

# Dennisse Calderon Bolivar

(+506) 8320-4164 | dennisse.cb31@icloud.com | www.linkedin.com/in/dennisse-calderon-bolivar-72285a121

## TECHNICAL SKILLS

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**Regulations Knowledge:** 21 CFR part 11 and 820 (FDA), Therapeutic Good Administration (TGA), ISO 13485 (2016), Good Manufacturing Practices, Good Laboratory Practices, Medicines and Healthcare Products Regulatory Agency (MHRA), EUMDR.

**Certifications:** ISO 13485:2016 Lead Auditor (TPECS), MD-Medical Devices Quality Management Systems ISO 13485:2016, AU-Management System Auditing ISO 19011:2018, TL-Leading Management Systems Audit Teams ISO 19011:2018, Internal Auditor ISO 13485:2016, Auditing Regulated Laboratories—LabTopia.

**Statistical Techniques:** Statistical Process Control (SPC), Design of Experiments (DOE), Root Cause Analysis (Pareto, 5whys, Ishikawa, 8D), ANOVA, Quality Control Tools (histograms, scatter plots, process capability and correlation analysis).

**Language:** Spanish (Native), English (C1-Certified by BELT Idioma Internacional).

## EXPERIENCE

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### Principal Engineer, Global CAPA Program

Feb 2023 – Jun 2024

*CooperSurgical*

*Costa Rica/Global*

#### Development and Implementation of a New CAPA Process

- Directed CAPA projects across various functional areas, including: Training, Research and Development (R&D), Labeling, Post Market Surveillance, Distribution, Information Technology (IT).
- Served as an SME during external audits specifically focused on the CAPA process.
- Trained personnel across sites on the CAPA process.

### Supplier Quality Engineer

Feb 2022 – Feb 2023

*CooperSurgical*

*Alajuela, Costa Rica*

#### Origio Transfer – Transfer of Manufacturing Operations to Costa Rica Plant

- Managed Supplier Non-conformance Material (NCEP/NCMR) and Supplier Corrective Action (SCAR).
- Executed Supplier Audits, led the negotiations of Supplier Quality Assurance Agreements, the validation of Supplier Manufacturing Process, and the Execution of Supplier Change Notification (SCN).
- Evaluated and qualified new suppliers according to established criteria, ensuring they meet quality and regulatory standards before onboarding.

### Supplier Engineer New Products

Dec 2020 – Feb 2022

*Boston Scientific*

*Alajuela, Costa Rica*

#### Hubble Project Launch – Improvement of the Opticross Device

- Conducted component qualification for new product release.
- Executed material composition assessment to ensure compliance with the medical devices regulations.
- Evaluated the supplier capacity to ensure a secure supply of critical components and collaborated with supplier to identify cost savings opportunities without compromising quality.

### Global Procurement Buyer

Aug 2018 – Dec 2020

*Boston Scientific*

*Alajuela, Costa Rica*

- Lead the preparation and issuance of RFQs and RFPs, managing the bidding process to solicit competitive proposals and negotiate favorable terms with suppliers.
- Utilized SAP for purchase orders, invoice reconciliation, contract negotiation, and participation in bidding processes, leveraging advanced features to optimize procurement workflows.
- Managed procurement budgets and expenditures, tracking costs and identifying opportunities for cost reduction while maintaining product quality and supplier relationships.
- Negotiate supplier contracts and agreements, ensuring terms and conditions meet company requirements while mitigating risks and maximizing value.

## EDUCATION

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### University of Costa Rica

*Licenciature in Industrial Engineering*

San Pedro, San Jose

March 2017 – May 2020

### University of Costa Rica

*B.S in Physics*

San Pedro, San Jose

Mach 2011 – Dec 2016