

Gideon Terry

Senior Principal Process Engineer, Aseptic Biotherapeutic Filling Equipment

☎ (919) 555-7314 ✉ gideon.terry@example.com

🌐 linkedin.com/example/gideonterry 📍 Raleigh, NC 27606

STRENGTHS

- ⚙️ **Aseptic design leadership**
When filling design decisions affected product protection, led practical reviews that built confidence across Manufacturing, Quality, and Facilities.
- ✅ **Qualification ownership**
FAT and SAT issues became clearer through focused follow up, helping teams reach C&Q and start up with fewer surprises.
- 👥 **Cross functional influence**
Design conflicts moved forward through shared facts and direct discussion, giving stakeholders a clearer path to sound decisions.
- 🎓 **Technical coaching**
Junior engineers gained useful context from hands on reviews, and colleagues increasingly sought guidance on aseptic design questions.
- 🛡️ **Contamination control**
Risk reviews connected equipment choices with product protection, creating stronger alignment around cGMP and Annex 1 expectations.

SKILLS

Aseptic filling systems
Biotherapeutic drug products
Sterile injectable biologics
Prefilled syringes Isolators
E Beam cGMP EU Annex 1
Contamination control URS
P&IDs PFDs FAT SAT C&Q

LANGUAGES

English Native

SUMMARY

Senior Principal Process Engineer with 13 years of process engineering and capital project experience in cGMP drug product manufacturing. Leads aseptic vial and prefilled syringe systems for monoclonal antibodies, recombinant proteins, vaccines, and other sterile injectable biologics. Guides isolator based filling, E Beam integration, contamination control, FDA cGMP, EU Annex 1, URS, equipment specifications, P&IDs, PFDs, supplier selection, FAT, SAT, commissioning, qualification, **start up**, and **operational readiness**. Has delivered greenfield and brownfield programs approaching \$90M while coordinating **Manufacturing**, MSAT, Quality, Facilities, EHS, Procurement, **A&E firms**, contractors, and equipment vendors. Brings practical technical leadership, sound decision making, CAPA experience, project controls, schedule risk management, coaching, and facility engineering judgment for safe, compliant, reliable sterile manufacturing.

EXPERIENCE

Senior Principal Process Engineer, Aseptic Drug Product

Aurevant Therapeutics 📅 July 2023 - Present 📍 Raleigh, NC

Leads greenfield aseptic filling design and delivery for vial and syringe systems supporting monoclonal antibody production. Owns technical definition, supplier engagement, qualification readiness, construction coordination, and operational transition while coaching engineers and aligning project stakeholders.

- Led isolator filling design for monoclonal antibody vial and syringe production lines.
- Governed URS, specifications, **P&IDs**, PFDs, layouts, **cGMP**, Annex 1, and contamination controls.
- Reviewed filling, **isolator**, and **E Beam** suppliers within a capital program approaching \$90M.
- Directed FAT, SAT, **C&Q**, and start up readiness, resolving qualification issues.
- Guided A&E firms, contractors, and vendors through schedule risk and **project controls** reviews.
- Coached engineers on aseptic design, CAPA, EHS by design, and operational readiness.

Principal Process Engineer, Sterile Filling

Novalume Biopharma 📅 March 2020 - June 2023 📍 Durham, NC

Owned brownfield integration of an isolator based syringe line in cGMP manufacturing. Translated manufacturing needs into executable design packages, coordinated cross functional decisions, and drove supplier, qualification, deviation, and process control work for recombinant protein filling.

- Owned brownfield integration of an isolator syringe line within cGMP manufacturing operations.
- Converted manufacturing needs into **URS**, P&IDs, process flows, interfaces, and contamination controls.
- Led supplier reviews, **FAT**, installation, **SAT**, and C&Q for recombinant protein equipment.
- Aligned Manufacturing, Quality, MSAT, EHS, **Procurement**, and **Facilities** on design conflicts.
- Resolved qualification deviations through root cause analysis and CAPA actions.
- Used equipment data to improve **process control**, maintenance access, and changeover strategy.

Senior Process Engineer, Sterile Filling Upgrades

BlueRidge Biologics 📅 August 2017 - February 2020 📍 Research Triangle Park, NC

Led vial filling upgrades for vaccine and monoclonal antibody products. Connected aseptic requirements with equipment specifications, acceptance planning, contamination risk review, construction sequencing, procurement timing, and engineering team development.

- Led **vial** filling upgrades supporting vaccine and monoclonal antibody manufacturing programs.
- Developed specifications translating aseptic requirements into equipment and facility criteria.
- Planned vendor acceptance and **commissioning** activities before **qualification** turnover.
- Assessed **contamination control** risks and interventions against cGMP expectations.
- Supported procurement, **construction** sequencing, lead time assessment, and project scheduling.
- Mentored junior engineers through technical issue resolution and **process engineering** reviews.

MY CAREER



- Senior Principal Process Engineer, Aseptic Drug Product at Aurevant Therapeutics (3.2 Years)
- Principal Process Engineer, Sterile Filling at Novalume Biopharma (3.2 Years)
- Senior Process Engineer, Sterile Filling Upgrades at BlueRidge Biologics (2.5 Years)
- Process Engineer II, Sterile Manufacturing at Sterigenix Pharma (2.1 Years)
- Process Engineer, Commercial Aseptic Filling at Carolina Sterile Products (1.9 Years)

Process Engineer II, Sterile Manufacturing

Sterigenix Pharma 📅 June 2015 - July 2017 📍 Clayton, NC

- Executed sterile vial filling engineering assignments in cGMP manufacturing. Supported requirements, change packages, vendor acceptance, field commissioning, qualification evidence, deviation investigation, procurement review, construction safety, and EHS assessment.
- Executed sterile vial filling engineering assignments within **cGMP manufacturing** operations.
 - Authored equipment requirements, process flows, and engineering change packages.
 - Supported FAT and SAT while coordinating vendor discrepancy closure.
 - Performed commissioning field checks with traceable qualification turnover evidence.
 - Investigated deviations using structured problem solving and **CAPA** methods.
 - Contributed to schedules, procurement reviews, **construction safety**, and **EHS** assessments.

Process Engineer, Commercial Aseptic Filling

Carolina Sterile Products 📅 June 2013 - May 2015 📍 Greensboro, NC

- Supported commercial aseptic vial filling process engineering and cGMP documentation. Maintained process records, analyzed line observations, supported installation and commissioning, and coordinated technical inputs across Manufacturing, Quality, EHS, and maintenance.
- Supported commercial aseptic vial filling **process engineering** and **cGMP** documentation.
 - Maintained process flow diagrams and equipment records for filling systems.
 - Analyzed line data and recurring equipment observations for engineering review.
 - Supported **installation** and commissioning through field verification and vendor documentation.
 - Prepared technical inputs for deviations and CAPA involving **process control**.
 - Coordinated engineering work with **Manufacturing, Quality**, EHS, and maintenance.

PROJECTS

Greenfield Isolator Filling Program 📅 2025

Led technical integration for vial and prefilled syringe systems supporting monoclonal antibody production. Built alignment across design, suppliers, qualification, construction, and operational readiness while keeping contamination control and Annex 1 expectations visible.

Brownfield Syringe Line Integration 📅 2023

Connected an isolator based syringe line with existing cGMP operations for recombinant protein filling. Resolved interfaces, qualification deviations, maintenance access concerns, and changeover needs through cross functional engineering decisions.

LEADERSHIP & AWARDS

- Technical Excellence Award, Aurevant Therapeutics, 2025
- Aseptic Engineering Mentorship Lead, Aurevant Therapeutics, 2024 to Present
- Technical Program Volunteer, ISPE Regional Chapter, 2022 to Present

EDUCATION

Bachelor's Degree in Mechanical Engineering

North Carolina State University 🎓 GPA: 4.0 📅 2013 📍 Raleigh, NC

Coursework: Process engineering, mechanical design, facility engineering, project management

CERTIFICATIONS

- ISPE Aseptic Processing Training Certificate 📅 2024
- Commissioning and Qualification Fundamentals, ISPE Training 📅 2022
- OSHA 30 Hour Construction Safety 📅 2021

TECHNICAL SKILLS

- **Aseptic Filling Equipment:** Vial fillers, prefilled syringe lines, isolators
- **Biotherapeutic Products:** Monoclonal antibodies, recombinant proteins, vaccines
- **Regulatory Compliance:** FDA cGMP, EU Annex 1, sterile manufacturing
- **Process Documentation:** URS, equipment data sheets, technical specifications

- **Process Diagrams:** P&IDs, PFDs, equipment layouts
- **Supplier Delivery:** Supplier evaluation, bid reviews, vendor management
- **Acceptance Testing:** FAT, SAT, discrepancy closure
- **Commissioning Qualification:** Commissioning, qualification, C&Q
- **Project Execution:** Greenfield projects, brownfield projects, capital projects
- **Facility Engineering:** Facility design, construction, installation
- **Quality Systems:** CAPA, deviation investigation, root cause analysis
- **Safety Engineering:** EHS by design, construction safety, industrial hygiene
- **Project Controls:** Project schedules, schedule risk reviews, procurement
- **Process Improvement:** Process control, changeover strategy, maintenance access
- **Technical Leadership:** Technical leadership, coaching, decision making

PROFESSIONAL AFFILIATIONS

- ISPE Regional Chapter, Technical Program Volunteer, 2022 to Present
- Aseptic Engineering Mentorship Lead, Aurevant Therapeutics, 2024 to Present

ADDITIONAL INFORMATION

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

REFERENCES

AVAILABLE ON REQUEST