

Benjamin Edwards

Principal / Senior Consultant – BGE Technical Services, Inc | Hollywood, FL

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Summary

Principal Engineering consultant with 30+ years of experience in pharmaceutical and biotech operations across FDA- and EU-regulated environments. Blow / Fill / Seal (BFS) machine subject matter expert (SME). Expertise in facilities, utilities, aseptic processing, Blow/Fill/Seal (BFS) technology, validation, compliance, process optimization, project management, and technical leadership. Trusted by global pharmaceutical manufacturers for facility build-outs, equipment commissioning, regulatory compliance, team development, and remediation of technical challenges.

Aseptic Vaccine Primary Packaging, Major Pharma, North Carolina June 2022 – July 2025, Tech Services Consultant / BFS SME

- Served as BFS validation subject-matter expert supporting CIP, SIP, extrusion, process simulation, and PPQ.
- Optimized filling processes for product potency; authored and executed development and qualification protocols.
- Delivered CPP and control strategy documentation, technical summaries, and final reports.

New Vision Pharmaceuticals, LLC, Sunrise, FL Aug 2018 – May 2022, Sr. Manager, Technical Services

- Transitioned from consultant to full-time role managing a team of 7 across validation, tech transfer, cleaning validation, and aseptic simulation.
- Led process validation of 3 BFS machines, aseptic processing, and 2 successful media fills.
- Oversaw development and validation of automated CIP recipes for tanks and BFS machines.
- Created a technical training program to qualify BFS operators.

Aveva Drug Delivery Systems, Miramar, FL Feb 2011 – July 2018, Sr. Manager, Quality Engineering

- Led 4-person team overseeing facility and equipment qualification, DoE studies, and engineering investigations.
- Managed installation and testing of PAT-based adhesive thickness measurement and Ignition data acquisition systems.

Commissioning Agents Inc. (CAI), North Carolina Offices Feb 2009 – Feb 2011, Project Manager

- Managed commissioning/qualification for two facility expansions.
- Supervised up to 4 reports, schedules, and budgets for C&Q projects.

AMEC E&C Services, North Carolina

Apr 2001 – Feb 2009, Manager, Southeast Operations

- Directed staff of 11; responsible for business development and project execution.
- Conducted FDA/EU/ISO compliance gap analyses for manufacturing and QC labs.
- Managed commissioning/qualification for chemical reactor facility, BSL-3 lab/vivarium, sterile water packaging line, HVAC, utilities, BAS, autoclaves, and WFI systems.

Transkaryotic Therapies, Inc., Boston, MA

Aug 1999 – Apr 2001, Metrology Supervisor

- Managed calibration programs at two sites; supervised 3 staff.
- Oversaw build-out, commissioning, and calibration of 30,000 sq. ft. cell culture plant, including utilities, tanks, HVAC, and analytical instruments.

Veteran U.S. Navy Submarine Force / Special Projects

Petty Officer First Class (E6) - Electronics Technician 10 years (Honorable Discharge)

- Supervised 12-man division on SSBN submarine operations.
- Specialized in calibration, repair, and certification of electronic systems.
- Maintained Top Secret clearance.

Skills & Expertise

- Leadership & Management: Team supervision, coaching, technical training and development.
- Aseptic Manufacturing: BFS operations, media fills, aseptic processing.
- Validation & Compliance: FDA/EU GMPs, ISO standards, VMPs, C&Q, software validation.
- Technical Expertise: PAT monitoring, DoE, process optimization, statistical analysis (Minitab).
- Utilities & Facilities: WFI, PW, CIP, HVAC, clean gases, autoclaves, BMS (Johnson, Siemens).
- Calibration: Critical instrumentation, utilities, analytical systems.
- Documentation: Control strategies, master plans, protocols, and FDA filing support.
- Software: MS Office (Word, Excel, PowerPoint, Project), Minitab, PM Manager, Calibration Manager.

Professional Training

- FDA Root Cause Analysis – 36 hours
- Tap Root Investigation & Root Cause (former FDA Inspector) – 40 hours
- Certified Investigator, Apotex – 16 hours + practicum
- AMEC Project Management – 36 hours
- ISPE C&Q Course – 16 hours
- Johnson Controls BMS Development & Operation – 32 hours
- Siemens Landis Staefa Advanced System 600 (BAS) – 32 hours
- Siemens Landis Staefa Computer Interface Software – 16 hours
- ISPE Seminar: GMP Water Treatment Systems – 10 hours
- AMSCO/Steris Factory Training – 2 months