

Greg Hartvigsen

Seeking opportunities in Pharma & Medical Device

Denver, CO

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- 5 years experience working in GMP/GLP labs
- Lead on Tech Transfer of client's FDA Phase 1 drug product to Manufacturing Operations
- Extensive experience managing GMP raw material inventories

WORK EXPERIENCE

Research Associate - Late Stage Cell Culture

Genentech - South San Francisco, CA - February 2012 to June 2013

- Collaborated large-scale experiments with Pilot Plant team members
- Conducted CHO cell culture product development experiments using 2L-20L bioreactors
- Designated Super User for NOVA Flex bioanalyzer
- Drafted technical reports for FDA submissions
- Managed GMP-retain raw material inventory and Certificate of Analysis records
- Member of cross-functional Bioburden Reduction Task Force
- Performed 5S exercise in newly acquired lab space
- Recognized for efforts supporting multiple Phase III, GMP campaigns in 2012

Development Associate II

Geron - Menlo Park, CA - October 2010 to November 2011

- Collaborated with QA & QC for Drug Product testing
- Coordinated Drug Product distribution to Pre-Clinical sites
- Implemented 5S & LEAN manufacturing principles
- Maintained production schedule (Gantt Charts) for Senior Management review
- Managed inventory of raw materials and cryopreserved products
- Produced Certificate of Analysis for all Pre-Clinical shipments
- Production of uhESC lines to support Pre-Clinical studies
- Supported Tech Transfer of R&D process to CMO for GMP manufacturing
- Trained new employees and CMO staff

Cell Culture Associate

MedImmune - Santa Clara, CA - October 2009 to June 2010

- Authored NCRs & CAPAs
- Coordinated Line Clearance and Change Control with QA personnel
- Investigated OOS readings for cleanroom set-points using the electronic BMS
- Performed candling and inoculation of SPF eggs; harvesting, large volume pooling, filtration and clarification of viral harvest fluid
- Revised SOPs and Batch Production Records

Cell Production Associate

Cognate BioServices - April 2008 to July 2009

- Authored NCRs and CAPAs
- Collaborated with QA, QC and Materials Management for shipment of Drug Product

- Cultured various cell lines for multiple clients, including: human Dendritic Cells, BMSCs, CD34+ cells and MPCs.
- Formulated and cryopreserved cellular Drug Products
- Performed cell counting with acetic acid and Trypan Blue
- Prepared Tumor Lysates
- Revised client protocols for use in GMP manufacturing
- Trained employees on new client processes

Operations Assistant

Cognate BioServices - January 2008 to April 2008

- Adhered to SOPs and performed document revisions
- Assembled tumor collection kit
- Monitored equipment daily and adhered to preventative maintenance schedules
- Set up Personnel Monitoring for ISO 5 & ISO 7 cleanrooms
- Stocked supplies for cleanroom and labs
- Prepared liquid nitrogen shippers for shipment to Clinical Trial sites

EDUCATION

BS in Cell & Molecular Biology

University of Washington - Seattle, WA

December 2004

SKILLS

Microsoft Word

ADDITIONAL INFORMATION

SKILLS

Computer

- Microsoft Word, Excel, Outlook, Sharepoint, Project & Visio
- Data analysis & DOE using JMP
- LIMS, TrackWise

Laboratory

- ATF/perfusion systems
- Aseptic cell culture in flasks, bags & bioreactors
- Gowning qualified for cleanroom operations
- FACS
- Maintenance of NOVA & NOVA Flex bioanalyzers
- Media preparation