

# Stella Beck

## Manufacturing Associate II, Downstream

📞 (919) 555-7428

✉️ stella.beck@example.com

🌐 linkedin.com/example/stellabeck

📍 Raleigh, NC 27609

### STRENGTHS

- ⚙️ **Downstream execution**  
Column and filtration work stayed orderly during busy shifts, giving teammates a dependable point of reference for process decisions.
- ♥️ **Documentation discipline**  
Real time EBR entries kept records clear and traceable, and peers sought help when documentation questions surfaced.
- ✔️ **Quality response**  
Floor observations became useful investigation evidence, helping quality partners see what happened and what required follow up.
- 🔧 **Equipment readiness**  
Readiness checks connected operator feedback with qualification work, making new equipment easier for teams to use safely.
- 👥 **Team communication**  
Shift handoffs covered open work, equipment status, and materials, so incoming operators could begin with fewer surprises.

### SKILLS

cGMP Manufacturing

Downstream Purification

Column Chromatography

Tangential Flow Filtration

Viral Filtration   Viral Inactivation

In Process Sampling

Aseptic Technique

Electronic Batch Records

Equipment Readiness

Deviation Support

Corrective Actions

### 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

Triangle Bioprocess Solutions 📅 January 2025 - Present 📍 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

Carolina Therapeutics Manufacturing 📅 June 2023 - December 2024 📍 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

Piedmont BioManufacturing Center 📅 August 2021 - May 2023 📍 Research Triangle Park, North Carolina

Operational Readiness

Microsoft Office

Team Communication

## LANGUAGES

English Native

Spanish Intermediate

## MY CAREER



● Manufacturing Associate II, Downstream at Triangle Bioprocess Solutions (1.8 Years)

● Manufacturing Associate, Purification at Carolina Therapeutics Manufacturing (1.5 Years)

● Bioprocess Technician at Piedmont BioManufacturing Center (1.8 Years)

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

North Carolina State University 🎓 GPA: 0 📅 2021 📍 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

## PROFESSIONAL AFFILIATIONS

- NC BioWorks professional certification community
- Bioprocess manufacturing and downstream operations community

- North Carolina State University bioprocessing alumni network

## **ADDITIONAL INFORMATION**

---

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

## **REFERENCES**

---

AVAILABLE ON REQUEST