Ashok Sriram Chandra Mohan

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SKILLS

- ISO 13485:2016
- ISO 14971:2019
- IEC 62304:2006 + AMD1:2015
- IEC 82304-1:2016
- IEC 62366-1:2015 + AMD1:2020
- IEC 60601-1, IEC 60601-1-2, IEC 60601-1-6, IEC 60601-1-11, IEC 60601-2-5
- Good Manufacturing Practice as per FDA 21 CFR Part 820
- Regulatory Affairs
- Technical Documentation
- Risk Management, GSPR
- Quality Assurance
- Regulatory Submission (510k, Denovo, Pre-sub, Breakthrough for US FDA, MDL & MDEL HC, EU MDR for CE Marking, UK MDR

PROFESSIONAL SUMMARY

Enthusiastic and aspiring Biomedical Engineer with more than 4 years of experience in the medical device industry working on regulatory submissions for various medical devices (Neurostimulators, HIFU systems, ultrasound diathermy, smartwatches) and submitted for US FDA, EU MDR, Health Canada and so on. Experience in drafting quality SOPs as per ISO 13485 and product documentation for Software as a Medical Device (SaMD) as per IEC 62304. Hands-on experience with IEC 60601 and ISO 14971 standards. Working on various SaMD projects (AI/ML algorithm-based software) for regulatory submissions. Working on drafting Denovo Submission for Kelvin-PD (SaMD), technical documentation for MDR 2017/745/EU and drafting technical documents such as software documents, Product Description, Labelling. Hands-on Experience with ISO 13485:2016 external audit with BSI for recertification. Hands-on Experience on software validation for tools such as Adobe Acrobat Signature for computerized systems validation. Expertise in the transition from ISO 27001:2013 to ISO 27001:2022 and proven record on achieving certification with no non-conformances. Successfully completed the entire QMS starting from building to implementation as per ISO 13485:2016 without non-conformities and established a good relationship with Notified body BSI.

WORK HISTORY

RAQA Manager 04/2025 - Present
Exroid – Sandwich, Kent

- Analyzing and enhancing existing Quality Management System (QMS) processes to drive continuous improvement and operational efficiency.
- Assessing critical suppliers in compliance with ISO 13485:2016 Clause 7.4 requirements, focusing on medical device manufacturing and authorized representative qualifications.
- Releasing and approving complete systems (devices and treatment kits) for market deployment in accordance with production control and service provision work instructions.
- Collaborating with reviewer on MDR compliance questions (2017/745, UK MDR 2002) to support certification for CE and UKCA marking
- Successfully led the ISO 13485:2016 surveillance audit in compliance with EU MDR and UK MDR requirements, achieving certification with only one minor non-conformance
- Maintaining stock checks and storage unit to maintain and store devices and treatment kits in a controlled environment condition

2002 for UKCA Marking, TGA, CDSCO)
- MDSAP
- GDPR compliance
- HIPAA compliance
- NIST SP-800 framework guidelines
- Cybersecurity
- ISO 27001:2022
- ISO 27701:2019
- Cyber Essentials
- Internal Auditor
- DTAC, DSPT Toolkit
- Device registration in Global Markets
- Supplier Management (Critical Subcontractors)

LANGUAGES

English

Upper intermediate
PTE UKVI Academic Score - 69

Tamil

Fluent

- Led a team of RAQA Officers to support QMS management, technical file preparation, and global device registration activities.
- Conducted supplier audits to verify compliance with ISO 13485 standards and ensure quality system alignment.
- Served as PRRC and Management Representative, providing strategic plans for continual system improvement and delivering RAQA updates to Top Management during board meetings.
- Implemented updated UK PMS requirements and revised post-market surveillance activities to ensure full regulatory compliance.

Quality & Regulatory Affairs Manager 03/2024 – 03/2025
Thymia – London

- Working on ISO 27001 (ISMS) transition from 2017 to 2022 and responsible for updating policies and procedures as per requirements and Statement of Applicability.
- Defining regulatory strategy for Thymia products into various markets such as US, UK, EU and Canada.
- Successfully conducted the transition audit for ISO 27001:2013 to ISO 27001:2022 and recertification for the organisation assessed by British Assessment Bureau with no non-conformities and achieved 100% success rate.
- Preparing Breakthrough devices designation request program for our software to the FDA.
- Working on setting up entire QMS for the organisation as per ISO 13485:2016 and other applicable regulatory requirements.
- Working on Cyber Essentials self-assessment certification for NHS government contracts and successfully achieved the certificate.
- Working on Digital Technology Assessment Criteria (DTAC) to ensure product meets clinical, quality, and safety standards.
- Working on self-assessment on DSPT Toolkit for security compliance of NHS
- Working on preparing technical documentation for UKCA marking Class I device through self-certification.
- Maintain an effective communication with Notified body for QMS and MDR certification.
- Drafting all relevant procedures (SOPs) for the organisation to implement QMS for the Stage I audit as per ISO 13485:2016 and successfully completed without Major NCs.
- Successfully completed Stage II audit for QMS with BSI and achieved QMS Certification by implementing the process, training the employees and generating the records.

QA & Technical Documentation Officer 05/2023 – 02/2024
Machine Medicine Technologies - London

- Drafting Product SOPs such as SDLC, Product Identification & Traceability, Change Control procedure, Control of Non-Conforming product, Protection Health Information and Sensitive data as the product is a SaMD used for estimating disease severity in Parkinson patients.
- Drafting Software documents such as Software safety classification, SDP, SRS, ADC, SDD, Software V&V, Software Release notes,

Maintenance plan, Risk Management file, cybersecurity checklist for security requirements of application as per IEC 62304 and IEC 82304-1, FDA guidance on content of premarket submission on Device Software functions and IMDRF SaMD - Clinical Evaluation, Risk categorization framework

- Successfully undergoing training on GDPR, HIPAA, ISO 27001 awareness on importance of data protection and security for an organization and achieved 100% success rate on all training.
- Conducting software validation for the tools such as Adobe and executing test scripts for validation of Adobe Acrobat Signature for computerized systems validation and Dropbox for electronic records storage.
- Successfully undergoing external audit with BSI for recertification of ISO 13485:2016 for organization, achieved a 98% success rate and only one non-conformity is observed during evaluation.
- Drafting contents for Pre-submission to the FDA for the submission works of Kelvin-PD
- Drafting all sections of Denovo application for the product Kelvin-PD as per recent FDA's nIVD eSTAR file.
- Sprint discussion & interaction with the FDA on finalizing the works on Intended use & Indications of Use for Labeling of Kelvin-PD
- Drafting & reviewing the technical documents for another product Kelvin-TD such as clinical evaluation, product description based on the IMDRF and FDA SaMD - Clinical Evaluation.
- Drafting technical documentation for Kelvin-PD as per Annex II - Technical Documentation of MDR (2017/745/EU) and UK MHRA MDR requirements
- Conducting internal and external audit for IEC 62304 standard for technical software documentation of Kelvin-PD.
- Addressing NCRs raised during Internal and external audit for ISO 13485 with CAPA's and achieved 100% effectiveness.
- Investigating various eQMS platforms and analyzing its need for an organization for QMS implementation.

Product Specialist - RA/QA 09/2021 - 06/2023
Elexes Medical Consulting - Bangalore, India

- Achieved a success rate of 90% in preparing and submitting 510(k) applications for various medical devices for clearance
- Reviewing Electrical safety and EMC test reports for various medical devices with an accuracy of 90% as per IEC 60601 test standards
- Reviewing Labeling, Biocompatibility test reports, Declaration of Conformity, and drafting various sections for 510(k) submission within a speculated timeline
- Working on SaMD products and setting up QMS as per ISO 13485, reviewing software documentation as per IEC 62304 standards and Agile methodology.
- Succeeded in preparing responses to 95% of all FDA requests for additional information on 510(k) applications within a 1-week deadline.
- Achieved a success rate of 100% in preparing HC applications for various medical devices and responded & resolved queries during submission.

- Exposure to MDD-MDR transition and working on change assessment, technical file and GSPR, PMS, PSUR, Clinical Evaluation Report as per EU MDR 2017/745, MHRA requirements
- Working on due-diligence for various regulatory submissions under US FDA, HC, TGA, CDSCO, EU MDR, MHRA

Junior Clinical Data Scientist 11/2018 - 07/2021
Curneu MedTech Innovations - Chennai, India

- Know-how of processing and analyzing clinical data using Python with a skillful rate of 80%
- Manual testing of software using test cases and hardware using protocols and conducting V&V activities of developing prototype with 90% effective test results
- Conducted a survey of needles requirements with acupuncturists from various countries of the world and collected the data based on questionnaires and analysis, represented in tools such as Power BI & Tableau with an accuracy of 92%
- Identified regulatory requirements for acupuncture devices and needles, the software which developed as per IEC and ISO standards
- Establishing relationships with collaborators and end-customers
- Clinical Data collection, processing and analyzing using Python and PowerBI
- Helping team in assist on design and development of medical devices in both software and hardware.
- Testing and Validation of medical devices (Software and Hardware), Quality check and assurance

EDUCATION

Bachelor of Engineering: Biomedical Engineering, 07/2015 - 04/2019
Sri Ramakrishna Engineering College - Coimbatore, Tamil Nadu, India

CERTIFICATIONS

- GDPR
- HIPAA
- Phishing
- Internal Auditor for ISO 27001:2022 by British Assessment Bureau
- ISO 13485:2016 e-Learning Requirements Course from BSI
- ISO 13485:2016 Lead Auditor from BSI

UDEMY CERTIFICATION

- IEC 62304:2006 + AMD1:2015
- ISO 27001:2022
- ISO 13485:2016

ACCOMPLISHMENTS

- **Best First Impression (Feb 07, 2022)**

As a valued member of our team and my sincere hard work and dedication paid me this award as a proud achievement

- **Appreciation from Management (Mar 03, 2023)**
  For value my work and contributions to the projects that I am currently working on and it is really making a difference, a token of appreciation in response to my work performance was presented. As a valued member of our team and my sincere hard work and dedication paid me this award as a proud achievement

- **Active RAPS member (Dec 9, 2024)**
  Successfully joined as a member in Regulatory Affairs Professional Society (RAPS) for an exciting journey to learn new set of knowledge and skills towards regulatory affairs.

FREELANCING

- Performing testing on Hoodin (Post-Market Surveillance and Vigilance Tool) to test their functionality, performance with respect to regulatory requirements and provided feedback to the Client

- Conducting Internal Audit on ISO 27001:2002 (ISMS) and ISO 27701:2019 (PIMS) to mdeg Gmbh (A cloud service provider company) and reviewing the documents to ensure compliance with respect to 2022 standard.

- Successfully completed Cybersecurity Assessment for an implantable Brain Interchange system for paralysis and identifying threats and vulnerabilities based on the assets, evaluating risks based on CVSS scoring and providing risk mitigations as per AAMI TIR 57 and NIST 800-1 guidelines.

- Assisting in a DTAC (Digital Technology Assessment Criteria) to support NHS compliance for drafting and reviewing the main file and its supporting documentation for Magic Tasks and successfully completed.

- Completed the DTAC project works by preparing the necessary documentation entirely and providing assist to the Project TMs for their product CareApps (Empathika).

- Currently working as Junior Quality Manager in improving QMS and ISMS for Medigital Gmbh to streamline the process in both systems as per applicable standards and help to market the device in UK market, helping them to complete the DTAC for hiToco Product.