ISO13485:2016 Quality Management System Implementation Plan

1. Introduction

Purpose: The plan describes the project goals, strategy, structure, controls, interfaces, roles and responsibilities for implementation of an ISO 13485:2016 quality management system to meet the regulatory requirements for placing [NASRAT (NeuroGuard AI Stroke Risk Assessment Tool)] on the market in the US and Europe. This report provides a background to the project, details of the product and the interactions of processes required for the plan.

2. Background

2.1 Organisation Description

NeuroGuard Ltd, is a revolutionary company in the Med Tech industry, which utilises artificial intelligence to transform preventative healthcare. Established in 2021, it is currently based in Manchester, UK and is operated by a team of 55 talented professionals, ranging from AI researchers to clinicians and regulatory experts. NeuroGuard's vision is to integrate the fields of big data, artificial intelligence, and healthcare to create a future where treatments are proactive and not reactive. Our aim is to build tools that remove the growing burden on healthcare systems globally by preventing healthcare problems before they even occur. The company's flagship product, NASRAT (NeuroGuard AI Stroke Risk Assessment Tool) is the first of many AIs integrated preventative healthcare tools that will allow NeuroGuard to revolutionise current reactive healthcare approaches into proactive ones.

Company Name: NeuroGuard Ltd

Location: Manchester, UK
Size: Small to Medium-sized (55 employees)

Organisation: Clinical Department. Engineering and Design Department, Data Department, Production Department, Quality Department, Regulatory Department, HR Department and IT Department.

What we do: Developing Software as a Medical Device (SaMD) solution for predictive diagnostics and preventative healthcare.

Target Market: USA, UK, and Europe
Company motto: Predict. Prevent. Protect

2.2 Product Details:

Name: [NASRAT (NeuroGuard AI Stroke Risk Assessment Tool)]

2.3 Use Specification

NASRAT is designed to provide a quantitative risk assessment for stroke by analysing and evaluating patient health data such as medical history, blood pressure, lipid profile data, and lifestyle and genetic factors. It is intended to be used by medical doctors to help them provide clinical recommendations to facilitate early intervention, patients to monitor their stroke risk, and for healthcare systems to recommend patients to get routine health checks based on their risk level for stroke.

Intended patient population

NASRAT is primarily intended to be used for:

- Adults aged 40+ with preexisting health conditions such as hypertension, diabetes, or hyperlipidaemia.
- Patients with a history of transient ischemic attacks (TIA's)
- Patients with a family history of stroke

Intended part of the body/tissue

NASRAT evaluates data from blood tests and patient history to provide a risk assessment for stroke which involves the brain and cardiovascular system

Intended user profile

NASRAT is intended to be used by:

- Medical healthcare professionals such as GP's, Cardiologists, and Neurologists to support clinical advice for patients.
- Patients using NASRAT risk assessment data provided through healthcare apps to remotely monitor their risk of stroke allowing them to make informed lifestyle choices.
- Healthcare systems integrate NASRAT into the workflow to better predict the number of stroke patients to effectively allocate resources for stroke treatment and provide suggestions to high-risk patients to get regular health checks as a preventative measure for strokes.

Intended use environment

NASRAT is intended to be used in:

- Clinical settings:
  - Hospitals: For outpatient departments or preventative screening or follow-up assessments.
  - GP clinics: To assess stroke risk in routine check-ups and provide preventative care recommendation
- Healthcare App: For patients to access their NASRAT data and track their stroke risk remotely.

Operating principle

NASRAT operates based on advanced machine learning algorithms that are trained on large amounts of patient health data such as medical history, blood pressure, lipid profile, genetic factors, and lifestyle information retrieved from electronic health records (EHRs) while following health data and privacy regulations. The software uses ensemble learning techniques to calculate a stroke risk score with high sensitivity and specificity by evaluating individual patient data based on the previously trained AI model through identifying patterns associated with elevated stroke risk.

Contraindications

Age limitation: NASRAT is not designed for use in individuals under 18 years of age.

Data Incompleteness: NASRAT is not suitable for patients with incomplete or inaccurate health data, as this may compromise the accuracy of the risk assessment.

Use in Emergencies: NASRAT is NOT intended for acute stroke diagnosis or emergency scenarios. It is a preventative tool and must not be relied upon in critical or time-sensitive situations.

Standalone Diagnosis: NASRAT is not a standalone diagnostic tool. All outputs must be interpreted by a qualified healthcare professional and used in conjunction with other clinical findings to assess stroke risk.

Intended Use (or Intended Purpose) statement (summary of the above)

NeuroGuard AI Stroke Risk Assessment Tool (NASRAT) is a Software as a Medical Device (SaMD) developed to calculate stroke risk scores by analysing individual patient health data on trained machine learning algorithms. Intended for use by healthcare professionals and high-risk patients, as it calculates a stroke risk score and allows healthcare professionals to provide evidence-based recommendations to support early intervention and preventative care and patients to monitor their stroke risk to make informed lifestyle changes.

2.4 Device Description

NASRAT (NeuroGuard AI Stroke Risk Assessment Tool) is a cloud-based Software as a Medical Device (SaMD) developed to provide a quantitative score to assess risk of stroke in patients by analysing and evaluating patient health data from electronic health records such as medical history, blood pressure, lipid profile tests, and lifestyle and genetic factors [3]. The AI model is trained on these factors as these are contributing factors to elevated stroke risk in patients and a correlation can be drawn from these factors to incidence of stroke. This will allow NASRAT to predict risk of stroke in a patient before it occurs as the model will compare the data from the Individual patients to the data from a large group of patients who suffered stroke.

Software infrastructure

A.I - Powered Predictions

The software utilises an ensemble learning approach and is combined with gradient boosted decision trees that allows for structured data and neural networks to be created, producing complex pattern recognition [4]. The prediction also employs explainability features such as SHAP (Shapley Additive Explanations) which offer insights into the factors contributing to risk scores, ensuring clinical trust and accuracy.

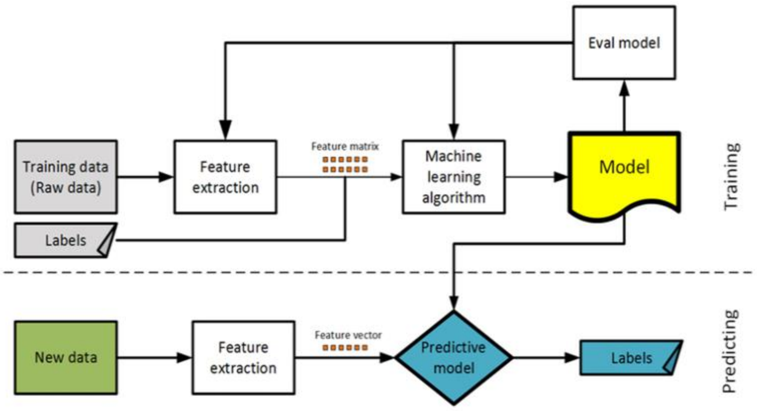


Figure 1: AI training model flowchart [6]

Data Integration and Processing

NASRAT's data integration module is designed to seamlessly integrate with Electronic Health Records (EHR's) which allows it to automatically retrieve healthcare data without the need of manual entry for each individual patient, thus decreasing risk of incorrect data entries and increased ease of use. However, the software still accepts manual entry to make the product usable in different healthcare infrastructures where health records may not be fully digitised. This is done following the data protection and security regulations for confidential health data.

User Interface

The user interface will comprise two different interfaces, one for clinicians and one for patients, the clinician-based interface will have more data on screen and will display stroke risk scores, contributing factors, patient history, and recommendations. The patient-based interface will be a simplified version of the clinician-based interface only showing a risk valuation and proactive health tips to reduce the likelihood of a stroke.

Secure Cloud Infrastructure

The device will employ a cloud-based system in which all data will be encrypted and will therefore be compliant with GDPR and HIPPA regulations, this ensures that all identifiable patient data will be secure. Further to this the cloud-based utility will allow for real time access to data from any location across multiple devices

Alert System

This provides alerts for high-risk patients, enabling timely clinical intervention from both the clinical and patient-based perspectives. These notifications will be sent to physicians and patients easily via the app.

General Architecture of the Device:

- **Input:** Patient health data (e.g., medical history, blood pressure, lipid profile tests, and lifestyle and genetic factors).
- **Processing:** Ensemble machine learning algorithms trained on relevant pre-existing patient data that can be used to analyse new patient data to generate risk scores.
- **Output:** A personalised stroke risk score and general health recommendations displayed via the interface.

3. Quality Management System Implementation

3.1 Organisational Process Map

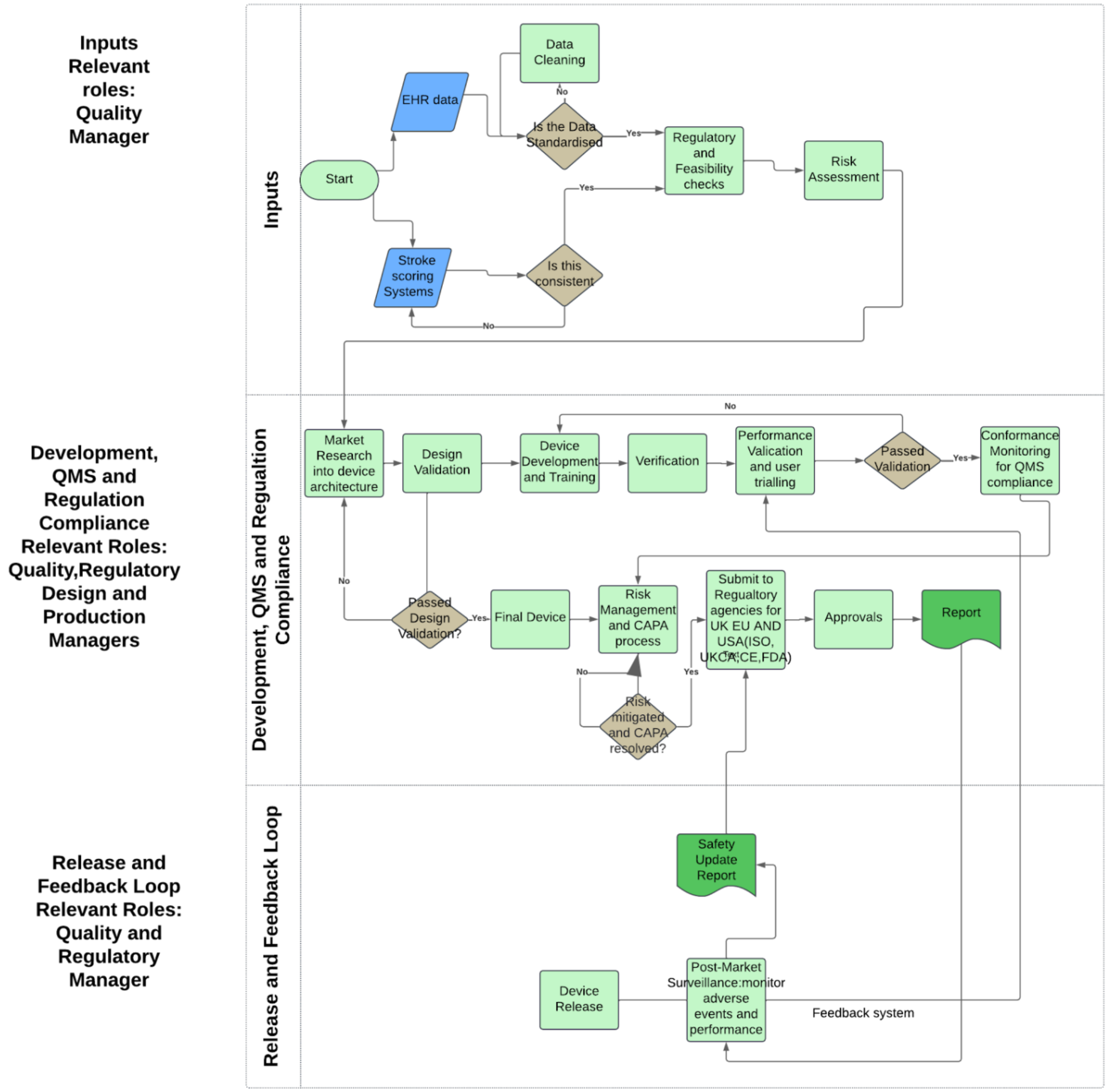

Inputs
Relevant roles: Quality Manager
Development, QMS and Regulation Compliance
Relevant Roles: Quality,Regulatory Design and Production Managers
Release and Feedback Loop
Relevant Roles: Quality and Regulatory Manager
Inputs
Development, QMS and Regualtion Compliance
Release and Feedback Loop
Start
EHR data
Data Cleaning
No
Is the Data Standardised
Yes
Regulatory and Feasibility checks
Risk Assessment
Stroke scoring Systems
Is this consistent
Yes
No
Market Research into device architecture
Design Validation
Device Development and Training
Verification
Performance Valication and user trialling
No
Passed Validation
Yes
Conformance Monitoring for QMS compliance
No
Passed Design Validation?
Yes
Final Device
Risk Management and CAPA process
No
Risk mitigated and CAPA resolved?
Yes
Submit to Regualtory agencies for UK EU AND USA(ISO, UKCA,CE,FDA)
Approvals
Report
Safety Update Report
Device Release
Post-Market Surveillance:monitor adverse events and performance
Feedback system

Figure 2: Organisational Process Map

3.2 Process Details

For each process list the relevant process inputs, resources, controls and outputs with the corresponding ISO 13485 clauses.

Inputs	**Process**	**Resources**	**Controls**	**Outputs**	**ISO 13485 Clauses**	**Relevant Roles**
EHR data, Blood Pressure ABCD Score	Data Cleaning	Cloud storage Forward Filling	Data Quality Checks	Clean data	4.2.3 7.5.2	Design Manager Quality Manager
Standardised Data	Regulatory and Feasibility Checks	Regulatory and ethical Guidelines GDPR HIPPA	Feasibility Assessment	Feasibility Results	7.3.2 7.3.3	Design Manager Regulatory Manager
Feasibility Results EHR data	Risk Assessment	Company Guideline GDPR HIPPA	ISO Compliance and data protection	Mitigated risk	7.1 7.3.7	Regulatory Manager
Design inputs Risk analysis	Design Validation	QMS MDR article 51	Design validation and review	Validated design	7.3.6	Design Manager Quality Manager
Developed software design Data	Development and training	Cloud storage GPU IDE	Network implementation and training	Trained device	6.2	Design Manager Production Manager
Network Test Criteria	Verification	IDE Test tools	Usability criteria	Verification report	7.3.5	Production Manager
User feedback Validation metrics	Performance Validation	User Trials Statistical analysis	Internal Audit Compliance	Performance Validation Report	7.3.6 8.2.3	Production Manger Quality Manager
Performance Validation Report	Conformance Monitoring	QMS Records ISO guidelines	Compliance SOP	Compliance Report	8.2.2	Regulatory Manager Quality Manager
Audit Report Non-conformance data	CAPA	CAPA system MDR article 10	Risk mitigation steps	CAPA report	8.5.2 8.5.3	Production Manager Regulatory Manager
Released device Safety data	Post Market Surveillance	Surveillance System Clinical Advice	Post-market SOP Feedback system	Safety Update Report Enhanced Device	8.2.1 8.4	Quality Manager

4. Summary

The implementation plan for ISO 13485:2016 at NeuroGuard Ltd. was developed through a structured, collaborative approach to ensure compliance with EU MDR 2017/745, UK MDR 2002, and FDA CFR 21 Part 820. The key roles of Regulatory Manager, Design and Development Manager, Quality Manager, and Production Manager, contributed to aligning the plan with quality, safety, and performance requirements.

This plan was developed by holistically looking at the broader steps required to obtain medical device approval in the EU, UK and USA with each manager provided in lecture 10. A combined approach was chosen to cover all areas in each market. The device is class II in the USA and IIa in the EU and UK. For the USA, pre-market notification is needed for class II devices following the steps outlined in FDA CFR 21 807. All target markets require extensive market research, explicit patient consent, risk mitigation and complete regulatory compliance. This is reflected in the implementation plan, there are processes regarding data protection and quality, security and multiple validation stages.

To implement a quality management system there are several key components to include:

- Device objectives, organisational structure, data management, technical documentation, regulatory compliance and post-market surveillance.
- Clear and attainable device objective of predicting stroke risk using patient data and scoring systems.

The organisation is composed of Regulatory, Quality, Production and Design managers with all the other roles being subcontracted to a third party. Each role has a clear and outlined set of responsibilities for implementing a quality management system and maintaining documentation at each step. The device uses confidential patient data, and we have complied with GDPR and HIPPA regulations, obtaining explicit patient consent, using the minimum amount of data necessary and encrypting this patient information. The FDA and EU MDR both require state-of-the-art cybersecurity; we have implemented this with the help of a third-party. Each process will be documented from data procurement to post-market surveillance allowing us to maintain traceability through the likes of validation reports, conformance testing, risk management files and technical documentation. Full compliance with regulations has been ensured by thoroughly reading ISO, FDA, EU MDR, UK MDR, GDPR and HIPPA documentations, outlining the relevant sections for NASRAT and software as a medical device. Each regulation was considered in the implementation process. A feedback loop process was developed for effective post-market surveillance, allowing the device’s performance to be assessed, its reception as well as any faults.

Key Requirements

- **Resource Allocation**: Dedicated personnel, tools, and infrastructure.
- **Training**: Cross-departmental training on QMS processes and compliance.
- **Documentation**: Robust traceability through validation reports, risk management files, and technical documentation.

- **Monitoring**: Regular audits and post-market surveillance for continuous improvement.

Assumptions

An assumption made is that third-party contractors will act fully in compliance with our quality management system. To ensure this, we have partnered with reputable firms and provide training on regulations and our QMS.

- Leadership commitment to QMS implementation.
- Availability of accurate EHR data for NASRAT.
- Timely regulatory approvals from FDA, UKCA, and EU bodies.
- Adoption of NASRAT by healthcare professionals and patients.

The plan ensures quality, safety, and regulatory compliance while supporting NASRAT’s role in transforming preventative healthcare.

5. References:

1. Maier, Ilko L., et al. "Risk prediction of very early recurrence, death and progression after acute ischaemic stroke." *European journal of neurology* 20.4 (2013): 599-604.

2. Rozenbaum, Zach, et al. "CHA2DS2-VASc score and clinical outcomes of patients with acute coronary syndrome." *European Journal of Internal Medicine* 36 (2016): 57-61.

3. NHS. “Causes - Stroke.” NHS, 2022, www.nhs.uk/conditions/stroke/causes/ .

4. “1.11. Ensembles: Gradient Boosting, Random Forests, Bagging, Voting, Stacking.” Scikit-Learn, 2022, scikit-learn.org/1.5/modules/ensemble.html.

5. Pietsch, D., Matthes, M., Wieland, U., Ihlenfeldt, S., & Munkelt, T. (2024). Root Cause Analysis in Industrial Manufacturing: A Scoping Review of Current Research, Challenges and the Promises of AI-Driven Approaches. *Journal of Manufacturing and Materials Processing*, *8*(6), 277.

6. Nguyen, Dong, et al. “Joint Network Coding and Machine Learning for Error-Prone Wireless Broadcast.” 2017 IEEE 7th Annual Computing and Communication Workshop and Conference (CCWC), Jan. 2017, https://doi.org/10.1109/ccwc.2017.7868415.

7. Imam, Was. “How to Manage ISO 13485:2016 Design and Development.” *Advisera.com*, 24 Aug. 2017, advisera.com/13485academy/blog/2017/08/24/how-to-manage-design-and-development-of-medical-devices-according-to-iso-134852016/.

8. Sirur, Sean, Jason RC Nurse, and Helena Webb. "Are we there yet? Understanding the challenges faced in complying with the General Data Protection Regulation (GDPR)." *Proceedings of the 2nd international workshop on multimedia privacy and security*. 2018.

9. Intersoft Consulting. “Chapter 2 – Principles | General Data Protection Regulation (GDPR).” *General Data Protection Regulation (GDPR)*, 2013, gdpr-info.eu/chapter-2/.

10. U.S. Department of Health and Human Services. “Summary of the HIPAA Privacy Rule.” *HHS.gov*, U.S. Department of Health and Human Services, 19 Oct. 2022, www.hhs.gov/hipaa/for-professionals/privacy/laws-regulations/index.html.

11. “EUR-Lex - 02017R0745-20240709 - EN - EUR-Lex.” *Europa.eu*, 2024, eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02017R0745-20240709.

12. Zinchenko, V. V., Arzamasov, K. M., Chetverikov, S. F., Maltsev, A. V., Novik, V. P., Akhmad, E. S., ... & Morozov, S. P. (2022). Methodology for conducting post-marketing surveillance of software as a medical device based on artificial intelligence technologies. *Современные технологии в медицине*, *14*(5 (eng)), 15-23.

13. *General Principles of Software Validation; Final Guidance for Industry and FDA Staff This Document Supersedes the Draft Document, "General Principles of Software Validation, Version 1.1, Dated June 9, 1997. U.S. Department of Health and Human Services Food and Drug Administration Center for Devices and Radiological Health Center for Biologics Evaluation and Research*. 2002, www.fda.gov/media/73141/download?attachment.

14. MDCG. *Medical Devices Medical Device Coordination Group Document MDCG 2021-24 Guidance on Classification of Medical Devices*. 2021, health.ec.europa.eu/system/files/2021-10/mdcg_2021-24_en_0.pdf.

6. Appendices

Appendix A: Individual Tasks

Regulatory Manager [Jamellia Frederick]

<u>Description of role in the organisation:</u>

The Regulatory manager ensures that each aspect of the device and the design process adhere to the necessary international standards and regulations. It's necessary to manage the boundary between regulations and company innovation, by empowering developments with the full confidence and knowledge of regulations and international standards.

This role involves working closely with:

- Clinical staff, ensuring a good standard of data quality and consistency.
- Machine Learning /Data engineers, to ensure data access control ***ISO 13485:2016*** (4.2.5) and the design of network architecture ***ISO 13485:2016*** (7.3.3) ensuring it is accurate and meets usability and safety criteria.
- Quality Manager- collaborating to ensure quality management processes align with regulations.

<u>Assigned roles and responsibilities:</u>

The overarching role of the Regulatory manager is to keep up to date with changes in regulation and remain knowledgeable of existing regulations especially in relation to NASRAT'S operations. NASRAT will be operating in the UK, EU and USA and each market has specific regulations governing them.

Some of the implementations of the role include:

- Compiling documents with regulations and changes to pass on to colleagues. Keeping them up to date with knowledge of applicable regulations in each market and ensuring its fully understood and implemented in accordance with EU MDR annex 1. As we also work with external contractors this will be conveyed through presentations and documents.

- Ensuring Data protection is compliant with GDPR [8] and HIPPA this is necessary from the beginning as patient data is used in our initial stages. As a medical device company, it's important to maintain patient and clinical trust as well as maintaining our reputation which improper data management could do. Therefore, to be fully GDPR compliant for the EU and UK, according to GDPR article 5: we must obtain explicit patient consent and only use the data for the legal and intended reason. In accordance with 5.1.c we have minimised our data collection and will only obtain the necessary biomarkers from the EHR. In accordance with article 32, we will encrypt patient data and in the event of a data breach, in accordance with article 33 and 34 we will notify the relevant authorities within 72 hours and patients if this affects their rights or freedoms [9]. To be data compliant in the USA we have developed processes in accordance with HIPPA [10]. This regulates the use and disclosure of public health information. We must obtain patient consent and use the minimum data required. To comply with security regulations for patients in the USA, we will assign a unique patient ID, and only necessary colleagues will be able to access this. In the event of a breach, we will need to notify patients and the US department of health and human services. Reports will be maintained of breaches.

- Following EU MDR 2017/745 for Europe, UK MDR 2002 for the UK and FDA for the US market and ***ISO 13485:2016*** regulations, implementing steps to best follow regulations surrounding compliance. Firstly, ensuring the device is properly classified according to risk, as the device is software but doesn't directly impact treatment according to article 51 of the EU MDR. It is class IIa, technical documentation has also been developed to obtain CE marking for the European market and UKCA marking for the UK. In compliance with article 83 of the EU MDR, we must continuously monitor device performance and develop a post-market surveillance plan. For NASRAT this will include updating our device and obtaining user feedback and producing an annual update report. In accordance with EU MDR articles 87 and 88, a CAPA process has been implemented as well as conformity assessment, and we will identify all non-conformities and make our regulatory bodies aware. For the US market we have followed regulations outlined by the FDA [13] and have implemented risk management processes using **ISO 14971.** In accordance with annex 1, clause 17 of EU MDR, we have chosen a state-of-the-art architecture for the device, we expect the device to be reliable and repeatable, we will update the device at least yearly with information gained in our post-market surveillance processes. A data management process has been developed following regulation implemented by HIPPA and GDPR, patient data use will be limited and encrypted, FDA cybersecurity guidance is to implement safeguards against unauthorised users. I have liaised with the IT department to use state-of-the-art cybersecurity.

- Ensuring that every department and step of development process is regulation compliant. Scheduling regular meetings with department leads going over each implementation and analysing data.
- Liaise with regulatory agencies such as UKCA and FDA to obtain necessary marking and license, presenting them with evidence from our trials, clinical opinion and demonstrable evidence of regulation adherence.
- Determine the device's classification.
- Write accessible usage instructions for patients and with clear labels in accordance with MDR article 10.
- Prepare a safety update report every year with data provided from post-market surveillance.

Key considerations for implementing a ISO 13485:2016 Quality Management System relevant to the role:

- Ensuring the quality of the EHR data is consistent: For accurate results they should have the consistent biomarkers (glucose levels, blood pressure) and use standardised time intervals. This will enhance the device's precision.
- Ensure a consistent scoring system is used for reproducibility, different scores give different weightings for example: The ABCD score gives all ages over 60 1 point, whereas CHA_2DS_2-VASc Score gives 1 point to ages 65-74 and 2 points for ages above 75[2]. For example, if different scores are used, there may be significant differences in score and treatment recommendation.
- Design Process- Colleagues should use a consistent style and design to maintain traceability and longevity. According to ISO regulations, each process should be well documented, this will include elements such as using GIT and producing update reports.
- Design Validation- should be safe and effective, it should work as intended, during the design process any additional risks should be identified and mitigated ISO 13485(7.3). If risks are unable to be mitigated the entire process will be repeated. in accordance with MDR annex 1, it will be ensured we meet the stated safety performance and risk-management regulations. The FDA CFR 21 [13] has requirements for testing: unit, integration, system and user acceptance testing.

- Documentation- Maintain document, in compliance with ISO standards of all control variables ***ISO 13485:2016*** (4.2.4) and network architectures used for full traceability and to be compliant in assisting with internal and external auditing processes. In compliance with MDR annex 2, technical documentation has been developed, it includes: A description of our device and its intended purpose as stroke risk software. Design and development, includes our input, each process and evidence from the validation and verification processes. Risk management documentation- we have developed approaches to risk management in accordance with regulation and a documentation process to maintain risk reports. Trial-Evidence- As we will conduct clinical trials and user testing, we have maintained documents with results and feedback from each round demonstrating the devices safety and performance to submit to our regulators.

Task: Device Classification

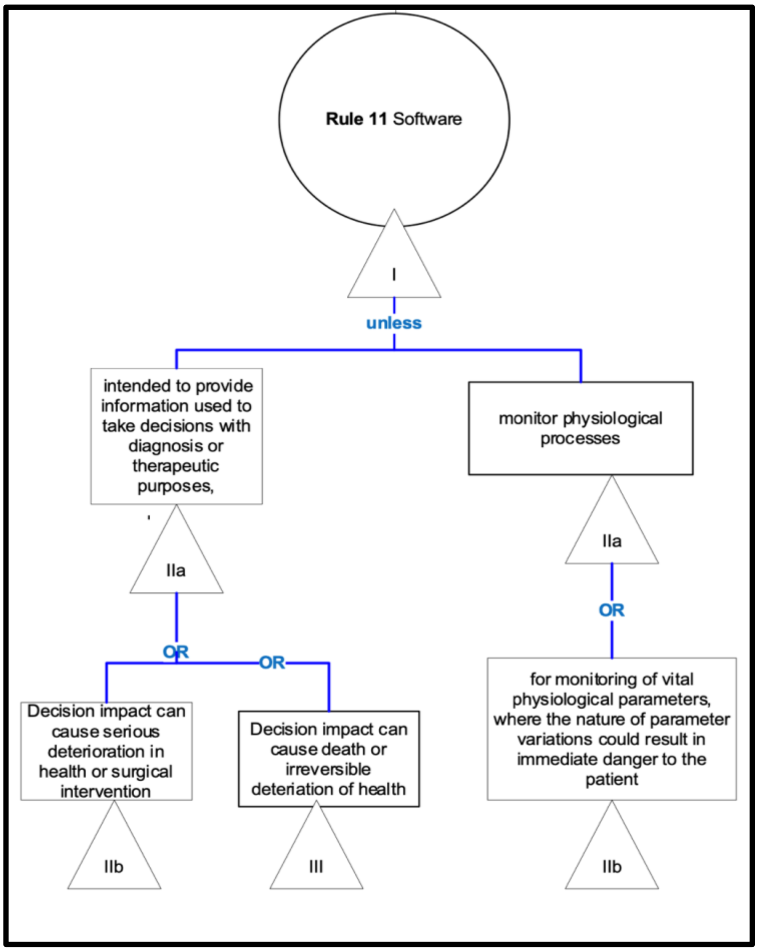

Rule 11 Software
I
unless
intended to provide information used to take decisions with diagnosis or therapeutic purposes,
monitor physiological processes
IIa
IIa
OR
OR
OR
Decision impact can cause serious deterioration in health or surgical intervention
Decision impact can cause death or irreversible deteriation of health
for monitoring of vital physiological parameters, where the nature of parameter variations could result in immediate danger to the patient
IIb
III
IIb

Figure 3: Software as a medical device classification tool [14]

The device is intended to provide a real time stroke risk for patients using the electronic health records and provides lifestyle recommendations to the patients' physician It will be used in conjunction with the physician's expertise and scoring. It analyses the data and assigns a score based on the ABCD scoring system. Under EU MDR Article 51 and according to rule 11 of the Medical Device Group Coordination document: software that is used to provide information for diagnosis is classed as IIa. NASRAT does not directly intervene in or provide treatment and any recommendations, and scores given will be taken into consideration by clinicians.

Roles that contributed to the task:

- Production Manager: Ensured consistency in the production process and the device met the necessary standards for production and deployment.
- Quality Manager: Ensured compliance and risk management standards were met.
- Design and Development Manager: Designed the device architecture and worked with third-party contractors to ensure it is validated and meets the clinical need.

Design and Development Manager [Louis Forgione]

Description of role in the organisation:

The role of Design and Development Manager includes leading the design and development lifecycle of the NeuroGuard AI Stroke Risk Assessment Tool (NASRAT), ensuring the system is designed effectively, validated for clinical use and complies with ISO 13485:2016. This comprises defining clinical needs, translating them into technical specifications, and managing validation activities. The role focuses on delivering a safe, effective, and compliant product that meets user and regulatory requirements.

Assigned roles and responsibilities:

Identification of user needs:
To collaborate with clinicians and stakeholders to determine user needs as outlined in Clause 7.3.3 (Design and Development Inputs) and to manage the design inputs ensuring that the product meets these clinical needs.[7]

Data protection:
The development manager will ensure that the device will comply with GDPR and HIPPA regulations, guaranteeing that all identifiable patient data will be secure and that only their physician has access to their data.

Design Specification and Implementation:
Develop technical and performance specifications that meet regulatory and user requirements as well as oversee the how the software is produced focussing on the balance between the AI algorithms and user experience. The AI will use machine learning algorithms to accurately predict the likelihood of stroke occurring based on each individual patient’s risk factors.

Verification and Validation:
Ensure that design outputs meet design inputs via verification activities outlined in Clause 7.3.6 of ISO 13485:2016 and conduct validation studies with representative product units to confirm alignment with intended use, Clause 7.3.7.[7]

Design Review:

Organise regular design reviews to evaluate progress, identify risks, and ensure adherence to the development plan, Clause 7.3.5.

Key considerations for implementing a ISO13485:2016 Quality Management System relevant to the role:

Traceability:
Maintain traceability from user needs to design outputs, ensuring clear documentation and compliance, Clause 7.3.2 Design Planning.

Risk Management Integration:
Identify and mitigate risks related to AI model bias, data security, and performance through iterative testing. Risk control measures must be documented in the risk management file, ISO 14971:2019.

Design Changes:
Document and evaluate the impact of design changes on safety, usability, and performance before implementation, Clause 7.3.9.
Regulatory Standards:

Align the design process with MDR 2017/745 and FDA CFR 21 Part 820 for software as a medical device (SaMD)

Individual Task:
Inputs relating to product requirements shall be determined. Include which other roles contributed to the task.

List 3 high-level product requirements relating to user needs.

User Need	High-Level Requirement
1. Real-Time Stroke Risk Assessment	The device shall provide a stroke risk score within 30 seconds based on health data inputs.
2. Integration with EHRs	The device shall integrate seamlessly with electronic health record systems to retrieve patient history automatically.
3. Custom Alerts for High-Risk Patients	The system shall notify clinicians and patients via an alert system when stroke risk crosses a critical threshold.

List 3 relevant product standards relevant to the design:

Standard:
1. ISO 13485:2016: Medical Devices – Quality management systems – Requirements for regulatory purposes.
2. ISO 14971:2019: Medical Devices – Application of risk management to medical devices this supports identification, evaluation, and control of risks during the design process
3. IEC 62304: Medical device software – Software life cycle processes, ensures proper design, testing, and maintenance of the software.

Roles that contributed to the task:

- Regulatory Manager: Advised on relevant standards.
- Production Manager: defines specifications for software production and release.
- Quality Manager: gave insights into the compliance and risk management of the device.

Quality Manager [Prithvish Ganguly]

<u>Description of role in the organisation:</u>

The role of the quality manager at NeuroGuard Ltd. is to develop, implement and maintain a Quality Management System (QMS) that meets ISO 13485:2016, UK MDR 2002(amended), EU MDR 2017/745, and FDA 21 CFR Part 820 requirements. This is required to ensure that NASRAT meets stringent quality, safety, and regulatory requirements for the US, UK, and EU markets and is eligible to be used there. Additionally, the Quality Manager must work closely with the Regulatory Manager, Design and Development, and IT teams to make sure that data protection processes such as encryption, access controls, and integrity checks are validated in the QMS and its compliance with regulations like GDPR and HIPAA. The quality manager must coordinate across departments to integrate quality-oriented practices, manage risks with AI and meet data security regulations to make the product eligible for the target markets and maintain the documentation necessary to demonstrate compliance during audits and inspections.

<u>Assigned roles and responsibilities:</u>

Development and Implementation of QMS

The Quality Manager is responsible for establishing and maintaining QMS policies and procedures in compliance with international standards. This includes adhering to **Clause 4.1 (General Requirements)** and **Clause 4.2 (Documentation Requirements)** to ensure all QMS documentation, such as validation reports, risk assessments, and audit findings are accurate, traceable, and available for audits and inspections. Moreover, the Quality Manager under **Clause 7.3 (Design and Development)**, must ensure proper validation, verification, and traceability of the design and development process behind NASRAT which helps to guarantee transparency, performance, and compliance with design controls.

Example task: Documenting the validation process for NASRAT's predictive AI algorithm in order to ensure transparency, performance, and accuracy.

Design and Development Controls

The Quality Manager must oversee the design and development process to make sure that critical requirements are met. This involves documenting procedures for planning and controlling design and development activities, as outlined in **Clause 7.3.1 (General)**. The Quality Manager must verify and validate in the design and development of NASRAT as it is are essential to confirm that design outputs meet input requirements and that NASRAT performs as intended in representative environments, adhering to **Clause 7.3.6 (Design and Development Verification)** and **Clause 7.3.7 (Design and Development Validation)**.

Example Task: Documenting NASRAT's algorithm validation process to demonstrate its accuracy and reliability in clinical applications.

Regulatory Compliance

The Quality Manager is responsible to ensure that QMS aligns with **ISO 13485:2016** for QMS development and maintenance, **EU MDR 2017/745** for CE marking in the EU and Northern Ireland, **UK MDR 2002** for UKCA marking in Great Britain, and **FDA CFR 21 Part 820** for US market approvals. For US markets, the quality manager must ensure adherence to **FDA CFR 21 Part 820.30 (Design Controls)**, to maintain design controls for NASRAT as a Software as a Medical Device (SaMD). Additionally, the quality manager is responsible for preparing documentation for CE marking which must be prepared and managed under **EU MDR Annex IX**, while for UKCA marking it must comply with **UK MDR 2002.**

Example task: Collaborating with the Regulatory Manager to submit NASRAT's technical file to the appropriate Notified Body for CE marking.

Data Protection and Cybersecurity

The quality manager must work with the IT team to ensure NASRAT meets **GDPR Article 32** and the **HIPAA Security Rule** for data protection, ensuring the security, privacy, and integrity of patient health data. This is because the software needs access to confidential patient data and data leaks can significantly damage the image of NeuroGuard and negatively affect its users. The Quality Manager must oversee the necessary implementation of data encryption, role-based access controls to avoid data leaks, and conduct regular security audits to evaluate and mitigate vulnerabilities. They are also responsible for documenting an incident response plan to handle potential data breaches adhering to **Clause 8.5 and** ensuring that all IT systems and data protection measures must adhere to **Clause 4.1.6 and Clause 4.2.5.**

Example task: Documenting an incident response plan for data leaks while working with the Regulatory and Design and Development managers

Post-Market Surveillance

The quality manager is responsible for conducting post-market surveillance which involves establishing procedures to monitor NASRAT's performance post-launch. This includes developing a feedback system to collect real-world data in compliance with **Clause 8.2.1 (Feedback)**, addressing issues arising from non-conformities according to **Clause 8.3 (Control of Nonconforming Product)**, and analysing post-market data to identify trends and improve product safety and efficacy under **Clause 8.4 (Analysis of Data)**.

Example Task: Conducting surveys to get clinician feedback to refine NASRAT's risk scoring algorithm and improve risk assessment accuracy

Internal Audits and Compliance Monitoring

The Quality Manager must conduct regular internal audits to evaluate QMS compliance and drive continuous improvement. This involves developing a structured audit program in accordance with **Clause 8.2.4 (Internal Audit)** and working with the regulatory manager to ensure the QMS constantly evolves based on findings and feedback, described in **Clause 8.5.1 (General).**

Example Task: Conducting quarterly audits of NASRAT's algorithm updates and cybersecurity measures to ensure consistently accurate stroke risk assessments and to prevent data leaks.

<u>Key considerations for implementing a ISO 13485:2016 Quality Management System relevant to the role:</u>

- Ensure compliance with **ISO 13485:2016**, **FDA CFR 21 Part 820**, **EU MDR 2017/745**, and **UK MDR 2002** for NASRAT to be sold and used in the US, UK, and EU.

- Integrating regulatory requirements specific to Software as a Medical Device (SaMD) as NASRAT is a stroke risk assessment software.

- Maintain thorough documentation under **Clause 4.2.3 (Medical Device File)** and adhere to **FDA CFR 21 Part 820.30 (Design Controls)**.

- Apply risk management principles to address AI based software-specific risks such as bias in machine learning algorithm, and cybersecurity to protect confidential EHR data, adhering to risk management state in **ISO 14971:2019 Clause 7.1.**

- Maintain high traceability throughout NASRAT's life cycle, from design inputs to post-market activities via thorough documentation, ensuring compliance with **ISO 13485:2016 Clause 7.5.9 (Traceability)** to support regulatory requirements and audit readiness.

- Ensure compliance with **GDPR Article 32**, **HIPAA Security Rule**, and **ISO 13485:2016 Clause 4.1.6** to protect confidential EHR data.

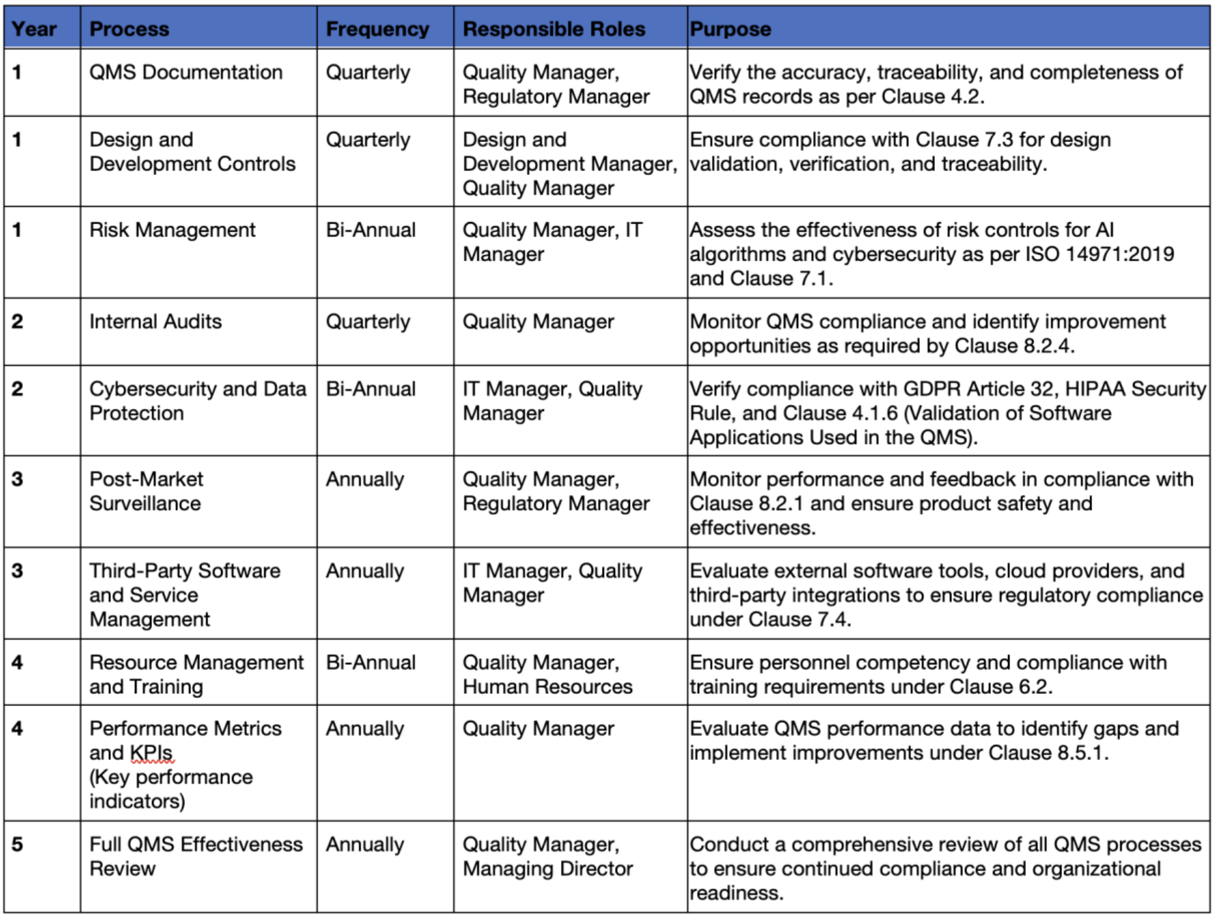
- Collaboration with Regulatory, IT, and Design and Development teams to integrate quality principles into all processes.

- Ensure compliance with **Clause 8.2.1 (Feedback)** and **Clause 8.4 (Analysis of Data)** to support post-market surveillance and continuous improvement.

- Prioritise critical processes such as software validation and cybersecurity to optimise resource availability, adhering to **Clause 6.1 (Provision of Resources)** for efficient and compliant operations.

Individual Task:

The organisation shall apply suitable methods for monitoring quality management system processes. Prepare an audit plan of the organisational processes, this should be presented as timetable over the next 5 years



Year	Process	Frequency	Responsible Roles	Purpose
1	QMS Documentation	Quarterly	Quality Manager, Regulatory Manager	Verify the accuracy, traceability, and completeness of QMS records as per Clause 4.2.
1	Design and Development Controls	Quarterly	Design and Development Manager, Quality Manager	Ensure compliance with Clause 7.3 for design validation, verification, and traceability.
1	Risk Management	Bi-Annual	Quality Manager, IT Manager	Assess the effectiveness of risk controls for AI algorithms and cybersecurity as per ISO 14971:2019 and Clause 7.1.
2	Internal Audits	Quarterly	Quality Manager	Monitor QMS compliance and identify improvement opportunities as required by Clause 8.2.4.
2	Cybersecurity and Data Protection	Bi-Annual	IT Manager, Quality Manager	Verify compliance with GDPR Article 32, HIPAA Security Rule, and Clause 4.1.6 (Validation of Software Applications Used in the QMS).
3	Post-Market Surveillance	Annually	Quality Manager, Regulatory Manager	Monitor performance and feedback in compliance with Clause 8.2.1 and ensure product safety and effectiveness.
3	Third-Party Software and Service Management	Annually	IT Manager, Quality Manager	Evaluate external software tools, cloud providers, and third-party integrations to ensure regulatory compliance under Clause 7.4.
4	Resource Management and Training	Bi-Annual	Quality Manager, Human Resources	Ensure personnel competency and compliance with training requirements under Clause 6.2.
4	Performance Metrics and KPIs (Key performance indicators)	Annually	Quality Manager	Evaluate QMS performance data to identify gaps and implement improvements under Clause 8.5.1.
5	Full QMS Effectiveness Review	Annually	Quality Manager, Managing Director	Conduct a comprehensive review of all QMS processes to ensure continued compliance and organizational readiness.

Comment on your considerations for how often a process should be audited e.g. risk, resources, etc.

Year 1:

- QMS Documentation (quarterly)- Frequent audits are required to ensure documents are updated, accurate, and traceable, which is crucial during the initial phases of implementation.

- Design and Development Controls (quarterly)- As mentioned in **Clause 7.3**, Design and development processes are very important during product realization. Regular audits work to ensure verification and validation processes are correctly followed, minimising risks of non-compliance or performance issues later in the development cycle.

- Risk Management (Bi-Annual)- Bi-annual audits are sufficient enough to minimise and monitor AI-specific risks, such as algorithm bias and cybersecurity vulnerabilities without overloading resources.

Year 2:

- Internal Audits (quarterly) - Regular internal audits are required under **Clause 8.2.4**, ensure ongoing compliance across all QMS processes and allow for early detection of any issues in the organisation.

- Cybersecurity and Data Protection (Bi-Annual) - Data protection under **HIPAA regulation** and **GDPR Article 32** is very important to maintaining patient trust and regulatory compliance, hence Bi-annual audits are required to monitor encryption, access controls, and cybersecurity measures.

Year 3:

- Post-Market Surveillance (Annually) – Annual post market surveillance audits are sufficient enough to make the required changes and improvements in NASRAT as feedback from patients and healthcare professionals must be assessed and solutions must be developed using the feedback hence the audits cannot be very frequent as it would be an ineffective of resources.

- Third-Party Software and Service Management (Annually) – Third party software used in NeuroGuard aren't changed frequently hence annual audits are sufficient to ensure compliance with **Clause 7.4 (Purchasing)** and regulatory standards like GDPR and HIPAA.

Year 4:

- Resource Management and Training (Annually) – Bi-annual audits make sure training programs remain aligned with regulatory requirements, and is the optimal frequency as employee's don't need to be retrained often.
- Performance Metrics and KPIs (Bi-Annual) – Annual audits ensure that the company has enough time to effectively analyse the data and make the required changes in accordance with Clause **8.5.1.**

Year 5

- Full QMS Effectiveness Review (Annually) - Annual reviews allows enough time for a comprehensive review of the QMS ensuring sustained compliance and identification of areas for improvement.

Roles that contributed to the task:

- Production Manager: Provided insights into third-party software, cloud services, and cybersecurity compliance.
- Regulatory Manager: Ensured audits meet regulatory standards
- Design and Development Manager: Validated the integration and performance of NASRAT and third-party software components.

Production Manager [Suhail Elhaj]

<u>Description of role in the organisation:</u>

The Production Manager ensures compliance to **ISO 13485:2016 standards** throughout the development, testing, and release phases of the NASRAT software. This involves managing production planning by overseeing the software development lifecycle (SDLC), including resource allocation, timeline management, and risk mitigation strategies. The role also makes sure of rigorous quality control by validating all software versions through functional testing, AI accuracy checks, and compliance with regulatory standards such as **FDA CFR 21 Part 820** and **MDR 2017/745**. Additionally, by maintaining thorough records of software versions, metadata, release identifiers, and validation results, the Production Manager also upholds strong traceability protocols that facilitate quick root-cause analysis and recalls when needed. Joining forces with the Quality Manager and technical teams, the Production Manager addresses non-conformities identified during quality control, implements corrective actions, and optimises production workflows to enhance efficiency, reliability, and software performance.

<u>Assigned roles and responsibilities:</u>

1. Production Oversight
    a. Ensure Compliance:
        i. Adhere to ISO13485 Clause 7.5 (Production and Service Provision) by overseeing all phases of the software development lifecycle (SDLC), including planning, execution, and validation of the NASRAT tool.
2. Validate Tools and Resources:
    a. Ensure all development tools, testing platforms, and deployment resources meet the required standards for safety, performance, and efficiency.
    b. Verify that version control systems, testing frameworks, and AI model training platforms are validated and reliable.
3. Monitor Production Activities:
    a. Consistent reviews of production activities to identify and address inefficiencies in software workflows.
    b. Ensure regulatory compliance with standards (e.g., ISO13485, FDA CFR 21 Part 820, MDR 2017/745).
4. Maintain Traceability:
    a. Establish robust traceability systems to track all development stages, software versions, and validation results throughout production and release.
5. Software Labelling and Release Management:
    a. Implement procedures to solidify proper digital labelling of software releases, including version numbers, intended use statements, and regulatory compliance details.
    b. Confirm that all software versions match the Master Device File (MDF) and add secure version control (e.g., hashes, checksums) to maintain integrity during deployment.
6. Traceability and Record-Keeping:
    a. Maintain detailed records of all software development stages, including design, coding, testing results, and deployment versions, in compliance with ISO13485 Clause 7.5.3 (Identification and Traceability).

   b. Track and document each software release (version control), as well as unique version numbers, build IDs, feature updates, bug fixes, and validation results to guarantee complete traceability.
   c. Establish a robust traceability system that links each software version to its correlating test records, release notes, and deployment history, allowing efficient identification and recall in the event of non-conformities or performance issues.

7. Collaboration and Compliance (Tailored for NASRAT Software):
   a. Collaborate with the Quality Manager to address issues identified during software quality control and validation. This involves addressing:
      i. Bugs or inaccuracies in AI stroke risk predictions.
      ii. Performance issues identified during edge-case testing or clinical validation.
      iii. Non-conformities in the software development lifecycle (SDLC), such as incomplete traceability records or insufficient test coverage.
8. Ensure compliance with FDA CFR 21 Part 820 (Quality System Regulation for medical devices) and MDR 2017/745 (EU Medical Device Regulation) by:
   a. Put in place a robust version control and traceability system to track all software versions, features, and fixes.
   b. Carry out a thorough software validation to confirm that NASRAT performs as needed under real-world and simulated conditions.
   c. Maintaining comprehensive technical documentation, including risk assessments, validation reports, and user instructions, to display compliance.
   d. Ensuring the software satisfies requirements for data integrity, cybersecurity, and electronic health data protection (e.g., GDPR for the EU).

This verifies that NASRAT, as Software as a Medical Device (SaMD), is developed, validated, and released in a supervised manner while meeting international regulatory and quality standards.

<u>Key considerations for implementing a ISO13485:2016 Quality Management System relevant to the role:</u>

Production Control

Develop and document systemise protocols for observing and managing all stages of the software development lifecycle (SDLC) to ensure consistency, quality, and compliance.

- Clearly define processes for:
   - Design and Development: Software specifications, AI model training, and coding standards.
   - Testing and Validation: Functional testing, edge-case validation, and performance monitoring.
   - Deployment: Secure release processes with version control and change documentation.
- Track adherence to these processes to minimise errors, ensure repeatable outcomes, and maintain traceability.

Relevance to NASRAT:
For NASRAT, production control makes sure that every version of the software is subjected to rigorous validation and follows documented workflows to satisfy performance and safety standards.

Software Release Traceability and Version Control Records
Impose a robust traceability system to monitor, identify, and track all software versions, updates, and releases, allowing rapid and effective recall actions when required.

- **Maintain detailed version records, including:**
    - Unique Version Identifiers: Structured labels (e.g., v1.0.0, v1.1.0) to differentiate software iterations.
    - Release History: Dates, deployment environments (e.g., cloud, healthcare systems), and version release timelines.
    - Change Logs: Complete lists outlining new features, bug fixes, security patches, and performance improvements.
    - Validation Results: Test reports and performance metrics verifying the software's accuracy, reliability, and regulatory compliance.
    - Deployment Details: Clear and concise identification of where the software version is deployed, ensuring full transparency across platforms and environments.
- **Establish links between version records and validation data**:
    - Integrate test results, change documentation, and release notes to streamline root-cause analysis in case of non-conformities or unexpected performance issues.

Relevance to NASRAT:
For NASRAT, an extensive version control and traceability system ensures every software iteration is fully identifiable, validated, and recallable. This reduces risks associated with AI-based predictions, assists compliance with regulatory standards, and strengthens the reliability of stroke risk assessments.

Tool and Platform Validation
Ensure all software tools, platforms, and systems used throughout the software development lifecycle (SDLC)—from development and testing to deployment—are validated to guarantee accuracy, reliability, and compliance, as required by **ISO13485 Clause 7.6 (Control of Monitoring and Measuring Equipment).**

- **Validate and document the following tools and platforms:**
    - AI Model Training Platforms: Tools like TensorFlow or PyTorch used to train machine learning models for accurate stroke risk predictions.
    - Testing Frameworks: Automated tools for functional testing, AI performance evaluation, and edge-case validation.
    - Data Integration Interfaces: Systems for securely accessing and processing Electronic Health Records (EHRs) while making sure of data integrity and compliance.
    - Deployment Pipelines: CI/CD (Continuous Integration/Continuous Deployment) systems and version control tools (e.g., Git) to control software releases reliably.
- **Regular updates and validation:**

  - Frequently review, calibrate, and validate tools and platforms to reduce errors, ensure consistent results, and maintain software reliability during development, testing, and deployment phases.

Relevance to NASRAT:
For NASRAT, validating tools and platforms reinforces that the AI model is trained and tested using robust, compliant systems. This guarantees the software accomplishes as intended under clinical conditions, decreases inaccuracies in AI stroke risk predictions, and makes certain compliance with regulatory requirements.

<u>Continuous Improvement</u>

Implement a continuous improvement framework by leveraging feedback from quality control processes and post-market surveillance to solve any inefficiencies and boost software performance.

- **Use data from**:
  - Quality Control: Results from software validation, identifying inaccuracies or AI edge-case failures.
  - Post-Market Surveillance: User feedback, incident reports, and real-world performance monitoring after deployment. Post-marketing surveillance (PMS) methodologies, particularly for AI-based SaMD, are critical to identify performance gaps and ensure continuous validation, as Zinchenko et al. (2022) demonstrate in their PMS framework for AI technologies **[12]**.
- **Continuously improve**:
  - AI model accuracy and reliability for stroke risk predictions.
  - User interface functionality and integration with healthcare systems.
  - Response to discovered non-conformities through Corrective and Preventive Actions (CAPA).

Relevance to NASRAT:
For NASRAT, continuous improvement ensures the software evolves to address clinical needs, improve accuracy, and maintain regulatory compliance in every part of its lifecycle.

Individual Task:
During QC release of the device a non-conformity was raised as the label contained the wrong information. Investigate the potential root-cause of the issue. Refer to the tutorial notes and select a suitable method for RCA.

Problem statement:
During the Quality Control (QC) release of NASRAT, a non-conformity was identified as the software version information displayed incorrect patient data.

Root-Cause Analysis (5 Whys Technique):

1. **Why was the version information incorrect?**
   The incorrect **metadata template** was applied during the production process.
2. **Why were the incorrect template chosen?**
   There was no automated system to cross-check metadata templates against batch data.
3. **Why wasn't there an automated system in place?**
   The process relied on manual selection of templates, which increased the risk of human error.
4. **Why was the metadata process manual?**
   No systematic review had been conducted to identify inefficiencies or flaws in the versioning workflow.
5. **Why wasn't the gap identified earlier?**
   The **Quality Control plan** lacked periodic reviews of versioning processes and metadata validation.

Proposed Solutions:

To address the root cause and prevent its recurrence, the following solutions are proposed, aligning with the **Corrective and Preventive Actions (CAPA)** framework:

1. **Implement AI-Driven Metadata Verification Tools:**
   - **a.** Integrate an AI-driven metadata validation system to automatically cross-check metadata templates with batch data in real time.
   - **b.** AI-driven solutions have been proven to improve accuracy and efficiency, reducing human error in software production processes **[5]**.
2. **Introduce Mandatory Pre-Release Validation:**
   - **a.** Ensure all metadata, including version numbers and patient data tags, align with batch records and regulatory requirements before deployment.
   - **b.** Pre-release validation will ensure compliance with standards like **ISO13485** and mitigate the risk of versioning errors.
3. **Train Staff on Automated Validation Systems:**
   - **a.** Provide focused training to production and QC teams on metadata validation tools, workflows, and automation systems.
   - **b.** Training will minimise manual interventions, reducing human error and improving compliance.
4. **Conduct Regular Metadata Audits:**
   - **a.** Schedule quarterly audits to review metadata workflows, validate software version records, and ensure adherence to Quality Control plans.
   - **b.** Audits will enable continuous improvement and identify areas of inefficiency for future optimisation.

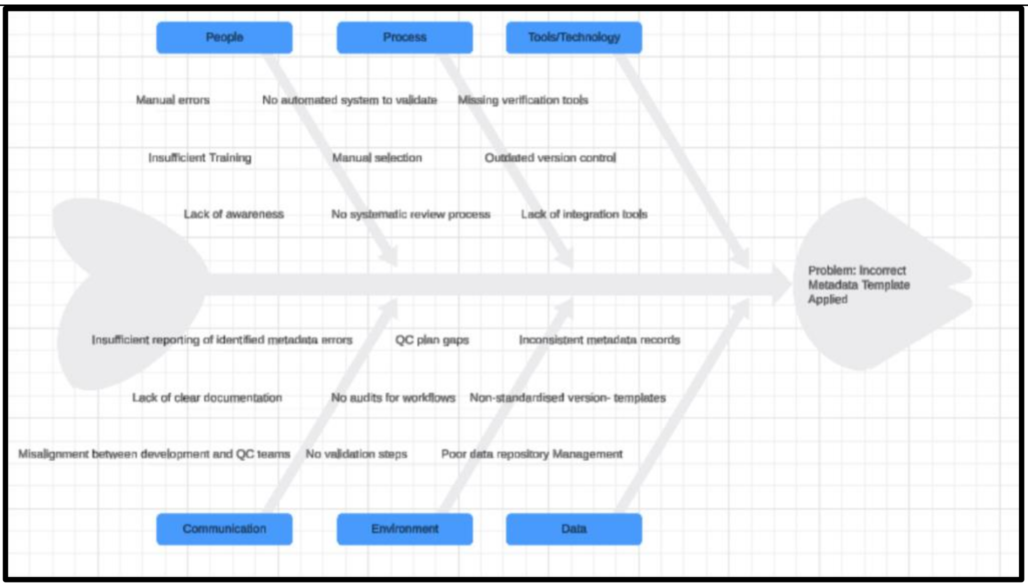

People
Process
Tools/Technology
Manual errors
No automated system to validate
Missing verification tools
Insufficient Training
Manual selection
Outdated version control
Lack of awareness
No systematic review process
Lack of integration tools
Problem: Incorrect Metadata Template Applied
Insufficient reporting of identified metadata errors
QC plan gaps
Inconsistent metadata records
Lack of clear documentation
No audits for workflows
Non-standardised version- templates
Misalignment between development and QC teams
No validation steps
Poor data repository Management
Communication
Environment
Data

Figure 4: Fishbone Diagram for Root-Cause Analysis of Incorrect Metadata Template Applied This diagram identifies key causes of the problem, categorised into People, Process, Tools/Technology, Communication, Environment, and Data. It highlights gaps in automation, training, validation steps, and metadata management as root causes contributing to the issue.

<u>Roles that contributed to the task:</u>

Quality Manager: Reviewed the non-conformance and provided guidance on corrective actions and root-cause analysis.
Design and Development Manager: Provided input on product specifications and labelling requirements.
Regulatory Manager: Ensured that proposed solutions complied with FDA and MDR 2017/745 regulations.

Appendix B: Attachments

15th November

- Agenda: Discuss device options for the project.
- Key Decisions: Settled on developing a Software as a Medical Device (SaMD) solution.
- Outcome: Agreed that SaMD aligns with the project's goals of predictive diagnostics and preventative healthcare.

3rd December

- Agenda: Review project specifications, assign roles.
- Discussions:
  - Read through the project's specification, focusing on regulatory, technical, and clinical requirements.
  - Discussed individual strengths and relevant expertise.

Key Decisions:

- Roles assigned as follows:
  - Regulatory Manager: Jamellia Frederick
  - Design and Development Manager: Louis Forgione
  - Quality Manager: Prithvish Ganguly
  - Production Manager: Suhail Elhaj

Outcome: Established team structure to leverage individual expertise effectively.

10th December

- Agenda: Review progress and address challenges in the initial phases.
- Key Activities:
  - Finalised device classification and clarified regulatory pathways for the US, EU, and UK markets.
  - Began outlining the Quality Management System (QMS) framework to ensure ISO13485:2016 compliance.

12th December

- Agenda: Discuss data integration and AI model requirements.
- Key Activities:
  - Focused on defining technical specifications, especially data integration with Electronic Health Records (EHRs).
  - Identified potential risks related to data security and machine learning bias.
  - Discussed mitigation strategies, including robust encryption protocols and iterative testing of AI algorithms.

15th December

- Agenda: Final review before report submission.
- Key Activities:
  - Reviewed draft implementation plan for the QMS, ensuring all regulatory and compliance elements were addressed.
  - Validated that individual tasks align with the overall project goals.
  - Confirmed timelines for future audits and post-market surveillance.