Filing strategies across Sandoz Sires and Key Suppliers
- Remediation of Consent decree and Warning letter
- Regulatory dossier assessment and preparation

Strengths include

- Establishing and directing effective Audit and Compliance programs involved all sites in the USA, Europe, LATAM & Asia. Kurt also has extensive experience in the Quality and Compliance aspects of R&D operations, including Clinical Trials materials.
- Vast experience in most dosage forms, including all forms of Drug Product (e.g. Steriles, Tablets, Ointments, etc.), Drug Substance, Biologicals/Biotech, Vaccines, Medical Devices, Combination Products, OTC Products Fractionated Plasma Products and Radiopharmaceuticals from both the quality and manufacturing perspective.

Education / Languages:

- B.S. from Florida Southern College and his M.S. and Ph.D. degrees from North Carolina State University. Fluent in both English and German.

Executive Consultant & President, Brian Burns

Brian Burns is President and a Quality leader at Validant, now part of Eliquent Life Sciences and is based in the New England region. Brian brings deep executive experience in Quality and Regulatory strategy and improvement with a track record of comprehensive quality performance improvement.

ELQIUENT Life Sciences (VALIDANT) – President (2016-Present)
Haemonetrics Corporation . Executive Vice President Global QA, RA and Medical Affairs (2014-2016)
Fresenius Medical Corporation – Senior Vice President, NA QA and RA (2012 to 2014)
Boston Scientific Corporation - Executive Vice President, Global QA, RA, Safety (2000-2012)
Allegiance / Cardinal Healthcare – General Manager, Thermal Business (1998-2000)
Baxter Healthcare Corporation - Interim Plant Manager/Plant Quality Manager, Mannford, OK (1996-1997)

Projects
- Institutionalizing corporate quality systems
- Management and improvement of complaint handling, operational metrics, supplier quality, clinical quality, and global quality systems
- FDA Remediation Support and strategy
- Training both prospectively and while under FDA Warning Letters
- Medical Device Regulatory Advisory Support

Extensive experience in:
- Quality Strategy
- ISO / FDA / MDD / EU MDR and IVDR / CMDCAS QSR, GMP, GLP, CFDA, JPAL and GCP Quality Systems
- Maintenance and Compliance Globally
- Corporate Warning Letter Remediation
- Quality Metrics
- Quality Culture

Education:
UNIVERSITY OF ARKANSAS, B.S., Chemical Engineering with minors in Mathematics and Chemistry

US Partner Group (Sample)

BRIAN CORRIGAN

EVP, Regulatory Policy

15+ years in the biopharmaceutical industry focused on regulatory policy development and strategic clinical development support.

JOHN TAYLOR

President and Principal, Compliance & Regulatory Affairs

Former FDA senior official, acting in high-profile positions at the Agency and senior leadership roles within industry.

JOHN JENKINS, M.D.

Principal, Drug & Biological Products

Former Director of the Office of New Drugs within the FDA's Center for Drug Evaluation and Research (CDER).

BOB MEYER, M.D.

Principal, Drug & Biological Products

A leader in drug and biological product lifecycle management with 30 years of regulatory and academic leadership.

KAREN MIDTHUN, M.D.

Principal, Drug & Biological Products

28-year career in public service, including as Director of the FDA's Center for Biologics Evaluation and Research (CBER), 2009-2016.

DANIEL SCHULTZ, M.D.

Principal, Medical Device & Combo. Products

35-year career includes service as a physician and as Director of the FDA's Center for Devices and Radiological Health (CDRH).

DAVID ELDER

Principal, Regulatory Compliance

23-year veteran of the FDA, with prominent roles in domestic and foreign inspections, recalls and emergencies, and compliance actions.

SANDRA KWEDER, M.D.

Principal, Drug & Biological Products

Former Deputy Director of the FDA's Office of New Drugs and Deputy Director of the FDA's Europe Office and Liaison to the EMA.

CYNTHIA SCHNEDAR

Principal, Regulatory Compliance

30-year career as a compliance expert; formerly Director of the Office of Compliance for the FDA's Center for Drug Evaluation and Research (CDER).

KALAH AUCHINCLOSS

EVP, Regulatory Compliance

More than 15 years of experience on Capitol Hill, in the private sector, and at the FDA, including role as Deputy Chief of Staff.

MAURA NORDEN

EVP, Medical Device & Combo. Products

15+ years of experience advising FDA-regulated entities, investors, and public health organizations on a broad range of FDA regulatory matters.

MARK KRAMER

EVP, Medical Device & Combo. Products

17-year FDA career includes establishing and directing the Office of Combination Products and leading interdisciplinary review teams in CDRH.

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