ATTRAYEE CHAKRABORTY, MSc., MS, CQSP

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SUMMARY

Highly motivated, reliable, results-driven regulatory and quality professional covering class I and II medical devices with 2 years medical device experience. Recognized for expertise in QMS remediation, design control, risk management, post-market surveillance, audit analysis, QARA compliance, labeling review. In-depth knowledge of Medical Device Regulations (21 CFR 820), ISO 13485, ISO 14971, ISO 9001, IEC 62304.

SKILLS & ABILITIES

● Certified ISO 13485 Lead Auditor ● ISO 15223-1 ● QMS Remediation ● MasterControl (eQMS) ● Special 510(k) ● Supplier quality ● FDA communication ● International regulatory strategy ● QMS documentation

PROFESSIONAL EXPERIENCE

Quality Systems Engineer, ***Analog Devices Inc. (ADI)*** **July 2024 - Present**

Providing quality and regulatory support to the Digital HealthCare team for CardioPulmonary Monitoring System (Software in a Medical Device) in a highly-matrixed, cross-functional team to ensure QMS compliance with international standards for successful regulatory market authorization in a global Fortune 500 company.

● Creating a Quality Management System (QMS) for new digital healthcare product lines across international teams to establish compliance with ISO 13485 and FDA 21 CFR Part 820.
● Providing thought leadership to senior management on Artificial Intelligence (AI) integration and deployment in manufacturing operations.
● Building AI governance models to develop responsible AI for ethical use throughout the organization.
● Managing, coordinating and organizing multiple internal audits and acting as backroom lead.
● Effectively closing 10 critical audit-related corrective and preventive actions (CAPAs) within record time (2 business weeks).
● Demonstrating project management skills through holding senior engineers responsible for timely closure of CAPAs.
● Improving quality culture through creating quality surveys and recognition of diligent CAPA owners in partnership with Human Resource programs.
● Performing risk assessments and managing risk management processes per ISO 14971.
● Managing non-conformance processes, including investigation, root cause analysis, and tracking trends to identify improvement opportunities.
● Developing and maintaining supplier quality requirements, conducting supplier audits.
● Leading continuous improvement projects using quality tools and methodologies such as Six Sigma and Lean to enhance product quality and process efficiency.
● Providing training and support to employees on quality system procedures and regulatory requirements.

Regulatory Affairs Project, ***RegDesk, Inc. (Remote)*** **Apr 2024 – June 2024**

● Providing thought leadership on global regulatory strategy for AI-enabled medical devices through

publication of company newsletters and whitepapers.
● Providing regulatory intelligence, comparative and future trends on artificial intelligence (AI) and cybersecurity medical device regulations for 20 nations.
● Analyzing AI/ML classification systems, requirements and registration of AI enabled medical devices.
● Preparing requirements and submission plans for AI enabled medical devices in US, EU and APAC nations to guide manufacturers.
● Risk management, validation and verification criteria analysis for submission of AI enabled medical devices to regulatory authorities.

Analog Devices Inc. (ADI), Wilmington, MA

Regulatory Affairs and Quality Project **Jan 2024 - March 2024**
● Participating as an audit observer for internal audit and MDSAP audit.
● Creating a regulatory matrix of timelines and requirements for launching a medical device product in Canada, Australia, Japan and other international markets.
● Taking decisions on product complaint escalation and adverse event reporting in product lifecycle.
● Building submissions for Canadian market authorization, conducting research on regulatory guidelines and updating SOPs for recall procedure, complaint investigation, corrective action, and labeling requirements.

Regulatory Affairs and Quality Co-op **July 2023 - Dec 2023**
● Built document control in MasterControl to support MDSAP audit readiness and successful FDA clearance.
● Authored Special 510(k) submission and supported Informational Request (IR) responses to the FDA.
● Led creation of Software Inventory List in 24 hours with international collaboration for FDA IR response.
● Authored audit report and prepared question checklist for ISO 9001 supplier audit.
● Analytical consolidation of 100+ CAPAs to illuminate areas of significant lack of QS process control.
● Established supplier accountability through supplier qualification, auditing and COC/traveler review.
● QMS remediation through gap analysis, Quality Plan authoring, internal audit finding analysis, traceability correction and authoring QMS documents such as SOP and WI as part of design and development control.
● Achieving risk management goals though complaint handling for post-market safety reporting.
● Closed root cause investigation for 75% CAPAs and non-conformances outstanding for over a year.
● Effectively establishing a strong quality culture through Lunch-And-Learns, CAPA training, and CAPA cheatsheet across functional roles to ensure compliance with internal procedures.
● Preparing a sample DHR, DMR review, PFMEAs and proactively providing regulatory intelligence.

Regulatory Affairs and Quality Project, ***Virtual Field, NY (Remote)*** **Apr 2023 – June 2023**
● Established regulatory pathway for Medical Device License (MDL) submission in Canada for a Class I Virtual-Reality headset for glaucoma diagnosis (SiMD).
● Developed a cybersecurity plan as per NIST and IMDRF guidelines.
● Influenced management on global product diversification through regulatory strategy development for UK, Australia, India and Mexico as well as establishing healthy supplier relations.
● Implemented Hazard Analysis and Critical Control Points (HACCP) to identify hazards and proposed risk controls for design plans using ISO 62304, ISO 27001, ISO 14971 and ISO 13485.
● Conducted gap assessment of procedures with ISO standards to achieve audit readiness.
● Designed packaging labels as per ISO 15223-1 and documented Instructions for Use (IFU).

Regulatory Affairs and Quality Project, ***Massachusetts Eye and Ear, MA*** **Jan 2023 - Apr 2023**
● Bolstered quality system for a Class II surgical eye implant (Boston KPro) to achieve audit readiness.
● Developed labels compliant with EU, FDA and Health Canada regulations as per ISO 15223-1.
● Developed strong documentation for 220+ internal procedures in line with internal audit findings.
● Provided support in content creation of Design History File (DHF), Device Master Record (DMR), Device

History Record (DHR) to manage design changes as per 21 CFR 820.
- Proactively made changes to Instructions for Use (IFUs) and Patient ID cards as per latest EU MDR.
- Provided management with supplier selection strategy and regulatory pipeline for entering emerging markets.

Regulatory Affairs Intern, ***HealthTech Incubator, IISc Bangalore, India*** **May 2022 – Sept 2022**
- Subject Matter Expert (SME) on regulatory strategy for launching Class II ophthalmic diagnostic software.
- Spearheaded establishment of quality systems compliant with CDSCO, ISO 13485 and ISO 14971.
- Established a culture of quality in early startups to ensure management accountability.

EDUCATION AND CERTIFICATES

M.S in Regulatory Affairs Drugs, Biologics and Medical Devices, GPA: 3.9 **June 2024**
Northeastern University, Boston, MA

Certified Quality Science Professional (CQSP) **April 2024**
Pathway for Patient Health, Cincinnati, OH

Certified ISO 13485:2016 Medical Device Lead Auditor, SGS **Dec 2023**
SGS, Certificate credentials: 127626249 / 168940236

Integrated M.S and B.S in Biotechnology - National Rank 23, University Rank 3 **July 2021**
St. Xavier's College, Kolkata, India

RECOGNITION & ACCOMPLISHMENTS

Invited Speaker. World Conference for Quality & Improvement, American Society for Quality **May 2025**
- Topic: Quality Crusaders: How Early-Career Professionals Can Revolutionize Culture and Communication

Invited Speaker, RAPS Global Regulatory Strategy Conference **March 2025**
- Topic: AI Governance in Healthcare: A Cross-Jurisdictional Global Analysis of Regulatory Approaches

Invited Speaker, MDM West **Feb 2025**
- Topic: Navigating Global AI Healthcare Regulations & Quality Requirements: Current Trends & Future Perspectives

Invited Speaker, Cybersecurity for Medical Devices Summit, Boston **November 2024**
- Workshop lead: Defining Requirements for AI enabled medical devices using a risk assessment template.
- Panel: Consolidating the Definition of AI Under the Context of Cybersecurity to Ensure Accurate Compliance of The New Generation Medical Devices.
- Talk: Leveraging Periodic Post-Marketing Checks to Ensure Devices in Market Remain Compliant & Secure.

Guest speaker, Northeastern University **November 2024**
- Invited to speak to students in regulatory courses on navigating a career in quality in the medical device space.

Poster presentation, Professional Society for Health Economics and Outcomes Research **November 2024**

(ISPOR Europe)

● Topic: AI/ML 510(K) Predicate Networks: A Potential for Amplification of Design-Related Recall

Invited Speaker, MD&M Minnesota **October 2024**

● Topic: Navigating Global AI Healthcare Regulations & Quality Requirements: Current Trends & Future Perspectives.

Poster presentation, Global Summit on Regulatory Science (GSRS), USA **September, 2024**

● Presenting poster on AI standards and regulations in healthcare to international regulatory bodies (FDA (US), Swissmedic (Switzerland), TGA (Australia), ANVISA (Brazil), and EMA (Europe)).

Course Chair and Presenter, Quality College, Society of Quality Assurance **September 2024**

● Leading and presenting a 4 hour course on quality and regulatory requirements for AI in medical devices to quality engineers across the US.

Invited Speaker, International Society of Pharmaceutical Engineering (ISPE) Annual Meeting **Oct 2024**

● Topic: Global Artificial Intelligence (AI) Healthcare Regulations: Trends and Future.

Invited Speaker, American Society of Quality (ASQ), Boston **Oct 2024**

● Topic: Global AI Healthcare Regulations and Quality Requirements: Building an Effective QMS for Medical Devices

Invited Speaker, Society of Quality Assurance **July 2024**

● Topic: Quality and regulatory requirements for AI in Healthcare.

Contributor, Indian Pharmaceutical Congress **July 2024**

● Partnering with the Indian regulatory government authority, Central Drugs Standard Control Organisation (CDSCO) to deliver a presentation on AI enabled medical device regulation in India.

Invited Speaker, Society of Quality Assurance, Mid-West Annual Conference **July 2024**

● Topic: Global AI Healthcare Regulations and Quality Requirements: Building an Effective QMS for Medical Devices.

Invited Speaker, RegDesk **July 2024**

● Topic: Quality and regulatory requirements for medical device companies using AI.

Instructor and Session Developer, Northeastern University **April 2024**

● Course title: INPR 0110 AI in Action: Generate Your Experience.

● Topic: Exploring Quality and Regulatory Considerations in AI for Healthcare: Asking the Right Questions.

● Learning Outcomes: Incorporating regulatory considerations in design and deployment of AI-enabled devices.

● Delivered to students, faculty and staff across 13 campuses globally (US, Canada and UK).

Regulatory and business advisor, HealthTech Incubator, Indian Institute of Science **April 2024 - Present**

● Advising 5 healthtech startups on business and regulatory strategy to achieve commercialization in India.

Selected Participant, MIT GrandHack 2024 **April 2024**

● Worked with a diverse cross-functional team to create a medical device prototype.

Selected Speaker, 40th Annual Meeting, Society of Quality Assurance **April 2024**

● Topic: Cultivating a Culture of Quality: Insights from an Early-Career Professional in Medical Devices.

● Sole recipient of the William J. Lander Sr. Memorial Scholarship for attending the meeting.

Honorable mention: Boston Congress of Public Health (BCPH) Thought Leader Fellowship **March 2024**

Invited member for specialized training in academic journalism, positioning as a future thought leader in the field.

Poster presentation, International Society for Pharmaceutical Engineering Career Workshop **Feb 2024**

Topic: Navigating Global AI Healthcare Regulations: Current Trends and Future Perspectives

Drug Information Association (DIA) Student Speaker, Boston, MA **June 2023**

National finalist in proposing solutions for combating drug misinformation in international regulatory conference.

Academic Excellence Award, Northeastern University **May 2023**

Awarded Student Travel Grant to attend MD&M West, Anaheim, CA.

Graduate Leadership Initiative, Northeastern University **Sept 2022 - Nov 2022**

Selected as a promising leader for a training program on healthy work culture and applying lean principles.

LEADERSHIP POSITIONS

Advisory Board, Institute for AI Governance in Healthcare (IAIGH) **Dec 2024 - Present**

● Contributing to the development and implementation of standards and best practices for AI governance in healthcare.

● Collaborating with industry leaders to address regulatory, ethical, and technical challenges in AI-enabled medical devices, fostering compliance and innovation.

Invited contributor, Coalition for Health AI (CHAI) **Dec 2024 - Present**

● Invited to provide expert opinion and additions to the current version of CHAI's Assurance Standards Guide in a regulatory context.

Steering Committee, ISPE GAMP Boston Chapter **Oct 2024 - Present**

● Contributing to strategic decision-making and project oversight as a member of the Steering Committee.

Secretary, Regulatory Affairs Professionals Society (RAPS) Boston Chapter **Oct 2024 - Present**

● Orchestrating comprehensive secretarial functions including meeting management, documentation, internal communications, and record-keeping while ensuring seamless information flow among members and leadership.

AI Collaborative Community Leader, Regulatory Affairs Professionals Society (RAPS) **June 2024 - Present**

● Chosen as subject matter expert (SME) for leading conversations in a regulatory professional platform on regulations surrounding medical devices, artificial intelligence and digital health.

Working Group, AI Global Health Initiative (AIGHI) **March 2023 - Present**

● Active contributor in FDA-recognized collaborative community publishing whitepapers on AI systems and AI regulations.

International Society for Pharmaceutical Engineering (ISPE), Boston, MA **Oct 2022 - Present**

● **Joel Goldenberg Memorial Scholarship, ISPE, 2023**

National winner of scholarship worth 10,000 USD in recognition of being a young leader in healthcare.

● **Secretary, ISPE Northeastern University Student Chapter (2023 - 2024)**

● **Volunteer recognition: Ethnocultural Diversity, Equity and Inclusion (DEI) Committee**

● **Student Travel Grant to attend ISPE Aseptic Conference, Washington D.C, 2023**

Working Group member, ISPE Artificial Intelligence Community of Practice **May 2024 - Present**

● Performing review of GAMP® Good Practice Guide: Artificial Intelligence (AI)/Machine Learning by ISPE.

Secretary, WG IEEE P3396 international standard development **May 2024 - Present**

● P3396: Recommended Practice for Defining and Evaluating Artificial Intelligence (AI) Risk, Safety, Trustworthiness, and Responsibility.

PUBLICATIONS

● Chakraborty (2024). 'AI-Enabled Medical Devices In India: Opportunities And Challenges' MedDeviceOnline. Website URL:
https://www.meddeviceonline.com/doc/ai-enabled-medical-devices-in-india-opportunities-and-challenges-0001

● Chakraborty, A. (2024, June 12). 'Quality as a Culture: How Can Early-Career Professionals Make an Impact?' Quality Matters, Volume 40.2, Quality Spotlight Article; Society of Quality Assurance.
https://sqa.org/sqa/News___Announcements/QualityMatters/2024/April/Spotlight_Apr24.aspx

● Chakraborty, A., & Karhade, M. (2024). Global AI Governance in Healthcare: A Cross-Jurisdictional Regulatory Analysis. ArXiv.org. https://arxiv.org/abs/2406.08695

● Chakraborty (2024, June 14). 'An in-depth look at AI enabled medical devices [White Paper]' RegDesk Newsletter, June 2024. RegDesk, Inc.
https://drive.google.com/file/d/1CGmx7UzMhNQUmYNsYuP3L1B9ZqcX2JEM/view

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FEATURES

● Content Hub - Cybersecurity Medical Devices (cybersecurity-medical-devices.com)

● Attrayee Chakraborty - Cybersecurity Medical Devices (cybersecurity-medical-devices.com)

● Regulatory Trends for AI in the United States & Beyond (mddionline.com)

● Attrayee Chakraborty | Northeastern University College of Professional Studies

● Op-ed: Lessons from an international student in regulatory affairs - The Huntington News (huntnewsnu.com)

● Transformative Impact: My Journey with ISPE from Aspiring Student to Emerging Professional – ISPE Boston

● From Concept to Care: Navigating across the Regulatory Framework in HealthTech | E05 | The Doc Suit - YouTube

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JUDGING ACTIVITIES

Reviewer, Heart Rhythm 2025

● Selected 44 abstracts for presentation and exhibition at Heart Rhythm, 2025, premier meeting for leaders in electrophysiology.

● The Heart Rhythm Society (HRS) is an international leader in science, education, and advocacy for cardiac arrhythmia professionals and patients — representing professionals in over 70 countries worldwide.

Reviewer, 2025 IEEE International Symposium on Biomedical Imaging (ISBI) November 2024

● Academic reviewer of 3 articles submitted for the 22nd IEEE International Symposium on Biomedical Imaging (ISBI 2025)

Reviewer. World Conference for Quality & Improvement, American Society for Quality October 2024

● Graded and made decisions around accepting proposals related to quality, healthcare, supplier quality, quality tools, quality management and quality education for world conference.

Reviewer, International Conference on Biomedical and Health Informatics June 2024- Present

● Academic reviewer of articles submitted for Institute of Electrical and Electronics Engineers Journal of Biomedical and Health Informatics (IEEE J-BHI).

● IEEE J-BHI is ranked as one of the top 3 (out of 47) Health Information Management Journals according to H-index (137), Journal Impact Factor (2022): 7.7, CiteScore for July 2023: 10.8.

Pathway Teaching Assistant for Quality Science Education September 2024- Present

● Courses: Global Regulatory and Legal Requirements of Quality (GRLR), Product Development and Validation (PV), Risk and Failure Analysis (RISK)

● Evaluating 200+ students across North & South America, Europe, Asia, Africa, and Australia.

● Link: Volunteer! — Quality Champions for Life

Reviewer, ADI General Technical Conference (GTC) Oct 2024

● The GTC is an annual technical conference that has been running for over 45 years across 45 locations and 25,000+ employees.

● Graded 50 submissions, abstracts and demo workshop proposals around healthcare technology to be accepted at the conference.

Reviewer of international standards (miscellaneous)

● ISPE GAMP Good Practice Guide: Validation of AI-enabled GxP Computerized Systems

Comments accepted and determined to hold merit. Will be incorporated in the next edition.

● AAMI/ISO 11135:2014 (AAMI ST-WG01: Industrial EO Sterilization Working Group)

Comments accepted and determined to hold merit. Will be incorporated in the next edition.

● Safe and Responsible Artificial Intelligence in Health Care (Australian Government: Department of Health and Aged Healthcare)

Comments published on the official website.

● Healthcare AI Governance Standard: Institute for AI Governance in Healthcare

Comments accepted and invitation to rewrite sections of the standard

Reviewer for course syllabus, Emory University/Georgia Tech **Nov 2024 - Present**

● Course: Master of Science Biomedical Innovation and Development – Advanced Therapeutics

● Invited to review syllabus and provide inputs for Masters program in regulatory and quality

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