LINDSAY HELMUTH

www.lindsayhelmuth.com

Bioprocess Engineer: Upstream Process Development, Conceptual Design, Manufacturing, Technology Transfer

Highly motivated individual possessing time management, problem solving & effectual decision making capabilities. Successful cross-functional team member, project lead & innovative contributor with Process Engineering, cGMP & pilot scale cell culture experience supporting development through technology transfer in clinical & commercial manufacturing of both recombinant proteins & cell therapies.

SELECTED ACCOMPLISHMENTS:

- Developed & implemented a novel flexible cell culture manufacturing process that increased productivity up to 4x, reduced culture duration by 60%, reduced cost per gram 70% & alleviated cell age impacts for robust performance & product quality; patent application submitted
- Cell culture subject matter expert for facility fit, design considerations & potential future process capability for single-use production plant for both recombinant proteins & new modalities
- Cell culture subject matter expert supporting process development & technology transfer of 2 phase III molecules
- Manufacturing campaign support including Phase I, Phase III, PPQ & commercial support both internally & with CMO
- Author to cell culture validation protocols & reports for 2 late stage molecules
- Subject matter expert of novel high throughput robotic system for cell culture. Created novel in process assays, innovative online pH control of Tubespin reactors & contributed to peer reviewed publication
- Managed clinical dose preparation technical support at 7 clinical sites for stem cell derived oligodendrocyte progenitor cell therapy drug product. Successful treatment of acute spinal cord injury in 5 human subjects
- Created novel separation procedure for downstream processing unit operation in pilot & cGMP cell therapy manufacturing

WORK EXPERIENCE:

Genentech-Roche – Pharma Technical Development, South San Francisco, CA

Principle Research Associate - Cell Culture & Bioprocess Operations 2020- Present

- Cell culture SME for facility fit & design considerations for Single Use Technology (SUT)
- Led bioreactor equipment considerations: reviewed P&IDs & vendor packages, authored User Requirements (URS), defined acceptance criteria & testing requirements for commissioning & qualification
- Upstream process considerations for Criticality Assessments (CA), automation & operational readiness
- Author on User Requirements Brief (URB), led consumables, reagents & equipment to support basis of facility design for new modalities suite in single-use production plant

Senior Research Associate - Late Stage Cell Culture 2016- 2020

- Designed, tested & implemented novel upstream cell culture process in pilot plant & GMP for Phase I molecule. Increased productivity 2-4x, reduced culture duration by 60%, reduced cost per gram 70%, & alleviated cell age impacts for robust performance & product quality; patent application submitted. Process became new platform for global process development organization. Delivered future process capability for Roche manufacturing network.
- SME for Phase III cell culture process development from clone selection to manufacturing stage
- SME for Phase III technology transfer from Roche Germany development to SSF manufacturing
- Author to cell culture validation protocols & reports for 2 late stage molecules
- SME for campaign support for commercial production in SSF manufacturing

Senior Research Associate - Global Manufacturing Sciences & Technology 2014 - 2016

- SME for technology transfer of commercial process to CMO, on-floor support & troubleshooting & contributed to PAS
- Facilitated risk management & gap analysis, authored report for Process Hazard Analysis (PHA)
- Facilitated scale down studies with vendor to assess filter sizing for CMO's equipment
- Supported the removal of depth filtration from the upstream process, resulting in a more robust process & alignment with Roche manufacturing network. Required execution of stability studies & ensured timely, successful implementation for Engineering & Qualification runs at CMO

Research Associate - Late Stage Cell Culture 2012-2014

- Subject matter expert of novel high throughput robotic system for cell culture. Created novel in process assays, innovative online pH control of Tubespin reactors & contributed to peer reviewed publication
- Application of engineering & cell culture expertise to design, perform, analyze, & document experiments on the high throughput system as well as at larger scales in R&D & Pilot Plant settings
- Created JMP® statistical analysis scripts in order to provide collaborators with real time data analysis of large data sets for high throughput robotic experiments

- Led improvements in sample handling, robotic movements & wrote complex robotic methods to improve processing time 20-60%
- Developed & optimized 2 novel metabolite assays & cell count & viability analysis methods for compatibility with high throughput environment
- Increased throughput of metabolite assays by 33% by development of combined 384 well plate based assay conditions

Geron Corporation- Regenerative Medicine, Menlo Park, CA
Process Engineer – Manufacturing Sciences, Product Development 2011 – 2012

- Member product development engineering team, responsible for technical proficiency of uhESC derived cellular drug product preparation in a Phase I Clinical Trial & animal studies, upstream & downstream process development, manufacturing & technology transfer
- Responsible for technology transfer, protocol & documentation management, supply chain management of clinical grade material, troubleshooting & indirect management of 25 operators at 7 cross continental clinical sites
- Corrective & Preventative Action (CAPA) & subject matter expert for drug product processing to collaborate between clinical site cell processing operators & Study Execution Team (SET) members for successful administration of drug product to patients
- Created novel separation procedure, executed data analysis, supporting documentation, formal reports &performed technology transfer of downstream processing unit operation to Pilot Plant & GMP manufacturing personnel
- Performed JMP® statistical analysis on multiple data sets to facilitate real time updates of production data to management, drive process changes in manufacturing, identify trends in production & reduce clinical dose preparation factor leading to inventory & supply chain stability of drug products
- Led design of experiments (DOE) for end stage drug product filtration, resulted in optimized drug product, increased viable cell yield & streamlined quality/analytical methods for screening end stage product
- Served as technical expert & author of training manuals, GLP & GMP protocols, interactive guides & presentations during training of personnel & technology transfer cross-departmentally in Geron & externally with line extension collaborators

Development Associate I - Manufacturing Sciences, Product Development 2009-2011

- Member of Pilot Plant team & manager of supply chain materials for pilot plant operations; specialized in cell culture, troubleshooting & optimization of uhESC manufacturing processes & end stage cellular drug products
- Completed execution & planning production of large scale manufacturing of 2 pilot grade cellular drug products
- Forecasted & managed Pilot Plant materials for manufacturing of 2 cellular drug products
- Tracked & analyzed trends of NOVA BioProfile® data of cell culture nutrients & metabolites- led to the development of production decisions based on analysis of cell culture growth
- Contributed to Lean Six Sigma time & motion studies to develop tools, placement of large equipment & refine processing techniques to improve ergonomics, decrease processing time & ultimately increase efficiency of operators by 25%
- Designed experiments (DOE) to optimize: fill & finish procedures of cellular drug products, seeding density of cell cultures during differentiation & selection, operator use of improved container closures, custom biocontainer prototypes

Santa Cruz Biotechnology, Paso Robles, CA 2007- 2008
Research Assistant, Polyclonal Antibody Production
Member of Polyclonal Antibody production team providing support for the purification & analysis of polyclonal antibodies

KEY SKILLS:

PROCESS ENGINEERING & MANUFACTURING

- Data Tracking & Trending
- Root Cause Analysis
- Technical Writing
- Process Flow Diagrams
- P&ID Review
- Criticality Assessments
- Commissioning /Qualification
- Ph1-3, PPQ , Commercial & Engineering Campaigns
- Facility Fit/Gap Analysis
- Technology Transfer
- Bioreactor Scale Up (Pilot & GMP)
- Mass Transfer/kLa
- Batch Record Review
- Filter Sizing
- Validation Studies
- Single Use Technology

LABORATORY

- Aseptic Technique
- Mammalian Cell Culture (Flask, Tubespin, Ambr15 & 250, 2L & pilot scales)
- High Throughput Robotics
- Assay development
- Dose Preparation of Cell Therapy Drug Products
- Perfusion techniques

DIGITAL

- JMP® Design of Experiment
- JMP® Data Analysis
- JMP® Scripting
- Biomek FXP & NXP scripting
- HTML scripting

EDUCATIONAL EXPERIENCE:

B.S Nutritional Science, Minors: Biotechnology & Biology - California Polytechnic State University, San Luis Obispo CA
Cal Poly Graduate Nutrition Lab - Extracurricular study: Protein purification & western blot analysis on rat cardiac, lung, & muscle cells in order to test the varied degree of transcription factor gene expression in young & aged cells
Senior Project – Cal Poly
"Effect of Docosahexaenoic Acid & Eicosapentaenoic Acid on Gene Expression & Regulation of Cellular Inflammatory Molecules"

PROFESSIONAL DEVELOPMENT:

- SAS/JMP® Engineering Statistics & Data Analysis, Design of Experiments using JMP® Software- Thomas A. Little Consulting
- Cellular Bioprocess Technology- University of Minnesota
- SAS/JMP® Modeling Multidimensional Data – SAS Institute Inc.
- Berlitz German Language Level 1-2 classes

PEER REVIEWED PUBLICATIONS:

AB Bos, JN Duque, S Bhakta, F Farahi, L Chirdon, JR Junutula, PD Harms, AW Wong (2014). Development of a semi-automated high throughput transient transfection system. Journal of Biotechnology 180: 10-16.