Matt Oremland, PhD

Director of Data & AI Governance

mattoremland@gmail.com • (518) 560-1473 • Saratoga Springs, NY 12866
https://www.linkedin.com/in/matthew-oremland-31a312101

PROFESSIONAL SUMMARY

Data and AI governance leader with 10+ years of experience building and operationalizing governance frameworks in FDA-regulated pharmaceutical and biotech organizations. Proven expertise establishing data quality standards, implementing AI risk management, and embedding technical governance controls into data pipelines and ML systems. Strong background in regulatory compliance (HIPAA, FDA, 21 CFR Part 11, GxP) with hands-on experience translating governance policies into practical technical implementations. Skilled at leading cross-functional governance initiatives with Legal, Quality, Compliance, and IT teams while fostering cultures of responsible AI adoption. Recognized speaker on AI applications in regulated industries.

PROFESSIONAL EXPERIENCE

Redica Systems 2024 – Present

Director, Data Strategy & Analytics *Remote*

- Built and operationalized AI governance framework for production LLM classifier processing FDA regulatory data—developed comprehensive risk management approach including validation framework (confusion matrices), documentation of model behavior and limitations, bias testing, monitoring dashboards, and audit trails ensuring compliance with regulatory standards
- Established enterprise data governance frameworks from scratch for pharmaceutical clients (Eli Lilly, Merck), defining data quality standards, metadata management, data lineage tracking, stewardship roles, and validation processes that ensure data accuracy, completeness, and compliance with FDA regulations
- Translated governance policies into technical implementations by embedding data quality controls directly into ETL pipelines, implementing automated validation rules and anomaly detection in Snowflake data platform, and ensuring governance guardrails were adopted without friction
- Developed data catalogs and reference data architecture that made data discoverable, trustworthy, and reusable across client organizations—implemented master data management for regulatory intelligence data including site profiles, product relationships, and quality metrics
- Collaborated cross-functionally with legal, compliance, quality assurance, and IT teams to integrate governance requirements into engineering delivery and operational workflows, ensuring policies were both robust and practically implementable

Gilead Sciences 2023 – 2024

Director, Data & Analytics (Medical Affairs) *Foster City, CA*

- Established comprehensive data governance program for Medical Affairs organization managing HCP/HCO healthcare reference data—defined enterprise data management strategy, implemented data quality frameworks with validation rules and automated testing, and ensured HIPAA compliance for healthcare professional information
- Built and maintained enterprise data catalog for HCP/HCO profiles, implementing metadata management, data lineage tracking, and stewardship model ensuring business units owned data while governance enforced consistency and compliance across the organization
- Chaired cross-functional governance forums with stakeholders from Legal, Regulatory Affairs, Quality, IT, and Medical Affairs to drive decision-making, accountability, and consistent adoption of data governance policies and standards
- Embedded data quality checks and lineage tracking directly into data pipelines supporting HCP/HCO data acquisition, cleansing, and standardization—ensured governance controls were integrated into engineering workflows from data ingestion through analytics delivery

- Developed and enforced vendor governance framework for third-party HCP/HCO data providers, establishing evaluation criteria for data quality, security, compliance posture, and ongoing monitoring processes

Takeda Pharmaceuticals 2021 – 2022

Associate Director, Digital & Data Science *Lexington, MA*

- Built and operated data governance framework for manufacturing and quality data operations, implementing policies for data quality, security, access controls, and compliance with 21 CFR Part 11 and GxP regulations in pharmaceutical manufacturing environment
- Served as platform administrator for Spotfire analytics system, establishing technical governance controls including user access management, validation documentation, audit logging, data lineage tracking, and change management processes ensuring regulatory compliance
- Embedded governance controls into ML model deployment pipelines for predictive manufacturing and quality models—implemented model registries, version control, drift detection, performance monitoring, and explainability documentation ensuring models met regulatory and quality standards
- Led cross-functional governance initiatives with Manufacturing, Quality Assurance, IT, Compliance, and Regulatory Affairs teams to ensure data and analytics capabilities aligned with enterprise policies and regulatory requirements
- Developed and delivered training programs on data governance, analytics best practices, and regulatory compliance requirements to data science and manufacturing teams, driving adoption of governance standards across the organization

Tidal Wave Analytics LLC 2023 – Present

Consulting Data Scientist *Saratoga Springs, NY*

- Implemented AI governance practices for production ML systems on Databricks including model documentation, risk assessment, performance monitoring, and audit trails ensuring responsible AI deployment for client engagements
- Built RAG system with governance guardrails for tax compliance advisory including prompt logging, output validation, and documentation of model limitations and appropriate use cases

Regeneron Pharmaceuticals 2016 – 2021

Senior Process Data Scientist *Rensselaer, NY*

- Implemented data governance and quality controls for biopharmaceutical manufacturing data pipelines, establishing validation rules, data lineage tracking, audit trails, and metadata management supporting GxP compliance and regulatory submissions
- Developed and documented governance standards for predictive models in regulated manufacturing environment including model validation, change control, performance monitoring, and regulatory documentation ensuring models met FDA and internal quality standards
- Collaborated with Quality Assurance and Regulatory Affairs teams to ensure data and analytics capabilities maintained compliance with pharmaceutical regulations and supported regulatory filings

EDUCATION

Doctor of Philosophy (PhD) in Mathematics 2014

Virginia Polytechnic Institute & State University

Dissertation: Optimization and control methods for agent-based models in biological systems.

SKILLS & TECHNOLOGIES

Data Governance: Enterprise Data Governance Programs • Data Quality Frameworks • Metadata Management • Data Catalogs • Data Lineage & Stewardship • Master Data Management • Data Standards & Policies • Vendor Governance

AI Governance & Risk Management: AI Risk Management Framework (RMF) • Model Validation & Testing • Bias/Fairness Testing • LLM/GenAI Governance • Prompt Logging • Drift Detection • Explainability • Model Registries • AI Use Case Risk Assessment

Healthcare Regulatory & Compliance: HIPAA Compliance • FDA Regulations • 21 CFR Part 11 • GxP (GMP/GLP) • CLIA (Awareness) • GDPR (Awareness) • NIST AI RMF (Awareness) • EU AI Act (Awareness) • Healthcare Data Privacy

Technical Governance Implementation: Governance in Code • ETL/ELT Pipeline Controls • CI/CD for ML Models • Automated Validation Rules • Anomaly Detection • Audit Trails • Access Controls • Change Management

Data & AI Platform Technologies: Snowflake • Databricks • AWS • Python • SQL • Data Pipelines • ML Model Deployment • Feature Stores • Model Monitoring

Leadership & Stakeholder Management: Cross-Functional Collaboration • Governance Council Leadership • Executive Communication • Change Management • Training & Awareness Programs • Policy Development • Federated Stewardship Models

PRESENTATIONS & PUBLICATIONS

- CHPA Regulatory, Scientific & Quality Conference (2025) — Solo Presenter: The Impact of AI on FDA-Regulated Industries
- Redica Systems Webinar (2025) — Solo Presenter: From Reactive to Proactive: Leveraging AI/ML to Improve the Quality Unit
- ISPE Annual Meeting & Expo (2025) — Solo Presenter: Navigating FDA Compliance - Outsourcing Facility Inspections

PUBLICATIONS

- "Optimization and control of agent-based models in biology: a perspective" — Bulletin of Mathematical Biology, 2017