

# Matt Oremland, PhD

*Director of Data and Biostatistics*

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## PROFESSIONAL SUMMARY

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Results-driven data science leader with 10+ years of experience in regulated industries, specializing in data management strategy, statistical analysis, and regulatory compliance. Proven expertise in designing and implementing scalable data systems, establishing data governance frameworks, and leading cross-functional teams to deliver high-quality clinical and quality data. Deep background in FDA-regulated environments with demonstrated success in building centralized data platforms, managing vendor relationships, and mentoring technical teams. Recognized speaker on AI/ML applications in regulated industries with strong knowledge of 21 CFR Part 11 compliance and data integrity requirements.

## PROFESSIONAL EXPERIENCE

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### Redica Systems

2024 – Present

*Director, Data Strategy & Analytics*

*Remote*

- Led data strategy and analytics operations for pharmaceutical clients (Eli Lilly, Merck) supporting regulatory intelligence and quality management, directly aligning with FDA compliance requirements and data integrity standards
- Designed and implemented reference data architecture from scratch to harmonize multi-source client data, establishing data governance frameworks and quality assurance processes that ensure accurate, validated datasets for regulatory reporting
- Built production LLM classifier (OpenAI API) that processes unstructured FDA 483 data, assigns severity levels and weighted topic categories—owned design, validation using confusion matrices, and collaborated with data engineering on deployment to ensure production accuracy
- Developed risk-scoring models using Python and Snowflake to evaluate regulatory compliance trends, applying statistical methods to large datasets and delivering actionable insights to senior leadership and cross-functional stakeholders
- Managed vendor relationships and internal teams to deliver analytics projects on time and within budget, establishing SOPs and best practices for data management and analytics workflows
- Presented at industry conferences (CHPA, ISPE) on AI/ML applications in FDA-regulated industries and regulatory compliance trends, demonstrating expertise in communicating complex data science concepts to diverse audiences

### Tidal Wave Analytics LLC

2023 – Present

*Consulting Data Scientist*

*Saratoga Springs, NY*

- Built production random forest model for Paradigm (building supply software) that groups quotes into projects using text and numerical features, running nightly in production—worked directly with VP of Product and data engineering teams using Databricks
- Developed RAG system for Denari (tax tech startup) that advises businesses on tax filing requirements, including downloading and ingesting IRS and state tax forms as document corpus and building retrieval pipeline using HuggingFace and PyTorch
- Delivered end-to-end modeling engagements across multiple industries, demonstrating versatility in applying statistical methods and machine learning techniques to solve diverse business problems

### Gilead Sciences

2023 – 2024

*Director, Data & Analytics (Medical Affairs)*

*Foster City, CA*

- Defined and executed enterprise data and analytics strategy for Medical Affairs organization, serving as strategic advisor to senior leadership on data governance, system design, and analytics capabilities

- Built centralized data lake as single source of truth, consolidating disparate data sources and establishing data standards, quality controls, and validation processes to ensure data integrity across the organization
- Designed and implemented dashboards from scratch in Spotfire, managing internal team of dashboard developers and establishing best practices for data visualization and reporting
- Established comprehensive data governance frameworks and wrote formal data requirements documentation aligned with regulatory standards and business needs
- Managed multiple vendor relationships and internal cross-functional teams, ensuring deliverables met quality standards and timelines while maintaining budget constraints
- Led hiring and performance development for technical staff, providing mentorship and establishing career development pathways for data professionals

## **Takeda Pharmaceuticals**

2021 – 2022

*Associate Director, Digital & Data Science*

*Lexington, MA*

- Led digital and data science group plus statistical monitoring group, managing teams of 3-7 people and establishing technical roadmaps for predictive analytics in manufacturing and quality operations
- Built predictive models using machine learning for manufacturing and quality decisions, applying appropriate statistical methods to evaluate process capability and product quality metrics
- Served as Spotfire system administrator, overseeing database design, user access controls, and system validation in compliance with 21 CFR Part 11 requirements
- Led semi-annual APQR (Annual Product Quality Review) meetings with cross-functional stakeholders, presenting statistical analyses and data-driven recommendations to senior leadership
- Developed digital dashboards for real-time process and quality monitoring, implementing automated data pipelines and alert systems to enable proactive decision-making
- Wrote formal data requirements and standard operating procedures for data management, statistical analysis, and system validation activities

## **Regeneron Pharmaceuticals**

2016 – 2021

*Senior Process Data Scientist*

*Rensselaer, NY*

- Developed predictive models for biopharmaceutical manufacturing including automated limit calculations, feed quantity optimization, and product quality prediction using ensemble methods, PLS, and PCA
- Built automated data pipelines for ingestion, cleaning, and transformation of manufacturing data, ensuring data quality and integrity throughout the process lifecycle
- Presented analytical findings and model recommendations to senior leadership and cross-functional stakeholders, effectively communicating complex statistical concepts to non-technical audiences
- Collaborated with Quality Assurance, Manufacturing, and Process Development teams to ensure models met regulatory requirements and supported GMP operations
- Promoted from Data Scientist to Senior Data Scientist over 5-year tenure, demonstrating consistent technical excellence and leadership within the organization

## **Mathematical Biosciences Institute**

2014 – 2016

*Postdoctoral Research Fellow*

*Columbus, OH*

- Conducted advanced research on agent-based models of biological systems including fungal lung infection, virus transmission, and cellular models, applying multi-objective optimization using genetic and evolutionary algorithms
- Published 5 peer-reviewed papers plus 1 textbook chapter during postdoc, demonstrating strong scientific writing skills and ability to communicate complex analytical methods to academic audiences

## **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 applying advanced statistical and optimization techniques to complex biological data, directly relevant to clinical data analysis and biostatistics.

## SKILLS & TECHNOLOGIES

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**Data Management & Database Systems:** Database Design • Data Standards (CDISC-adjacent) • Data Quality Assurance • Data Governance • ETL/ELT Pipelines • Snowflake • Databricks • AWS • Supabase

**Statistical Analysis & Biostatistics:** Statistical Methods • Random Forest • Ensemble Models • PLS • PCA • Multi-Objective Optimization • Predictive Modeling • Confusion Matrices • Risk Scoring Models

**Programming & Analytics Tools:** Python (Advanced) • SQL • Scikit-Learn • Pandas • TensorFlow • PyTorch • HuggingFace • Spotfire • Sigma

**Regulatory & Compliance:** FDA Regulations • 21 CFR Part 11 • GMP/GLP • Data Integrity • SOP Development • Validation • Regulatory Reporting

**Leadership & Project Management:** Team Management (3-7 direct reports) • Vendor Management • Cross-Functional Collaboration • Strategic Planning • Stakeholder Communication • Hiring & Mentorship

## PRESENTATIONS & PUBLICATIONS

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- 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

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- "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