Matt Oremland, PhD

Responsible AI Manager

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PROFESSIONAL SUMMARY

Data science leader with PhD in Mathematics and 10+ years of experience developing, deploying, and governing AI/ML systems in FDA-regulated pharmaceutical and biotech environments. Proven track record building and operationalizing governance frameworks for AI/ML systems across their full lifecycle, from validation and documentation to ongoing performance monitoring. Deep expertise in regulatory compliance (FDA, 21 CFR Part 11, GxP), data governance, and translating complex requirements into clear, practical workflows. Recognized speaker on AI applications in FDA-regulated industries with strong cross-functional collaboration skills across Legal, Quality, Compliance, and IT teams.

PROFESSIONAL EXPERIENCE

Redica Systems
2024 – Present

Director, Data Strategy & Analytics — *Remote*

- Built and operationalized production LLM classifier (OpenAI API) that processes unstructured FDA 483 data—owned end-to-end governance including design requirements, validation framework using confusion matrices, documentation of model behavior and limitations, and collaboration with data engineering to ensure production accuracy and auditability
- Designed reference data architecture and data governance frameworks from scratch for pharmaceutical clients (Eli Lilly, Merck), establishing data quality standards, validation processes, lineage tracking, and audit-ready documentation to ensure compliance with regulatory requirements
- Defined and documented AI/ML model lifecycle processes including development, validation, deployment monitoring, and ongoing performance assessment, providing traceability and evidence of responsible oversight across all analytics systems
- Presented at industry conferences (CHPA, ISPE) on AI/ML applications in FDA-regulated industries, including ethical considerations, regulatory compliance requirements, and practical guidance for implementing AI responsibly in quality and regulatory intelligence use cases
- Collaborated cross-functionally with data engineering, product teams, and client stakeholders to translate complex governance requirements into clear, actionable workflows and documentation that teams could understand and apply in practice

Tidal Wave Analytics LLC
2023 – Present

Consulting Data Scientist — *Saratoga Springs, NY*

- Built production random forest model for Paradigm using Databricks, establishing model documentation, performance monitoring, and lifecycle management practices—worked directly with VP of Product and data engineering teams to ensure model governance and operational controls
- Developed RAG system for Denari using HuggingFace and PyTorch, implementing data sourcing documentation, model behavior characterization, and guardrails for responsible deployment in tax compliance advisory context
- Owned end-to-end ML system design and deployment across multiple client engagements, establishing documentation standards, validation approaches, and operational monitoring that ensured models were traceable, explainable, and aligned with business and ethical requirements

Gilead Sciences
2023 – 2024

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

- Established comprehensive data governance framework for Medical Affairs organization, including data standards, quality controls, access policies, validation processes, and audit documentation aligned with FDA regulatory requirements and internal compliance standards
- Built centralized data lake as single source of truth, designing data inventory, lineage tracking, and metadata management systems to maintain visibility and traceability across all enterprise data assets
- Wrote formal data requirements and governance documentation that translated complex regulatory and business objectives into clear, practical workflows and decision points for cross-functional teams
- Collaborated with Legal, Quality Assurance, Regulatory Affairs, and IT teams to integrate data governance requirements into existing enterprise processes, ensuring governance was robust, auditable, and accessible to stakeholders at all seniority levels
- Managed vendor relationships and internal teams to ensure deliverables met governance standards, timelines, and compliance requirements, maintaining continuous oversight of data operations

Takeda Pharmaceuticals 2021 – 2022

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

- Led development and deployment of predictive ML models for manufacturing and quality decisions, establishing model validation frameworks, documentation standards, and ongoing performance monitoring to ensure models met GMP compliance and regulatory expectations
- Served as Spotfire system administrator, designing and managing data platform governance including user access controls, validation documentation, and compliance with 21 CFR Part 11 requirements for electronic records and signatures
- Wrote standard operating procedures and formal requirements documentation for data management, statistical analysis, and system validation activities, translating regulatory requirements into clear operational guidance
- Led cross-functional teams across Quality, Manufacturing, IT, and Regulatory to integrate data science and digital capabilities into existing enterprise processes, ensuring alignment with business objectives and compliance requirements
- Monitored analytics systems performance and compliance signals across manufacturing and quality operations, maintaining visibility into model behavior, data quality, and emerging risks

Regeneron Pharmaceuticals 2016 – 2021

Senior Process Data Scientist *Rensselaer, NY*

- Developed predictive models for biopharmaceutical manufacturing with rigorous validation and documentation to support GMP operations, including ensemble methods, PLS, and PCA for automated limit calculations, feed quantity optimization, and product quality prediction
- Built automated data pipelines for ingestion, cleaning, and transformation of manufacturing data, implementing data quality checks, validation rules, and audit trails to ensure data integrity throughout the lifecycle
- Collaborated with Quality Assurance, Manufacturing, Process Development, and Regulatory Affairs teams to ensure models met compliance requirements and supported regulatory submissions
- Documented model assumptions, limitations, validation results, and operational controls to provide audit-ready evidence of responsible model development and deployment in regulated manufacturing environment

Mathematical Biosciences Institute 2014 – 2016

Postdoctoral Research Fellow *Columbus, OH*

- Conducted research on agent-based models of biological systems, applying multi-objective optimization using genetic and evolutionary algorithms—published 5 peer-reviewed papers plus 1 textbook chapter demonstrating strong technical writing and ability to communicate complex analytical methods

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. Research focused on developing algorithmic frameworks and validation methods for complex computational models.

SKILLS & TECHNOLOGIES

AI/ML Systems & Lifecycle Management: Production ML Deployment • Model Validation • Performance Monitoring • OpenAI API • Scikit-Learn • TensorFlow • PyTorch • HuggingFace • Random Forest • Ensemble Models • LLM Classification

Data & Technology Governance: Data Governance Frameworks • Data Quality Standards • Data Lineage & Metadata Management • Validation & Documentation • Audit Trail Design • Access Controls • System Administration

Regulatory & Compliance: FDA Regulations • 21 CFR Part 11 • GMP/GLP Compliance • EU AI Act (Awareness) • NIST AI RMF (Awareness) • Ethical AI Principles • Risk Management • SOP Development

Technical & Analytical: Python (Advanced) • SQL • SDLC Knowledge • Database Design • Snowflake • Databricks • AWS • Data Pipelines (ETL/ELT) • Analytics Platform Management

Process Design & Collaboration: Process Design & Documentation • Cross-Functional Collaboration • Stakeholder Management • Requirements Translation • Workflow Optimization • Communication Across Seniority Levels

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
- CHPA Quality and Manufacturing Meeting (2025) — Solo Presenter: Decoding FDA Enforcement Trends in OTC and Dietary Supplements

PUBLICATIONS

- "Optimization and control of agent-based models in biology: a perspective" — Bulletin of Mathematical Biology, 2017
- "A computational model of invasive aspergillosis in the lung and the role of iron" — BMC Systems Biology, 2016
- "Optimization of agent-based models: scaling methods and heuristic algorithms" — Journal of Artificial Societies and Social Simulation, 2014