Randy Montesino

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## **Professional Summary**

Detail-oriented healthcare and regulatory compliance specialist with over five years of experience in quality assurance, post-market surveillance, and clinical support across the medical device and pharmaceutical industries. Proven track record of upholding regulatory standards, including FDA and ISO guidelines, and managing high-stakes projects in fast-paced, highly regulated environments. Bilingual in English and Spanish, with strong verbal and written communication skills, and proficiency in various regulatory and analytical tools such as Trackwise, Salesforce, Smartsheet, and Microsoft Office Suite. Currently pursuing a Master’s in Industrial Healthcare Systems Engineering, specializing in quality systems, and committed to delivering exceptional results in compliance, project management, and continuous process improvement.

## **Technical Skills**

**Regulatory & Quality Systems**

* Trackwise ( 6 Years Experience) CAPA management, Complaint management, and MDR reporting.
* Documentum (1 Year) Updated information and quality documentation to Documentum. I participated in pre-audits and data verification.
* Veeva Vault (3 Years) Used to archive quality documentation.
* Agile (5 Years) Used to archive quality documentation and Map document and update.
* FAST Database (1 Year) Used for data reconciliation and data verification.

**ERP Systems**

* SAP (5 Years) Have used to aid my investigations, and for data reconciliation at Medtronic and Intuitive Surgical.
* JD Enterprise (1 Year) Used for data reconciliation and to retrieve customer information to follow up.
* Expandable

**Data Analysis & Project Management**

* Microsoft Office Suite (Excel, PowerPoint, Access, Outlook) (8 Years) Have used all through profession experience.
* SharePoint (6 Years) Used a place to keep information to use for different workflows
* Smartsheet (3 years) Used at Medtronic and Intuitive surgical for team collaboration, work and project management.
* Lucid Chart (Used to visually collaborate on drawing, revising and sharing charts and diagrams, and improve processes, systems, and organizational structures.
* Tableau (5 Years) Used to track data and to create reports / Track metrics)
* Salesforce (5 Years) experience using to retrieve customer information and as a method to enhance my investigation).

**Medical & Imaging Software**:

* Mimics (4 Years) Used to create treatment plans for total hip replacement)
* Repsuite (4 Years) Used as a segmentation specialist)
* Life Image (4 Years) Used as a segmentation specialist to upload completed patient treatment plans)
* DICOM (4 Years) Used as a Segmentation specialist)
* TDA- Treatment Design Application (4 Years) Used as a Senior Segmentation Specialist to create patient treatment plans)

**Laboratory & Compliance Tools**:

* Laboratory Management Information Systems LIMS (Used at Noven Pharmaceutical)
* HIPAA Compliance (8 Years)(Used Throughout a professional career at Stryker, Noven, Intuitive Surgical and Medtronic)
* ISO 13485 (5 Years) (Used Throughout a professional career at Stryker, Noven, Intuitive Surgical and Medtronic)
* ISO9000-9001 (5 Years) (Used Throughout a professional career at Stryker, Noven, Intuitive Surgical and Medtronic)
* CFR 11.1 (Used Throughout a professional career at Stryker, Noven, Intuitive Surgical and Medtronic)

**Quality & Process Improvement**

* Lean Six Sigma (Green Belt & Yellow Belt) (5 year) (Have used to manage my projects and bring efficiency into department.)
* Root Cause Analysis (6 Years) (Used to identify which failure mode caused the problem when conducting my investigation)
* CAPA (5 Years) (Used in Intuitive Surgical, Stryker, and Medtronic)
* 806 Termination Request (1Year) (Used at Medtronic to close out my Field Corrective Actions FCA’s)
* Field Corrective Actions (1 Year) (Closed filed corrective actions as a part of my workflow in Medtronic.)
* Water fall methodology (3 Years) Project management
* Agile Methodology (3 Years) Project management

**Clinical & Healthcare Compliance**

* Familiarity with FDA regulations (5 years) Have used to work with quality and maintain compliance.)
* cGMPs, (5 years) Have used to work with quality and maintain compliance.)
* Infection control standards (1 Year) (Used while managing the decontamination room at Stryker).
* Clinical Research Associate Certification (CRA)
* GCP for Clinical Trials with Investigational Drugs and Medical Devices (U.S. FDA Focus) Course
* Process EU, APAC, US, and global MDR’s (5 Years)

## **Employment Experience**

**Compliance Specialist QC FCA Execution (Contractor) – Medtronic – Remote| 01/01/2024- Present Role**

* Compile final FCA file and all supporting evidence according to processes and regulations
* Manage multiple projects at one time.
* Reconcile large amounts of data
* Work with Product Hold Order (PHO) team and Operating Unit (OU) to ensure all the evidence is obtained.
* Report information to senior management department VP’s and Senior Directors.
* Use Smartsheet to track work progress
* Responsible for the execution and closure of Field Corrective Actions (FCAs) globally
* Provide project or program support to a functional group or business process
* Monitor project status and timetables
* Gathers and compiles information for regulatory reports
* Provides reconciliation of data to ensure all requirements/evidence is available
* Draft 806 termination request and Field Corrective Action (FCA) summaries, coordinate review, and submit regulatory reports.
* Ensure compliance of FCA files to regulations and client processes, identifying gaps and following up with OUs/regions/applicable owners to resolve
* Assist department with pre-audits.
* Coordinate with CAPA owner to document information from Trackwise CMS
* Present project progress to senior director/ management

**Regulatory Post Market Surveillance Analyst (Contractor) – Intuitive Surgical – Remote| 9/2022 – 01/2024**

* **Investigating complaints daily**
* **Perform the preliminary classification of complaints and escalate complaints that require additional review.**
* **Perform Failure Analysis investigation review and escalate complaints that require additional review.**
* **File Malfunction MDR Reports as identified.**
* **Escalate Adverse Event or Incident reports as identified.**
* **Evaluate documentation for completeness and consistency and assign additional actions as necessary to close the complaint file.**
* **Approve final complaint file for closure after all applicable actions are completed.  
  Manage complaint workload to required backlog goals.**
* **Review and analyze lot documentation (DHRs) to determine if there are any anomalies that may be related to reported product failures.**
* **Escalate complaints to the Regulatory Post Market Surveillance Manager or Lead when new failure modes are encountered.**
* **Evaluate complaints for reporting requirements in accordance with company procedures and Regulatory requirements.**
* **Interface with Customer Service and hospitals to gather additional information required for complaint investigation, including retrieval of RMA.**
* **Create customer response letters as needed.**
* **Provide peer review and feedback on complaints and reports.**
* **Participate in process improvement activities to continuously improve process effectiveness  
  Execute on projects as required.**
* **Create supplementals to the FDA.**

**Quality Assurance Complaint Specialist (Contractor) – Noven Pharmaceuticals – Miami, Fl | 7/2022 – 9-2022**

* Initiate, investigate, summarize, and close complaint records for Noven products using the Track Wise System.
* Become Lead Investigator
* Interact with individuals internally and externally to obtain information required for completion of complaint investigations.
* Identify critical complaints and complete investigations within the required time period.
* Generate and report complaint metrics in weekly progress reports and meetings.
* Summarize complaint data for APR reports.
* Update and draft SOPs as deemed necessary.
* Comply with all Company policies and procedures, including safety rules and regulations including: cGMPs,FDA regulations and other regulatory requirements.
* Perform other duties and projects as assigned by the Director.
* Identify what test are required for further investigation.
* Utilize Laboratory Management Information Systems (LIMS) to initiate testing for further investigations.
* Keep track of data associated with samples, experiments, laboratory workflows, and instruments.
* Utilize JD Enterprise ERP systems.
* Veeva Vault

**Post Market Product Complaint Analyst Stryker– Weston, Fl |03/2022- 07/2022|**

* Perform preliminary analysis and data gathering for complaint investigations.
* Input data into investigation templates and complaint databases.
* Add investigation part, lot, and serial number into spreadsheets for traceability purposes.
* Add investigation inquiries to Unidentified spreadsheet as needed.
* Identify and prioritize priority 1 complaints.
* Connect with customer service team to add RMAs to products undergoing investigation.
* Input data into Trackwise- To track investigations/ Set investigation priority.
* Input data into ERP Expandable database to close
* Process and check product defect complaints.
* Address and expedited product complaints under the company's complaint policy and procedures and ensures compliance with regulatory agencies.
* Monitor complaint activity and provide suggestions to appropriate company authorities to modify existing manufacturing or packaging process based upon pattern and related analyses.
* Maintain unified product defect investigation operating procedures.
* Interface with health care providers, sales representatives, and patients about complaint investigations.
* Complete complaint investigation.
* Process devices through the on-site decontamination facility
* Disinfected and sterilized surgical /healthcare equipment.
* Maintained detailed sterilization records for the facility.
* Monitored inventory and stocked areas with proper supplies.
* Maintained infection control standards for health and safety of patients, and all the health care team.
* Perform preliminary analysis of complaint investigation devices.
* Generate and analyze metrics and make recommendations as required to Quality Engineers.
* Assist Quality Engineers with tasks related to complaint investigations.
* Develop process improvement techniques for high efficiency.
* Learn existing product portfolio and business procedures.

**Senior Segmentation Specialist Stryker - Davie, FL | 01/2019 – 02/2022**

* Input information into a database
* Review CT scans for conformity to required protocol.
* Segment CT Scan Data using specialized software to create 3D Anatomical Bone Models.
* Create Pre-Operative Surgical Plans for robotically assisted Total Hip and Total Knee Arthroplasty.
* Create patient individualized treatment plans TKA, THA, TDA
* Review CT segmentations and Surgical Plans for accuracy of anatomical landmark selection, and implant sizing and positioning.
* Upload completed Pre-plans to field based personnel.
* Document all activities according to prescribed methods and procedures.
* Help train new segmentation specialist.
* Lead a group of four people.
* Use judgment to reject, place on hold, or know when to proceed with cases.
* Fallow-up with MPS or surgeons on surgical preferences
* Collect patient data and comply with HIPPA standards.
* Escalade cases to clinical support for further evaluations.
* Create reports, metrics, proposals, and presentations.
* Evaluate optimal solutions and recommend comprehensive upgrades to prevent future issues.
* Ensures the safety and confidentiality of all study subjects through diligent surveillance and training of patience on safety aspects of compound under study.
* Maintains records and documentation of the safety related events.

**Education**

**ASSOCIATE DEGREE IN ARTS: PRE- NURSING |07/2013- 07/2015 | MIAMI DADE COLLEGE**

* Major: Pre- Nursing
* Graduated with highest honors.
* 3.89 / 4.00 GPA

# **BACHELOR OF HEALTHCARE ADMINISTRATION |07/2016-08/2018| FLORIDA INTERNATIONAL UNIVERSITY**

* Major: Bachelor of Health Service Administration
* Graduate Highest Honors
* 3.85 / 4.00 GPA

# **MASTER’S DEGREE OF INDUSTRIAL HEALTHCARE SYSTEMS ENGINEERING | UNIVERSITY OF CENTRAL FLORIDA**

* Major: Industrial Healthcare systems Engineering
* Concentration: Quality Systems
* 4.0/4.0

## **References**

* Upon request.