

415-385-4984

JASON HOGEBROOM

jasonhogeboom@gmail.com

AREA OF EXPERTISE

- DS Manufacturing
- Process Engineering
- Process Scale Up
- Tech Transfer
- Quality Systems
- FDA, ICH, EU Standards
- CAPA
- Technical Writing
- Lean Black Belt
- Situational Leadership
- Risk Management
- Project Management

PROFESSIONAL EXPERIENCE

August 2024 to Present **Corcept** **Redwood City, CA**

Document Control Specialist (Contract)

- Organizing, categorizing, filing, and creating an inventory catalog for legacy records.
- Reviewing documentation to ensure audit readiness.
- Transitioning documents to the Veeva QualityDocs system.

October 2023 to March 2024 **SmartLabs** **South San Francisco, CA**

Clean Suites Product Specialists

- Good Manufacturing Practice (GMP) Technical/Regulatory Subject Matter Expert (SME) for nationwide sales team.
- Networked for potential clients at conferences, networking events, seminars, and trade shows as well as led laboratory tours for potential clients.

March 2023 to August 2023 **Grifols** **Emeryville, CA**

Process Engineer (Contract)

- Contracted to cover for Process Engineer Manager while on temporary leave. Completed and closed large capital project by authoring, routing, and closing change controls via SAP, uploading, and recovering documents in Meridian, routing controlled documents through DCM, and closing work orders through Maximo.

January 2021 to March 2023 **Vaxart** **South San Francisco, CA**

MSAT Manager

- Led team through first internal GMP process to create oral vaccine pills for COVID stage II clinical trials.
- Person-in-plant oversight for Contract Manufacturing Organization (CMO) and batch record review and technical manufacturing support in accordance with current Good Manufacturing Practices (cGMP) for internal and external CMOs.

March 2020 to December 2020 **Amyris** **Emeryville, CA**

Pilot Plant Manager

- Managed upstream, downstream, and technical support for small scale bioproduction efforts in pilot plant during shelter in place order limited capacity since the team and work was considered essential.

October 2018 to January 2020 **Ultragenyx** **Novato, CA**

Operational Excellent Consultant (Contract) 02/19-01/20

- Mapped, streamlined, mistake proofed business processes including change control, master services agreements, and/or oversite and product recall strategies as well as created operational user manuals for Veeva and Compliance Wire.

Technical Writer/Document Control Consultant (Contract) 10/18-01/19

- Authored, updated, and routed documents including SOPs, quality standards, work instructions, job aids, and user manuals in Veeva EDMS, created visual aid instructions for Veeva and Compliance Wire, and audited quality standards for compliance with FDA and ICH standards.

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April 2016 to March 2018

Audentes

South San Francisco, CA

Biotech Manufacturing Supervisor

- Designed master control batch record templates, created SOPs, defined procedures, and qualified all equipment for the purpose of moving the manufacturing of clinical materials into a GMP state.

September 2004 – April 2016

Baxter Bioscience

Hayward, CA

Biotech Lead, Supervisor

- Managed daily activities for the Cell Culture Production Department by mentoring associates, reviewing documents, leading investigations, and scheduling process runs.
- Created and updated SOPs, bath records, forms, and visual aids, launched a Total Productive Maintenance Program (TPM), and continued to be upstream point person for Contract Manufacturing Organization (CMO) Clients.
- Performed weekly inventory cycle counts as a JDE “Super User” for inventory control and earned designation as the upstream point person for regulatory audits from the FDA, EMA, Health Canada, Japan Markets, clients, and internal audits.
- Led dozens of continuous improvement projects across manufacturing, warehouse, facilities, and quality control for the purpose of improving the inspection of Japanese Market Goods and reducing sample submission errors, equipment downtime, and processes error rates.
- Mentored new supervisors and was certified as Lean Six Sigma Green Belt.

September 2000 to September 2004

Baxter Bioscience

Thousand Oaks, CA

Manufacturing Associate, Process Development 10/03-9/04

- Ran small-scale experiments for yield improvements on an Upstream Process Development Team and authored experiment protocols and summaries.

Manufacturing Associate, Start-up Specialist 6/01-10/03

- Reviewed and submitted input on equipment piping and instrumentation designs, identified and purchased equipment, reviewed automation codes, and created documents for User requirements including URS, function specs, and procedures as an upstream representative assisting in creating a new manufacturing facility to produce Advate via tech transfer from Switzerland Plant.

Manufacturing Associate 09/00-6/01

- Conducted aseptic cell expansions, ran fixed stir tank bioreactors, and clarified harvested materials for upstream manufacturing of Advate.

June 1993 to September 2000

Genentech

South San Francisco, CA

Technical Writer 06/99-09/00

- Created procedures for scientists bringing their product to clinical stage manufacturing which involved explaining GMP/GCP requirements to research scientists and negotiating timelines as well as conducting 2-year SOP review, maintenance and procedure updates when needed.

Cell Culture/Purification Manufacturing Technician 06/96-06/99

- Produced and purified mammalian cell cultures per cGMP including bioreactor, columns, filtration unit operation and Media and Buffer formulation as well as managed High Temp Short Duration (HTSD) Skid which pasteurized media and the protein A column for Herceptin.

EDUCATION

June 2017: Master of Business Administration
University of California, San Bernadino, CA

June 2015: BS, Business Administration
University of California, Dominguez Hills, CA

CERTIFICATIONS

July 2018: Lean Six Sigma Black Belt (SgijmZbe3x),
Council for Six Sigma Certification

November 2011: Lean Six Sigma Green Belt
Baxter International