



# Profile and Capabilities

Caraballo Consulting focuses on understanding your needs and providing you with exceptional consulting resources. We have the right level of experience for the task at hand to ensure innovative and cost-effective consulting solutions.

## Regulatory

- Worldwide Regulatory Strategies
- Submissions (IDE, PMA, 510K, Dossiers, NDA & IND)
- Notified Body Certifications
- International Registrations
- Clinical and Post Market Studies

## Operations

- Process and Product Validation
- Manufacturing Process
- Equipment Validations
- Supply Chain Management

## Quality Assurance

- R&D New Product Development
- Supplier Qualification and Auditing
- CAPA Investigation and Documentation
- Quality Systems Implementation
- Sterilization Sciences
- Change Management

## Engineering

- Process Control Automation
- Packaging Engineering
- Process Excellence Methodologies
- Lean/Six Sigma

Caraballo Consultants are considered Subject Matter Experts (SMEs) in their respective fields and combine extensive training as well as best practices learned from working in state of the art manufacturing plants with years of on-site experience. We bring excellence and experience to the table while getting the job done in a timely and cost effective manner.

## CCA's Edge

*We will customize a solution based on your specific needs.*

*We offer excellence in consulting, ensuring the highest quality result.*

*Resources will be fully dedicated to your project to ensure timely completion.*

## Contact Us

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