ELIQUENT
LIFE SCIENCES

Pharmacovigilance & Risk Management **Solutions**

Regulatory clarity – from thought to finish.

ELIQUENT Life Sciences.

Setting a new standard for regulatory clarity - from thought to finish.

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Who is ELIQUENT?

ELIQUENT Life Sciences is a leading global regulatory, quality & safety consulting firm delivering integrated solutions across the product lifecycle. We are a premier team of regulatory experts delivering the solutions that life sciences innovators need to gain and maintain market authorization for their products.

Trusted **Partner**

ELIQUENT is the singular regulatory resource that clients around the world trust.

No matter your pathway position, regulatory requirements, global market or therapeutic area – ELIQUENT's integrated solutions align with your regulatory goals to unlock regulatory success.

Unprecedented **Assembly**

ELIQUENT's foundation is built on experts with the foremost strategic and technical skill.

Our unprecedented assembly of regulatory leaders, industry experts, and technical specialists collaborate seamlessly to deliver objective, reliable guidance across the product lifecycle.

Integrated **Solutions**

Our unique platform and team of cross-functional experts deliver integrated solutions that equip clients with a premier regulatory resource.

Together, we redefine regulatory consulting with integrated solutions that unlock success and clear the path to better health.

Why ELIQUENT?

ELIQUENT's full-service platform and team of cross-functional experts deliver integrated solutions that equip clients with a premier regulatory resource. Together, we redefine regulatory consulting and clear the path to better health.

Skilled

Our unprecedented assembly of global regulatory experts set the industry standard with an unmatched level of skill, capabilities, and insight.

Specialized

We specialize in life sciences. No matter the pathway or complexity of your challenge, our premier team of life science regulatory consultants have the skills to help.

Scale

Our carefully curated network of global experts enables the right team, with the right expertise, at the right size, in the right location to meet your needs.

Speed

When time is of the essence – around the corner or across the globe – our agile expert teams are ready on-demand for your most complex challenges.

Scope

Our capabilities run deep – the ELIQUENT team offers a rare blend of knowledge spanning therapeutic areas, regulatory pathways, quality systems, and global markets.

375+ years

of combined experience at **global health authorities**

Michele **Dougherty**, Ph.D.
Regulatory Affairs – U.S.
10+ years at **FDA**

Kalah **Auchincloss**, J.D.
Quality & Compliance
6+ years at **FDA**

John **Taylor**, J.D.
Quality & Compliance
20+ years at **FDA**

Kristen **Grumet**
Quality & Compliance
8+ years at **FDA**

Sandra **Kweder**, M.D.
Drugs & Biologics
33+ years at **FDA**

Sarah **McGary, M.D.**
Drugs & Biologics
18+ years at **FDA**

Dan **Schultz**, M.D.
Medical Devices
20+ years at **FDA**

Heather **Rosecrans**
Medical Devices
33+ years at **FDA**

David **Elder**
Quality & Compliance
23+ years at **FDA**

Chris **Leptak**, M.D., Ph.D.
Drugs & Biologics
14+ years at **FDA**

Mark **Kramer**
Combination Products
17+ years at **FDA**

Donald **Ashley**, J.D.
Quality & Compliance
6+ years at **FDA**

Shelley **Gandhi**
Pharmacovigilance
19+ years at **MHRA**

Brian **Mayhew**
Regulatory Policy
4+ years at **FDA**

Tom **Berry**, Pharm.D.
Quality & Compliance
20+ years at **FDA**

Steven **Bowen**, Ph.D.
Drugs & Biologics
8+ years at **FDA**

Lydia Martynec, M.D.
Drugs & Biologics
20+ years at **FDA**

Tiffany **Lucas**, Ph.D.
Drugs & Biologics
6+ years at **FDA**

Silvana **Borges**, M.D.
Drugs & Biologics
17+ years at **FDA**

Grace **McNally**
Quality & Compliance
30+ years at **FDA**

Robin **Huff**, Ph.D.
Drugs & Biologics
7+ years at **FDA**

Ann **O'Connor**
Combination Products
17+ years at **HPRA**

William **Tillet**
Regulatory Affairs - EU
2+ years at **UKHSA**

Shenggang **Wang**, Ph.D.
Regulatory Affairs
3+ years at **FDA**

Vincent **Li**, Ph.D.
Drugs & Biologics
5+ years at **FDA**

Dawn **Wydner, Ph.D.**
Quality & Compliance
10+ years at **FDA**

Integrated Solutions

ELIQUENT's integrated suite of solutions enables a full-service engagement that delivers end-to-end support. **Together, we unlock regulatory excellence.**

Regulatory Affairs

From the earliest phases of development, through regulatory submissions, ELIQUENT guides companies to approval and beyond.

PV + Safety

Customized global pharmacovigilance and safety solutions empower companies to operate with confidence.

Quality & Compliance

Specialized solutions equip companies with best-in-class strategic support, technical expertise, and project-based solutions.

Remediation Solutions

Unmatched level of credibility and trust when interacting with regulators and guiding companies to remediation solutions.

Talent Solutions

Network of hand-picked, ready to deploy global experts ensure the right talent at the right place and time.

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.

Market Solutions

Guided by decades of experience, we understand what it takes to bring innovations to market.

- Drugs & Biologics
- Medical Devices & Diagnostics
- Combination Products
- Advanced Therapies & CGT
- Cosmetics
- Radiopharmaceuticals

Pathway Solutions

Clients turn to our team of former regulators and industry leaders for objective guidance across the regulatory pathway.

- Nonclinical
- Preclinical
- Clinical
- Regulatory Submissions
- Manufacturing & Distribution
- Post-Market Solutions

Global Solutions

ELIQUENT'S established global presence spans the regulatory process and provides expert support across global markets.

- Global Market Entry
- United States
- Europe
- Asia

Specialized Solutions

ELIQUENT provides specialized solutions that are tailored to the unique needs of the life sciences industry.

- Industry Due Diligence
- Regulatory Policy
- Expert Training
- Regulatory & Medical Writing
- Litigation Support

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 combo 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

Radiopharma-ceuticals

ELIQUENT understands and meets the unique challenges and opportunities facing radiopharmaceuticals - complex oversight, short-lived isotopes, evolving global requirements, and cutting-edge scientific advancements.

Areas of expertise:

Regulatory submissions
Market Authorization
Strategy & Development
Lifecycle Management
Regulatory Compliance

Pathway Solutions

ELIQUENT guides innovators on their path to approval and beyond. As former regulators and industry leaders, our understanding of the product lifecycle is unrivaled. ELIQUENT's highly specialized experts provide both strategic direction and hands-on execution services to to support clients from the earliest phases of development to post-approval regulatory support.

Nonclinical & Preclinical Support

ELIQUENT's customized support guides companies through crucial nonclinical and preclinical development phases with precision and expertise.

Clinical Programs

With a proven track record of regulatory success, our team delivers objective guidance and unparalleled support for your complex clinical program.

Regulatory Submissions

ELIQUENT applies extensive regulatory experience to develop the best regulatory approach for a product and develop a comprehensive strategy to achieve a successful result.

Manufacturing & Distribution

ELIQUENT evaluates and strengthens systems with an eye toward optimizing processes, mitigating risks, and creating a culture of compliance, while meeting business objectives.

Post-Market & Lifecycle Support

Our industry-recognized experts deliver valuable insight throughout the product lifecycle to ensure sustained post-market vigilance.

Global Solutions

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

United States

ELIQUENT is a leading FDA regulatory consulting firm. 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.

Global Market Expansion

ELIQUENT provides end-to-end solutions that support companies navigating complex global regulations. Whether launching a new product or expanding into new regions, ELIQUENT works with innovators to mitigate risks, streamline approvals, and maintain compliance across evolving regulatory landscapes.

Europe

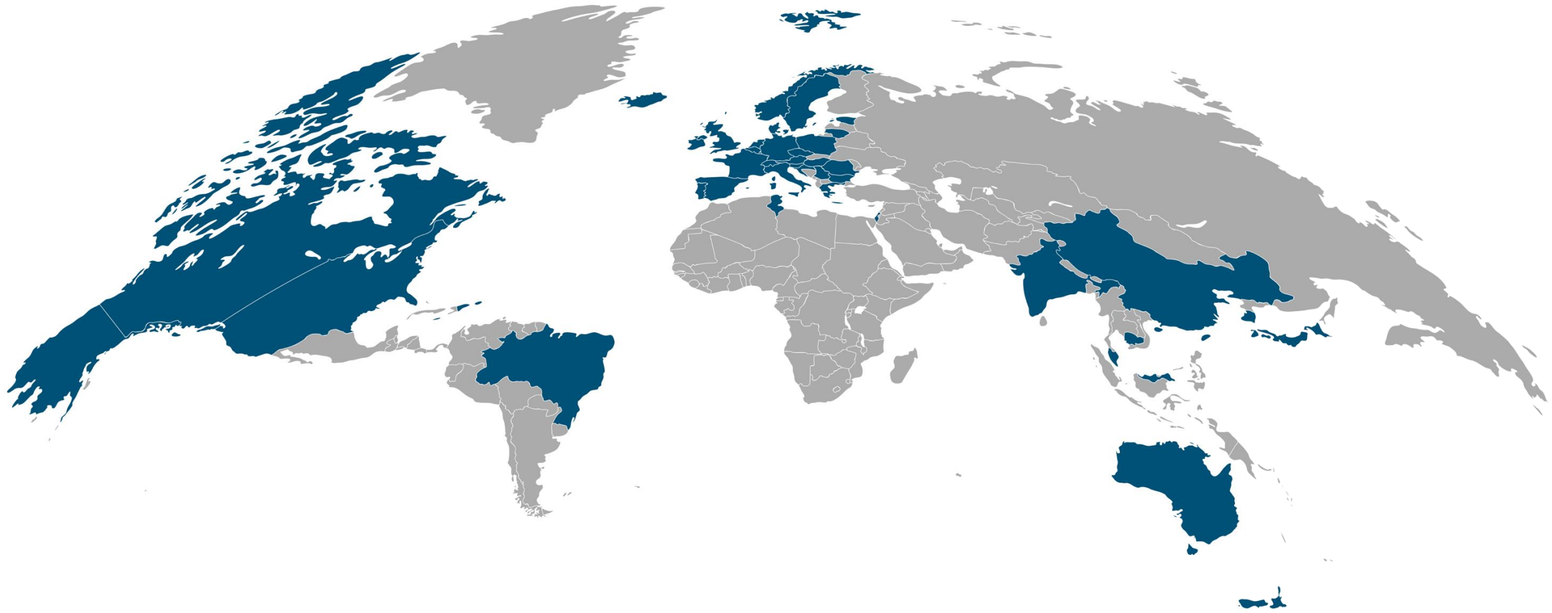
With decades of experience in the European market, our team understands the intricacies of the European Medicines Agency (EMA) and offers tailored solutions that keep clients in lock-step with evolving global standards.

Asia

ELIQUENT offers regionally specialized solutions for innovators across Asia. Our team of highly specialized experts partner with innovators to develop a synchronized, global go-to-market approach that unlocks the full potential of the Asia market and leverages the strategic advantages of Japan's regulatory landscape.

Expertise
Beyond Borders

Since 2022, ELIQUENT has provided expert support to clients across **51 countries** - ensuring seamless market access, regulatory solutions, and compliance worldwide.



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- Serbia
- Singapore
- Slovenia
- Spain
- Sweden
- Switzerland
- Taiwan
- Tunisia
- United Kingdom
- United States

Pharmacovigilance & **Risk Management** Solutions

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Integrated Solutions

ELIQUENT's integrated suite of solutions 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, ELIQUENT guides companies to approval and beyond.

Customized global safety and pharmacovigilance solutions empower companies to operate with confidence.

Specialized solutions equip companies with best-in-class strategic support, technical expertise, and project-based solutions.

Unmatched level of credibility and trust when interacting with regulators and guiding companies to remediation solutions.

Network of hand-picked, ready to deploy global experts ensure the right talent at the right place and time.

Integrated Solutions

Pharmacovigilance & Risk Management

ELIQUENT's pharmacovigilance capabilities are the industry gold-standard. Our expert team optimizes practices to ensure consistency, compliance, and operational efficiency, while aligning with evolving global demands. **ELIQUENT's full-service pharmacovigilance solutions include:**

Technology Enablement

ELIQUENT modernizes pharmacovigilance systems to align with business goals and ensure scalable, compliant performance.

Safety System Modernization

Our team delivers inspection-ready pharmacovigilance systems that streamline data, support oversight, and scale with compliance.

Compliance Capabilities

ELIQUENT ensures inspection readiness and practical solutions to keep safety operations ahead of regulatory expectations.

Operational Harmonization

Our experts drive compliant, scalable safety operations by aligning people, processes, and performance across global teams.

Risk Management

ELIQUENT embeds proactive, lifecycle-wide risk management
to strengthen safety strategy and ensure compliance.

Organizational & Talent Solutions

We build scalable pharmacovigilance teams - equipping your organization to lead in a dynamic regulatory environment.

Pharmacovigilance | Comprehensive Capabilities

ELIQUENT's integrated regulatory, quality, and safety solutions are designed to support companies bringing their products to market and maintaining global compliance. ELIQUENT provides the expert guidance to ensure regulatory success.

Operational Harmonization

Driving performance, efficiency, and compliance across global safety operations

Process Optimization: Streamline and redefine pharmacovigilance processes using LEAN, Six Sigma, and ISO principles.

Safety Operations: Ensure alignment with global safety standards across all operational levels.

Risk Reduction: Improve compliance through documentation, process, and team alignment.

Cost Optimization: Identify and implement strategies to reduce operational costs while maintaining quality.

Safety Systems Optimization

Building reliable, scalable systems to manage safety data and reporting

ELIQUENT works with clients to optimize the following systems:

Regulatory Reporting Platforms: Ensure timely and accurate submissions across complex global requirements.

Adverse Event Reporting: Support systematic identification, analysis, and management of safety data.

Signal Detection & Risk Management Tools: Early identification of potential safety concerns.

Compliance Capabilities

Strengthening readiness, resilience, and regulatory alignment

Regulatory Requirements: Operationalize evolving global requirements within safety systems.

Inspectional Readiness: Prepare systems, teams, and documentation for successful inspections.

Audits & Gap Assessments: Conduct proactive assessments to identify and close compliance gaps.

CAPA Close-Outs: Drive effective, sustainable resolutions through root cause analysis and action planning.

Pharmacovigilance | Comprehensive Capabilities

ELIQUENT empowers organizations to achieve compliant, scalable safety operations that flex with evolving demands. Whether you're scaling globally or refining internal workflows, we ensure your people, processes, and performance are in sync.

Technology Enablement

Modernizing safety infrastructure for scale, agility, and efficiency

Technology Audits: Assess technology options to meet business needs

Select and Implement New Technology: Guide full lifecycle from vendor selection through implementation.

Data Migrations: Manage validated, risk-mitigated transfer of safety data between systems

Safety System Upgrades: Manage enhancements and configuration updates to ensure performance.

Organizational & Talent Solutions

Building capable, adaptable teams that power your pharmacovigilance strategy

Staff & Project Augmentation: Provide skilled resources to support implementation and ongoing operations.

Capacity Planning & Management: Forecast and manage team needs in step with growth.

Organizational Design: Structure teams for efficiency, compliance, and adaptability.

Global PV Training: Deliver customized training programs aligned with regulatory standards.

Risk Management Strategies

Designing proactive, lifecycle-based approaches to effectively manage product risks

Proactive Risk Identification: Anticipate safety concerns before they become problems.

Integrated Risk Planning: Create risk strategies that are aligned, actionable, and scalable.

Effective Risk Mitigation: Translate strategy into meaningful action.

Ongoing Monitoring & Continuous Improvement: Sustain compliance and safety across the product lifecycle.

Pharmacovigilance | Unmatched Expertise

Trusted **Partners**

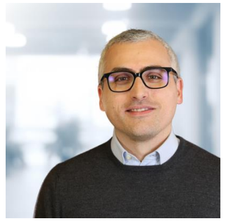
ELIQUENT's team of pharmacovigilance and risk management experts collaborate seamlessly to unlock excellence across the product lifecycle.

Our proven track record of success in navigating complex regulatory challenges makes us a trusted partner for companies seeking strategic guidance, streamlined approvals, and long-term compliance solutions.

Jamie **Portnoff**

Shelley **Gandhi**

Emma **Brookes**



Vincenzo **Pace**

Rosa **Qian**

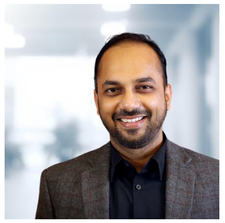
Lacey **Lucree**, MPH

Dan **Zenker**

Ishan **Samaddar**

Saurabh **Khurana**

Indy **Ahluwalia**



Abhishek **Kumar**

Douglas **Hill**

Pharmacovigilance | Targeted Solutions

Is Your Pharmacovigilance Function **Built for What's Next?**

Many organizations struggle to keep pace with the demands of modern pharmacovigilance. ELIQUENT's integrated solutions are designed to **solve the most complex pharmacovigilance challenges.** Together, we transform risk to readiness.

Siloed & Inefficient PV Operations

The Challenge. Fragmented pharmacovigilance operations lead to inefficiencies and inconsistencies

Our Solution. Unify global pharmacovigilance operations using tailored frameworks and best practices

Evolving Regulatory Requirements

The Challenge. Rapidly evolving global regulations demand proactive adaptation to avoid compliance risks

Our Solution. Navigate regulatory change with proactive intelligence and compliance strategies

Modernize Legacy Safety Systems

The Challenge. Legacy systems don't keep pace with regulatory complexity - leading to data integrity risks

Our Solution. Modernize outdated safety systems with scalable, inspection-ready solutions

Complex Technology Enablement

The Challenge. PV technology is complex - companies struggle to identify and implement the best option

Our Solution. Independently evaluate and select technology solutions that meet the needs of today and the future

Reactive Risk Management

The Challenge. Reactive risk planning creates misaligned internal processes and increased regulatory scrutiny

Our Solution. Embed risk management across the product lifecycle to meet expectations while preparing for what's next

Talent Gaps & Structural Disconnect

The Challenge. Specialized PV talent is in short supply - many teams lack the structure to scale effectively

Our Solution. Close talent gaps with organizational design, training, and expert support

Pharmacovigilance | Targeted Solutions

Leveraging both subject matter expertise and technology-enabled tools, we help clients streamline operations, manage complex reporting demands, and scale effectively to meet the evolving demands of global pharmacovigilance.

Reactive **Risk Management**

The Challenge.
Reactive risk planning creates misaligned internal processes and increased regulatory scrutiny.

Our Solution.
ELIQUENT embeds proactive, lifecycle-spanning risk strategies to monitor signals, assess benefit-risk, and meet regulatory expectations.

We Deliver.
Integrated Risk Management across the product lifecycle
Gap Assessments incorporating cross-functional perspectives
Benefit-risk Evaluations to support informed decision-making
Signal Detection and management support strategies
Strategic Planning and implementation for RMPs and REMS
Post-marketing Surveillance optimization for risk oversight
Inspection Readiness for successful audits and reviews
Training for a culture of proactive risk ownership

Siloed & Inefficient **PV Operations**

The Challenge.
Many life sciences organizations operate with fragmented pharmacovigilance systems, leading to inefficiencies, inconsistent reporting, and compliance risk.

Our Solution.
ELIQUENT unifies global pharmacovigilance through process optimization, system alignment, and scalable solutions that adapt to evolving business and regulatory needs.

We Deliver.
Operational Harmonization to align workflows across regions
Change Management to drive adoption and reduces disruption
Technology Integration for seamless system implementation
Process Optimization designed for performance improvement
Cost Rationalization without compromising quality or compliance
Scalable Pharmacovigilance Frameworks built to support growth

Pharmacovigilance | Targeted Solutions

ELIQUENT provides integrated solutions that guide life sciences organizations to overcome regulatory complexity, talent shortages, and structural misalignment by delivering practical, scalable solutions tailored to their unique challenges.

Evolving Regulatory **Requirements**

The Challenge.
Rapidly evolving global regulations demand proactive adaptation to avoid compliance risks.

Our Solution.
ELIQUENT delivers actionable regulatory intelligence and strategic change management to help you anticipate impact, implement updates, and stay ahead of regulatory change.

We Deliver.
Regulatory Intelligence to stay ahead of global requirements
Impact Assessments that clarify the effect on your business
Implementation Planning for coordination of new requirements
Compliance Gap Analysis identifying risks and opportunities
Policy & Procedure Development aligned with global standards
Quality Management Solutions tailored to requirements
Global Compliance Strategies that scale with your business

Talent Gaps & **Structural Disconnect**

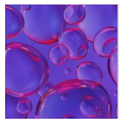
The Challenge.
Specialized pharmacovigilance talent is in short supply, and many teams lack the structure to scale effectively.

Our Solution.
ELIQUENT strengthens PV capabilities through targeted staffing, organizational design, training, and change management to build agile, high-performing teams.

We Deliver.
Staff Augmentation to bridge pharmacovigilance talent gaps
Project-based Resourcing for specialized initiatives
Organizational Design to align teams with business objectives
Global Capacity Planning to scale operations across markets
Targeted Training empowering teams for success
Change Management to drive seamless adoption
Interim Leadership to maintain critical PV roles

Pharmacovigilance | Targeted Solutions

ELIQUENT works with life science organizations to evaluate and implement integrated, inspection-ready systems in a technology agnostic manner that meet today’s regulatory requirements while preparing you for tomorrow's challenges.



Modernize Legacy Safety Systems

The Challenge.
Legacy systems often can’t keep pace with regulatory complexity, leading to inefficiencies and data integrity risks.

Our Solution.
ELIQUENT works with companies to ensure the core systems behind your pharmacovigilance operations are integrated, efficient, and inspection-ready across all operational levels and global standards.

We Deliver.
Systems Planning & Implementation for rollout of new processes
Safety Operations Modernization to ensure alignment with international safety standards
Safety System Upgrades to manage enhancements and ensure performance.
Data Migrations for the validated, risk-mitigated transfer of safety data
Regulatory Reporting Systems that are timely, accurate, and compliant
Risk Communications that maintain trust and transparency

Complex Technology Enablement

The Challenge.
Pharmacovigilance technology is complex - companies often struggle to select, implement and upgrade technologies

Our Solution.
ELIQUENT provides end-to-end, vendor-neutral support to assess, select, and implement integrated safety systems that scale with your organization.

We Deliver.
Technology Strategy Assessment to evaluate and align with business goals
Technology Roadmaps that define paths for digital transformation
Vendor-Neutral Selection Support to choose the right tools
Implementation Planning & Execution for seamless process rollout
Validation Excellence to meet standards through compliance support
Data Migration & Integrity that safeguards critical information
Integration Architecture to connect legacy and new systems
Training & Knowledge Transfer to equip teams for sustained success

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Your premier regulatory resource – **from thought to finish.**

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