

BIOTECH ▪ DOWNSTREAM ▪ PURIFICATION

Performance-driven Lead Tech with 11+ years experience welcomes new challenge and Opportunity to apply consummate skills to optimize operations of a dynamic organization.

◆ KEY AREAS OF EXPERTISE ◆

- Laboratory Research
- Strategic Planning
- Protein Purification
- Stability Studies
- Increase Process Efficiency
- Procedure Development
- Leadership & Training
- Inventory Control
- Document Management

PROFESSIONAL PROFILE

- Escalate business development through research, testing, and accurate document management and reporting; consistently exceed goals and expectations
- Silver Recognition award for involvement in the Process Constraints project team. Leading the Batch Record Improvement team and along with the other project efforts was instrumental in enabling the 5 day batch interval here at Medimmune
- Increase downstream process efficiency by decreasing nonvalue added waiting time in the MPRs
- Organized and detail-oriented with military professionalism; specialize in complex protein purification, and expertly analyze and interpret data
- Demonstrate exemplary leadership and training skills; create a positive work environment ensuring compliance to mandatory polices and procedures
- Superior communication and interpersonal skills; write, edit, and review Standard Operating Procedures (SOPs), and MPRs
- 5 years experience serving the community as a Paramedic

EMPLOYMENT HISTORY

The Lead Production Technician

01/2013- present

Medimmune ▪ Frederick, MD and ▪ Boulder, Co

- Ensure the completeness and accuracy of manufacturing documentation per approved procedures
- Identify and support the implementation of process efficiencies and areas for improvement
- Assign daily tasks to more junior production technicians
- Provides input into annual performance evaluations of production technicians as applicable
- Demonstrate ability to perform all process steps of downstream production operations
- Serves as the area supervisor when the Supervisor is unavailable
- Responsible for training junior staff
- Provides clear and concise communication to Supervision/Management
- Cross-trained in multiple areas within Manufacturing
- Ability to generate SOPs, MPRs, and SPRs for equipment and procedures used in the manufacture of biological based products
- Execution of validation protocols as required
- Perform Steam-In-Place (SIP), Clean-In-Place (CIP), and manual cleaning and sanitization of equipment
- Perform and document production operations according to cGMPs
- General housekeeping of controlled area
- Perform and document production operations according to cGMPs
- Able to motivate team members

Purification Technician III **06/2009–01/2013**
Medimmune • Frederick, MD

- Maximize efficiencies through strategic planning and complex large scale purification of recombinant proteins under cGMP conditions
- Key player who prepares buffers >1000L and utilizes IEX – affinity chromatography and UF/DF skids
- Spearhead filter testing, product nanofiltration, and CIP/SIP of buffer tanks/skids
- Display excellent leadership and organization skills; effectively train new personnel, manage and maintain documentation, provide inventory control of raw materials, and order needed equipment and supplies

Research Associate, Protein Discovery **09/2008 – 06/2009**
Advance Vision Therapies • Gaithersburg, MD

- Escalated operations by devising experiments for the development of purification methods; expertly analyzed and interpreted data obtained, and identified best course of action
- Played essential role in maintaining data records and documentation of experiments
- Launched strategies for the purification of proteins from cellular supernatant

Manufacturing Associate III **02/2006 – 09/2008**
National Cancer Institute/SAIC Inc. • Frederick, MD

- Formulated and performed small scale purification of recombinant proteins and virus under cGMP conditions; proficiently conducted in process High Performance Liq-Chromatography (HPLC) analysis
- Effective communicator with strong writing skills; developed manufacturing SOPs and edited/reviewed MPRs
- Exhibited exemplary leadership qualities; positively motivated and supervised team, provided necessary cGMP procedure training, scheduled assignments, maintained documentation, and ordered and maintained equipment/supplies

Senior Purification Specialist **09/2001 – 02/2006**
Clinical Research Management Senior Purification Specialist
Walter Reed Army Institute of Research • Silver Spring, MD

- Enhanced research operations through planning and performing complex small-scale purification of recombinant proteins and virus under cGMP conditions
- Ensured efficient document management; developed manufacturing SOPs and reviewed/edited MPRs
- Possessed excellent leadership and training skills; oversaw team members, scheduled tasks, managed data records and documentation of the production, and provided inventory control

PREVIOUS EMPLOYMENT

- Research Associate, Comforce at Biomérieux • Raleigh, NC** **02/2001 – 09/2001**
Help Desk Level I, EDS • Raleigh, NC **11/2000 – 03/2001**
Research Assistant, American Red Cross • Rockville, MD **09/1992 – 11/2000**

LABORATORY/RESEARCH/PRODUCTION SKILLS

- Develop activity assays and immunoassays of plasma proteins
- Small scale purification of recombination proteins under cGMP condition for use in clinical trails
- Microfluidization and column chromatography (IEX and affinity, SEC, Reverse Phase)
- Viral filtration using Planova filters
- SDS-Page, Native and Western blots
- HPLC, Size exclusion (SEC), Reversed Phase (RPC) and Ion Exchange (IEX)
- Animal studies; half-lives of human plasma proteins and effectiveness for delivery of anti cancer drugs
- Development of pilot scale purification of human plasma proteins for commercial sale
- Stability studies of plasma proteins used in clinical settings

- Development and evaluation of viral in activation techniques in plasma proteins
 - Work performed under cGMP condition for the production of recombinant protein
 - Ultrafiltration/Diafiltration and Microfiltration using hollow fiber and flat sheets
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TECHNICAL/SOFTWARE SKILLS

Chemstation ▪ TrackWise® ▪ Aegis ▪ Laboratory Information Management Systems (LIMS) ▪ Unicorn
Millipore ▪ Akta Explorer ▪ PC Networking ▪ Systems Management Server SMS 2.0 ▪ Rockwell RS3

EDUCATION

Bachelor of Science in Biochemistry **1992**
Virginia Polytechnic Institute ▪ Blacksburg, VA

Associate of Science in Emergency Health Science **1987**
College of Health Science ▪ Roanoke, VA