GOPAL P. MOHANTY

Stevenson Ranch, CA 91381 760.429.8445
drgopalmohanty@gmail.com
www.linkedin.com/in/gopal-mohanty-phd

Transformational Regulatory Affairs, Quality, Compliance, and Clinical Affairs Executive with extensive global leadership experience driving efficiency and improvement in New Product Development and Launch, Quality Systems and Compliance, Regulatory Affairs, Product Submissions and Approvals, Operations Quality, Supplier Quality Management and Pre and Post Market Product Quality. Solid proficiency in managing regulatory agency investigation, and communication, organizational design and talent development, project management, training, coaching, mentoring, and obtaining measurable business results. Skills are in the following areas:

Medical Device, Pharmaceutical, Combination Products, Lab Mgmt.	Audits, Investigations, Warning, 483s, Consent Decree remediation	Organizational Design, Mentoring & Coaching, Talent development
Design Control, Risk Mgmt., Design Transfer, OPS Quality, Post Market, Supplier Quality, Human Factors	Regulatory Strategy, Regulatory Submission, Clinical Evaluation, Sterilization, and Biocompatibility	Acquisition and Integration, Long/ Short Term Strategy, Budgeting, Customer Management

Industry Specific Knowledge and Expertise:

- cGMP, ISO 13485, 14971, 62304, SaMD, MDSAP, MDD, MDR, IVDR, 21 CFR Part 820, 814, 812, 210, 211
- 510K, De Novo, PMA, Labeling, CE Marketing
- Design Control, Process Validation, RI, SPC, KAIZEN, CAPA, NCRs, TDs, DfSS, DMAIC, DfR, GLP, GCP

Key Accomplishments

- Received product approvals in multiple countries and cleared regulatory paths for commercialization.
- Deployed quality management system meeting global regulatory requirements (ISO 13485:2016, ISO- 14971, MDR, IVDR, 21 CFR part 820, CMDR, other MDSAP countries, ISO 62304, SaMD).
- Drove significant improvement in quality across 4 product platforms. Reduced complaints, MDRs, and FA.
- Implemented Medical Device Single Audit Program (MDSAP) and initiated deployment of EUMDR.
- Led multiple critical CAPAs resulting in cumulative savings of $ 3.9MM and addressing regulatory issues.
- Championed several six sigma (DMAIC) projects improving complaint resolution timing by 40%.
- Created Design Assurance & Reliability Engineering Organizations. Implemented enterprise-wide quality management systems including risk management (ISO 14971), Design Control (Part 820.30), software life cycle process (ISO 62304), and SaMD involving hardware, software/firmware, and consumables.

PROFESSIONAL EXPERIENCE

Nervonik, Inc. Los Angeles, CA **May 2024 - Current**

Advisory Board Member

Nervonik is a leading-edge biotechnology company developing improved alternatives to dangerous opioid prescription and complex spinal-cord stimulators in the treatment of chronic neuropathy.

Clarix Imaging Corporation, Chicago, IL **Mar 2023 - Current**

Clarix Imaging's mission is to empower clinicians with clear tumor visualization and intelligent analysis for precision and personalized medicine based on breakthrough innovations in imaging science and AI.

Vice President of Regulatory Affairs, Quality Assurance, Compliance, and Clinical Affairs

Responsibilities include all aspects of Regulatory, Quality, Compliance, and Clinical Affairs across the company. Achievements include the following:

- Organizational development, product, and site registrations, QMS implementation, and ISO 13485 and MDSAP certifications, CE marking readiness, and launching products in global markets.

- Product approvals with regulatory bodies i.e. FDA, EU, PMDA, TGA, UK, Canada, and Clinical Trials (phase II, and III) Management at multiple sites involving cutting edge technologies.

California State University, Los Angeles, CA **January 2022 – Current**
Adjunct Professor and Member of Industry Advisory Board, Industrial Management Graduate Program
Teach Lean Manufacturing, Operations Control & Management, Quality Assurance with Industrial Advisory Role

Integer Holdings Corporation, Plano, TX **May 2021 – Oct 2022**
World-wide medical device outsource manufacturer serving the cardiac, neuromodulation, vascular and portable medical markets.
Vice President Regulatory Affairs, Quality, Compliance, and Life Sciences
Global leader overseeing 300 associates across 8 factories and design centers driving new product introduction and growth in existing product lines. Improved quality and compliance performance and drove regulatory strategy for MDSAP regions appropriately scaling to product classification. Directly interfaced with agencies receiving QS certifications, manufacturing site approvals, and mitigating MDR gaps for CE Marking. Presented weekly regulatory performance metrics to CEO ensuring alignment and support for regulatory strategy.

- Improved First Pass Yield to 98% by integrating product development processes across 3 businesses and enhancing new product introduction processes.
- Grew revenues by $50MM through successfully partnering with engineering, operations, commercial leaders, and customers in implementing numerous product and process changes.
- Protected $25MM in revenue through managing MDR transition across 17 workstreams obtaining 4 MDR compliant CE marks.
- Completed review of labeling (IFU, Device Labels), compiled reports of significant changes for Notified Body review and approvals toward receiving MDR CE Marks.
- Improved complaints, NCRs, CAPAs, yields, and OTD performance greater than 15% in 1 year by establishing annual metric improvement targets working with site Vice Presidents, Directors of Operations and QA/RA site teams.

Advanced Energy Industries Inc., Fort Collins, CO **May 2018 – May 2021**
Provider of highly engineered mission-critical precision power conversion, measurement, and control solutions to global customers including medical device manufacturers.
Global Director of Quality, Regulatory, and Reliability Engineering
Global functional leader overseeing acquisitions in medical device manufacturing space and next wave in higher product regulatory compliance by regions, and improvement in quality and reliability of high precision products.

- Introduced 5 new products in multiple global regions through effective regulatory processes.
- Redesigned product development and manufacturing processes launching products with a transformational outcome reducing complaint rate by 30%. Implemented DfX (cost, reliability, service, test, assembly, manufacturability).
- Integrated enterprise systems SAP-HANA, Tableau, and ReliaSoft for faster product development, failure investigation, product enhancement, and product transfer to manufacturing.
- Evaluated, selected, and monitored critical outsourcing partners for continuity of supplies.

Danaher Corp. (a Beckman Coulter company), Chatsworth, CA **Dec. 2014 – Jan. 2018**
Director of Regulatory Affairs and Quality
Member of the Business Unit Leadership Team nurturing a performance-driven culture within the blood and urine analysis business. Led Compliance, NPD, Operations & Supplier Quality, Regulatory Submissions (Class II, III, and CE Mark), and pre/post market activities. Led numerous successful internal audits and inspections.

- Deployed quality management system meeting global regulatory requirements (ISO 13485:2016, ISO- 14971, MDD, IVDD, 21 CFR part 820, 814, 812, 50, 56, 11, CMDCAS, ISO 62304, SaMD).
- Implemented Medical Device Single Audit Program (MDSAP) and initiated deployment of EUMDR.

- Drove operational excellence in supplier quality, incoming and final QC, and in-process quality through DBS and CI tools. Improved the compliance rating across 4 manufacturing sites in 2 years from red to green.
- Drove significant improvement in product quality across 4 product platforms. Reduced complaints, MDRs, and field actions when demand for products grew 3-fold in 2 years.
- Deployed product development and NPI governance for hardware, software-ISO62304, and consumables. Maintained product quality through entire value stream from supplier quality to customer delivery.
- Proactively drove pre/post market activities involving complaints, MDRs, MDV, and product recalls minimizing adverse exposure of the company to market and regulatory bodies.
- Received numerous 510k clearances, CE Marking, and product registrations

Regulatory Compliance Associates Inc., Thousand Oaks, CA **Mar. 2014 – Dec. 2014**

Provider of quality, regulatory, and compliance services to assist both domestic and global companies with obtaining product clearance and approval in the US.

Principal Consultant

Led compliance programs involving medical devices and combination products and processes.

- Remediated WARNING LETTER for a major pharmaceutical and combination medical device company in Southern California in 9 months. Improved DHF, DMR, design control, risk management, design and process validation, and companywide procedures, and WIs to complying with 21 CFR regs and standards.
- Remediated and improved quality systems gaps of various operations including R&D and Product Release test laboratories with another major pharmaceutical company.

ASP, Johnson & Johnson, Irvine, CA **Feb. 2013 – Mar. 2014**

Worldwide Director, Operations Quality and Compliance

Global Operations Quality leader for 3 major manufacturing sites across USA and OUS focusing compliance, continuous improvement and growth.

- Improved the CAPA and NC timeliness by 200%. Reduced total NCs from 1,000 to 80. Improved First Pass Yield by 20% for consumables and capitals. Improved complaint investigation timing by 50%.
- Improved receiving inspection timing by 30% by implementing actions from Kaizen. Drove audit readiness.
- Improved chemistry and microbiology lab compliance to regulatory requirements. Improved timeliness of sample testing and failure investigation by implementing computerized systems (LIM) and adding resources.
- Improved timeliness of calibration and preventive maintenance program from Kaizen events.
- Hosted FDA, TUV, customer, corporate, internal audit, and inspections. Led Warning Letter Remediation.

Life Technologies (Acquired by Thermo Fisher Scientific), Carlsbad, CA **Jan. 2011 – Dec. 2012**

Director, Global Quality Systems & Compliance

Global leader of Quality Systems leading teams in design control, enterprise system validation, quality systems, audit and compliance, and supplier quality management. Introduced new products within and outside of USA. As a Product Approval Committee member, drove key decisions during product development, design transfer, manufacturing, and post market activities.

- Spearheaded the 510K approvals of 3 new products by developing and executing the 510K strategy, reviewing and submitting documentation, and interfacing with the FDA.
- Drove standard practices by harmonizing quality systems - QM, Management Reviews, CAPA, Design Control, Risk Management, Audit Processes, and other key quality systems.
- Drove improvement globally in the new supplier qualification and existing supplier evaluation Process. Developed and implemented the Supplier Performance Metrics for quality, delivery, and service.
- Streamlined the complaint handling process for all regions globally. Installed and led a global cross-functional team to perform the gap in the current system, developed and implemented solutions.
- Implemented statistical process control tools and processes over major processes improving yield by 25%.

Boston Scientific, Valencia, CA **Mar. 2009 – Dec. 2010**

Director, Design Assurance and Systems Validation

Design Assurance and Systems Validation leader driving efficiencies in new product development and product transfer.

- Streamlined the DA department to support D&D and V&V activities best suited for new product launches.
- Implemented Reliability Charter, software static & dynamic analysis process/tools, design/reliability analysis tools/methods, product/software metrics, and risk management practices in Neuromod environment.
- Leaned the product development process and maintained traceability of design outputs to inputs by implementing issue management system (ClearQuest) and product requirement management system (ReqPro). Enhanced compliance.
- Reduced product development costs by $2MM by optimizing V&V samples for new programs: Deep Brain Stimulation & next generation of Spinal Cord Stimulation.
- Sponsored a tier II CAPA-Feed Thru triggered by a significant field issue and other NCs and CAPAs improving design and manufacturing processes.
- Standardized the process that integrated product design output requirements with the manufacturing process requirements and parameters. Championed implementation of product and process performance monitoring system in manufacturing.

Baxter Healthcare Inc., Round Lake, IL **Nov. 2001 – Mar. 2009**

Director, Corporate Reliability and Quality Engineering, Illinois**,** 2004 – 2009

Functional leader for 3 businesses driving improvements in QS, computer systems, and infrastructures globally.

- Pioneered the implementation of Design for Reliability (DfR), Design for Six Sigma (DfSS) and processes for Competitive Intelligence Benchmarking. Improved capabilities of test labs and set up a reliability test lab with $1.8MM investment.
- Supported New Product Approvals by developing, reviewing, and submitting documentations with FDA for 510K and PMA approvals as part of the Regulatory Affairs communication and negotiation team.
- Managed a $10MM budget and directed resources (multiple facilities) in quality and reliability engineering, and complaint (death/adverse events) evaluation labs delivering uncompromised cGMP/QSR results.
- Improved compliance with FDA and NB for blood infusion, and renal systems (drug, instrument, disposable)
- Implemented management review and CAPA processes. Improved timeliness of complaint handling.
- Implemented enterprise-wide Risk Management Process (ISO 14971) applicable during product life cycles.

Senior Manager, Quality Engineering, Illinois/France/Arkansas, 2001 – 2004

- Led CAPA teams on issues pertaining to whole blood sample dilution resulting in $1.9MM savings. Led QA in 510k clearance for of Pathogen and Inactivation, and Therapeutic Plasma Exchange products.
- Implemented automated SPC system to monitor critical processes such as filling, E-Beam sterilization, bonding, etc. Improved needle and tube manufacturing processes that resulted in $2MM savings.
- Led P-FMEA, SPC, DoE, IQ, OQ, PQ; Gage R&R, Control Plan activities for manufacturing complex instruments and disposable devices. Trained the President, VPs, and Directors in lean and 6-Sigma methodologies.

EDUCATION

Executive Education received from Harvard, Kellogg, and Chicago Business Schools
Ph.D. in Industrial Engineering (Specialization in Quality), Wayne State University, Detroit
M.S. in Manufacturing Engineering, Wayne State University, Detroit
B.S. in Mechanical Engineering, Regional Engineering College (National Institute of Technology), India

CERTIFICATIONS

Regulatory Affairs Certificate: Medical Devices and Pharmaceuticals (Dual)
BSI Certified ISO 13485:2016 Lead Auditor (TPECS); ASQ Certified Quality Manager; ASQ Certified Quality Auditor; ASQ Certified Quality Engineer; ASQ Certified Six Sigma Black Belt; ASQ Certified Reliability Engineer