Durham/Raleigh, NC | Willing to relocate (U.S.) | Hybrid or On-site | Willing to travel 10–25%

ERIC J. YEARLEY, PHD

Durham, NC • Phone: (419) 410-4218 • Website: https://www.ericyearley.com • Email: contact@ericyearley.com

PROFESSIONAL SUMMARY

Distinguished leader with 13+ years of comprehensive experience in therapeutics and vaccines analytical development, specializing in mass spectrometry, biophysical characterization, separations, cell-based potency assays and molecular biology methods. Proven expertise in developing and implementing analytical control strategies for complex biologics across multiple modalities including monoclonal antibody therapeutics, antigen-based vaccines, nucleic acid/nanoparticle platforms and viral vector gene therapy products from early-phase development through Phase 3 clinical.

CORE EXPERTISE

- Analytical Development and Characterization Expertise Across Multiple Biologic Modalities (recombinant protein, nucleic acid/nanoparticle, viral vectors)
- People Leadership: 10+ Direct Reports with hiring, performance management, and talent development responsibility
- Cross-Functional CMC Team Leadership with regulatory submissions experience (IND, BLA, MAA, IMPD)
- Method Development, Validation, Qualification & Transfer across global sites
- Analytical Control Strategy Development and Critical Quality Attribute (CQA) assessment
- Quality-by-Design (QbD) Implementation and method lifecycle management
- Digital Transformation & AI Integration (ELN/LIMS implementation, AI-assisted technical writing)
- CDMO/CRO Management and external partner coordination
- Regulatory Compliance (cGMP, GSP, ICH, FDA, EMA guidelines)

PROFESSIONAL EXPERIENCE

Associate Director: Cell, Molecular, Separations and CMC Analytical Analytical Development

CSL Seqirus, Holly Springs, NC

July 2023 – Present

Leadership & Strategic Direction

- Directed a 13+ member analytical development organization across cell-based, molecular biology, separations, and CMC analytical teams with five direct reports full responsibility for hiring, performance management, promotions and talent development
- Spearheaded analytical control strategies for biologics and vaccine platforms, ensuring robust testing and characterization of drug substance & drug product across multiple testing laboratories from pre-IND to clinical phase 3.
- Collaborated with cross-functional CMC teams to align analytical strategies with program milestones, ensuring adherence to regulatory requirements and quality standards

Method Development & Implementation

- Directed development and implementation of 10+ novel analytical methodologies for biologics and vaccine platforms, leveraging state-of-the-art technologies for enhanced product characterization
- Drove development and qualification/validation of critical release and characterization assays, supporting product development through preclinical, clinical and late-stage programs
- Orchestrated transfer and qualification/validation of analytical methods from GSP analytical development to cGMP testing environments across global development sites, achieving seamless integration into both internal and external cGMP laboratories

Regulatory & Quality Systems

- Established and maintained robust GSP-compliant quality system, ensuring adherence to ALCOA+ principles and regulatory guidelines while designing methods for seamless cGMP implementation
- Authored and reviewed analytical CMC sections for regulatory submissions, including INDs, IMPDs(EU), MAAs (EU) and BLAs (US)
- Conducted comprehensive technical reviews of method development, qualification, and validation reports, analytical change requests, and out-of-specification investigations
- Justified more than $1M annual CAPEX & head-count requests, aligning spend with portfolio priorities

Digital Transformation, AI-Implementation and Laboratory Systems

- Expert in AI-assisted technical writing utilizing internal Microsoft Copilot tools for CMC documents including protocols, reports, and regulatory submissions, achieving 30% reduction in drafting time
- Leveraged AI Copilot for data analysis, graph/visualization generation, and presentation development, accelerating deliverable preparation across analytical programs
- Led implementation of IDBS electronic lab notebooks (ELN), converting 20+ paper notebooks and achieving 50%-time savings with 100% adoption rate across analytical teams
- Drove dramatic data improvements through contemporaneous ELN documentation, reducing deviations from 150/year to 2-3/year (~98% reduction)
- Developed method-specific ELN templates with standardized work instructions and led ALCOA+ training program across analytical teams
- Implemented automated instrument data uploads to centralized server for streamlined data retrieval and traceability
- Utilized Labware LIMS for sample management and data tracking; managed Teams channels and implemented Jira for AGILE project management workflows

AGILE Project Management & Leadership

- Served as Product Owner for critical program analytical deliverables, implementing AGILE methodologies combining leadership and project management to accelerate program success and ensure analytical readiness for key milestones
- Led cross-functional Analytical AGILE group through comprehensive Sprint planning, weekly Scrums, Sprint Reviews, and Sprint Retrospectives, improving analytical delivery timelines by 25%
- Coordinated analytical workstreams across multiple stakeholders with strong negotiation skills, ensuring alignment with program objectives and maintaining transparent communication through AGILE framework

Key Achievements

- Recognized as high potential employee after first year, demonstrating exceptional performance in analytical development
- Co-delivered analytical control strategies for 3 clinical and 3 platform programs, enabling critical product advancements
- Contributed analytical expertise to specification setting initiatives for multiple biologics platforms
- Achieved 25% reduction in method variability through workflow optimization and automation integration
- Achieved dramatic throughput improvements: 10x increase in the integrity fragment analyzer (FA) assay throughput and 7x increase in protein antigen potency assay throughput method optimization and automation implementation

Associate Director - Principal Scientist: Cell, Molecular, Separations and MS/Biophysical Characterization
Analytical Development
BridgeBio Gene Therapy, Raleigh, NC
September 2019 – July 2023

Leadership & Strategic CMC Role
- Managed 11+ direct and indirect reports ranging from associate scientist to senior scientist level, responsible for project escalation, group objective setting, and employee growth, promotions, calibration, and compensation decisions
- Served as AD representative on chemistry, manufacturing, and controls (CMC) leadership team
- Lead AD head for novel pre-IND stage viral vector gene therapy program - with analytical support, process team successfully moved from CMC project initiation to process development and in-house completion of IND-enabling toxicology drug substance material generation within 6 months

Regulatory Leadership & Documentation
- Preparation of CMC section of pre-IND briefing book for viral vector gene therapy program
- Preparation and review of CMC sections for multiple viral vector gene therapy IND annual updates for FDA
- Authored and reviewed CMC regulatory documentation, including IND and IMPD submissions

Quality-by-Design & Process Development
- Analytical head for accelerated viral vector gene therapy program for transition from early to late-stage development
- Implemented quality-by-design (QbD) tools: 1) defined critical quality attributes (CQAs), pCQAs, and key performance attributes (KPAs), 2) failure modes and effects analysis (FMEA) to define key and critical process parameters (KPPs, CPPs)
- Led comparability efforts to enable change from FIH Process A to commercial Process B through process change risk assessments, comparability plan submission to FDA, and definition of statistical analysis for low manufacturing batch sample-size program

Technical Operations & Method Development
- Led development, transfer, and qualification of three in-vitro enzymatic potency assays for viral vector programs with phase-appropriate validation/qualification and analytical control strategy implementation
- Directed creation of peptide mapping method using mass spectrometry to monitor post-translational modifications
- Oversaw development and implementation of advanced analytical methods, including ddPCR, ELISA, and residual impurity assays

Laboratory Expansion & Operations
- Co-led initial design of cGMP QC release testing facility in Raleigh, NC for phase-appropriate testing and clinical batch release
- Successfully transferred and re-qualified entire analytical panel from one cGMP testing site to another, maintaining regulatory compliance
- Established comprehensive analytical panels, transferring methods to CDMOs for in-process, release, and stability testing

Key Achievements
- Led comprehensive analytical transfer and re-validation of entire analytical panel from one cGMP testing site to another, maintaining regulatory compliance and ensuring seamless continuity of testing capabilities for multiple viral vector programs
- 6-month timeline achievement from CMC project initiation to IND-enabling toxicology material generation for novel viral vector program - exceptional speed for gene therapy development

- Pivotal analytical leadership enabling successful IND submissions and regulatory readiness for two viral vector gene therapy programs
- Implemented quality-by-design framework defining CQAs, CPPs, and comparability strategy that supported transition from FIH Process A to commercial Process B Enhanced program efficiency by troubleshooting and resolving critical out-of-specification (OOS) results and establishing reference standard program for multi-site lot comparability

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Senior Scientist
Precision Biosciences
Durham, NC
March 2019 – August 2019

- Co-led development of two assays to quantitate critical nucleic acid species and metabolites for gene therapy programs, including development of assay to quantify 5' capping species of nucleic acid samples with reverse phase ion pairing liquid chromatography and mass spectrometry, while assisting in determination of critical quality attributes (CQAs) and appropriate analytical techniques from quality target product profile (QTPP).

Expert Scientist
GSK Vaccines
Rockville, MD
2016 – 2019

Strategic Leadership & Critical Vaccine Development

- Served as expert scientific and matrix leader for LC-MS, separations, biophysical and computational activities within GSK Vaccines Analytical Development US division
- Served as critical analytical contributor to Arexvy's (RSVPreF3 OA) development, GSK's first-in-class RSV vaccine for older adults, providing essential analytical support for successful regulatory approval and commercial launch
- Developed over ten critical methods and techniques in both protein-based and nucleic acid-based vaccine programs at GSK Vaccines
- Elected as Matrix Analytical Leader and single Point-of-Contact (POC) for US analytical department supporting Phase I GMP Batch Development Taskforce

Regulatory & Process Innovation

- Co-led initial design and development of Good Laboratory Practice Program in US Analytical R&D Department and wrote ten Good Laboratory Practice guidance documents aligned with ICH Q14/Q2(R2) and FDA guidelines
- Initiated program to implement JMP statistics to eliminate redundant assays from analytical panel that highly correlate with other analytical assays
- Co-led laboratory move from Research Triangle Park, NC to Rockville, MD, ensuring seamless transition of analytical operations

Key Achievements:

- Awarded **two Silver Performance Awards** for completion of critical and vital scientific programs contributing to vaccine development success

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Scientist I in Pre-Clinical/Early Development
MacroGenics, Inc.
Rockville, MD
2012 – 2016

- Established and managed protein LC/MS program for bispecific antibody and antibody-drug

conjugate (ADC) engineering and characterization, led implementation of SEC-MALS and DSC technologies for enhanced characterization capabilities, and supported computational modeling for antibody design through analytical insights and collaborative development.

TECHNICAL COMPETENCIES

Analytical Technologies

- **Liquid Chromatography:** RP-HPLC, SEC, IEX, HILIC
- **Mass Spectrometry:** LC-MS, LC-MS/MS, peptide mapping, intact mass analysis
- **Bioassays:** Cell-based potency assays, ELISA, immunofluorescence, FACS
- **Molecular Biology:** qPCR, ddPCR, nucleic acid quantification
- **Electrophoresis:** SDS-PAGE, CE-SDS, gel electrophoresis, capillary electrophoresis
- **Biophysical:** SEC-MALS, DSC, DLS, analytical ultracentrifugation
- **Protein Characterization:** Modern glycoprotein & carbohydrate characterization, peptide mapping

Product Categories

- **Biologics:** Monoclonal antibodies, bispecific antibodies, peptides, bioconjugates, antibody-drug conjugates (ADCs)
- **Vaccines:** Recombinant protein and nucleic acid/nanoparticle
- **Gene Therapy:** Viral vectors (protein capsid and nucleic acid payload characterization)
- **Complex Formulations:** Stability assessment, degradation pathway analysis

Regulatory & Quality

- **cGMP/GMP Compliance:** Method validation, qualification, transfer, method lifecycle management
- **Regulatory Submissions:** IND, BLA, MAA, IMPD documentation
- **Quality Systems:** GSP, ALCOA+, change control, deviation management
- **Laboratory Systems:** LIMS (Labware), ELN (IDBS), CDS
- **International Guidelines:** ICH Q14/Q2(R2), FDA, EMA, USP requirements

EDUCATION & PROFESSIONAL DEVELOPMENT

PhD in Chemistry and X-ray Crystallography
University of Toledo, Toledo, OH | December 2007
Dissertation: Electron Density Studies of Selected Nonsteroidal Estrogens

Postdoctoral Research:

Genentech, Inc. / University of Delaware (2010-2012): Advanced characterization of high concentration FDA-approved monoclonal antibodies with small angle x-ray and neutron scattering

Los Alamos National Laboratory (2008-2010): Development of rheo-scattering instrumentation for synthetic polymeric systems analysis

Select Journal Publications

Qian, J.; Yearley, E.J. e*t al.* Non-Enzymatic and Site-Specific Glycan Shedding: ANovel Protein Degradation Pathway Observed in a Stabilized Form of RSV Prefusion F Protein. *Anal. Chem.* **2018**, 90, 10897.

Yearley, E. J. *et al.* Observation of Small Cluster Formation in Concentrated Monoclonal Antibody Solutions and Its Implications to Solution Viscosity, *Biophys. J.* **2014**, *106,* 1763.

Yearley, E. J. *et al.* Small-Angle Neutron Scattering Characterization of Monoclonal Antibody Conformations and Interactions at High Concentrations, *Biophys. J.* **2013**, *105,* 720.

Yearley, E. J. *et al.* Binding of Genistein to the Estrogen Receptor Based on an Experimental Electron Density Study. *J. Am. Chem. Soc.* **2007**, *129*, 15013.