Katie Gerstley (Pokiniewski), Ph.D.

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PROFESSIONAL SUMMARY

Results-driven scientific leader with a Ph.D. in Microbiology and Immunology and extensive experience in GMP QC laboratory operations, analytical instrument lifecycle management, computerized system validation, and data integrity compliance. Proven ability to lead and develop high-performing CQV teams, oversee qualification and calibration programs, and drive continuous improvement in cGMP-regulated CDMO environments supporting clinical and commercial biologics programs. Experienced SME for regulatory inspections, audit readiness, deviation management, and CAPA implementation. Skilled at cross-functional collaboration with QA, Manufacturing, IT, Facilities, and client teams to ensure compliant, efficient QC operations and uninterrupted supply.

CORE COMPETENCIES

QC CQV Leadership (Commissioning, Qualification & Validation) • Analytical Instrument Lifecycle Management • Computerized System Validation (21 CFR Part 11, EU Annex 11) • Data Integrity & ALCOA+ Compliance • LIMS / Empower / STARLIMS Administration • Calibration & Preventive Maintenance Program Oversight • Deviation Management, Change Control & CAPA • GMP / GLP Regulatory Compliance • People Management & Team Development • Audit & Inspection Readiness (FDA, EMA) • Cross-Functional & Client Stakeholder Engagement • SOP & Technical Documentation Authorship

PROFESSIONAL EXPERIENCE

Sample Operations & Stability Leadership | *Minaris Advanced Therapies* July 2025 – Present

Laboratory Systems & Compliance Oversight

- Oversee two scientists managing stability programs, including protocol design, execution, data trending, and regulatory-compliant report writing; ensure timely delivery to support product lifecycle and client regulatory submissions (IND, BLA).
- Supervise a team of eight responsible for sample receipt, login, verification, and transfer; enforce chain-of-custody integrity and documentation compliance within STARLIMS to maintain traceability, data integrity, and GMP compliance.
- Ensure all sample and stability operations adhere to ALCOA+ data integrity principles and applicable regulatory standards; drive timely resolution of gaps identified through self-inspections and audits.
- Develop and maintain SOPs and procedural controls governing sample management and stability execution; ensure staff training and competency are current and documented.

Associate Principal Scientist | *Minaris Advanced Therapies* July 2021 – July 2025

QC Operations, Instrumentation & System Management

- Provided strategic and operational oversight of GMP QC testing operations supporting clinical and commercial-stage gene and cell therapy programs across multiple client portfolios.
- Owned lab environmental monitoring systems (REES/ELPRO), ensuring real-time responsiveness to alerts, routine review, and compliant documentation — directly analogous to instrument and system lifecycle management in a QC CQV framework.
- Managed biological critical reagent (BCR) inventory and antisera programs, developing short- and mid-term sustainability strategies to ensure continuity of testing operations across the laboratory network.
- Led oversight of computerized systems including STARLIMS (LIMS), ensuring compliant data capture, audit trail integrity, and user access controls aligned with 21 CFR Part 11 and data integrity requirements.

Computerized System Validation & Data Integrity

- Ensured GMP data integrity compliance (ALCOA+) across all QC operations; led investigations into data integrity deviations and implemented corrective actions to restore and maintain compliant system states.
- Collaborated with IT and digital manufacturing teams on assay digitization initiatives, harmonized data capture platforms, and system upgrade projects to support QC modernization and cross-site alignment.
- Authored and reviewed system-related SOPs, policies, technical reports, and validation documentation; ensured all QC records were inspection-ready and met regulatory standards.

People Management & Team Development

- Directed and mentored a diverse team of scientific personnel; established performance management cadence through structured one-on-ones, coaching, and transparent performance tracking.
- Ensured appropriate training, qualification, and competency documentation for all team members; fostered a culture of quality, accountability, and continuous improvement.

- Allocated resources and managed workload across competing priorities to ensure timely execution of analytical deliverables aligned with client and regulatory timelines.

Quality Systems, Audit & Inspection Readiness

- Served as SME for regulatory inspections, client audits, and PAI readiness activities; authored and reviewed responses to audit observations, RTQs, and CAPA documentation.
- Led scientific investigations as deviation SME, driving root cause analysis and resolution of non-conforming events, change controls, and deviations in compliance with FDA/ICH and ISO standards.
- Partnered with Quality, Regulatory, and Manufacturing counterparts to embed a proactive compliance culture, maintaining continuous audit readiness.

Cross-Functional & Client Collaboration

- Served as principal operational lead across cross-functional core teams (QA, Manufacturing, MSAT, client teams); aligned QC operations with supply chain and regulatory milestones.
- Interfaced directly with clients to author technical proposals, communicate operational status, and ensure alignment of scientific deliverables with commercial expectations.
- Escalated key analytical and operational challenges to senior management in a timely and concise manner; maintained regular status reporting across internal and client stakeholders.

Scientist | *WuXi AppTec (ATU)* March 2019 – June 2021

- Operated as independent scientific authority in the Virology QC Department; served as Study Director with full ownership of scientific direction, GMP compliance, client engagement, and documentation integrity.
- Led design, execution, and oversight of GLP/cGMP assays in accordance with CFR and Points to Consider guidelines; participated in automation and assay modernization initiatives.
- Ensured all batch records, protocols, and client-facing study reports were accurate, compliant, and inspection-ready; drove continuous improvement in documentation quality and efficiency.
- Provided authoritative training to scientific staff on technical protocols, regulatory requirements, and quality standards; supported onboarding and competency qualification of new personnel.

Associate Scientist / Study Director | *WuXi AppTec* December 2017 – March 2019

- Served as Study Director for multiple critical GLP/cGMP virology assays; maintained flawless documentation practices across batch records, assay data packages, and technical reports.
- Executed laboratory operations under GLP, cGMP, CFR, and PTC standards; ensured audit readiness and product integrity through rigorous procedural compliance.
- Authored and refined SOPs, protocols, and study reports; managed lab scheduling and resource planning with operational foresight aligned to project timelines.
- Engaged directly with clients to communicate study progress, manage expectations, and ensure satisfaction — functioning as both technical expert and strategic partner.

Technical Lead, Manufacturing | *Advaxis* April 2017 – December 2017

- Led biologic manufacturing operations in a cGMP clinical environment; applied technical knowledge to troubleshoot manufacturing challenges and drive process consistency.
- Led document governance including SOP development, batch production records, manufacturing protocols, and deviation reports across multiple departments.

Manufacturing Associate III / II | *WuXi AppTec* March 2016 – March 2017

- Executed GMP upstream and downstream large-scale rAAV production; developed and reviewed batch records and trained associates on GMP manufacturing operations.

Research Assistant | *Temple University Medical School* 2010 – 2016

- Conducted preclinical gene therapy research; managed IACUC/IBC regulatory submissions, lab operations, and protocol development. Applied broad molecular and cellular biology techniques in a compliance-oriented academic research environment.

EDUCATION

Ph.D., Microbiology and Immunology January 2016
Lewis Katz Medical School at Temple University
Dissertation: Understanding the Cellular Mechanism of Adeno-Associated Virus Stabilization
Awards: Biomedical Sciences Travel Award; Meritorious Achievement Travel Award, ASGCT 18th Annual Meeting

B.S., Science (Life Science Option), Magna Cum Laude 2010
Penn State University
Awards/Scholarships: Abby Sutherland Scholarship; PSU Abington Study Abroad Scholarship

SELECTED PUBLICATIONS

- Q Wang, J Firrman, Z Wu, KA Pokiniewski, et al. High density recombinant AAV particles are competent vectors for in vivo transduction. Human Gene Therapy (Accepted).
- Q Wang, B Dong, KA Pokiniewski, J Firrman, et al. Syngeneic AAV pseudo-particles potentiate gene delivery efficiency. Molecular Therapy (Accepted).