PENBRAN
Regulatory Consultancy

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Regulatory and Quality Project Examples

Introduction

My career to date has been in medical device manufacturing and, latterly, consulting. I have worked for and with a range of companies of various sizes and complexity, in the UK and globally. My work in start-ups has given me broad operations experience as well as quality and regulatory. This summary is a non-exhaustive overview of the regulatory and quality projects I have been engaged in.

Software Devices

Market Focus	Clinical Area	Devices	Projects	Company size
Brazil	Acute stroke	AI SaMD for acute stroke diagnosis from CT imaging	ANVISA Clearance	SMEs
China		AI SaMD for acute stroke diagnosis from CT imaging	• Device classification of AI SaMD for China • Class III submission: Product Technical Requirements authoring	
EU & UK	Acute stroke	AI SaMD for acute stroke diagnosis from CT imaging (CADe)	CE Certification	
		AI SaMD for acute stroke diagnosis from CTP and MR imaging		
		SaMD for acute stroke diagnosis from CTA imaging		
	oncology	SaMD Image registration, display and multi-timepoint analysis for CT, MR, PET SPECT and planar NM, for cancer diagnostics & treatment monitoring	CE Technical Files (multiple devices)	

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	lung cancer	SaMD AI enabled lung nodule detection and diagnostic software	Regulatory requirements analysis, design direction and strategy: regulatory options analysis for CE marking and UKCA marking utilizing an equivalent MDR device.	
	Social anxiety	CBT Mobile app	Requirements Analysis: CSO responsibilities	Start-up
Japan	Oncology	SaMD Image registration, display and multi-timepoint analysis for CT, MR, PET SPECT and planar NM, for cancer diagnostics, treatment monitoring	PMDA registration	SME
US		SaMD Image registration, display and multi-timepoint analysis for CT, MR, PET SPECT and planar NM, for cancer diagnostics, treatment monitoring	FDA 510(k) clearance (multiple devices)	Start-up & SME
		AI SaMD for auto-segmentation of organs at risk for Radiotherapy treatment planning	• FDA Pre-submission • FDA 510(k) clearance	SME
		SaMD AI enabled real-time diagnostic analysis of endoscopy gastrointestinal imaging	• Regulatory requirements analysis and strategy: regulatory assessment on existing protocols potential use for US clearance • Advice on clinical trial protocol design and requirements	Start-up
		AI SaMD for PET imaging analysis and dosimetry for y90 SIRT for liver cancer	• FDA Pre-submission • FDA 510(k) clearance	SME partnered with Large multinational
	Acute stroke	SaMD for SaMD for vessel density analysis in acute stroke from CT imaging	• FDA Pre-submission	SMEs

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			• FDA 510(k) clearance	
		AI SaMD for stroke - large vessel occlusion detection and notification (CADt)	• FDA Pre-submission • FDA 510(k) clearance	
		AI SaMD for acute stroke diagnosis from CT imaging	FDA 510(k) clearance	
		AI SaMD for acute stroke diagnosis from CT imaging (CADe)	• FDA Pre-submission • FDA 510(k) clearance • FDA 510(k) Additional Information Request • FDA Submission issue request	
US	Parkinson's Disease	AI enabled therapeutic Mobile app	Regulatory requirements analysis and strategy	Start-ups
	Stimulant use disorder	CBT Mobile app	• FDA Pre-submission	
	Suicide prevention	CBT Mobile app	• FDA 510(k) clearance	
	Muscular Dystrophy	SaMD AI enabled detection and recording of physical clinical assessment	Regulatory requirements analysis: digital endpoint analysis	Large multinational
	Pathology & Immunohistochemistry	Cloud hosted SaMD AI enabled digital pathology imaging and diagnostics	Regulatory requirements analysis and strategy: analysis of early stage development of SaMD to identify likely software development partners and route to market	Large multinational Pharma
		SaMD AI enabled digital pathology imaging and diagnostics	Regulatory requirements analysis, design direction and strategy	Start-up
	Dementia and Alzheimer's	SaMD AI enabled Medical Imaging diagnostics	• Requirements Analysis: assessment of additional features regulatory impact on existing clearance	Start-up

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			• Gap analysis and advice: Review of cybersecurity process and information to support clearance against updated FDA cybersecurity requirements	
US	Liver fibrosis	SaMD for image analysis and diagnostics from MRI scans	• FDA Pre-submission • FDA 510(k) clearance	SME partnered with a Start-up

Physical Devices

Market Focus	Clinical Area	Device Type	Projects	Company size
Global	Acne	Acne patch	global regulatory analysis and appraisal of applicability of existing US and EU clearance	Large multinational health products
	Sexual health	Condoms	global regulatory analysis and applicability of existing US and EU clearance	Large multinational health products
	Allergies and colds	Nasal spray	global regulatory analysis and appraisal of applicability of existing US and EU clearance	Large multinational health products
US	General surgery	Electrosurgical cutting device	• FDA Cybersecurity Requirements Analysis • FDA Pre-submission • FDA 510(k) clearance	SME
		Ultrasonic surgical device	Technical analysis of claims for updated device version	SME

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	Pre-term labor	Photo biomodulation/light therapy device	Regulatory analysis, strategy and design direction	Start-up
	Sleep apnea	Dental	FDA 510(k) clearance	SME

Combinations

Market Focus	**Clinical Area**	**Device Type**	**Projects**	**Company size**
US	Heart failure	Combination: cloud hosted AI analysis software, mobile app & electronic stethoscope	FDA Pre-submission	Large multinational Pharma
	Menstrual migraine	Combination: Mobile app, wearable device and AI diagnostic algorithm	Regulatory pathway and requirements analysis and strategy	Large multinational Pharma
	breast cancer	Combination: sensor glove, mobile app and cloud hosted AI analysis algorithm.	Regulatory requirements analysis and strategy	Start up
	Post-partum hemorrhage	SaMD AI enabled device to detect and predict PPH from biometric data from wearables	Regulatory requirements analysis, design direction and strategy Regulatory requirements analysis: Clinical study analysis and requirements for BDD submission. Break through Device Designation submission FDA pre-submission	Start up

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QA

Project Type
Gap analysis and remediation of QMS for ISO 13485:2016 requirements
Gap analysis and remediation of QMS against MDR requirements
CER, Risk management and development process design updates against MDR
Gap analysis and remediation against ISO 14155:2020 Clinical investigation of medical devices for human subjects — Good clinical practice
Gap analysis and remediation of QMS against IEC 62304 requirements
Gap analysis and remediation of QMS against ISO 14971 requirements
Gap analysis and remediation of QMS against ANVISA requirements
Gap analysis against China regulatory standards requirements for AI SaMD
Creation and development of FDA 21 CFR Part 820, EU MDR and UK MDR compliant QMS
QMS process design for ISO 13485, ISO 14971, IEC 62304, IEC 82304 IEC 62366, CFR 820
Internal and supplier auditing
Software Development Lifecycle processes remediation