**Dhritikshama Roy, Ph.D., M.B.A**

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**SUMMARY**

* 15+ years' of experience in the medical device, pharmaceutical quality and regulatory, research and development, and consumer products
* Extensive experience in new product development, utilizing product development phases and quality plans, product specification, design procurement, prototyping in pharmaceutical and medical device quality and regulatory
* Experience working with Medical devices class I-III with sterile devices, cGMP, and GDP
* Extensive documentation experience including Design Control Documentations; Tec file, DHF, DMR, DHR, WI, MP, BOM, FMEA, IQ, OQ, PQ and SPC
* Sound management expertise in managing and developing staff in the facility by ensuring that direct reports are appropriately trained; manages employees career development opportunity
* Developed and managed quality management systems by establishing procedures in compliance with FDA regulations and ISO requirements and, performed global harmonization
* Expert in ISO13485, regulatory compliance, EU MDD to MDR transition/remediation/gap analysis, Annex, IVDD, and FDA QSR compliant Quality Systems for medical device manufacturing for Class I- III and sterile devices
* Acted as a liaison to ensure alignment between the department's collaboration strategy to improve the company's broader quality systems improvements
* Experienced in Project Management and strategies with a wide variety of simultaneous projects
* Expert in problem-solving, conflict resolutions among with proven leadership skills with a proven record in establishing technology improvements in both structured and unstructured environment
* Ability to work with a diverse and with cross-functional groups in all level of the working community
* Trained in leading investigating contamination, environmental monitoring, and source tracking; expert in usage, analysis, and troubleshooting of instruments
* Strong in Minitab, MS Excel, SAS, and SPSS, verbal and written communication and writing in scientific journals and magazines

**EDUCATION**

* **Executive MBA**  2022

University of Oxford, Oxford, UK

* **Ph.D. Environmental Engineering** 2011

North Dakota state University, Fargo, ND, USA

* **MS in Biotechnology** 2006

Nicholls State University, Thibodaux, LA, USA

* **BS in Biological Sciences (Chemistry minor)** 1999

North Bengal University, WB, India

**PROFESSIONAL EXPERIENCE**

**Technical Leader- Regulatory Affairs Manager 09/2020 – Present**

HCL America (Client: Abbott Laboratories)

Minneapolis, Minnesota, United States

* Manage and guide robust regulatory applications supporting International geographies to achieve departmental and organizational objectives; supports EU MDR transition activities and manage product technical files
* Creates, reviews, and approves engineering change order and prepare worldwide regulatory assessments
* Act as a regulatory management representative on core product development teams, communicates regulatory requirements and impact of regulations to the development team. Provided guidance and expertise
* Assis as liaison between the Company and the various appropriate regulatory agencies, ensuring that communications on both sides are germane, specific and convey all necessary detail
* Maintain ongoing surveillance and analysis of all pertinent domestic and international medical device regulations to ensure submission requirements world-wide are current, up-to-date and are entered into regulatory submission data base and file systems
* Ensure that information of such regulations and requirements, especially those that are new or modified, are distributed to appropriate personnel
* Review device labeling and marketing materials for compliance with submissions and applicable regulations
* Support the product release process by completing requests for product release
* Conduct reviews of product and manufacturing changes for compliance with applicable regulations. Review protocols and report to support regulatory submissions
* Support all Company initiatives as identified by management and in support of Quality Management Systems (QMS), Environmental Management Systems (EMS), and other regulatory requirements
* Comply U.S. Food and Drug Administration (FDA) and international regulations, other regulatory requirements, Company policies, operating procedures, processes, and task assignments
* Maintain positive and cooperative communications and collaboration with all levels of employees, customers, contractors, and vendors
* Performs other related Regulatory Affairs duties and responsibilities, as assigned

**Advisor of Quality, Regulatory and Research 03/2020 – Present**

Sonoscope (A start up company backed by deep-tech investment in Canada)

Montreal, Quebec, Canada (Remote: Minneapolis, MN, U.S.A)

* Prepare robust medical device regulatory applications targeting F.D.A., Health Canada and EU by playing a central role in the development of a novel medical device under the authority of the Chief Technology Officer.
* Define and lead the execution of the regulatory strategy.
* Support all company initiatives as identified by management and in support of Quality Management Systems (QMS), Environmental Management Systems (EMS), and other regulatory requirements.
* Manage and participate in the development of medical devices and design reviews.
* Review required technical specifications taking into account the applicable standards.
* Take part in the assessment of risks associated with products and processes.
* Oversight of the Quality Management System (QMS) and its activities (GCMP, CAPA, V&V). Write and execute design verification and validation protocols in accordance with applicable standards.
* Prepare documentation in support of design history files and regulatory submissions.
* Definition and revision of operational procedures (SOPs) Protocols and tests
* Develop and execute product testing methods in accordance with applicable standards.
* Supervise and perform testing and inspection of prototypes; provide training to employees on QMS and regulations
* Collaborate with the company's partners and subcontractors and perform additional duties as assigned by the Chief Technology Officer.
* Take part in designing and planning any clinical research required for device homologation
* Perform other tasks necessary to achieve the objectives/key results set forth by the Company

**Product Quality Leader 10/2019 – 09/2020**

Smiths Medical ASD, Inc.

Minneapolis, Minnesota, United States

* Escalated and proactively reported product quality issues to business leadership and/or escalates to CAPA process when needed.
* Assured timely product quality communications with both external customers and the internal Smiths organization (R$D, Ops, GPM, Sales, and Marketing).
* Establish product quality improvement strategies and initiatives in coordination with counterparts in GPM, R&D, and Ops; Creates or contributes to related specifications and project plans;
* Provide product quality feedback to design control and risk management processes; Assure proposed design and process changes are aligned with the strategies.
* Assure timely and compliant execution of distributed product risk assessments, leading and coaching risk assessment owners and teams.
* Oversees compliance with Post-Market Surveillance requirements and standards; Lead scheduling and execution of PMS review, reporting, and follow-up with business leadership.
* Responsible for the EU MDR remediation project; working closely with Medical Device manufacturing, quality, and clinical teams to ensure timely submission of regulatory documents; involved in reportability of complaints to Government Agencies; responsible for appropriate complaint database in record and audits.
* Developed quality systems and establish procedures in compliance with FDA regulations and ISO requirements
* Performed regulatory and quality consultation to identify strategic pathway to launch new device and/or upgrade of existing medical device products following country-specific regulatory guidance based on clients requirements.
* Independently assessed clinical research evaluation plan and participated the report writing for various products; performed PubMed or Embase literature based CER activities.
* Managed the team on conversion MDD documents to MDR/MDD format according MDR, Annex.
* Managed quality systems and performed 510 (K) and CE filing for new class medical devices
* Provide support and helps develop effective strategies for execution of needed Field Corrective Action plans with the Compliance Team and GPM.
* Develop and conduct Smiths Medical facilitated training and development programs for internal departments or vendors designed to increase knowledge in issues related to functional area of expertise and/or medical device manufacturing and development including GMP, Quality Systems, and specific applications at Smiths Medical.
* Plan and assign work / project tasks / responsibilities to personnel (typically technicians and engineers assigned to the specific project)
* Provide functional supervision to project team members for the duration of project assignment and assists in the evaluation of personnel performance.
* assure compliance of Company operations to all applicable laws, regulations and standards, good business practices and company documented procedures (including knowledge of all standards, government occupational health and environmental regulations and statutes related to the site).
* Engage others, promote, and participate in Environmental, Health, and Safety initiatives, focusing on continuous improvement

**Regulatory Affairs & Quality Systems Project Manager 08/2019 – 11/2019**

Regulatory & Clinical Research Institute, Inc. (Covance, Inc.)

Minneapolis, Minnesota, United States

* Performed regulatory and quality consultation to identify strategic pathway to launch new device and/or upgrade of existing medical device products following country-specific regulatory guidance based on clients requirements
* Independently assessed clinical research evaluation plan and participated the report writing for various products; performed PubMed or Embase literature based CER activities
* Managed quality system activities as needed/requested by clients. This may include, but is not limited to: setting up R&D plan, client’s quality systems, conduct gap assessments, perform audits, manage field corrective actions, post market surveillance, device tracking, complaint reporting, MDR and vigilance activities, etc
* Maintained RCRI’s internal quality system to ensure compliance with FDA and ISO standard
* Ensured compliance with applicable national and international regulations and standards during all phases of the product life cycle
* Directed the development and implementation of systems for the preparation of quality submissions, which meet regulatory requirements to ensure timely device approval and maximize market opportunities
* Assisted clients in the development of documentation designed for FDA, Competent Authorities, Notified Bodies, and other related authorities
* Contributed to the development and implementation of product development, manufacturing and strategic operating plans.
* Established MDR project timelines/schedules.
* Interacted with clients and potential clients throughout all levels of industry and corporate management
* Other duties as assigned

**Senior Engineer Quality Engineering 08/2018 – 10/2019**

Abbott Laboratories Inc.

Minneapolis, Minnesota, United States

* Performed consulting for Design Assurance for Catheters segments (Cardiovascular and Neuromodulation) of Abbott, lead Quality Engineers and Technicians to achieve departmental goals; ensured successful planning, management and execution of area projects
* Developed with individual contribution to Design for Reliability and Manufacturing competency by providing guidance and leadership to department and organization
* Guided the conceptualization of new methodologies, materials, machines, processes or products and directed the development of new concepts from initial design to market release
* Availed opportunities to assure compliance to all applicable internal, domestic and international quality regulations, US 21 CFR 820 (QSR), ISO 13485, etc.
* Purposefully identified and lead activities related to adding value to the organization through risk reduction, cost improvement, and budgetary responsibility
* Provided influential peer leadership with international partner site to drive quality improvements; approved/authored experimental plans, protocols and reports, including supporting teams on appropriate statistical techniques; identified Quality Initiatives and lead multi-functional teams to complete them
* Provided enthusiastic, diligent, and fact-based communication to Sr. Management team, peers and team; assessed resource needs to assure that the accurate level of quality support is provided when needed with the competencies needed32
* Participated as an effective member of the cross-departmental Functional Management Team to foster continuous quality compliance, cost, and improvements; maintained effective Quality Metrics and define and execute activities to resolve decreases in performance

**Sr. Quality and Regulatory Manager 12/2016 – 02/2018**

Halo Innovations, Inc

Minneapolis, Minnesota, United States

* Developed and delivered quality compliance strategy in alignment with global quality by harmonization, divisional, business unit requirements and local and international regulations and standards for Consumer Products and medical device
* Responsible for the EU MDR remediation project; working closely with Medical Device manufacturing, quality, and clinical teams to ensure timely submission of regulatory documents; involved in reportability of complaints to Government Agencies; responsible for appropriate complaint database in record and audits.
* Developed quality systems and establish procedures in compliance with FDA regulations and ISO requirements
* Supported and lead the risk management process by ISO 14971, including risk management plans, hazard analyses, FMEAs, and risk management reports, throughout all product phases and manufacturing processes
* Managed and developed staff in the facility, assigned resources, trained, managed, and generated reports with career development opportunity
* Ensured that CAPA, supplier/internal audits, calibration system, supplier development engineering, Quality engineering, and complaint handling is staffed with qualified employees
* Ongoing execution and improvements to the following quality system activities: Document Control, IQ, OQ, PQ; training Internal and External Quality System Audits Management Review Field Actions (recalls, field corrections and withdrawals) CAPA System, Nonconformance management, the product holds
* Monitored the performance of local quality systems (document control, training, CAPA, recalls/corrective field actions, corporate holds, and audits, withdrawals) and report to management periodically on compliance health, inspection readiness, and audit results
* Developed and implemented a cross-functional internal & supplier audit program to ensure that all worldwide regulatory and global quality system requirements are implemented and met
* Represented the local quality system during regulatory and external inspections
* Manages local regulatory and external audits by providing the following activities: Pre-inspection readiness; Inspection activities; Post-inspection activities
* Took QMS initiatives to ensure standardization throughout the organization
* Partners with and leads functional quality management to develop and maintain a high performing, scalable and compliant quality systems
* Provided leadership and guidance for effective and timely communication and appropriate escalation of quality system issues to all levels of the organization
* Assured compliance to in-house and external specifications and standards
* Identified and highlighted quality issues by providing input to drive corrective actions to problems identified
* Performed / lead root cause analysis to determine corrective & preventative action(s), as necessary; managed and performed an investigation of root cause and determination of corrective and preventive actions (CAPA) relating to NCRs and CARs
* Worked continuous improvement projects from beginning to end; characterizes the problem, identifies key process inputs, determines optimal operating window, implements controls to maintain output at the desired level, and quantifies the improvement in savings, avoidance, or value

**Quality and Regulatory Manager 08/2013 – 12/2016**

Waters Medical Systems, LLC –

Rochester, Minnesota, United States

* Managed the team on conversion MDD documents to MDR/MDD format according MDR, Annex.
* Managed quality systems and performed 510 (K) and CE filing for new class medical devices
* Managed and developed staff in the facility, provided training and reviewed performance
* Managed several direct reports for manufacturing activities/projects/initiatives including validations, equipment qualifications (IQ, OQ, PQ), change orders, product quality plans, device history records, in-process quality monitoring, manufacturing scale-up activities, equipment calibration, and environmental monitoring
* Managed and implemented improvements to the quality system management while maintaining
* compliance with applicable FDA Quality System Regulations, EU Medical Devices Directives, Health Canada and or ISO standards where applicable
* Developed quality systems and establish procedures in compliance to FDA regulations and ISO requirements; managed activities in Internal Quality Audits, CAPA (Corrective and Preventive Actions), Production support, Quality Management Reviews, Quality Audits, and other associated tasks
* Ensured that the Quality System following Regulatory and Quality System requirements
* Managed and facilitated ISO Registration audits, implemented corrective actions as required
* Facilitated sponsor, or 3rd party/customer audits and interactions
* Managed to identify non-conformances with requirements and provide suitable recommendations to employees
* Assured that audit rare completed to timelines using project management skills and ensured audit results are communicated to upper management
* Managed and ensured that suitable responses and action plans are provided for resolution
* Supported special projects requiring QA input
* Managed suppliers and production personnel in eliminating non-conformances to ensure product quality and continuous improvement
* Managed document control system
* Acted as a company-wide expert in Quality Management by ISO 13485:2016, 21 CFR Part 11, MDD/MDR, AAMI, and EU Quality Management systems requirements for regulatory purposes
* Actively participated in the regulatory paths and any other regulatory requirements for the introduction of products to the market

**Sr. Quality Engineer 12/2011 – 08/2013**

Aldevron, LLC

Fargo, North Dakota

* Analyzed microbiological aspects of drug products, components, and processes for purposes of product and process development, quality control, quantitative and qualitative analysis
* Tested and purified plasmid DNA, yield test on cell bank qualifications (CBQ), stability sample and protein (CAS9) using spectrophotometry, gel, densitometry, restriction digestion, RNA- CYBR gold, endotoxin-LAL, qPCR, osmolarity, antibiotic resistance assays,
* Lead environmental monitoring, and other appropriate tests for pharmaceutical/clinical services
* Performed out of spec (OOS) and CAPA related activities; tested samples to ensure compliance with FDA and cGMP requirements according to SOPs; prepared test data for appropriate review
* Documented the procedures and results obtained in laboratory notebooks/LIMS according to established regulatory guidelines
* Cultivated isolates and assisted in identifying bacteria and other microorganism contaminants
* Prepared and performed functions utilizing aseptic techniques including environmental water and water sampling, testing, and analysis; qualified media growth promotion testing for the company independently
* Worked on special projects and validations, as required and performed data entry and peer review
* Presented graphical data, analyzed data and assisted with environmental trend reports as per schedules; assisted associates with more complex microbiological tests and projects, as required
* Collected required monthly calibration items used in analyses, such as spectrophotometer, water bath, incubators, thermometers, stopwatches, and timers; assist with calibration as required
* Reviewed department SOPs for accuracy and provided revisions as required
* Assisted general lab duties/functions and housekeeping in all Microbiology Laboratory areas, as required.

**Environmental Engineer 08/2008 – 12/2011**

Environmental Engineering, North Dakota State University

Fargo, North Dakota

* Designed and implemented microbial groundwater remediation projects with nanoparticles
* Microbial community evaluation for biodegradation of common environmental pollutants by standard
* microbiology
* Tracked contamination source track
* Performed regular analysis and troubleshooting for High-Performance Liquid Chromatography Mass Spectrometry (HPLC-MS by Agilent) and Ultra Performance Liquid Chromatography-mass spectrometry (UHPLC-MS by Dionex) for wastewater contaminants including pesticides
* Helped in maintaining and analyzing laboratory data, maintain databases and trained lab personals
* Performed water quality analysis
* Microbial analyses of water and soil for isolation and identification of ammonia oxidizers using
* Molecular methods- PCR, qPCR, sequencing, Fluorescence in-situ hybridization (FISH)
* Performed produced-water sample collection, preparation, water quality analysis and data analysis
* from oil rigs at Western ND (Bakken)
* Analyzed COD, BOD, turbidity, alkalinity, hardness, pH (using Thermos Scientific instruments and Metrohm), and nitrogen species by UV-VIS spectrophotometer
* Used HPLC-MS and UPLC-MS for chemical analysis
* Performed data analysis using Minitab, SAS, Microsoft Excel, and SPSS

**Quality Control Scientist 08/2006 – 08/2008**

R&A Oyster

Mobile, Alabama

* Managed several direct reports for manufacturing activities/projects/initiatives including validations, equipment qualifications (IQ, OQ, PQ), change orders, product quality plans, device history records, in-process quality monitoring, manufacturing scale-up activities, equipment calibration, and environmental monitoring
* Verified and validate a final product before market, following standards and environmental food safety
* Environmental monitoring, and other appropriate tests for pharmaceutical/clinical services
* Performed out of spec (OOS) and CAPA related activities
* Tested samples to ensure compliance with FDA and cGMP requirements according to SOPs
* Prepared test data for appropriate review
* Documented the procedures and results obtained in laboratory notebooks/LIMS according to established regulatory guidelines
* Cultivated isolates and assisted in identifying bacteria and other microorganism contaminants

**CERTIFICATIONS**

* Certificate for Quality Management Systems-Understanding and Auditing ISO 13485:2016
* Certified Lead Auditor- ISO 13485:2016
* Certificate for Fundamentals of Medical Device Sterilization
* ASQ Certified Quality Engineer (CQE)
* ASQ Certified Quality Manager (CQM)

AWARDS AND HONORS

**2015** – The second winner for national poster competition participated by the winners from 48 states in the USA, Annual Conference and Exhibition, American Water Works Association (AWWA), Anaheim, CA, received $1200 travel award plus invitation to publish the presented research in AWWA journal, June 6-10, Anaheim, CA

**2014** – Best Poster, Young Professionals (YP) and Students’ poster competition, North Dakota Chapter of American Water Works Association, represented North Dakota chapter to Annual Conference and Exhibition, American Water works Association, Anaheim, CA in 2015, received $1500 travel grant

**2012** – Received honorarium for ambassadorship of Environmental and Conservation Sciences Graduate Program at North Dakota State University, received $500 in 2012 for service

**2005** – Nationally ranked in prestigious all India National Eligibility Test (NET) organized by University Grant Commission (UGC) /CSIR, India for higher education

**2004** – Received National Scholarship from Government of India for outstanding performance in undergraduate study, received stipend during graduate study

PEER REVIEWED PUBLICATIONS (Selected)

**Roy, D.**, McEvoy, J., Khan, E. 2020. Abundance and activity of ammonia oxidizing archaea and bacteria in bulk water and biofilm in water supply systems practicing chlorination and chloramination: Full and laboratory scale investigations. *Science of the Total Environment.* 715: 137043

**Roy, D.**, McEvoy, J. Blonigen, M., Amundson, M., and Khan, E., 2017. Seasonal variation and ex-situ nitrification activity of ammonia oxidizing archaea in biofilm based wastewater treatment processes. *Bioresource Technology*.244: 1, 850-859.

**Roy, D.**, Hassan, K., Boopathy, R. 2010. Effect of carbon to nitrogen (C: N) ratio on nitrogen removal from shrimp production wastewater using sequencing batch reactor. *Journal of Industrial Microbiology and Biotechnology*.37: 10, 1105-1110.