LORENA CASTAÑEDA

M: +1 (954) 793-3297
Lorena.Castaneda.M@gmail.com
Lorena-Castaneda.com
115 Lake Emerald Dr.
Oakland Park, FL 33309

EDUCATION

B.S BIOMEDICAL ENGINEERING
FL INTERNATIONAL UNIVERSITY
December 2017

CERTIFICATIONS

LEAN SIX SIGMA – YELLOW BELT

TECH SKILLS

ISO 13485
STATISTICAL RELIABILITY
PLM
WINDCHILL
SOLIDWORKS
MS PROJECT
MINITAB
RISK MANAGEMENT
21 CFR 820

SOFT SKILLS

TEAM PLAYER
COMMUNICATION SKILLS
ANALYTICAL SKILLS
DATA TRANSLATOR
LEADERSHIP EXPERIENCE
PUBLIC SPEAKING

MEMBERSHIPS

SWE
SHPE
BMES

PROFILE

Dynamic and action-driven quality-oriented Biomedical Engineer with a foundation in Quality, Supplier Quality and a passion for improving advancements in the medical field. A dedicated self-starting professional with excellent interpersonal, communication and collaboration skills who excels in seeing shared missions to completion.

EXPERIENCE

QUALITY ENGINEER | STRYKER — Apr 2019 – Present

- Interface with cross-functional teams to develop and execute strategies for resolving issues with compliance with the QMS and external regulations
- Lead NC/CAPA investigations with supplier and internal teams to identify and execute solutions to ensure sucessful outcomes and ensure timely closure of records
- Lead and execute changes to documents and procedures in support of Global Quality Operations, in compliance with the Change Control policy
- Monitor and report site NC/CAPA KPIs as well as update quality review boards on an as needed basis
- Audit supplier files for compliance and provide support during external audits
- Lead and participate in the execution of continuious improvement and remediation projects to enhance quality performance and ensure compliance with updates to regulations and standards

QUALITY ENGINEER | COOK MEDICAL, INC — Mar 2018 – Apr 2019

Manage and perform work in coordination with cross-functional teams to augment the design files in support of submissions.

- Develop requirements and provide guidance to support NC & CAPA owners in post market investigations
- Generate RMF documents and update as needed in compliance with ISO 13485
- Conduct complaint analysis from root cause investigations
- Perform and update Post Market Hazard Analysis, Clinical Effects Analysis, Risk/Benefits Analysis, FMEA in compliance with ISO 13485 and ISO 14971
- Review ongoing complaint investigations in Trackwise in support of CAPA team
- Assist in process characterization and validation

RELEVANT PROJECTS

C-SCOPE: POLARIZED, PORTABLE COLPOSCOPE | PROJECT MANAGER — Jan - Dec 2017

R&D of a portable colposcope which utilizes polarization to aid in cervical cancer detection.

- Obtained a budget of $4,000 for project completion
- Lead a team of 4 in the research, development, validation and documentation of the proposed prototype
- Established LAN network and set-up on Linux microcomputers and developed script for image acquisition
- Developed testing protocols to ensure device complied with MRs, DIs & FDA standards
- Authored, revised and collaborated in the documentation compilation including DMR, DHF, FMEA