Luis Beyles

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Professional Summary

Quality Systems and Training Manager with 15+ years of experience in regulated medical device manufacturing environments.

Proven ability to build quality infrastructure from the ground up, including establishing a full training department from scratch, developing all controlled procedures, recruiting and leading a team of 10+ trainers, and achieving ISO 13485 certification in under 6 months.

Experienced managing quality and training operations for large-scale manufacturing sites with 1,500+ employees, supporting FDA and ISO audits with zero major observations. Deep expertise in document control, change management, LMS administration, and regulatory compliance across ISO 13485, 21 CFR Part 820, and 21 CFR Part 11.

Professional Experience

Quality Training & Document Control Specialist · Nuclein · Austin, TX 2024 – Present

- Administer the medical device document control system, ensuring controlled distribution, versioning, and full regulatory compliance with 21 CFR Part 820 and ISO 13485.
- Coordinate Change Control Board (CCB) activities, including meeting facilitation, document revision workflows, and training impact assessments.
- Manage the LMS training system and training assignment matrix, maintaining workforce compliance and audit-ready traceability between document revisions and training records.
- Deliver quality onboarding training covering FDA awareness, GDP, document control procedures, and training system usage for all new hires.
- Support production quality activities including Incoming Inspection, In-Process Quality, DHR review, and NCMR processing.
- Generate training and document control evidence packages for internal and external audits and regulatory inspections.

Operations Training Manager · Flex · Austin, TX2020 – 2023

- Led training operations for a regulated medical device manufacturing site with 1,500+ employees, reporting directly to senior site leadership.
- Supported multiple FDA and ISO 13485 audits with zero major observations — providing training records, system evidence, and compliance documentation under inspection conditions.
- Selected, configured, and administered the LMS platform for the site, owning all system decisions and training architecture.
- Built and led a team of trainers, establishing consistent OJT delivery standards and certification workflows across all production areas.
- Developed and maintained controlled training procedures and documentation aligned with ISO 13485 and 21 CFR Part 820.
- Implemented improvements to OJT tracking systems that increased training visibility and compliance reporting accuracy across the site.

Operations Training Manager · Flex · Columbia, SC 2019 – 2020

- Built the training department from the ground up for a newly established medical device manufacturing facility — developed all controlled training procedures, defined workflows, and recruited and onboarded a team of 10+ trainers.
- Achieved ISO 13485 certification for the facility within 6 months of site launch, with the training system fully operational and audit-ready at the time of certification.
- Executed LMS software validation (IQ/OQ/PQ) for the training platform deployed at the new site.
- Integrated training requirements directly into the document control lifecycle, establishing the traceability framework between document revisions and training completions.
- Developed onboarding and GDP/GMP training programs from scratch for an incoming workforce with no prior regulatory manufacturing experience.

Training Specialist · Flex · Guadalajara, Mexico 2013 – 2019

- Delivered onboarding and OJT certification programs for multiple regulated medical device manufacturing customers across different product lines.
- Developed and validated in-house training systems to meet regulatory and customer-specific documentation requirements.
- Ensured ongoing compliance with training and documentation requirements through regular audits of training records and certification status.

Education & Certifications

- Bachelor of Science, Electronic Engineering
- ISO 13485:2016 Certified
- Certified IPC Trainer (CIT) IPC-A-610

Systems & Tools

- Greenlight Guru
- Master Control (QMS / Document Control)
- Compliance Quest
- MS & Document Control Platforms (Master Control, Greenlight Guru, Compliance Quest, Agile PLM)
- Advanced Microsoft Excel (compliance dashboards)
- SQL & system configuration for training
- Adobe Creative Suite (Captivate, Photoshop, Premiere, After effects)

CORE COMPETENCIES

- Quality Management Systems (QMS)
- Training Department Build-Out
- Document Control & Change Management
- Instructional Designer
- LMS Administration & OJT Systems
- FDA & ISO Audit Support
- Training Matrix & Compliance Tracking
- 21 CFR Part 820 / ISO 13485 / Part 11
- Cross-functional Quality Operations