# Kristin H. (Long) Clement, Ph.D.

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Cornelius, North Carolina 28031

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kristinhclement@gmail.com

## PROFESSIONAL SUMMARY

- **Accomplished biomedical research scientist** with combined 24 years of academic, contract research, and consulting experience, developing quantitative MOA-based bioassays to support all stages of non-clinical and clinical assay development, supporting immunogenicity, PK/PD, stability indicating, and lot release under **GLP and GMP applications.**
- **Skilled leader and program administrator**, as evidenced by supervision of up to 12 full time technicians on various analytical projects, while managing multimillion-dollar government contract timelines, budgets, and deliverables and providing guidance on program issues. **Coached and mentored staff engaged in related research** engaged in biomedical research and programming**.**
- **Expert program management skills**, with 20 years' experience planning, organizing, and conducting of biomedical research on federal government contracts (NIH and BARDA funded), including writing, scientific and administrative review, and analysis of program announcements, solicitations, applications proposals, RFPs, RFQs, amendments, inclusive of extensive statements of work (SOW), scope, milestones, budgets, and tracking program progress and deliverables in Microsoft project.
- **Experienced Auditor,** having participated in rigorous regulatory audits for over 11 years by FDA, EPA, USDA, and ISO, and having performed quality/technical audits of contract research organizations and visits universities for government and pharmaceutical contracts evaluating phase appropriate preparedness (from early development to GMP release testing readiness).
- **Broad scientific experience** spanning cell and gene therapy, medical mycology, infectious diseases, host defense, cell and molecular biology, cancer, toxicology, neurology, and more specifically medical countermeasures against biological and chemical weapons.
- Accomplished scientific communicator, having **prepared and published peer reviewed manuscripts** in scientific journals, and have presented at professional scientific meetings.
- **Qualifying degrees:** Doctor of Philosophy (Ph.D.) in Cell and Molecular Biology, University of Cincinnati
- **Security Clearance:** Maintained Secret clearance continuously from 2003 – 2011 (9 years).

## EDUCATION

**Doctor of Philosophy (Ph.D.)**: Cell and Molecular Biology,
University of Cincinnati– Cincinnati, OH (1997 – 2002).

**Bachelor of Arts (B.A.)**: Biology Pre-Medicine Major; Chemistry Minor (magna cum laude)
Capital University – Columbus, OH (1993 – 1997)

## PROGRAM ADMINISTRATION EXPERIENCE

**Director of Analytical Development (private industry job)**
**Aruvant Sciences (fully remote, Cornelius, NC)**
**Chemistry Manufacturing and Controls (CMC) Department**
**Aruvant Sciences | Gene therapies for rare diseases.**
**06/19/2019 – 08/01/2022 (position eliminated due to company closure)**
**Hours per week: 40**
**Salary: 225K USD Per Year (inclusive of bonus)**
**Manager: Dr. Kathy Leach, Ph.D. - leachkj70@gmail.com (206-399-8303)**
**Okay to contact this manager: YES**

Aruvant's mission was to bring hope to patients living with rare diseases by developing life changing and potentially curative gene therapies, with a near-term focus on sickle cell disease (SCD). Aruvant was a part of the Roivant family of companies. The lead product candidate, ARU-1801, was an investigational lentiviral gene therapy as a potential one-time curative treatment for SCD. Preliminary clinical data from the ongoing Phase 1/2 study demonstrated durable efficacy in reducing the negative impacts of SCD. Aruvant was also in pre-clinical development of ARU2801, an AAV8 product in the pipeline for the treatment of hypophosphatasia.

- Led operations for the development of MOA-driven cell-based potency assays for lentiviral vector (LVV) and adeno-associated virus (AAV) products. Part of leadership team in charge of CMC supporting of Ph I/II and pivotal clinical studies.
- Directed Analytical Development (AD) internal and outsourced activities for the company's proprietary AAV and lentivirus-based programs. Primary responsibilities included monitoring Phase appropriate release, characterization, and stability analytical testing of lead product candidates ARU1801 (LVV-modified autologous stem cells) and ARU2801 (AAV8) for the treatment of sickle cell disease and hypophosphatasia, respectively.
- Vector operations team member assisting in trending analytical results in support of upstream and downstream process development for LVV and AVV manufacturing at external vendors using quadruple (LVV) and triple (AVV) transfection platforms.
- Worked closely with external CROs/CDMOs, collaborators, and/or partners through IND filing, clinical trials, in preparation for commercialization.
- Assisted in the effort to efficiently evaluate, select, and manage contract service providers (CDMOs and CROs). Primary responsibilities include analytical method development, method transfer, method qualification / validation, generation of standards and key reagents, comparability, and stability studies.
- Partnered with Project Management to ensure that assay development timelines were in place and aligned with the project's overall objectives.
- Assisted in developing and/or providing critical review of development documents (batch records, experimental data, protocols, reports, analytical methods, SOPs, etc.). Supported the creation, maintenance, improvement, and routine use of Quality Systems.
- Authored and reviewed analytical technical sections for company's global regulatory submissions related to programs.
- Assisted in adhering to a CMC budget for assigned program activities, including the preparation of cost estimates for new work. Work with the Office Manager to track invoices and proactively verify versus work performed. Partner with Finance to periodically review and report on the status of project spend versus the approved

budget. Recommend appropriate budgetary adjustments in conjunction with changing project scope and timelines, **managing research fund distribution amongst competing interests** within Aruvant (e.g., pre-clinical, versus clinical and CMC, and between products such as ARU1801 versus ARU2801). Reviewed proposal and budget applications from contractors for scientific merit, research plan, budget, timeline, qualified laboratories and staff, quality systems, and deliverables.

- Reviewed for completeness applications for contracts and studied scientific literature to place proposed research projects in its relationship to research being done in the subject matter area and respond to issues and concerns about specific applications or proposal pertaining to assigned program areas.
- Reviewed the technical and scientific merit of applications and proposals received requesting contract funds; provided advice in program planning, solicitation, and evaluation to perform day-to-day administrative functions related to research in analytical areas. Identified new basic, translational, and clinical research concepts, projects, and initiatives to appropriate advisory groups (CMC, quality, pre-clinical, clinical, regulatory), and formulated and developed Program Announcements, RFAs, RFPs to achieve objectives.
- **Managed multiple research teams concurrently -** Oversaw all analytical projects at 11 CRO/CDMOs: Catalent MO, Catalent, NC, Catalent MD, Avance BioSciences, BioReliance, WuXi, AGC, Thermo Fisher, Cincinnati Children's Hospital Medical Center (CCHMC), and Lonza. Managed analytical programs with respect to **project execution to ensure adherence to budget, schedule, and scope.**
- Manage initial scientific and administrative review of proposals submitted in response to RFPs, evaluate program activities for a portfolio of research projects, research and other awards, agreements/contracts in the assigned program area and the discovery, development, and evaluation of associated prevention and therapeutic strategies. Review and evaluate periodic and interim progress reports to determine effectiveness of support and achievement of objectives. As part of proposal review, **have appointed review panels to discuss the merit versus budget and timelines,** and evaluated using risk assessment scoring. These evaluations included **weighing scientific merit and approach with applications for funding.** Recommend funding plans/amendments for initiatives. Between 2019 – 2022 managed the following:
    - Competative RFP issuance, multi-proposal review, CRO selection, and contract management of 2.3M multi-year cell-based bioassay contract with Catalent Pharma Solutions, Kansas City, MO.
        - **Analyzed technical and scientific merit** of working and master cell banking approach, cell-based assay viral transduction process, and flow cytometry and ddPCR readouts. During these deliberations **recommended** that frozen-ready-to-use cell banking rather than continuous culture approaches were most appropriate for the program direction.
        - **Analyzed trends in scientific fields** such as determination if most appropriate viral vector protein expression platform would be FACS, Western Blot, or Protein Simple's JESS instrument. From these **analyses identified and recommended** that FACS was the be the most appropriate program direction.
        - For the AAV8 potency assay **identified scientific gaps**, including that the original potency assay developed by the Nippon Medical School in Japan was using a mouse cell line, and it was critical to switch to a human cell line. Further, since the mechanism of action for the potency assay was to inject the product in the muscle cells, a human muscle cell line must be identified. Identified a human skeletal muscle cell line from a vendor in Austria that was instituted.

- A decrease in investor funding required the contract to be amended to remove non-critical path milestones, **managed, and developed updated company policies in response to funding changes** to require that non-GMP testing be authorized in advance by Aruvant in writing before the testing was performed as a firm fixed price fee for service test to assist in tracking testing budgets more cleanly. To that end, **served as Aruvant's program officer** for the Catalent analytical projects and **monitored scientific progress of research programs to assure that objectives** were met using tools such as Excel, Microsoft Project, and weekly meetings with Catalent's technical and program management teams. To stay on task and within budget, created project plans (sample testing progress tracker), including project scope, goals, tasks (cell banking, development, qualification, release testing), resources (available technicians, supply chain even with Covid delays), schedules (timing for sample receipt, testing, QC review, QA review, etc.), costs (pass through cost, milestone under-runs, over runs), contingencies (testing failures), and communications (online meetings, face to face meetings, emails, reporting).
- During weekly meetings, discussed development of GMP potency assays to ensure that they **aligned with the regulatory guidelines** such as FDA's guidelines for product release. **Monitored performance of research project and provided technical feedback** in weekly meetings, ad hoc meetings, email, and quarterly management meetings.
- **Presented briefings on research to Aruvant's senior executive team** at regular intervals pertinent matters relating to biomedical and analytical research progress. In addition to presenting data, also summarized "headwinds" and "tailwinds" of things going well and things that need attention**, providing multiple alternatives and advice on best course of action.**
- **Resolved conflicts and differences among staff members and colleagues on differences in opinion on execution of research and programming.**

- Competative RFP issuance, multi-proposal review, CRO selection, and contract management of 1.4M multi-year HPLC testing contract with Catalent Pharma Solutions, Morrisville, NC.
- Competative RFP issuance, multi-proposal review, CRO selection, and contract management of 0.8M multi-year contract with Avance BioSolutions, Houston, TX for Next Generation Sequencing.
- Competative RFP issuance, multi-proposal review, CRO selection, and contract management of 0.5M multi-year analytical contract with BioReliance, Baltimore, MD, for cell bank, lentiviral and AAV safety and impurity testing (e.g., residual host cell DNA, residual host cell protein, mycoplasma testing, RCL, etc.)
- Competative RFP issuance, multi-proposal review, CRO selection, and contract management of 4.8M multi-year analytical contract with WuXi for cell bank, lentiviral and AAV safety and impurity testing (e.g., sterility, residual DNA sizing, etc.)
- Contract management of 10.8M multi-year analytical testing contract with the University of Cincinnati (cell-based bioassay testing, flow cytometery, CFU testing, etc.).

**Chief Executive Officer (sole proprietor consultant working in part on NIH/NIAID/DMID projects,)**
**Bio-Val Consulting, LLC (fully remote, Cornelius, NC)**
**www.BioValConsulting.com**
**06/01/2013 – Present**
**Hours per week: 1-15 (variable)**
**Salary: 25-60K USD Per Year**

Bio-Val Consulting (BVC) is a woman-owned small business (WOSB) that provides consulting services specializing in all phases of assay development and validation for large molecule ligand binding assays (LBA) and many types of cell-based assays, including proof of concept qualification, partial or full method validation, and technology transfer. Dr. Clement has applied her expertise in the assay life cycle starting with initial development all the way through GLP or GMP validation. In addition, BVC offers a variety of technical writing products, such as assay training packages (complete with proficiency testing protocols, SOPs, laboratory forms), final reports, white papers, manuscripts, and business development packages.

- Focused scientific medical/technical writer; able to prepare manuscripts, final reports, white papers, SOPs, laboratory manuals, training packages, laboratory forms, etc.
- Strong business development skills: experienced in the preparation of government and commercial proposals, liaising information to key personnel, and preparation of marketing material.
- Provides recommendations for all phases of bioanalytical assay development, method qualification and/or validation, technology transfer. Primary focus includes large molecule ligand binding assays (LBA; e.g., ELISA, ECL), and cell-based assays (macrophage lysis assays, binding assays, phagocytosis assays, T-cell proliferation) to meet the FDA's regulatory requirements.
- Offers guidance on how to evolve laboratory facilities to meet GLP regulations.
- Proficient in identifying or helping to produce rare critical reagents needed to support a validated assay for long term maintenance. In addition, able to guide reagent tracking for performance, stability, and inventory purposes.
- Performed instrument validation efforts (IQ/OQ/PQ of raw data gathering instruments such as plate readers, colony counters, etc.).
- Subject matter expert for NIH/NIAID/DMID extramural programs (2013 – present) on SARS-CoV-2, anthrax, Ebola, and RSV ligand binding assays (ELISA, ECL, and cell-based viral or toxin neutralization assays), chaired validation committees, and served as the principal investigator of critical reagent repository program to produce and rare reagents for emerging infectious disease and biothreat assays.
- Audits/visits universities, research institutions, commercial organizations, and other government/public/private organizations to review phase appropriate project progress or quality systems framework. Have participated in NIAID Viral Respirator Diseases Section visits at Emory and Vanderbilt Universities for progress audits. Prepared materials summarizing scientific successes, analysis of progress, and future goals. **Summarized audits for NIAID in the form of report, including evaluations of the progress, summary statements.**
- Scientific Board Member (March 2019 – present) for BEBPA (BioPharmaceutical Emerging Best Practices Association) conferences:
    - Conference moderator and session chair (both USA and EU bioassay conferences held biannually).

- Conducts workshops, help organize speaker content for conferences that support analytical development and validation, facilitate communication among stakeholders (speakers, attendees, and vendors)

**Biology Content Developer (part time contractor position)**
**Sapling Learning (fully remote – Austin, TX) – Now Macmillan Learning**
**www.macmillanlearning.com**
**06/01/2013 – 04/03/2014**
**Salary: $50/hour USD**
**Hours per week: 15**
**Manager: Amber Jonker *linkedin.com/in/amberjonker* (512-298-1693)**
**Okay to contact this manager: YES**

Sapling Learning develops customized scientific online instruction through problem-solving practice and coaching and tracking of student performance through grade book and analytic tools. At Sapling Learning, there is a rare blend of professional educators, scientists, textbook authors, editors, instructional technologies experts, animators, artists, designers, and software developers. Sapling Learning provides students with rich, discipline-specific interactions and learning tools, such as molecule drawing and graphing, to promote engagement and comprehension in Science, Technology, Engineering and Mathematics (STEM), and economics courses.

- Responsible for writing clear questions and solutions of varying difficulties that test students' understanding and application of biological concepts.
- Develops hints, solutions and feedback that provide insightful diagnosis of student mistakes and misconceptions and coach students toward mastery.
- Reviews work written by other content authors and providing constructive criticism and guidance to those authors.

## INDEPENDENT RESEARCH EXPERIENCE

**Product Development Specialist (Government contractor job: BARDA and NIH/SBIR)**
**Countervail Corporation (Charlotte, NC)**
***http://www.countervailcorp.com***
**04/04/2014 – 06/15/2019 (full time 2014-2015, part time 2015-2019)**
**Hours per week: 40 (2014-2015), 2-20 (2015-2019)**
**Salary: 75K USD Per Year**
**Owner/Manager: Mr. Bill Basinger: bbasinger@countervailcorp.com (704-804-8612)**
**Okay to contact this manager: YES**

Countervail Corporation focuses on providing protection and treatment of military and civilian populations from exposure to chemical and biological weapons. Countervail technology is also targeted toward the protection from and treatment of acute organophosphate pesticide exposure. Established a strategic partnership with Countervail Corporation (2014 – 2019) as a product development specialist. In collaboration with the CEO of Countervail, Bill Basinger, submitted a provisional patent in 2015 to secure the intellectual property for a baseline free lateral flow assay that quantitates degree of exposure to organophosphate (OP) poisoning (pesticide or nerve agent). The provisional patent was accepted March 2019 (Patent ID 10,288,614). Dr. Clement was awarded an SBIR Phase I grant in 2018 that funded the development of the prototype lateral flow device. Results from the prototype have been submitted for Phase II SBIR funding and are

currently under review. Meanwhile, assisted Mr. Basinger with scientific writing (proposals, reports, manuscripts) in support of other Countervail products, namely Galantamine hydrobromide, a reversible acetylcholinesterase inhibitor that Countervail has demonstrated in guinea pigs, rats, and NHPs to be highly effective in protecting neurological deficits and death from sublethal and lethal challenges from highly toxic nerve agents such as sarin, soman, and VX (work funded by BARDA).

- Prepared and edited manuscripts, patents, and **co-authored research grant** proposals (see below).
- Determined application risks to research and business plan with new technologies.
- Evaluated data from ongoing studies conducted on products currently under investigation and contribute toward literature searches assessing product application in humans and animals.
- Past performance of extramural research:
  - NIH/SBIR Grant No. 1 R43 NS102080-01A1 (PoP 1 year [2019] Awarded $210,491) developed a proto-type lateral flow point of care test that separated and semi-quantitated OP-bound from free butyrlcholinesterase (BChE) in a baseline free manner. Demonstrated proficiency in developing a novel biomarker assay with clinical implications. **First author on grant and principal investigator, obtaining independent grand funding for research.**
  - SBIR Fast Track Phase II Grant (Awarded $845,000) continued development of AverTox® (galantamine) for pre-exposure administration to protect against soman toxicity.
  - BARDA Contract HHS0100201100030C (PoP 4 years [2011-2015] Awarded $: $10.6M development of AverTox® (galantamine) for pre-exposure administration to protect against OP toxicity.

**Senior Research Scientist/GLP Study Director (Government contractor job: NIAID and BARDA)**
**Battelle Memorial Institute, Biomedical Research Facility (BBRC), West Jefferson, OH**
**Department of Molecular and Cell Biology**
***www.battelle.org***
**06/16/2002 – 05/31/2013**
**Hours per week: 40**
**Salary: 110K USD Per Year**
**Director (Life Sciences Research): Dr. Andrew (Drew) Cawthon, Ph.D.:**
**cawthona@battelle.org**
**Okay to contact this director: YES**

The BBRC specializes in the evaluation of medical countermeasures against highly pathogenic organisms, biological toxins, and highly toxic chemicals to support medical product efficacy testing for the Department of Health and Human Services, and the Department of Defense, for approval by regulatory agencies such as the Food and Drug Administration (FDA) licensing, the U.S. Environmental Protection Agency (EPA), and for non-U.S. regulatory agencies. Battelle is responsible for innovative and cutting-edge research performed in biological safety level 2 and 3 (BSL-2 and BLS-3) laboratories.

- Senior Research Scientist from 2006 – 2013, Principal Research Scientist from ’04 – ’06, and Research Scientist from ’02 – ’04.
- Study Director for a total of 43 non-clinical and clinical studies (10 of which were GLP) performed in support of pivotal investigational new drug efficacy studies conducted

under the “Animal Rule.” [Animal Rule: “Approval of Biological Products (New Drugs) When Human Efficacy Studies Are Not Ethical or Feasible;” CFR § 601.90-95 (biologicals) And 21 CFR § 314.600-650 (drugs)].

- Point of contact for NIAID/BARDA program officers for all analytical matters on extramural research programs, preparing proposals and proposal amendments, cooperative agreements, and review of contracts.
- Served as subject matter expert (SME) for assay validation and technology transfer on the BBRC Validation Committee. Helped to establish the BBRC Master Validation Plan and completed eleven (11) assay validations (reviewed and approved by either CBER or CDER), six (6) equipment validations, and fourteen (14) assay qualification studies. Examples include:
  - Developed and validated anti-anthrax cell-based toxin neutralization assays (TNA), Anti-PA IgG ELISA, PA ELISA, and PA ECL assays for human, monkey, rabbit, and guinea pig serum matrices.
  - Developed and qualified vaccine lot release ELISAs for the quantification of glycoprotein for Ebola Zaire and Ebola Sudan virus like particles (VLPs).
  - Performed anthrax spore lot release studies using validated *in vivo* guinea pig potency assay.
- Continuously monitored overlapping project timelines and budgets while serving as a scientific liaison to both government and commercial clients. [Completed program management training for obtaining Program Management Professional (PMP) Certification.]
- Principal Investigator of four Internal Research and Development (IR&D) projects; of which the largest project managed $400,000 leading to the successful production, qualification, and validation of rare critical reagents that support anthrax *in vitro* assays. These reagents/assays in turn are used to investigate anthrax vaccine and therapeutic candidates in various stages of drug licensure critical path through the FDA.
  - Established new master and working cell banks, purified polyclonal IgG, new reference standards, and quality control samples.
  - Tracked reagent inventory, freeze thaw cycles, and assay performance in a multi-faceted database (supported by SQL server).
- Proposed, procured, and managed $26 million in commercial and government contract research funding. Contributed to proposal writing and cost estimations leading to awards totaling >$100 million dollars in total research funding over 10 years, including Indefinite Deliverable Indefinite Quantity multi-task order contracts.
- First author to 68 internal and client final reports, 18 Standard Operating Procedures, 39 proposals, 6 training protocols, 2 peer reviewed manuscripts, 9 abstracts/posters, and additionally co-authored 7 manuscripts, 8 abstracts, and 2 clinical investigator laboratory manuals.
- Supervised technical staff within the Molecular and Cell Biology group; managed lab work, quality documentation, and billable hours.
- Study monitor and quality assurance experience – audited collaborator’s facilities for regulatory compliance.
- Attended scientific seminars and regularly studied scientific literature to stay informed of national and international research efforts and scientific advances in the field, particularly extramural work supported by NIAID.

**Doctoral Research Candidate**
**Dept. of Internal Medicine, Division of Infectious Diseases**
**University of Cincinnati, Cincinnati OH**
**September 1997 – May 2002**
**Thesis Advisor (Retired): Dr. Simon Newman, Ph.D. captnfungus@gmail.com**
**(513-484-6849)**
**Okay to contact this advisor: YES**

- Doctoral Dissertation (1998 – 2002): "Identification of Heat Shock Protein 60 (Hsp60) as the Ligand on *Histoplasma capsulatum* (Hc) that Mediates Binding to CD18 Receptors on Human Macrophages."
- Rotating Research Project (1997 – 1998), Children's Hospital Research Foundation – Cincinnati, OH – Department of Pulmonary Medicine, Division of Allergy and Immunology: Cloned the 5' region of the mouse eosinophil peroxidase (EPO) gene including the promoter to be used to create a conditional eosinophil knockout mouse.
- Rotating Research Project (1997), University of Cincinnati – Cincinnati, OH – Department of Cell Biology, Neurobiology, and Anatomy: Characterized the intermediate filament distribution of mitochondria in dorsal root ganglia neurons from wild type and transgenic mice that contain a disrupted peripherin network.

**Research Technician**
**Dept. of Immunology**
**Ross Laboratories, Division of Abbott Laboratories**
**September 1996 – August 1997**
**Manager (Retired): Dr. Christopher Cordle 7405046984chris@gmail.com**
**(704-504-6984)**
**Okay to contact this advisor: YES**

- Responsible for hypoallergenic product analysis. Performed quality control assays (SDS-PAGE, ELISAs, etc.) on pediatric and adult nutritionals to monitor lot to lot potency and reproducibility.
- Contributed to organizing lab operations to ensure GLP compliance.

## TEACHING EXPERIENCE:

**Adjunct Faculty**
**Wright State University, Dayton, Ohio**
**Department of Pharmacology and Toxicology**
**January 2003 – May 2012**

- Lecturer in the master's level course, "Principals of Toxicology: Applications to Medical Biological Defense." (Part B: PTK770).
- Course material taken from: Textbook of Military Medicine: Medical Aspects of Chemical and Biological Warfare.
- *Ad hoc* reviewer for student's master's thesis proposals.

**Senior Research Scientist/Trainer**
**Battelle Memorial Institute's Mentorship Program, Columbus, Ohio Department of**
**January 2006 – May 2013**

- Online lecturer in routine the "Brown Bag Lunch" seminar series regarding various pathologic agents of bioterrorism (e.g., Plague, Anthrax, Brucella, Tularemia, etc.)
- Delivered online webinars and remote presentations to staff and clients on training and project initiatives, completed milestones, data, and future directions.

**Adjunct Faculty ('01 – '02), and Graduate Teaching Assistant ('00 – '01)**
**Department of Biology**
**Xavier University, Cincinnati, Ohio**

- Lecturer: Life Growing and Evolving (Biology 112-21). Independently generated original lectures; syllabus and exams on cell structure and function; basic principles of molecular genetics; and an in-depth analysis of each biological kingdom.
- Life Investigations Lab II (Biology 127-OB). Taught vertebrate anatomy via fetal pig dissection. Analyzed the origins of life, Darwinian theories of evolution, and comparative anatomy.
- Life Investigations Lab I (Biology 127-OF, -OG). Guided scientific inquiry and critical thinking skills by working in cooperative teams and using the scientific method to design and execute original research on select organisms. Facilitated student peer review via poster presentations and publication in the "Journal of Undergraduate Biology" (JUBI).

**Instructor**
**Howard Hughes Excellence in Science Education and Learning (ExSEL) Program**
**Department of Cell Biology, Neurobiology, and Anatomy**
**University of Cincinnati, Cincinnati, Ohio**
**August 2001 – May 2002**

- Five-week enrichment series of research modules focused in five biomedical disciplines, geared for selected high school seniors.
- Authored the cell biology curricula, and significantly contributed to the design of the laboratory manual, which included written protocols and schematic representations of each laboratory procedure.
- Guided students through brief research projects and taught science content.

**Instructor**
**Yeast Mutants as an Educational Tool (YMET) Program**
**Department of Molecular Genetics**
**University of Cincinnati, Cincinnati, Ohio**
**2000**

- Instructed middle school students in basic molecular research, introducing modern biological research methods.
- Demonstrated cell and molecular biological techniques to enhance scientific interest and motivation, and overall understanding of life sciences.

**Instructor**
**Summer Science Institute**
**Department of Chemistry**
**Capital University, Columbus, Ohio**
**1994-1995**

- Teaching and laboratory assistant for a full scholastic year undergraduate organic chemistry course condensed into an intense 8-week summer science program.
- Assisted faculty with preparation and delivery of lectures and lab demonstrations, as well as tutored students in structure of molecular compounds and multi-step chemical reactions.

## SKILLS:

- Laboratory:
    - Immunological: ELISA, ECL (MSD), cell-based assays (neutralization, binding and phagocytosis assays, ELISpot, Promega GloMax® luciferase assays), qPCR, ddPCR, ouchterlony, protein purification via affinity chromatography, Western blot, Far-Western blot, Immunohistochemistry with analysis by fluorescent-, confocal-, and electron microscopy, flow cytometry.
    - Cellular: protein extraction, in vitro wound filling assays, cytosolic and cell membrane protein preparation, mammalian/bacterial/fungal cull culture (aseptic technique), isolation of monocytes, lymphocytes, and neutrophils from human peripheral blood
    - Molecular: Southern Blot, plasmid DNA preparation, transfection of bacterial plasmids into bacteria by electroporation, PCR, restriction enzyme digestion and ligation cloning, radio-labeling of DNA probes, transgenic mouse genotyping.
- Computer: Microsoft Office (Word, Excel, PowerPoint, Outlook, Communicator, and Project), Softmax Pro, ELISA for Windows, various SAS and R programs, SharePoint, and Pilgrim SmartDOC, SmartTRAIN, SmartAUDIT, Compliancewire, and Docusign.
- Document Control: Veeva, Pluto

## AWARDS AND HONORS:

2010 – Battelle Biomedical Research Center Employee of the Month (June 2010)
2008 – Capital University Athletic Hall of Fame Induction
2006 – Ohio Hoop Zone Hall of Fame Induction (May 2006)
2003 – Key Contributor Award (KCA), Battelle Memorial Institute
2002 – Nominated for the Presidential Leadership Medal of Excellence, University of Cincinnati
2002 – 1st Place, Life Science Division, University-wide Graduate Student Research Forum, University of Cincinnati
2001 – Honorable Mention, 22nd Annual Graduate Student Research Forum, University of Cincinnati
1999 – Graduate Student Summer Research Fellowship, University of Cincinnati
1997 – GTE Academic All-American, Capital University (Selected by CoSIDA)

1997 – Outstanding Biology Student of the Year, Capital University
1997 – Division III Women's Basketball Team Captain; Achieved 1,000 Point Milestone
1993-94, and 1994-95 Division III Women's Basketball National Champions; team captain

## QUALIFICATIONS AND TRAINING:

**2013** OHSA Bloodborne Pathogens (annually 2002 – 2013)

**2012** PHS Conflicts of Interest - Instructions for PHS Conflicts of Interest
Effective Relationships with Business Partners
Effective Relationships with Customers
Developing Strong Customer Relationships
Identifying and Managing Customer Expectations
Difficult Interactions
Interpersonal Communication: Communicating with Confidence
Interpersonal Communication: Listening Essentials
Annual Security Refresher Briefing for DoD and/or NRI Cleared Staff (2003 – 2012)

**2011** Cyber Security Annual User Awareness Training
Creating a Safety Culture Refresher: Staying Safe in Hazardous Environments - Staying Safe in Hazardous Environments
**2010** Creating a Safety Culture Refresher: Reducing Errors Through Human Performance Improvement - Reducing Errors Through Human Performance Improvement
Informed Consent Training: Developing and Administering Informed Consent
Informed Consent: Developing and Administrating Informed Consent

**2009** Project Closing
Fire Extinguisher Awareness
ISO 9001:2008 QMS Requirements
Eradicating Bullying in the Workplace Awareness
Equal Employment Opportunity and Affirmative Action Training for Managers
Managing Generations

**2008** Workplace Harassment
Saf-T-Pak
Diversity Awareness
Generations: M.E.E.T. for Respect in the Workplace
Harassment and Discrimination

**2007** Project Management Basics - PM Basics Web-based course from IIL
Basis of Estimate: Your Formula for Success
High Performance Communication

## REFERENCES

- Dr. Kathy Leach, Director of CMC, Aruvant Sciences (Leachkj70@gmail.com) 206-399-8303
- Dr. Laureen Little, President of BEBPA and FasTrain, Principal Consultant of Quality Services, and Publisher of BioQuality; 951-312-5609 (biotech@ix.netcom.com)

## PEER REVIEWED PUBLICATIONS

**Clement, KH** and Basinger WG, "Detection of the Degree of Exposure to Chemical Warfare Nerve Agents and Organophosphate Pestidicides with Lateral Flow Assays." U.S. Patent Application No. 10,288,614.

Ionin, B, R Hopkins, B Pleune, G Sivko, F Reid, **KH Clement**, T Rudge, G Stark, A Innes, S Sari, T Guina, C Howard, J Smith, ML Swoboda, E Vert-Wong, V Johnson, G Nabors, and M Skiadopoulos. 2013. Evaluation of Immunogenicity and Efficacy of Biothrax® (Anthrax Vaccine Adsorbed) for Post-Exposure Prophylaxis. Microb Immun Vaccines. Manuscript in Press; Accepted with Revisions.

**Clement KH**, TL Rudge Jr, HJ Mayfield, LA Carlton, A Hester, NA Niemuth, CL Sabourin, AM Brys, and CP Quinn. 2010. Vaccination of rhesus macaques with the anthrax vaccine adsorbed vaccine produces a serum antibody response that effectively neutralizes receptor-bound protective antigen in vitro. Clin Vacc Immun. 17(11):1753-62

Omland KS, AM Brys, D Lansky, KH **Clement,** and F Lynn. 2008. Interlaboratory Comparison of Results of an Anthrax Lethal Toxin Neutralization Assay for Assessment of Functional Antibodies in Multiple Species. Clin Vacc Immun. 15(6): 946–953

Campbell JD, **KH Clement**, SS Wasserman, S Donegan, L Chrisley, and KL Kotloff. 2007 Safety, reactogenicity and immunogenicity of a recombinant protective antigen anthrax vaccine given to healthy adults. Hum Vacc. 3(5):205-11

**Long KH,** FJ Gomez, and SL Newman. 2003. Identification of Heat Shock Protein 60 as the ligand on *Histoplasma capsulatum* that Mediates Binding to Human Macrophage CD11/CD18 Receptors. J Exp Med**.** 170:487-494

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Multiple contributing authors to the voluntary consensus standard, including **KH Clement,** "Standardization of in vitro Assays to Determine Anthrax Toxin Activities." American National Standards Institute (ANSI); ANSI/ATCC ASN-0001-2009

## PUBLISHED ABSTRACTS

**Clement KH,** TL Rudge, Jr., NT Huber, KA Newman, KA Sankovich, RH Migliozzi, and CL Sabourin. 2012. Production and Qualification of Unrestricted Reagents to Support Anthrax Assays. ASM Biodefense. February 26 – 29, Rockville, Maryland.

Gainey M, A Puttmann, TL Rudge, Jr., **KH Clement,** R Krile, E Vela, and J Blank. 2012. A Validated Procedure for the Rapid Detection of the *Bacillus anthracis* Protective Antigen in Serum by the Electrochemiluminescence Screening Assay During Studies Testing

Therapeutic Products. Women in Science and Engineering (WISE) Symposium 2012, Battelle Memorial Institute, Columbus, Ohio.

O'Conner E, **KH Clement,** RH Migliozzi, C Howland, and L Casey. 2011. Observations on the Development of an ELISA for Protective Antigen of *Bacillus anthracis* in Serum. The International Conference on *Bacillus anthracis, B. cereus and B. thuringiensis* (Bacillus ACT) 2011 Meeting, August 7-11, Bruges, Belgium.

**Clement KH,** TL Rudge Jr., HJ Mayfield, LA Carlton, A Hester, NA Niemuth, CL Sabourin, AM Brys, and CP Quinn. 2009. Vaccination with Anthrax Vaccine Adsorbed (AVA) Provides Protection Against Multiple Molecular Targets from Inhalation Infection with Bacillus Anthracis Spores. The International Conference on *Bacillus anthracis, B. cereus and B. thuringiensis* (Bacillus ACT) 2009, Meeting August 3 – September 3, Santa Fe, New Mexico.

**Clement KH,** JL Mango, and TL Rudge Jr. 2009. Development of an Interspecies Enzyme Linked Immunosorbent Assay (ELISA) to Detect Bacillus Anthracis Protective Antigen (PA) in Serum. The International Conference on *Bacillus anthracis, B. cereus and B. thuringiensis* (Bacillus ACT) 2009, Meeting August 3 – September 3, Santa Fe, New Mexico.

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**Clement KH,** D Lansky, C Wager, TL Rudge, DR Watson, E Luzano, C Landsettle, J Senft, and C Sabourin. 2007. Validation of the Rabbit Anthrax High Throughput Toxin Neutralization Assay (htpTNA). The International Conference on *Bacillus anthracis, B. cereus and B. thuringiensis* (Bacillus ACT) 2007, Meeting June 17 – 21, Oslo, Norway.

Rudge TL, **KH Clement,** LA Carlton, A Hester, AM Brys, D Pohlman, D Robinson, N Marano, CP Quinn, and C Sabourin. 2007. PA63 Toxin Neutralization Assay in Non-Human Primates Vaccinated with Anthrax Vaccine Adsorbed (AVA): AVRP Immune Correlates of Protection Study. The International Conference on *Bacillus anthracis, B. cereus and B. thuringiensis* (Bacillus ACT) 2007, Meeting June 17 – 21, Oslo, Norway.

Mott J, G Meister, RE Hunt, **KH Clement,** M Babin, R LeClaire, J Estep. 2006. Rabbit Model for Inhalation Anthrax. ASM Biodefense. February 23 – 26, Washington, DC.

Marano N, K Hogan, **KH Long,** D Rodabaugh, N Rosenstein, R Besser, CA Dykewicz, and CP Quinn. 2005. Anthrax Immune Globulin Efficacy in Animals. The International Conference on *Bacillus anthracis, B. cereus and B. thuringiensis* (Bacillus ACT) 2005, Meeting September 25-29, Santa Fe, New Mexico.

**Long KH,** CM Matthews, TR Moir, KE Kersey, RE Hunt, JE Estep, AV Tatro, Quinn CP, and L Falk. 2005. Analysis of Rabbit Serum Samples by Enzyme Linked immunosorbent Assay (ELISA) and Lethal Toxin Neutralization Assay (TNA) for the Detection, Quantification, and Assessment of Neutralizing Capability of Anthrax Protective Antigen (PA) Specific
Antibody. The International Conference on *Bacillus anthracis, B. cereus and B. thuringiensis* (Bacillus ACT) 2005, Meeting September 25-29, Santa Fe, New Mexico.

Sabourin PJ, RE Barnewall, PH Olson, TL Rudge, **KH Long,** EB Heller, KE Sayers, E Nuzum, JA Hewitt, JM Mott, RD LeClaire, RE Hunt, and JE Estep. 2005. Short Duration Ciprofloxacin Therapy Provides High Protection to Non-Human Primates Challenged with Aerosolized *B. anthracis* Spores. The International Conference on *Bacillus anthracis, B. cereus and B. thuringiensis* (Bacillus ACT) 2005, Meeting September 25-29, Santa Fe, New Mexico.

**Long KH,** FJ Gomez, and SL Newman. 2002. Identification of Heat Shock Protein 60 as the ligand on *Histoplasma capsulatum* that Mediates Binding to CD18 Receptors on Human Macrophages. American Society for Microbiology, Meeting May 20 – 23, Salt Lake City, Utah.

## INVITED SPEAKER

March 2011. Validation of BioAssays. Battelle Memorial Institute Brown Bag Luncheon, Battelle Biomedical Research Center, West Jefferson, Ohio.

February 2009. Overview of the Anthrax Protective Antigen Enzyme Linked Immunosorbent Assay. Food and Drug Administration Symposium on Anthrax Animal Model Update sponsored by the National Institutes of Allergy and Infectious Diseases. White Oak Campus, Silver Spring, Maryland.

July 2007. Alternative Careers in Science. Kristin H. Clement, The Ohio State University, The Bennett Society, Doctoral Career Day. Columbus, Ohio.

May 2006. My Career in Science – Past, Present, Future. Danville High School Career Day, Danville, Ohio.

April 2005. Brucellosis; Undulant Fever. Battelle Memorial Institute Brown Bag Luncheon, Battelle Biomedical Research Center, West Jefferson, Ohio.

April 2004. Validation of the Bio-Tek® ELx800 Microplate Reader and KC4 Software. IBC's 8th International Symposium of the Biological Assay Development & Validation Course, San Diego, California.