

Stella Beck

☎ (919) 555-7428 ✉ stella.beck@example.com 🔗 linkedin.com/example/stellabeck 📍 Raleigh, NC 27609

SUMMARY

Biopharmaceutical manufacturing professional with five years of regulated production experience supporting downstream purification, equipment readiness, cGMP floor execution, and electronic batch documentation. Hands on work includes **column chromatography**, column packing, **tangential flow filtration**, viral filtration, viral inactivation, conjugation fundamentals, final fill support, **in process sampling**, equipment cleaning, sanitization, and controlled manufacturing environments. Experience includes EBR/MES, Delta V, **Electronic Quality Systems**, SOPs, manufacturing procedures, JHAs, CFR expectations, aseptic practices, deviation initiation, investigation support, qualification activities, and production ramp up. NC BioWorks certified with a bachelor's degree in bioprocessing science. Consistently supports safe shift execution, accurate records, clear handoffs, and practical feedback that helps manufacturing teams protect quality, maintain readiness, and improve reliable biologics production.

EXPERIENCE

Manufacturing Associate II, Downstream

January 2025 - Present

Triangle Bioprocess Solutions

Raleigh, North Carolina

Supports clinical and commercial biologic intermediate production across downstream purification, electronic documentation, equipment readiness, qualification activities, and floor level quality response. Provides operator feedback during readiness work and helps production teams move safely from preparation through routine execution.

- Executed chromatography, TFF, **viral filtration**, and **viral inactivation** under approved cGMP procedures.
- Prepared single use and **stainless steel equipment**, confirming line clearance before manufacturing execution.
- Completed EBR/MES entries and monitored Delta V displays during critical process steps.
- Collected in process samples and operated designated **analytical equipment** with full traceability.
- Initiated deviations and **quality events**, supplying observations that supported investigations and **corrective actions**.
- Supported qualification checks for new downstream equipment, improving operator readiness during production transition.

Manufacturing Associate, Purification

June 2023 - December 2024

Carolina Therapeutics Manufacturing

Durham, North Carolina

Performed purification operations in a regulated **biotechnology** facility, supporting chromatography, filtration, buffer related steps, equipment care, electronic records, and shift readiness. Worked closely with manufacturing and quality personnel to keep controlled areas organized, documented, and prepared for continuing production.

- Prepared equipment and materials for chromatography, filtration, and buffer related process steps.
- Followed SOPs, manufacturing procedures, JHAs, **gowning** requirements, and **cGMP** documentation practices.
- Operated **TFF** and filtration equipment within defined parameters, recording observations in electronic records.
- Completed **cleaning**, **sanitization**, and washroom activities, maintaining controlled area readiness.
- Provided contemporaneous records and equipment status for deviation fact gathering activities.
- Communicated open tasks, equipment conditions, and material needs during shift handoffs.

Bioprocess Technician

August 2021 - May 2023

Piedmont BioManufacturing Center

Research Triangle Park, North Carolina

Supported supervised cGMP bioprocess operations through area preparation, component staging, **equipment setup**, downstream processing support, sampling, documentation, and contamination control. Progressed through structured training toward independent execution of qualified technician tasks while preserving safety, traceability, and record accuracy.

- Prepared manufacturing areas and staged components under qualified procedures and operator oversight.
- Supported column preparation, chromatography workflows, filtration, and controlled material transfers.
- Maintained paper and electronic records, correcting documentation issues through approved practices.
- Performed routine **cleaning and sanitization** while applying gowning and contamination control expectations.
- Collected in process samples and preserved identification, timing, and traceability requirements.
- Completed structured training in safety, quality, cGMP behavior, and **equipment operation**.

PROJECTS

Downstream Equipment Readiness Program 📅 2025

Supported readiness checks for new downstream equipment, combining operator feedback, approved verification steps, and practical floor preparation for reliable manufacturing use.

Electronic Batch Record Accuracy Initiative 📅 2024

Improved daily documentation discipline through timely EBR entries, clear shift communication, and careful review of process observations before handoff.

LEADERSHIP & AWARDS

- NC BioWorks Certification Program completion, 2021
- Recognized for safe cGMP execution and dependable downstream production support
- Selected to support equipment readiness and qualification activities during production ramp up

EDUCATION

Bachelor's Degree in Bioprocessing Science

2021

North Carolina State University GPA: 0

Raleigh, North Carolina

Coursework: Biopharmaceutical manufacturing, downstream processing, cGMP operations, process analytics

CERTIFICATIONS

- NC BioWorks Certification Program 📅 2021
- Bachelor of Science, Bioprocessing Science 📅 2021

TECHNICAL SKILLS

- **Downstream Processing:** Column Packing, Column Chromatography, Tangential Flow Filtration
- **Viral Processing:** Viral Filtration, Viral Inactivation, Conjugation
- **Manufacturing Systems:** EBR, MES, Delta V
- **Quality Systems:** Electronic Quality Systems, Deviations, Investigations
- **GMP Documentation:** SOPs, Manufacturing Procedures, JHAs
- **Equipment Operations:** Single Use Systems, Stainless Steel Equipment, Analytical Equipment
- **Facility Readiness:** Commissioning, Qualification, Operational Readiness
- **Cleaning Controls:** Cleaning, Sanitization, Washroom Operations
- **Aseptic Operations:** Gowning, Aseptic Technique, Contamination Control
- **Compliance Standards:** cGMP, CFR Compliance, Controlled Manufacturing
- **Manufacturing Records:** Electronic Batch Records, Paper Records, Sample Traceability
- **Process Support:** In Process Sampling, Process Monitoring, Final Fill Support

SKILLS

- | | | | |
|------------------------------|-----------------------|----------------------------|-------------------------|
| • cGMP Manufacturing | • Viral Filtration | • Electronic Batch Records | • Operational Readiness |
| • Downstream Purification | • Viral Inactivation | • Equipment Readiness | • Microsoft Office |
| • Column Chromatography | • In Process Sampling | • Deviation Support | • Team Communication |
| • Tangential Flow Filtration | • Aseptic Technique | • Corrective Actions | |

PROFESSIONAL AFFILIATIONS

- NC BioWorks professional certification community
- Bioprocess manufacturing and downstream operations community
- North Carolina State University bioprocessing alumni network

LANGUAGES

- English (Native)
- Spanish (Intermediate)

ADDITIONAL INFORMATION

Work Status : Authorized to work in United States. No sponsorship required.

REFERENCES

AVAILABLE ON REQUEST