

# RICHARD STEWART

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## BIOLOGIST (GS-0401)

Food and Drug Administration  
Center for Biologics Evaluation and Research (CBER)  
Citizenship: US

### QUALIFICATIONS PROFILE

**Forward-thinking and accomplished professional, with a solid background in bioprocess development; backed by proven success in creating downstream GMP manufacturing processes that drive innovation and excellence in biologics production.** Known for proven adeptness in advancing biologics purification technologies that enable efficient, scalable, and high-quality manufacturing of groundbreaking biopharmaceutical products. Skilled at leading process development, scale-up, and technology transfer from early-stage discovery through clinical and commercial manufacturing. Equipped with proven ability to collaborate cross-functionally with chemistry, manufacturing, and controls (CMC) teams; regulatory agencies; and manufacturing partners to drive robust and cost-effective downstream processes.

### AREAS OF EXPERTISE

Downstream/Purification Process Development | Good Manufacturing Practice Integration  
Scale-Up Processes | Scientific Writing | Technology Transfer | Quality Control | IND/BLA Submission  
Process Characterization | Data Analysis and Visualization | Chromatography | Continuous Manufacturing  
Project Management/Innovation | Manufacturing Process Optimization | Team Building and Leadership

### PROFESSIONAL EXPERIENCE

Large Multinational Biopharmaceutical Company | St Louis, MO

**Senior Principal Scientist ■ Scientific Mentor/Innovation Lead**

06/2021–03/2025

Hours per week: 40

Annual Salary: \$XXX,XXX

- Drove significant improvements in biologics manufacturing through leadership in next-generation manufacturing projects, in partnership with Boehringer Ingelheim, by introducing integrated continuous biomanufacturing (ICB) systems.
- Optimized operations across all stages of development, scale-up, tech transfer, and manufacturing that drove the successful creation of downstream cGMP-compliant processes for over 25 biopharmaceutical products.
- Enabled the delivery of seamless clinical and commercial manufacturing support by streamlining processes for scales ranging from 5L to 12,000L with improved efficiency, yield, and quality.
- Accelerated technology transfer to global facilities enabling rapid manufacturing of clinical and commercial biologics through strategic alliances and influence.
- Pioneered the development of robust, scalable, cost-effective purification processes that prompted the generation of regulatory filings for monoclonal antibodies, complex proteins from mammalian cell culture, and plasmid DNA from microbial fermentation.
- Delivered strategic direction to cross-functional CMC teams of up to 40 members with up to \$20M budget that ensured the timely completion of critical deliverables, while overseeing resource allocation, budget planning, and project timelines.
- Authored 20 peer-reviewed publications with >2,000 cumulative citations, >10 conference presentations, and 8 patents, showcasing a strong commitment to advancing scientific knowledge, innovation, continuous improvement, and external influence.
- Achieved a 30% reduction in FTE, 40% reduction in cost, 30X increase in output, and two additional projects start per year for monoclonal antibodies (mAb) using the ICB system, with a GLP system that enabled rapid production of toxicology material and a GMP system that led to two successful INDs.
- Generated a 100X increase in throughput and a 20X rise in user adoption by driving the rollout of high-throughput screening (HTS) technologies and workflows.

**Senior Principal Scientist ▪ Group Leader**

01/2013–05/2021

Hours per week: 40

Annual Salary: \$XXX,XXX

- Improved team performance by skillfully managing groups of up to 20 scientists and engineers, providing effective mentorship, coaching, and development of direct reports.
- Steered ICB, and Downstream Team, to achieve rapid project advancement through efficient collaboration with manufacturing, engineering, analytical, upstream, downstream, regulatory, and quality groups.
- Gained recognition from the FDA Emerging Technology Team (ETT) for outstanding contributions to the ICB project.
- Led the CMC team for a complex Fc fusion multimer protein with unique Critical Quality Attributes (CQAs) and challenges with timelines, resources, and process issues such as upstream batch refeed, cell line clonality, and low column capacities.
- Navigated manufacturing at CMO/CDMOs in Seattle, WA, and Copenhagen, Denmark, and at company facilities in St Louis and Andover for the Fc fusion protein with tech transfer and site transfers <6 weeks.
- Spearheaded technology transfer and extensive support for manufacturing operations for plasmid DNA across five global facilities leading to over 30 successful batches, driving clinical and commercial production of mRNA vaccines.
- Repurposed facilities in Orth, Austria, and Zagreb, Croatia to manufacture plasmid DNA with timelines <4 months.
- Provided expert knowledge for manufacturing investigations and drove risk-based completion and closure of investigations enabling the release of drug substances.
- Authored and reviewed mRNA Flu vaccine investigational new drug (IND) applications and Biologics License Application (BLA) that expedited clinical start and laid the groundwork for product approval.
- Led platform process improvements to mitigate lipase-driven polysorbate degradation/hydrolysis in drug substances and drug products.
- Championed the reorganization and expansion of an under-resourced non-GMP downstream manufacturing group, doubling headcount, expanding space, and securing \$2M in capital equipment, resulting in a more effective, reenergized, and reengaged team and a 4X increase in throughput.

**Earlier Positions Held**

Major Biotechnology Research &amp; Development Organization | South San Francisco, CA, USA

**Senior Scientist and Senior Group Leader**

2 years

Hours per week: 40

Annual Salary: \$XXX,XXX

**Scientist and Group Leader**

6 years

Hours per week: 40

Annual Salary: \$XXX,XXX

**EDUCATION**

**Bachelor of Arts in Physics**  
Sample University | Santa Barbara, CA

**PROFESSIONAL DEVELOPMENT**

People Leadership | Operations Management | Innovation Leadership and Coaching  
Management Communication | Scientific and Business Writing | Visual Communication  
Financial Reporting | Data Visualization | Entrepreneurship

**TECHNICAL SKILLS**

Microsoft Office Suite (Word, PowerPoint, Excel, OneNote, and Teams)  
Visio | GMP Document Management Systems