Problem Description

The medical device industry faces a formidable challenge with the complexity and ever-changing nature of regulations. The European Union's Medical Device Regulation (MDR) is particularly stringent, requiring comprehensive and up-to-date documentation to ensure product safety and efficacy. This creates a significant burden for manufacturers, who must navigate intricate regulatory requirements and continually update their documentation to remain compliant.

Research Objective

This thesis aims to explore the potential of leveraging generative AI to streamline and enhance the regulatory compliance process for medical device manufacturers. Specifically, it will compare the performance of two advanced AI models, T5 and GPT-4, in terms of their ability to:

1. **Text Generation Quality**: Evaluate the coherence, relevance, and accuracy of the documentation produced using BLEU and ROUGE scores.
2. **Execution Time**: Measure the time each model takes to generate compliant documentation.
3. **Resource Utilization**: Assess the computational resources (CPU and memory usage) required by each model.

GOAL : The goal is to determine which model provides superior performance for generating high-quality, accurate, and compliant documentation, ultimately aiding manufacturers in meeting regulatory standards more efficiently.

Can AI help navigate the complexities and dynamic nature of medical device regulations, ensuring timely and accurate compliance while reducing the burden on manufacturers?

Yes it can.

Use Cases

Use Case 1: Generating Compliance Documentation for New Devices

Scenario: A medical device company is developing a new product and needs to create comprehensive clinical evaluation reports, technical files, and risk management plans to meet MDR requirements.

Steps:

1. Input: The company provides the AI with detailed technical specifications, clinical study data, and other relevant information about the new device.
2. Process: The AI model analyzes the input data and generates the necessary documentation, ensuring it meets MDR guidelines.
3. Output: The AI produces high-quality, compliant documents that the company can submit to regulatory bodies.

Objective: To significantly reduce the time and effort required to generate initial compliance documentation, enabling faster market entry for new devices.

Use Case 2: Updating Documentation for Regulatory Changes

Scenario: MDR guidelines are updated, requiring manufacturers to revise their existing documentation to maintain compliance.

Steps:

1. Input: The AI is fed the updated MDR regulations along with the company's current documentation.
2. Process: The AI compares the existing documentation against the new regulations, identifies gaps, and suggests necessary updates.
3. Output: The AI provides revised documents or a list of specific changes needed to ensure ongoing compliance.

Objective: To automate the process of updating documentation in response to regulatory changes, ensuring that the company’s records remain current and compliant with minimal manual effort.

Use Case 3: Post-Market Surveillance and Compliance Monitoring

Scenario: After a device is launched, the manufacturer must continuously gather and analyze data to demonstrate ongoing compliance with MDR standards.

Steps:

1. Input: The AI receives post-market surveillance data, including adverse event reports, customer feedback, and performance data.
2. Process: The AI analyzes the data, identifies trends, and generates periodic compliance reports.
3. Output: The AI produces comprehensive post-market surveillance reports, highlighting any areas of concern and suggesting actions to maintain compliance.

Objective: To streamline the generation of post-market surveillance reports, ensuring timely and accurate compliance monitoring with reduced manual intervention.

Implementation

1. Feeding Regulations into AI

1. **Data Ingestion**: Input the MDR guidelines and relevant regulations into the AI models.
2. **Training and Fine-Tuning**: Fine-tune the models on specific regulatory texts to enhance their understanding and contextual accuracy.

2. Use Case Implementation

1. **Documentation Generation**: Implement algorithms to generate, compare, and update compliance documents based on input data and regulations.
2. **Evaluation and Validation**: Use BLEU and ROUGE scores to assess the quality of generated text. Measure execution time and resource utilization to ensure efficiency.

By addressing these use cases, the thesis will demonstrate the potential of AI to revolutionize the regulatory compliance process, making it more efficient and less burdensome for medical device manufacturers.