Matt Oremland, PhD

Regulatory Data Science and Analytics

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PROFESSIONAL SUMMARY

Data science leader with a career spanning biological systems modeling, pharmaceutical manufacturing, and FDA regulatory intelligence. Combines deep domain knowledge in life sciences with advanced computational expertise - from multi-objective optimization of agent-based biological models to production LLM classifiers analyzing FDA Form 483 observations. Proven track record delivering analytics solutions for pharma clients including Eli Lilly, Merck, and ProQuality Network, and presenting at industry conferences including CHPA and ISPE. Available for independent consulting engagements with pharmaceutical and biotech organizations seeking analytically rigorous approaches to regulatory and quality challenges.

PROFESSIONAL EXPERIENCE

Redica Systems April 2025 – February 2026

Senior Director, Data Strategy & Analytics *Remote*

- Built production LLM classifier using OpenAI API to automatically categorize FDA Form 483 observations by severity level and weighted topic categories, enabling risk-based prioritization across pharmaceutical client base
- Designed and operationalized risk-scoring models from scratch for regulatory intelligence platform serving Eli Lilly, Merck, and ProQuality Network
- Developed reference data architecture to harmonize multi-source regulatory and quality data, creating unified views for client analytics and reporting
- Delivered solo presentations at CHPA Quality & Manufacturing Meeting and ISPE Annual Meeting on FDA enforcement trends and compliance analytics
- Built Python visualization library for generating brand-specific analytics outputs tailored to individual pharmaceutical client needs

Tidal Wave Analytics LLC January 2025 – Present

Consulting Data Scientist *Saratoga Springs, NY*

- Delivered end-to-end ML modeling engagements across multiple industries as independent consultant, managing client relationships from requirements gathering through production deployment
- Built production random forest model for quote classification using Databricks, collaborating directly with VP of Product and data engineering stakeholders
- Developed RAG system for tax compliance using HuggingFace and PyTorch, ingesting IRS and state regulatory documents to generate filing recommendations

Gilead Sciences January 2023 – March 2025

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

- Led team of 5 managing healthcare professional and healthcare organization reference data operations, dashboard delivery, and analytics for Medical Affairs organization
- Built centralized data lake consolidating HCP/HCO data from multiple sources as single source of truth for enterprise analytics
- Established data governance frameworks and formal data requirements for healthcare reference data across Gilead Medical Affairs
- Managed vendor relationships and internal teams for data acquisition, cleansing, and standardization of regulatory-critical HCP/HCO profiles

Takeda Pharmaceuticals May 2021 – December 2022

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

- Led digital and data science group plus statistical monitoring group supporting manufacturing quality and compliance decisions
- Built predictive models using ML for manufacturing process optimization and quality risk assessment in FDA-regulated production environment
- Served as Spotfire system administrator, delivering digital dashboards for real-time process and quality monitoring
- Led semi-annual APQR (Annual Product Quality Review) meetings, presenting quality analytics to cross-functional stakeholders and regulatory affairs teams

Regeneron Pharmaceuticals — May 2016 – May 2021

Senior Process Data Scientist — *Rensselaer, NY*

- Built predictive models for biopharmaceutical manufacturing quality including automated limit calculations, feed quantity optimization, and product quality prediction using ensemble methods
- Developed automated data pipelines for manufacturing data ingestion, cleaning, and transformation in compliance with FDA data integrity requirements
- Presented analytics solutions and recommendations to senior leadership and cross-functional manufacturing, quality, and regulatory stakeholders

Mathematical Biosciences Institute — 2014 – 2016

Postdoctoral Research Fellow — *Columbus, OH*

- Developed agent-based computational models of biological systems including fungal lung infection, virus transmission in cattle, and cellular dynamics, establishing foundational domain expertise in life sciences modeling
- Applied multi-objective optimization using genetic and evolutionary algorithms to solve complex biological parameter estimation and system control problems
- Published 5 peer-reviewed papers and 1 textbook chapter on computational methods for biological systems, contributing to the emerging field of data-driven biological modeling

Virginia Tech — 2009 – 2014

Doctoral Research Fellow — *Blacksburg, VA*

- Conducted dissertation research on optimization and control methods for agent-based models in biological systems, developing novel mathematical frameworks for analyzing complex adaptive systems
- Applied multi-objective optimization, genetic algorithms, and evolutionary computation to extract actionable insights from high-dimensional biological simulation data
- Built computational pipelines integrating mechanistic biological models with data-driven optimization techniques, establishing technical foundations directly applicable to pharmaceutical process modeling and quality analytics

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

Regulatory & Quality Analytics: FDA 483 Analysis • Risk Scoring Models • Regulatory Intelligence • Quality Systems • APQR Analytics • Compliance Dashboards

AI/ML & Data Science: LLM Classification (OpenAI API) • Random Forest • Ensemble Models • PLS • PCA • Agent-Based Modeling • Multi-Objective Optimization

Platforms & Technologies: Python • Snowflake • Databricks • Spotfire • Sigma • AWS • HuggingFace • PyTorch

Leadership & Consulting: Client Relationship Management • Data Strategy • Team Leadership • Data Governance • Stakeholder Engagement • Conference Speaking

PRESENTATIONS & PUBLICATIONS

- CHPA Quality and Manufacturing Meeting (2025) — Solo Presenter: Decoding FDA Enforcement Trends in OTC and Dietary Supplements
- ISPE Annual Meeting & Expo (2025) — Solo Presenter: Navigating FDA Compliance - Outsourcing Facility Inspections
- 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
- PDA Korea (2025) — Author: Regulatory trends in Asia and Korea

PUBLICATIONS

- "Optimization and control of agent-based models in biology: a perspective" — Bulletin of Mathematical Biology, 2017
- "Optimal control of sugarscape agent-based model via a PDE approximation model" — Optimal Control Applications and Methods, 2016
- "A computational model of invasive aspergillosis in the lung and the role of iron" — BMC Systems Biology, 2016
- "Optimal harvesting of a predator-prey agent-based model using difference equations" — Bulletin of Mathematical Biology, 2015
- "Optimization of agent-based models: scaling methods and heuristic algorithms" — Journal of Artificial Societies and Social Simulation, 2014
- "Agent-based models and optimal control in biology: a discrete approach" — Mathematical Concepts and Methods in Modern Biology (Elsevier), 2013 (Textbook chapter)