KALIF SHEAR

Los Angeles, CA | khshear@outlook.com | linkedin.com/in/kalifshear | kalifshear.netlify.app

SUMMARY

Analytics, data science, and quality professional with 10+ years across public health research and regulated cell therapy development, and founder of TrueGate Bio, an independent analytics practice serving cell and gene therapy developers. Turns complex analytical datasets into defensible decisions with R, Python, JMP, and GraphPad Prism, from flow cytometry analytics to method comparison and trending. Brings the regulated discipline that makes numbers hold up: method validation and lifecycle management, Part 11 data integrity, and direct engagement with FDA inspectors.

CORE COMPETENCIES

Quality and Validation: Method Validation (ICH Q2, Q5E) | Method Lifecycle (ICH Q12, Q14) | 21 CFR Part 11 | Deviations, CAPA, and Change Control

Presentation Design: Microsoft PowerPoint | Slide Reconstruction | Visual Storytelling | Executive Readouts | Iterative Feedback Cycles

Data Analysis and Statistical Reasoning: Regression and Method Comparison | ANOVA | Partial Correlation and Confounding | Design of Experiments

Analytics Reporting: KPI Definition and Management | Trend Analysis | Findings, Trends, and Recommendations

Content Editing and Written Communication: Technical and Validation Reports | Decision Memos | SOPs | Peer Review of Slides and Reports

EXPERIENCE

AI Model Training Contractor | **micro1 Inc.** | Remote | **Jul 2026 to Present**

- Evaluate AI-generated content against written criteria and record a rationale a second reviewer can reproduce.
- Write the evaluation criteria and acceptance standards other reviewers apply to AI output.

Senior Domain Expert, Multi-Discipline AI Research Program | **AfterQuery** | Remote | **May 2026 to Present**

- Direct a multi-system AI production pipeline with separated build and audit roles, and hold the release audit personally.
- Document every reported number with its inputs, commands, and tool versions so each conclusion stays traceable.

Founder and Independent Consultant | **TrueGate Bio** | Los Angeles, CA | **Jan 2026 to Present**

- Run an analytics and data science consultancy for cell and gene therapy, with flow cytometry analytics, statistical tools, and QC data dashboards.
- Deliver 21 CFR Part 11 validation package reviews with traceability matrices, test cases, gap registers, and related SOPs.

Scientist | **Kite Pharma / Gilead Sciences** | Santa Monica, CA | **Sep 2022 to Jun 2026**

- Built and reconstructed PowerPoint decks weekly for QC, program, regulatory, and QA stakeholder readouts across three concurrent programs.
- Revised own slides after manager and peer review, and edited teammates' decks for clarity, visual consistency, and narrative flow.
- Compressed complex analytical findings into executive-level briefings, and translated one result into the decision each of ten functions owned.
- Separated confounded variables in multi-site field data with partial correlation and a designed factorial experiment, and overturned the leading root-cause hypothesis.
- Drove the resulting multi-site failure down from a chronic rate to a rare exception, and held it against a pre-set CAPA criterion.
- Defined and managed the KPIs and effectiveness criteria reported to executive leadership, and tied program decisions to measured performance.

- Wrote SQL against LIMS and connected systems to extract and trend analytical datasets for reporting.
- Engineered automated cloud pipelines that synced instrument data to structured storage and triggered downstream analysis as each run landed.
- Drafted and reviewed validation reports, investigation reports, and decision memos that summarized findings, trends, and recommendations.

QC Senior Scientist | **Fate Therapeutics** | San Diego, CA | **Jun 2018 to Sep 2022**

- Designed stakeholder decks for QC and program readouts and internal training, and revised each after manager and peer review.
- Qualified analytical methods and reported linearity, precision, accuracy, and robustness statistics against pre-set acceptance criteria.
- Authored and reviewed SOPs, method qualification reports, and investigation reports, and held each to GMP documentation standards.
- Transferred analytical methods between sites, trained receiving teams, and set the acceptance criteria that cleared each to operate.

QC / R&D Scientist | **Cellphire, Inc.** | Gaithersburg, MD | **Feb 2017 to Jun 2018**

- Executed GMP and GLP quality control testing and controlled documentation for freeze-dried platelet and cell products.

Research Assistant | **Centers for Disease Control and Prevention** | Kisumu, Kenya | **May 2014 to May 2015**

- Ran ELISA and PCR diagnostics on clinical serum and plasma specimens, and maintained version-controlled study records and protocols.

TECHNICAL SKILLS

Presentation and Visualization: Microsoft PowerPoint, Slide Reconstruction, Presentation Design, Data Visualization, Visual Storytelling, Content Editing

Data Analysis: R, Python (NumPy, SciPy, pandas in Azure ML), JMP (One-Way ANOVA, Passing-Bablok Regression, Fit Model, Multivariate), GraphPad Prism, MATLAB, SQL

Statistical Methods: Linear Regression and Residual Analysis, ANOVA, Partial Correlation, Design of Experiments, Method Comparison, Precision (%CV)

Analytics Reporting: KPI Reporting, Analytics Reports, Executive Briefings, Technical and Validation Reports, Decision Memos

EDUCATION

B.S. Molecular Biology, George Washington University, 2017