LUKE HERGERT

Address: 424 Palisades Trail, Keller, Texas 76248
Mobile: 414.364.6759 | **Email:** chemlu2002@yahoo.com

QUALIFICATIONS PROFILE

Highly analytical, performance-focused, and results-driven professional with hands-on experience in analytical research and development; backed by strong background in quality control and quality assurance.

Solid ability in providing analytical chemistry services, implementing various methods and programs, as well as improving quality and production processes. Expert in pertinent quality systems pertaining to change controls, deviations, CAPA's, and complaints as well as audit support for FDA, USP, EP, JP, and CP inspections. Skilled in instrument installation and repair, product validation and release, materials handling, and regulatory compliance. Effective leader and concept-to-execution driver, with proven expertise in accomplishing various projects from inception to completion and delivery. Recognized for strategic management approach in directing and coordinating team efforts to achieve seamless and productive operations. ~16 years of pharmaceutical experience with ~8 years in a managerial role

EDUCATION

UNIVERSITY OF WISCONSIN–MILWAUKEE | Milwaukee, WI
Master of Business Administration: May 2012

UNIVERSITY OF WISCONSIN–MILWAUKEE | Milwaukee, WI
Master of Science in Chemistry, Major in Inorganic Chemistry: Dec 2005

UNIVERSITY OF WISCONSIN–OSHKOSH | Oshkosh, WI
Bachelor of Science in Chemistry: May 2003

TECHNICAL ACUMEN

Trackwise | Master Control | SABA Cloud | AZ Docs | Power BI | DocuSign | Veeva QMS | Enablon | Adobe | Workday | Minitab | Scifinder | Chemdraw | Microsoft Office Suite & Teams | Salesforce | ChemStation/OpenLab | Chromeleon 6 & 7 | Empower 1 & 2 & 3 | LabLynx | SAP

PROFESSIONAL EXPERIENCE

ASTRAZENECA (FORMERLY ZS PHARMA) | Coppell, TX
Senior member of QA - Operations: Sep 2019–Present

- Conduct QA area investigations and support internal / external audits through various audit roles (e.g., subject matter expert (SME), scribe, document logger, or coach)
- Mentor in team and project meetings, advising project teams with respect to quality / compliance solutions and potential new approaches for consideration
- Perform deviation (minor through critical) risk assessments / reviews / approvals in IDM (International Deviation Management System) and CAPA reviews / approvals in IDM
- Assess, review, and approve change management records in OCM (Operational Change Management System) and Veeva quality management system (QMS)
- Support local complaint investigations, identify, and rectify any trends in GCM (Global Complaints Management System)
- Review/approve drug substance batch documentation and drug product vendor data for compliance to specifications, correctness, and completeness to release product for further processing or commercial trade
- Review / approve laboratory investigations and extended laboratory investigations
- Provide expert advice on Good Manufacturing Practice and Good Laboratory Practice to Operations / Quality Control and ensure compliance with the associated quality standards
- Utilize Lean Six Sigma problem solving tools such as level 0, practical problem solving (PPS), DMAIC, and human error root cause analysis (HERCA) as well as other lean tools such as Hoshin Kanri, Poka-Yoke, A3, etc.
- Collaborate with other quality assurance colleagues to ensure consistent application of quality systems / processes across the site

LUKE HERGERT

Address: 424 Palisades Trail, Keller, Texas 76248
Mobile: 414.364.6759 | **Email:** chemlu2002@yahoo.com

- Apply the first level of risk management by using analytical skills and experience to make decisions, develop solutions, or more complicated judgments, within general operating guidelines

Career Highlights:

- ✓ Cross trained and actively involved in a wider range of quality systems than anyone else in the quality organization (change controls, deviations, CAPA's, complaints, laboratory investigations, and drug substance/product batch release)
- ✓ Supported completely revamping the laboratory investigation process which allowed for considerable time savings and ease of use; completely revamping approximately 110 SOP's, test methods, and forms over a 6 - month period to bring QC up to a current high-quality state

ASTRAZENECA (FORMERLY ZS PHARMA) | COPPELL, TX

Interim Lead Investigator: Jan 2021–Mar 2022

- Conducted QA area investigations and supported internal / external audits through any of the audit roles (subject matter expert (SME), scribe, document logger, or coach)
- Trained and mentored all new Coppell site investigators requiring access to IDM
- Site business process owner (BPO) for deviations / CAPAs and sole Coppell member of the America's regional deviation/CAPA team supporting global initiatives, actions items, and improvement activities
- Worked within and across functions, sites, and regions to ensure connectivity of investigations between functional areas and sites
- Leveraged the skills and technical expertise of internal and external resources to continuously improve the robustness, rigor, and lead time of investigations
- Conducted organized investigations with a well-defined scope, strategy and timeline, documenting status and progress of the investigation and CAPAs within IDM
- Collaborated with an investigation team to determine escalation and communication strategy so all stakeholders have appropriate information and may act in a timely manner, investigation strategy including a clear and actionable problem statement, investigation tools, investigation action plan and timing, solution selection, and CAPA action plan and effectiveness checks
- Prioritized work to aid in timely decisions and completion of investigations and escalated issues as appropriate
- Utilized the appropriate and approved investigation tools necessary to drive the team to root cause including but not limited to: Level Zero, Practical Problem Solving, or Six Sigma process robustness tools
- Authored reports that document the investigation of issues including definition, scope, product impact, root cause and corrective actions to prevent the recurrence of the issue.
- Tabulated weekly, quarterly, monthly, and annual metrics; presented data at weekly tier and monthly management review meetings

Career Highlights:

- ✓ Held two separate AstraZeneca jobs for 14 months (70+ hour work weeks) due to a severe lack of personnel at the time
- ✓ 30% year over year reduction in overall deviation rate

BIOCHROMA ANALYTICAL LABS, LLC | Dallas, TX

Director of Chemistry: Nov 2018–Sep 2019

- Provided strategic leadership and training to a group of ten quality control scientists, to support comprehensive analytical testing under Food and Drug Administration (FDA), United States Pharmacopeia (USP), Association of Analytical Communities (AOAC), and International Conference on Harmonization (ICH) guidelines in a good manufacturing practice (GMP) and ISO17025 environments
- Assisted with company budgeting, customer quotes, audits, out of specification (OOS)/deviation reports, and corrective and preventative actions (CAPA's)
- Actively created, implemented, and improved analytical training and tools/methods for release of raw materials, intermediates, final products, and stability, utilizing high-performance liquid chromatography (HPLC), gas chromatography (GC), mass spectrometry (MS) for over-the-counter medications (OTC's), nutraceuticals, and personal care products

- Responsible for policies on data administration, organization, and reporting while maintaining a defensible quality assurance/control program
- Collaborated with President and VP of Scientific Affairs to resolve company, customer, and regulatory issues
- Created new test groups, parameters, and entities as one of the Laboratory Information Management System (LIMS) administrators
- Excel at organizing/tracking excessive amounts of information
- Responsible for all screening/hiring of new scientists

Career Highlights:

- ✓ Proficiently resolved a 4-month backlog in LIMS within the first month of employment
- ✓ Completely revamped the reference standard storage system which allowed for significant daily time savings
- ✓ Under my direction, for the first time in company history across a 1-month span, the Chemistry department not only outperformed the Microbiology department, but was two-fold more profitable

STERLING PHARMA SOLUTIONS (FORMERLY ALCAMI CORPORATION) | Germantown, WI

Supervisor, *Analytical Research and Development*: Aug 2014–Jul 2018

- Provided strategic leadership and training to the following teams and/or individuals:
  - A group of five analytical research and development (AR&D) scientists to support comprehensive drug substance development and validation projects under Food and Drug Administration (FDA), United States Pharmacopeia (USP), European Pharmacopoeia (EP), and International Conference on Harmonization (ICH) guidelines in a good manufacturing practice (GMP) and ISO9001 environments, along with fifteen indirect reports; and
  - Training Team to produce and implement analytical training materials and standard operating procedures (SOP's) for AR&D and Quality Control (QC) departments
- Completed investigations, deviations, and corrective actions preventive actions (CAPA), in partnership with internal and external stakeholders
- Assisted actively in creating, implementing, and improving analytical methods for release of raw materials, intermediates, final products, stability, and in-process testing, utilizing high-performance liquid chromatography (HPLC), gas chromatography (GC), mass spectrometry (MS), and ion chromatography (IC) for early, late, and commercial phase projects
- Defined project scope based on client request for quotation (RFQ) to prepare analytical activities for development, manufacturing, and release, in collaboration with site leadership
- Conducted presentation of key performance indicators to site leadership on a biweekly basis, which involved lost time from poor quality or repeat work, resource utilization, and on-time delivery
- Took charge of formulating and/or reviewing certificates of analysis (CoA), failure mode effects analysis (FMEA) reports, and batch records for GMP processes, as well as 190 test methods and 130 validation protocols/reports
- Communicated effectively with vendors in relation to raw material method transfers, as well as method transfers between company facilities
- Maintained active client interactions, from project implementation through closeout
- Contributed to the hiring, onboarding, and training process of all new AR&D and QC employees

Career Highlights:

- ✓ Led the execution of test method, validation protocol/report, and method transfer templates, which resulted in the reduction of turnaround time by threefold
- ✓ Established reputation for being trustworthy as the only member of the AR&D department to have access to the controlled substances safe
- ✓ Boosted company efficiency by applying 5S in QC and AR&D laboratories and devising a Kanban system
- ✓ Successfully and consistently trained and developed top performing team members for the AR&D department
- ✓ Created and pioneered "Alcami University" to success, Alcami's official training program

CEDARBURG PHARMACEUTICALS, A DIVISION OF AMRI | Grafton, WI

Analytical Scientist II: Aug 2007–Aug 2014

- Served as a supplier and manufacturer quality auditor in China and the United States

LUKE HERGERT

Address: 424 Palisades Trail, Keller, Texas 76248
Mobile: 414.364.6759 | **Email:** chemlu2002@yahoo.com

- Effectively utilized HPLC, GC, MS, and IC methodologies to handle all analytical development, validation, and support for various high-visibility projects
- Managed multiple temporary employees' daily activities in support of short-term toxin quantification projects
- Proficiently dealt with all major HPLC, GC, and MS (LC and GC) training, repairs, and calibrations
- Efficiently oversaw installation qualification (IQ's)/operational qualification (OQ's)/ performance qualification (PQ's) for all new analytical equipment
- Expertly assessed and implemented companywide paperless server-based system for analytical data collection, processing, and storage using Chromeleon 7
- Carried out isolation of impurities in support of their identification and structural elucidation as part of drug substance development projects through establishment of preparative HPLC conditions

Career Highlights:

- ✓ Set a record high for audits accomplished in China
- ✓ Championed the instrument installations/repairs program, thus reducing the need to hire third-party auditors and instrument metrologists

FONTAROME CHEMICAL, INC. | Cudahy, WI

Analytical Development Chemist: Jan 2006–Aug 2007

- Conducted all HPLC, GC, and GC-MS related maintenance, calibrations, IQ/OQ/PQ's, and training
- Developed new and improved analytical methods for in-process and release (both non-GMP and GMP) following regulatory requirements set by the FDA and FCC

PROFESSIONAL DEVELOPMENT

Handling and Storage of Schedule II through V Controlled Substances
Six Sigma Yellow Belt and other Lean tools (Level 0, PPS, DMAIC, etc.)

PRESENTATIONS

Hergert, L. (2004). *Functionalization, localization, and charge transfer of poly-metalated complexes*. Spring 2004 Annual Awards Day, University of Wisconsin-Milwaukee, Milwaukee, WI.

Hergert, L. (2005a). *Nitrogen activation through metal complexes*. University of Wisconsin-Milwaukee, Milwaukee, WI.

Hergert, L. (2005b). *Polyoxometalate (POM) derivatization*. University of Wisconsin-Milwaukee, Milwaukee, WI.

THESES

Hergert, L. (2003). *Polyhedral Oligomeric Silsesquioxane (POSS) synthesis and industrial uses.* (Bachelor thesis). University of Wisconsin–Oshkosh, Oshkosh, WI.

Hergert, L. (2005). *Studies on the Arylimido functionalization of Tetra-N-Butylammonium Hexamolybdate.* (Master thesis). University of Wisconsin–Milwaukee, Milwaukee, WI.