Leveraging AI for Enhanced Quality Assurance in Medical Device Manufacturing

Abstract:

The medical device sector adheres to strict regulatory frameworks, requiring precise adherence to quality assurance (QA) processes during the production process. Conventional quality assurance (QA) approaches, although successful, sometimes require substantial time and resource allocations, resulting in possible obstacles and higher expenses. The emergence of Artificial Intelligence (AI) in recent years has completely transformed quality assurance (QA) methods in different sectors, providing unparalleled prospects for improved productivity, precision, and scalability. This research examines the possibility of using AI technologies to enhance quality assurance processes in the manufacturing of medical devices. Manufacturers may improve product quality and streamline production workflows by utilising AI techniques like machine learning, computer vision, and natural language processing to automate and optimize important QA procedures. Artificial intelligence systems can analyse large amounts of data to find abnormalities, uncover flaws, and anticipate any problems in real-time. This allows for proactive intervention and reduces the chances of non-compliance hazards. In addition, AI-powered QA systems provide adaptive learning capabilities, constantly enhancing performance through feedback and adapting to changing regulatory needs. The incorporation of artificial intelligence (AI) into current quality management systems enables smooth and efficient sharing of data and compatibility, promoting a comprehensive approach to quality control throughout the whole production process.

Key words: QualityEnhancedAI, quality assurance, Artificial Intelligence

1) INTRODUCTION:

In the context of the fourth industrial revolution (Industry 4.0), Artificial Intelligence (AI) is a field of study that utilizes advanced algorithms and processing skills to generate valuable insights from relevant data[1, 2]. In the era of the Internet of Things (IoT), manufacturing will become more efficient, with higher quality, easier management, and increased transparency. This will be achieved by integrating physical and cyber technologies in smart factories based on Industry 4.0. The implementation of sensors and artificial intelligence plays a crucial role in enhancing the intelligence of factory automation systems[3, 4]. The progress and innovations in sensor technology, specifically in relation to Industry 4.0, are crucial for the widespread growth of many industries and the economic prosperity of nations. Manufacturing organisations and supply chains must have access to the most up-to-date and affordable sensor technologies in order to gather data and utilise it effectively. Common sensor types encompass location sensors, flow sensors, temperature sensors, flow rate sensors, pressure sensors, and force sensors. Various industries, including as motorsport, healthcare, industry, the military, and agriculture, rely on them regularly. The objective of Industry 4.0 is to enhance productivity by implementing automation[5, 6]. In recent times, AI approaches have made significant advancements in the field of healthcare, sparking a lively debate over the potential future replacement of human physicians by AI doctors[7, 8]. In the foreseeable future, it is unlikely that computers will completely replace human physicians. However, artificial intelligence (AI) has the potential to greatly aid physicians in making more accurate clinical choices. In fact, AI may even be able to replace human judgment in specific areas of healthcare, such as radiology[9, 10]. The growing accessibility of healthcare data and the quick advancement of big data analysis techniques have facilitated the recent successful implementation of AI in healthcare. By utilizing advanced AI algorithms, pertinent clinical questions may be answered and valuable information can be extracted from the vast amount of data. This knowledge can then be used to aid in clinical decision making[11, 12].Ensuring the utmost level of quality in constantly changing industries such as manufacturing, medical devices, pharmaceuticals, and food and beverages is not merely an objective but an essential requirement[13, 14]. Artificial Intelligence (AI) is a transformative technology that is changing the Quality Management System (QMS) sector. It is revolutionizing how businesses approach Quality Control (QC) and Quality Assurance (QA). Quality management is vital in many industries, as it guarantees that items and services adhere to defined benchmarks and surpass client anticipations[15, 16]. The incorporation of artificial intelligence (AI) is transforming conventional business procedures as technology progresses. The field of quality assurance (QA) has been completely transformed by the advent of artificial intelligence (AI)[17, 18]. The significant value that AI contributes to optimizing testing processes and boosting efficiency cannot be disregarded. Organizations who possess the knowledge and ability to integrate artificial intelligence (AI) into their testing processes will obtain a significant advantage over their rivals in the market. This article provides a comprehensive analysis of the capabilities of artificial intelligence (AI) in quality assurance (QA) and discusses how QA teams might transition from inefficient manual testing to advanced autonomous testing technologies[19, 20].

1.1.An overview of Artificial Intelligence (AI) in the field of Quality Assurance: AI is capable of executing significantly more sophisticated activities that previously necessitated human cognitive abilities, particularly:

1.2. Natural language processing (NLP) is a field of study that involves the ability to comprehend, analyze, and generate human language, while also considering the subtleties and complexities of linguistics. In the context of Quality Assurance (QA), artificial intelligence (AI) has the capability to comprehend customer requirements expressed in simple language and convert them into test cases or even automation scripts [21, 22].

1.3.Machine learning (ML), a subset of artificial intelligence (AI), allows an AI system to autonomously learn from its own experiences without the need for explicit programming. QA teams have the ability to educate the AI by conducting testing sessions. Gradually, the AI will learn and adapt to the testing patterns of the QA teams, resulting in more tailored recommendations that are specific to the organization [23, 24].

1.4.Computer vision is capable of analyzing and interpreting visual input, enabling it to discover irregularities in the user interface (UI). For quality assurance teams, this implies enhanced precision in doing visual regression testing [25, 26].

The goal of implementing AI in quality assurance is to overcome the bottlenecks in manual testing. Manual testing is a time-consuming process that is prone to human error. It requires significant effort to write, manage, execute test cases, document the outcomes, and verify results. Limitations of manual testing are highlighted in fig 1.

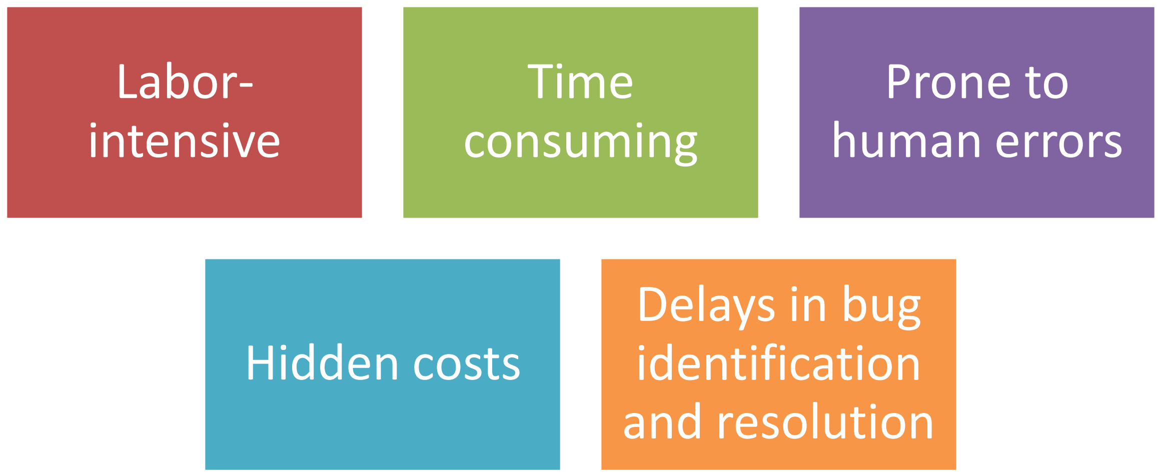

Figure 1 Limitations of manual testing

As software complexity grows, scaling manual testing becomes much more challenging, leading to prolonged testing periods[27-29]. Moreover, manual testing can cause delays in identifying and resolving bugs, especially during major software updates or releases. When performed manually, regression testing, which is essential for software maintenance, becomes tedious and counterproductive. The hidden costs associated with training new testers and managing testing environments are also often overlooked.Automation testing accelerates the process by streamlining repetitive and resource-intensive tasks. As we move closer to autonomous testing, even the common challenges of automation testing can also be addressed[30-32].

2. Application Of AI In Medical Manufacturing Devices:

The adoption of artificial intelligence (AI) is rapidly increasing in almost every industry. Artificial intelligence (AI) in manufacturing has great potential, particularly in specialized areas that require high levels of accuracy and efficiency, such as the production of medical devices. To properly exploit this potential, medical makers must possess a comprehensive understanding of how to efficiently implement AI[33].

2.1. Devices Equipped With Artificial Intelligence Capabilities:

One of the most revolutionary AI uses for manufacturers is found in the medical items themselves. Artificial intelligence (AI) enabled gadgets provide considerable benefits to users, making the development and sale of these goods a lucrative opportunity for firms to achieve big revenue growth. In 2022, the FDA granted authorization to 91 AI medical devices that are equipped with 91 technology, indicating a significant industry transition towards the use of this technology. The rationale behind this progression is comprehensible, as AI medical technology has the capability to assist doctors, nurses, and EMTs in diagnosing diseases with greater speed and precision[34].

2.2. Expanding the Market:

The demand for the precision and speed of AI will grow as labor constraints continue and care standards improve. As a result, medical devices with AI capabilities will rapidly dominate the market, presenting a favorable opportunity for device makers at present[35].

2.3. Artificial Intelligence in Clinical Trials

Clinical trials serve as an additional transformative AI manufacturing application for medical device producers. The average time required to obtain FDA 510(k) clearance is 31 months, although in certain instances it might exceed 130 months. Artificial intelligence (AI) has the capability to optimize and expedite this process, resulting in quicker returns on investment (ROIs). Machine learning algorithms can examine demographic data during the pre-trial phase to identify optimal groups for testing, including regions with individuals who are willing to participate. AI tools may then automate the process of reaching out to individuals and entering data, resulting in quicker on boarding and more precise record-keeping. Consequently, producers can expedite the commencement of trials and eliminate inaccuracies in their documentation. Utilizing artificial intelligence (AI) to automate the process of record-keeping reduces the potential for human mistakes and accelerates the identification and organization of data. These enhancements facilitate the provision of precise and pertinent information to regulatory authorities, hence expediting the clinical trial procedure[36].

2.4. Artificial Intelligence For Ensuring Adherence To RegulatoryRequirements:

Likewise, AI can be employed by medical device producers to enhance their adherence to regulatory requirements. Ensuring regulatory compliance across several countries can be a complex task, prone to significant human error, which can lead to substantial financial penalties. Nevertheless, artificial intelligence has exceptional proficiency in intricate analysis and tasks thatinclude a substantial amount of data.AI models have the capability to observe and analyze product development data and then make comparisons with the most up-to-date regulatory framework that is relevant. These algorithms can identify and emphasize procedures or documentation that present regulatory problems or require additional study. Manufacturers might thereafter modify their production or paperwork as requiredto ensure compliance[37].The value of these noncompliance warnings increases as global rules evolve, due to their rapid and precise nature. Given the COVID-19 pandemic and the increasing importance of new technology, it is highly probable that there will be changes in medical rules. Therefore, it is essential to priorities the ability to quickly adapt in order to survive.

2.5. Digital Twins

Medical device firms can utilise digital twins as a promising application of artificial intelligence in production. This technology use artificial intelligence to generate digital reproductions of tangible processes and equipment seen in the physical world. Machine learning methods can subsequently replicate different events and alterations in these twins to emphasise inadequaciesand identify optimal solutions.Significant enhancements can arise from seemingly minor alterations. For instance, air compressors offer greater ease of maintenance and higher efficiency compared to alternative power sources for equipment, resulting in considerable improvements in uptime and energy consumption. However, manufacturers may disregard this chance because the technology that powers systems does not undergo significant changes. Digital twins have the ability to identify solutions that humans would overlook, leading to cost savings.

These simulations for identifying savings can be advantageous for all manufacturers, but they hold particular significance for medical device companies. These things are frequently costly, rendering them unattainable for many individuals, but enhancements in procedures can reduce expenses and diminish clients' obstacles to participation. Digital twins can also reduce the margin for mistake, hence preventing the introduction of noncompliant products into the market[38].

2.6. Anticipatory Maintenance

Predictive maintenance, utilizing artificial intelligence (AI) to analyse real-time data from Internet of Things (IoT) sensors that monitor machine health variables, can also be advantageous for medical device manufacturing lines. These artificial intelligence models have the capability to anticipate the timing for equipment repair and notify the appropriate staff. Research indicates that implementing predictive maintenance can lead to a significant reduction in downtime, up to 50%, by proactively preventing equipment faults and minimising the need for wasteful repair interventions. Additionally, it reduces maintenance expenses and guarantees that production equipment yield a higher level of consistent quality. These enhancements lead to enhanced quality assurance for goods of medical device companies, hence reducing expensive legal ramifications. Reducing repair expenses also allows for lower prices, same to the way digital twins do[39].

2.7.Utilizing Machine Vision For The Purpose Of Quality Control.

Medical device companies can derive benefits from machine vision, which is a prominent artificial intelligence use in manufacturing. These systems have the ability to rapidly process and analyze visual data, surpassing the speed of human perception. As a result, they are highly suitable for quality control operations.Unidentified flaws can result in expensive legal action in the field of medical devices, and artificial intelligence (AI) can detect subtle mistakes that people are prone to overlook with greater precision. Additionally, it is more efficient than manual inspections, allowing for comprehensivequality assurance without causing delays. Another benefit of employing AI for quality control is that sophisticated algorithms can analyze data from errors to pinpoint their origin. Manufacturers have the ability to modify their production lines in order to proactively avoid future errors. The conservation of resources is of utmost importance in the medical equipment business due to its high costs[40].

2.8. Identification Of Product And Market Opportunities:

Artificial intelligence (AI) in the manufacturing industry can facilitate the creation of novel product designs for companies. Several pharmaceutical makers utilise artificial intelligence (AI) to discover novel medications, while device companies can employ comparable models to initiate or enhance their products. AI tools have the capability to analyse a collection of information on device objectives and design factors, and generate a proposal for the optimal design. Manufacturers have the option to utilize artificial intelligence (AI) in order to examine current blueprints or prototypes and identify modifications that could enhance their efficiency. Subsequently, they can develop superior items and expedite their entry into the market. Machine learning models can utilize consumer data to identify untapped markets and unfulfilled demands. Manufacturers can thereafter focus on these specific market segments by introducing new items, thereby increasing sales while facing little competition [41].

2.9. Artificial Intelligence Greatly Enhances Productivity In The Manufacturing Process.

AI enables the automation of operations, resulting in uninterrupted production cycles, hence minimizing downtime and enhancing efficiency. Machine learning algorithms can enhance production schedules by leveraging real-time data, hence maximizing resource utilization. Moreover, AI has the capability to optimize administrative duties like inventory management, allowing employees to allocate their time and effort towards more essential responsibilities. To gain further understanding of how AI can be utilized for automation in this particular sector, we encourage you to read our essay on the automation of medical device manufacturing[41].

2.9. Improved Accuracy and Excellence:

Accuracy and excellence are of utmost importance in the field of medical device manufacture. Artificial intelligence (AI) has the ability to greatly improve these parameters by minimising human mistakes and enhancing the quality of products. Machine learning algorithms have the capability to identify and rectify small flaws in real-time while the manufacturing process is ongoing, guaranteeing the production of products that are of superior quality and dependable.

Moreover, AI has the capability to enhance accuracy in activities like cutting and assembly, resulting in superior products and less waste. This is only a single facet of AI-powered advancements in the medical devices sector, which is further examined in further detail in this context[42].

Stages	Objectives
selection	Pick most appropriate CDSS in term of match with target use case and clinical work flow, five “rights,” performance and user acceptability
Acceptence testing	Test that CDSS satisfies security, privacy and safety requirements applicable to medical devices, covering typical error scenarios, exception and unforeseen conditions
Commissioning	Prepare the CDSS for optimized use in the clinic(including potential customization) and test its safety and performance within the local context
Implementation	Roll out the CDSS and transition from the old workflow to the new after training the end user and managing their exceptations
Quality assurance	Ensure that the quality of the CDSS remains fit for purpose by monitoring internal and external updates as well as context drift

Figure 2 Stages of adoption of AI in supply chain

2.10. Cost Reduction

AI in medical devices production offers a notable advantage in terms of cost reduction. Artificial intelligence has the capability to optimize the allocation of resources, hence minimizing inefficiencies and decreasing production expenses. Predictive maintenance, an artificial intelligence (AI) program, utilizes advanced algorithms to forecast the occurrence of equipment failure, enabling prompt maintenance actions and preventing expensive periods of inactivity.

Moreover, AI has the capability to decrease labor expenses by automating monotonous work[43].

3. The Role of Artificial Intelligence in Quality Management

AI plays a crucial role in quality management software by automating quality control operations. Organizations may optimize inspections, testing, and other essential operations for quality control by employing AI-driven data collecting and analysis tools[44, 45]. Artificial intelligence algorithms have the capability to rapidly analyze extensive quantities of data, facilitating immediate decision-making and minimizingthe requirement for manual labor[46, 47]. Artificial Intelligence elevates predictive analytics to a prominent position in quality assurance. Organizations can utilize historical data and machine learning techniques to detect probable flaws and deviations in the quality process[48, 49]. By taking a proactive approach, it becomes possible to apply preventative steps that can stop quality concerns from happening in the first place. AI-driven insights enable the attainment of real-time monitoring and ongoing development. Artificial intelligence (AI) powered sensors and monitoring systems are essential for ensuring and maintaining high standards of quality control[50-52]. These systems have the capability to gather data in real-time, oversee quality metrics, and detect anomalies. AI utilises adaptive algorithms to uncover intricate patterns, trends, and anomalies that may be a challenge for human operators to discern[53, 54]. This enables timely resolution of quality concerns and enhances product uniformity and customer contentment.

3.1. Advantages of Artificial Intelligence in Quality Management:

3.1.1. Enhanced Precision and Dependability: AI eradicates the potential for human fallibility in the quality process through work automation and the utilization of sophisticated algorithms. Through this process, artificial intelligence improves the precision and dependability of quality control tasks. Artificial intelligence (AI) systems have the ability to accurately identify and examine flaws, resulting in consistent and dependable quality results[55, 56].

3.1.2. Enhanced effectiveness and output: The utilisation of artificial intelligence (AI) in automation and data processing greatly enhances efficiency and productivity in quality management. Organisations can expedite data processing and analysis by automating manual operations, resulting in reduced time for quality checks. The decrease in manual labour results in time and cost efficiencies, enabling more efficient use of resources. AI enhances organisations' decision-making capacities in quality management. Through the utilisation of AI-driven insights, organisations may make well-informed decisions, pinpoint areas in need of enhancement, and optimise their quality control procedures[56].

3.1.3. Advancements in Medical Devices: Enhancing Precision The medical devices sector requires a high level of accuracy that allows for no mistakes. AI is revolutionising the field of medical device manufacturing by effectively analysing and deriving insights from large datasets. AI-powered Quality Management Systems (QMS) guarantee adherence to the highest quality standards across the whole process, including design, prototyping, production, and post-market surveillance[57, 58]. The FDA mandates rigorous adherence to its severe standards from medical device producers. Artificial Intelligence (AI) not only assists in complying with these regulatory criteria but also improves the efficiency and precision of the approval process. Through the use of artificial intelligence (AI), medical device corporations can greatly diminish the duration required to bring their items to the market, while maintaining the utmost safety and quality standards[59, 60].

3.1.4. Pharmaceuticals and the field of life sciences: Enhancing the speed of progress and adherence to regulations Artificial Intelligence (AI) is a transformative force in the pharmaceutical and lifesciences industry, where the combination of innovation and adherence to regulations is crucial[61-63]. The process of developing and commercialising novel pharmaceuticals entails intricate procedures and stringent quality assessments. An AI-driven Quality Management System (QMS) accelerates this process by automating repetitive operations, allowing scientists and researchers to concentrate on innovation. Moreover, in a business where strict adherence to FDA standards is very essential, AI serves as a vigilant protector of compliance. It guarantees that each stage of drug research and manufacture adheres to regulatory standards, so greatly minimizing the possibility of non-compliance problems. This accelerates the approval procedure and protects the reputation of pharmaceutical firms. Ensuring the safety and consistency of food and beverages Ensuring a steady level of excellence is of utmost importance for guaranteeing consumer safety and contentment in the food and beverage sector[64-66].

4. AI and QMS:

The integration of artificial intelligence (AI) in quality management systems (QMS) provides essential accuracy and immediate monitoring capabilities that are crucial in this industry. AI guarantees that every stage, from acquiring raw materials to packaging and delivery, adheres to the most stringent quality criteria[67, 68]. Cloud-based Quality Management System (QMS) solutions enable firms to achieve traceability by providing the capacity to monitor and record the movement of every ingredient and product along the entire supply chain[69]. Traceability is essential for promptly taking corrective measures in case of a quality problem, so preventing extensive recalls and protecting the reputation of the brand[70]. AI is utilized in Quality Assurance to also facilitate predictive maintenance in industrial equipment, mitigating the possibility of unforeseen malfunctions that may jeopardise the quality of the finished product[71]. This proactive strategy not only guarantees the uniformity of the output but also improves the effectiveness of operations. The Quality Management System (QMS) solutions play a crucial role in driving the AI revolution in quality management[72]. They offer a centralized platform for the storage, analysis, and collaboration of data, enabling stakeholders to access up-to-date information from any location in the world[73]. This high level of connection is especially beneficial in industries that have several manufacturing units or worldwide supply chains[74]. The cloud-based Quality Management System (QMS) strategy improves cooperation and guarantees the protection and accuracy of data[75]. By implementing strong encryption and reliable backup systems, firms may have confidence that their valuable quality data is safeguarded from unauthorised access or accidental loss. This enhances the confidence of regulatory agencies and consumers, hence strengthening the credibility of the industry[76]. AI is transforming the field of quality management by improving efficiency, precision, and decision-making abilities. The capacity to automate procedures, offer predictive insights, and enhance overall quality results is revolutionising various sectors[77, 78]. Organisations that adopt AI in quality management can greatly enhance quality control, productivity, and customer happiness. Through harnessing AI-powered insights, organisations may make well-informed decisions, optimise quality control procedures, and maintain a competitive edge[79]. Integrating Artificial Intelligence into the Quality Management System is a significant change in thinking and approach. Industries such as manufacturing, medical devices, pharmaceuticals, and food & drinks are currently undergoing a significant transformation towards achieving unparalleled levels of precision, efficiency, and compliance[80].

By adopting AI-powered next-generation QMS and cloud-QMS solutions, firms position themselves as leaders in innovation and competitiveness[81]. The integration of artificial intelligence with quality management guarantees adherence to regulations and establishes a path towards a future where the pursuit of excellence is not only a goal but a continuous endeavour. In the current age of quality management powered by artificial intelligence, the combination of advanced technology and industry knowledge pushes us towards a future where we not only meet but surpass the highest quality requirements, establishing a new level of excellence in the QMS business[82, 83].

5. Visual inspection:

The Medical Device market is a dynamic and highly competitive field that is constantly changing. Anticipating a projected worth of $800 billion by 2030, individuals involved in the sector are formulating tactics to augment their significance to those with a vested interest and maintain a competitive advantage[84-86]. Numerous businesses are incorporating innovative and sophisticated technology into their manufacturing procedures in an effort to counteract the risk posed by new competitors and developing markets. Medical device manufacturers are actively exploring Artificial Intelligence (AI) as a vital technology to enhance quality control and efficiency[87, 88]. Visual inspection is a crucial process in the manufacturing of medical devices.

Visual inspection is essential in the quality control and assurance procedures of medical device manufacture[89, 90]. Inspections are conducted to detect any defects, flaws, or inconsistencies that may impact the device's functionality, safety, or usage. While manual visual inspection is widely used in the medical device business, it is prone to human error and inconsistency[91]. An inadequate visual examination of a medical device poses significant danger and can cause the device to malfunction, resulting in serious and potentially deadly outcomes[92, 93]. Companies have incurred significant financial losses, seen declines in share prices, and suffered damage to their brand as a result of product recalls and lawsuits. Quality control is essential for protecting patient safety, ensuring device operation, and ensuring compliance with regulatory standards[94, 95]. This ultimately enhances the overall effectiveness and reliability of medical devices. Minimally invasive medical equipment, such as catheters, stents, balloon catheters, guidewires, and biopsy needles, are specifically developed to carry out procedures with minimal disturbance to the patient's body[96]. Their production and quality assurance necessitate rigorous attention to detail. For instance, when considering a catheter device, the criteria for visual inspection may differ depending on aspects such as the specific type of catheter, its intended purpose, the materials utilised, and the relevant regulatory guidelines. Surface imperfections such as scratches, dents, cracks, and discolouration that have the potential to compromise the device's structural integrity or provide a risk to the patient's tissue[97, 98]. The tip shape and integrity must be accurately moulded, sleek, and devoid of any imperfections that may result in harm or discomfort during insertion[99, 100]. Lumen must be clear of any obstacles, obstructions, or abnormalities that could hinder the movement of fluids or result in difficulties during usage. Strong adhesive and bonding properties to ensure secure attachment during use. A hub and connector are essential for ensuring accurate alignment, secure attachment, and the absence of any faults that may impede the appropriate connection to other devices[101, 102]. The radiopaque markers are positioned precisely and are clearly visible, which helps ensure accurate placement[103]. It is necessary to verify dimensional correctness to identify any deviations from the given measurements, such as length, diameter, and curvature, in order to guarantee appropriate fit and functionality[104]. It is necessary to examine tapered transitions between different portions to ensure they are seamless and free from any imperfections that may result in harm to the tissue[105]. The consequences of overlooking any of these flaws can be substantial, with potential implications for patient well-being, the reputation of healthcare providers, adherence to regulatory requirements, and financial viability. Consequently, it is imperative for medical device manufacturers to give utmost importance to stringent quality control systems and utilize sophisticated inspection technologies in order to mitigate any potential risks[106].

5.1. Artificial intelligence Visual examination:

AI-powered visual inspection is a very advanced technology that can analyse medical device components with exceptional precision. It reliably detects even the most minute flaws or departures from specifications[107]. In addition, it effortlessly produces detailed reports to assure traceability and promote process improvements, among other advantages[108]. Minor blemishes such as scratches, dents, cracks, misalignments, and other flaws that are hard to see without magnification can be identified and assessed more quickly than by human vision[109]. This enhances the precision and efficiency of quality control inspections[108]. Integrating AI visual inspection into the production of medical devices would not only enhance the quality of the products, but also improve the efficiency of manufacturing, lower costs, and most importantly, guarantee the safety of patients. The transformative potential of AI visual inspection in the medical device manufacturing business is becoming increasingly apparent[110].

5.2. Deploying artificial intelligence for visual inspection: Medical device manufacturers who choose to implement AI visual inspection should adopt a methodical approach and, if they lack internal experience, should consider collaborating with AI technology vendors or specialists[111, 112]. Defining objectives for deploying AI visual inspection is crucial. These objectives may include enhancing accuracy, expediting inspections, or minimising flaws for the desired use case. After selecting an appropriate AI technology, the responsibility is handed over to the process engineering departments. Their task is to create, set up, and improve the inspection models and process from the beginning to the final implementation[113].

It is necessary to gather a thorough dataset of photos that accurately depict the many types of flaws, together with the anticipated fluctuations and lighting situations that the AI system may experience. Subsequently, this dataset can be employed to train artificial intelligence inspection models utilising artificial intelligence techniques. Iteratively optimising an AI inspection model to attain optimal performance is necessary[114, 115]. To ensure the reliability of the AI system, it is necessary to validate its accuracy by comparing it to known defect cases. An incremental incorporation of the AI visual inspection system into the production process should be carried out. AI-assisted visual inspection is a method that enhances the ability of inspection operators to detect problems by utilising AI technology, while still allowing the operators to make the final judgement. It is imperative to closely evaluate the functioning of the system throughout the pilot period and make any necessary improvements. Regularly assess the performance of the AI system and collect input from the team and production lines. Utilise this feedback to make adjustments to the AI models and enhance the precision and effectiveness of the inspection process[116, 117].

5.2. Artificial Intelligence (AI) capabilities incorporated into medical devices

The primary effect of AI on medical device production is the incorporation of AI technology directly into the devices. AI-enabled technologies have the potential to enhance accessibility to healthcare, enhance diagnostic accuracy, and expedite medical response times[118, 119]. AI models exhibit a diagnostic accuracy of 90% in detecting cancer, which is comparable to that of numerous human doctors. This equipment has the capability to conduct tests at a faster rate than human beings, thereby assisting medical personnel in providing assistance to a greater number of patients within a shorter period of time. AI can also be advantageous for consumer medical products, as wearable technology can track users' physiological functioning to provide deeper understanding of their health. Manufacturers who take advantage of this potential could experience a significant increase in demand. With the increasing integration of artificial intelligence (AI) capabilities in medical equipment, it is expected that AI will become the prevailing norm in the market. All stakeholders, including patients, doctors, and device manufacturers, will reap the advantages of this transition[120, 121].

5.3. Efficient Manufacturing Processes

Artificial intelligence (AI) in the manufacturing industry can also enhance the efficiency and effectiveness of internal operations for medical device companies. Many organisations acknowledge the necessity of optimisation; however, achieving optimisation demands a precise comprehension of the specific issues inside an operation and the most effective methods to resolve them[122]. Artificial intelligence can provide producers with that comprehension.

Machine learning algorithms can utilise production data, such as lead times, material waste, and error rates, to identify bottlenecks and other inefficiencies[123]. Once the areas of improvement have been identified, certain AI models have the capability to provide suggestions for potential enhancements. Artificial intelligence (AI) frequently outperforms human analysts in pattern recognition and outcome prediction, making it a more dependable source of solutions[124]. Medical device manufacturers can utilise this AI study to identify inefficiencies in their utilisation of time and materials. The enhanced efficacy will result in reduced expenses for patients and hospitals. These internal enhancements will enhance the accessibility of healthcare. Automated Quality Control refers to the process of using automated systems and technology to ensure the quality and accuracy of products or services[125, 126]. AI in manufacturing is well-suited for quality control. Medical device makers are required to follow a series of processes to ensure compliance with the FDA, which includes implementing stringent quality assurance methods during the production process. Meeting those criteria using traditional methods can present challenges, but artificial intelligence simplifies the process[127]. Machine vision systems, equipped with artificial intelligence, have the capability to examine products for any flaws, eliminating the need for manual inspection by personnel. AI surpasses humans in accuracy when it comes to analysis-related jobs, and machines do not experience fatigue or distraction. As a result, this automation significantly enhances the accuracy of quality checks[128]. Artificial intelligence (AI) is capable of conducting these inspections at a faster rate compared to human staff, hence decreasing the amount of time required. Another benefit of implementing AI for quality control is its ability to detect patterns and trends over a period of time. If they detect recurring faults, they can notify manufacturers and identify the root causes of these failures, enabling modifications to the production process to avoid such problems in the future[129].

5.3.Optimizingthe efficiency of clinical trials:

AI can be utilized by medical device producers to enhance the efficiency of the clinical trial process. Prior to marketing and promotion, these products must undergo rigorous clinical trials. The duration of trials typically ranges from two to three years, while the associated expenses can amount to anywhere between $10 million and $20 million[130]. Artificial intelligence has the potential to reduce the duration and expenses associated with this rigorous testing phase. Utilizing technologies and assessing their effectiveness still requires a significant amount of time, but artificial intelligence (AI) has the capability to identify optimal research participants and proactively contact them, hence reducing the time required to initiate the trial. Subsequently, sophisticated algorithms can automate the process of entering data and guarantee adherence to regulatory requirements. Artificial intelligence optimizes the administrative aspects of clinical studies and substantially decreases their duration. Additionally, it reduces the likelihood of faults that could impede the advancement of a technology and necessitate retesting. Consequently, producers are able to expedite the introduction of their products to the market while reducing expenses[131].

6. Optimizing the supply chain:

Artificial intelligence (AI) can potentially enhance the efficiency and effectiveness of the medical device supply chain in manufacturing. AI models have the capability to examine internal operations and identify inefficiencies, as well as detect supply chain bottlenecks and dangers. Identifying these areas of enhancement can assist manufacturers in restructuring their supply networks to enhance resilience. Machine learning is a valuable tool for modelling and predicting disruption and risk. Medical device firms that collect sufficient data on their supply chain have the ability to utilise artificial intelligence (AI) to generate a digital replica of the network. This virtual representation can simulate different disturbances to assess its resilience and provide manufacturers with insights on essential modifications. This data can be utilised to enhance predictive AI models, enabling manufacturers to proactively identify and address supply shortages or any other potential interruptions. Companies might mitigate the impacts by augmenting their safety stocks or implementing other measures[132, 133].

6.1. Accelerated Research and Development:

Artificial intelligence is facilitating expedited research and development in the creation of medical devices. The cost of obtaining regulatory approval for a Class 2 medical device can range from $2 million to $5 million, excluding expenses related to research and development. AI can optimise processes by identifying specific areas to focus on and facilitating quick development of prototypes [134]. AI models have the capability to examine the present market in order to identify patient demands that have not been addressed. Manufacturers can utilise this information to create innovative products that outperform existing options in areas where they are lacking. Subsequently, they might exploit an untapped market, thereby guaranteeing enhanced sales performance and advancing patient outcomes[135].

AI tools can aid in development by providing suggestions for new designs or identifying potential enhancements in current designs to optimise the prototype process. Manufacturers can thus attain a more expedited time to market, thereby enhancing their return on investment (ROI) [136]. The implementation of artificial intelligence (AI) in the manufacturing industry has significant and wide-ranging effects. Artificial intelligence (AI) in the manufacturing industry is still a relatively recent development, so it is expected that more applications will arise in the

future. As more manufacturers take advantage of these current and future applications, this technology will become a widely adopted industry standard[137].
AI deployment can enhance the efficiency, accuracy, and resilience of medical device manufacturers. As a consequence, the patients they cater to will have the ability to obtain superior healthcare at reduced costs. Considering these extensive consequences, wider implementation of AI will enhance the sector for all participants[138].The objective of artificial intelligence (AI) in software quality assurance is to address the limitations and obstacles associated with manual testing. Nevertheless, the execution of this plan presents numerous obstacles that organisations must tackle. Several of these challenges include:

6.1.1. Data management

A recent study conducted by Towards Data Science revealed that over 40% of initiatives experience failure as a result of inadequate data quality assessments. AI-driven quality assurance testing largely relies on extensive datasets, and the process of cleaning and maintaining data is frequently difficult. Insufficiently clean data during the training process of AI hinders its ability to distinguish genuine faults and may erroneously offer testers with false positive results[139].

6.1.2. Adherence to HIPAA regulations

The healthcare business is using Quality Assurance and Testing (QA&T) to improve outcomes. Nevertheless, this poses a difficulty in guaranteeing adherence to the Health Insurance Portability and Accountability Act (HIPAA), a federal statute that rigorously safeguards Protected Health Information (PHI)[140]. Introducing biased or erroneous data into the system can result in distorted AI outcomes, posing a threat to patient safety and breaking HIPAA regulations. AI models and algorithms operate based on the information that was included throughout the training process; therefore, high-quality data is essential for adherence to standards[140].

6.1.3. AI Models Training and Fine-Tuning

The incorporation of artificial intelligence (AI) into quality assurance encounters the obstacle of biassed data throughout the training procedure. AI models have the ability to acquire bias from the data they are trained on, which might result in unfair or erroneous testing outcomes. For optimal training, it is advisable to utilise varied training datasets that closely represent the target population and real-life situations to achieve effective results[141].

6.1.4. The comprehensibility and clarity of AI outcomes
Ensuring comprehensibility of AI outcomes poses a difficulty with the integration of AI into quality assurance processes. Interpretability and explainability, facilitated by Explainable Artificial Intelligence (XAI), enable testers to swiftly comprehend the context and rationale underlying the decisions made by AI. Explainable Artificial Intelligence (XAI) enhances the effectiveness and precision of testing and generates comprehensible results in a very efficient manner[142, 143].

6.1.5. Ethical Considerations: Ethical considerations arise in the testing of AI due to the possibility of AI models acquiring biases from the data they are trained on, which might result in discriminating consequences. This presents possible hazards in the event of prejudices towards various user populations. The importance of ethical considerations in quality assurance testing for AI models is paramount[144]. Inadequate data can impede the effectiveness of algorithms during the training process, as evidenced by the potential dangers such as biassed results or unintended repercussions in medical treatments. The healthcare business is highly reliant on data and any oversight can undermine the credibility of a product.

The following are the ethical considerations for integrating AI into quality assurance and testing:

1. Testing the design and implementation of digital health products.
Due to the sensitivity of health data, it is crucial to build the product in a way that does not prioritise data collecting at the expense of compromising the results. It is crucial to maintain patient anonymization in order to comply with HIPAA and GDPR regulations and to establish trust with the user[145].

2. Testing using Artificial Intelligence
AI tools enhance the autonomous testing process by providing effective quality assurance. AI models must undergo thorough testing to ensure their explainability and transparency in making judgements, hence establishing confidence and guaranteeing accountability in AI-driven testing[146].

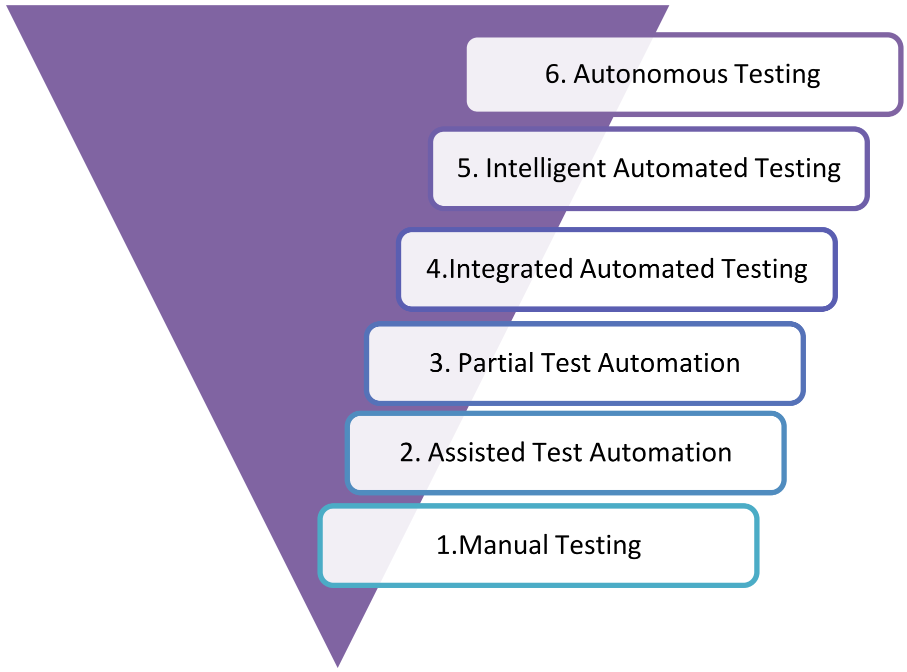

Figure 3 Levels of autonomy

3. Optimising AI to achieve its maximum capabilities and attain optimal outcomes necessitates the involvement of human testers. Create test protocols that incorporate human supervision of AI-driven testing procedures to mitigate the occurrence of unwanted outcomes resulting from artificial intelligence in diagnostic processes[147].

4. ChatGPT for Medical Products Healthcare product quality assurance (QA) can be conducted using chatGPT or any other artificial intelligence (AI) model. Prior to conducting any exam, it is essential to verify ChatGPT's proficiency in comprehending intricate medical terms and sophisticated patient language to ensure comprehensive testing[148]. The healthcare industry necessitates a compassionate attitude towards patients, while also acknowledging the potential for AI models to inaccurately assess and exploit patients' data. ChatGPT should undergo testing to assess the accuracy of its analysis and prevent any inconsistencies in the process[149]. Utilising ChatGPT for Test Automation

In order to employ generative AI, such as ChatGPT, for the purpose of test automation, it is necessary to train the AI model using healthcare regulations and guidelines. This training will enable the model to automatically produce a wide range of realistic test cases for medical applications and equipment[150]. ChatGPT's analysis and communication are significantly improved by exposure to real-world events. Evaluating the efficacy of AI-driven medical assistants and virtual nurses can be achieved by employing chatbots powered by ChatGPT[151].

5. Application of Generative AI in Quality Assurance and Testing
The incorporation of generative AI is expanding the scope of quality assurance. Generative artificial intelligence (AI) in quality assurance aids in the testing process by creating intricate scenarios and a wide range of test cases, hence improving the overall effectiveness and scope of identifying potential problems[152]. For example, it is capable of producing artificial medical images to be used for training, thus decreasing expenses and reliance on limited data. Comprehending the primary AI applications in healthcare is essential for guaranteeing efficient quality testing utilising generative AI, which may encounter specific difficulties[153]. Challenges related to the use and integration of generative AI in quality assurance. Artificial intelligence revolutionises quality assurance by optimising the several facets of the testing procedure. Organisations may have difficulties when implementing and integrating AI in QA, such as:

1. Discrepancy in skills
Accenture's 2023 analysis revealed that a mere 20% of healthcare organisations possess the requisite artificial intelligence (AI) expertise. Consequently, the healthcare industry is experiencing a shortage of professionals that possess expertise in both healthcare and artificial intelligence (AI). To address this deficiency, it is necessary to implement comprehensive training programmes that can keep up with the rapid speed of the industry and guarantee high-quality service for patients[154].

2. Expenses associated with implementing Artificial Intelligence in the healthcare industry. Integrating artificial intelligence (AI) into healthcare is an enticing prospect, but it necessitates a substantial initial financial commitment, as the expenses associated with AI in healthcare can range from hundreds of thousands to millions of dollars. Implementing generative AI in place of outdated software is a worthwhile investment for smaller businesses[155].

3. Adherence to regulations and standards

The development and implementation process of generative AI in healthcare is challenging due to the need to comply with HIPAA and GDPR laws. To successfully navigate these restrictions, it is necessary to possess legal understanding and utilise specialised technical solutions in order to prevent any infractions[156].

4. Ongoing Education

Continuous updates with new data are necessary for generative AI models to uphold accuracy and efficacy. The implementation strategy must take into account the continuous expenses, both in terms of finances and resources.

5. Management of Organisational Change

The introduction of generative AI has the potential to significantly alter established workflows and elicit concerns among healthcare workers. Implementing effective change management measures, such as comprehensive training and clear communication, is essential for ensuring successful adoption[157].

Artificial intelligence (AI) is utilised for risk management in the field of digital health. Effective risk management is essential in the field of digital health due to the potential for AI models to provide erroneous outcomes relying on historical data and patterns. Human testers play a crucial role in ensuring that dynamic and adaptive techniques comply with regulatory standards. It is crucial to guarantee that digital health systems comply with the most stringent security and privacy standards[158].

Artificial intelligence algorithms have the ability to generate erroneous outcomes, which could result in incorrect diagnoses or the failure to identify certain medical conditions. Introducing measures and systems to ensure human supervision can reduce these hazards. Effective risk management should be tailored to specific needs and closely monitored.

Artificial Intelligence for ensuring adherence to regulatory requirements.

Navigating digital healthcare is intricate and demanding. Generative AI, as well as AI in general, provides convenient answers, but the regulations are still developing, leading to uncertainty for all parties involved[159].

Data transparency is of utmost significance in the realm of digital healthcare. AI adheres to the compliance process by examining regulations and autonomously producing compliance reports to satisfy regulatory requirements. Adopting data governance strategies and mechanisms to ensure proper data ownership and comply with protection rules can be beneficial[160]. Securing Data and Protecting PHI While Utilising AI Tools Ensuring the security of Protected Health Information (PHI) or data is of utmost importance while utilising AI techniques. Encryption is a security feature used to protect data while it is being transmitted and to prevent unauthorised access. It ensures that personal health information (PHI) is rigorously anonymized in order to protect patient privacy, while still allowing for legitimate AI analysis[161]. Adherence to industry rules, such as HIPAA and GDPR, is crucial. Organisations should restrict access and implement robust authentication methods to comply with comprehensive data security policies in order to safeguard against breaches and leaks[33]. Potential Avenues and Prospects for Artificial Intelligence in Quality Assurance The potential advancements and prospects of artificial intelligence in quality assurance are optimistic provided that appropriate approaches are employed.

7. Current Challenges Of Quality Assurance In Medical Industry:

Several obstacles may discourage organisations from using AI. These obstacles encompass issues pertaining to data, such as the process of converting data into a digital format and merging it together, as well as ensuring the availability of data. In addition, they encompass obstacles pertaining to privacy and legal matters, encompassing issues of privacy, legal concerns, and government laws. The last category within this dimension encompasses issues pertaining to the patient, including judgement errors, treatment errors, data errors, and human interventions. Following is a comprehensive explanation of each category[162].The medical industry is crucial in society as it ensures the welfare and physical condition of individuals. Ensuring quality assurance (QA) in healthcare is crucial to safeguard patient safety, adhere to regulatory requirements, and uphold public confidence. Nevertheless, the medical business encounters a multitude of obstacles when it comes to establishing efficient quality assurance systems. This article will examine the present difficulties faced in ensuring the quality of medical services and investigate possible remedies[163].

7.1. Issues Pertaining To Privacy And Legal Matters

There are evident privacy concerns associated with accessing, modifying, distributing, and utilizing patient data. Cloud computing and AI are frequently utilized in many applications within the healthcare industry. These systems gather, analyze, retain, oversee, and distribute health information. Although these technologies offer benefits, they also present concerns in terms of security, privacy, cyber security, and ethics. Hospitals and government institutions typically establish ethical protocols for the collection and dissemination of data. Obtaining authorization from a government-sanctioned entity is necessary in order to gather and utilise data, even for research endeavors. Additional ethical concerns related to AI in the healthcare and other industries include disparities in access and opportunities, job displacement, preservation of human values, adherence to ethical principles, regulatory strategies, cognitive biases, demographic biases, and association biases. Efforts are being made to address ethical concerns in the implementation of AI in healthcare by doing research on mitigating adverse consequences, preventing manipulation of rewards, ensuring safe experimentation, and enhancing resilience. Machine learning algorithms are utilised for the early anticipation, management, and identification of diseases, and they have the capability to make decisions independently or provide assistance to professionals in their decision-making process[164]. Authorities have voiced their apprehensions over these automated procedures in terms of safeguarding patients' rights. These concerns have resulted in the implementation of many restrictions regarding the collecting, processing, and usage of data, as well as the quality of such data and the methodology used for its gathering and analysis. Furthermore, researchers in the healthcare field must priorities meticulous attention to data quality, thorough testing of data, and comprehensive documentation prior to the utilization of AI applications[165].

7.2. Obstacles Associated With The Process Of Combining And Merging Different Sets Of Data.

Certain AI techniques necessitate a substantial amount of data for processing. Collecting data, particularly patient data, can be challenging due to the ethical considerations associated with such data. Applying certain classification and clustering techniques to a small dataset can result in high accuracy, but it may lack practicality and applicability. Preprocessing is necessary for the obtained data to be utilised in AI approaches. Specifically, text data necessitate extensive natural language processing prior to use. Integrating many types of data, including text, quantitative, image, and video, using a single algorithm might be one of the most complex issues in medical data processing. Medical data can be gathered from diverse sources and forms, including medical pictures, 3D video sequences, photographs, and numerical data. Acquiring accurate, resilient, and effective data poses a difficulty in the study of healthcare data[166].

7.3. Issues Pertaining To The Safety OfPatients

Machine learning, natural language processing, and expert systems utilise medical data as input to analyse and generate models that aid in making medical decisions within health systems. The majority of AI applications in health systems pertain to the field of diagnostics. Erroneous conclusions in automated diagnosis might have highly detrimental consequences. The data collected from hospitals may occasionally lack sufficient quality or be inherently erroneous. Data mistakes pose significant hurdles in the AI-based processing of medical data. Another obstacle arises from the occurrence of decision errors made by machine learning algorithms. Occasionally, the chosen algorithm may not be appropriate for the provided data, or the data may lack the necessary reliability to be utilised in classification algorithms like neural networks, decision trees, and Bayesian networks. Multiple research have provided evidence of potential difficulties in making decisions related to health and proposed corresponding remedies. Presently, a substantial quantity of artificial intelligence (AI) and Internet of Things (IoT) equipment and software are employed inside the healthcare industry. Nevertheless, it is important to note that not all of these processes are automated. Ultimately, it is the doctors who have the last say in making decisions. This interaction between healthcare practitioners and AI models can sometimes lead to inaccurate diagnoses and treatment outcomes[167].

7.4. The Intricate Nature Of Regulations And The Burden Of Ensuring Compliance:

A primary obstacle in ensuring quality assurance in the medical industry is the intricate regulatory environment. Healthcare regulations are complex and undergo regular revisions, which makes it challenging for healthcare providers and organisations to ensure compliance. The task of navigating through many rules such as HIPAA (Health Insurance Portability and Accountability Act), FDA (Food and Drug Administration) requirements, and CMS (Centres for Medicare &Medicaid Services) guidelines presents substantial difficulties.In addition, the differences in regulatory standards among various locations contribute to the intricacy, particularly for healthcare organisations operating in multiple countries. Complying with these regulations requires significant resources, effort, and skill. Noncompliance can result in significant repercussions, such as legal sanctions, loss of accreditation, and harm to one's reputation[168].

Figure 4 Factors involoved in the approval of AI enabled medical devices by FDA

7.5. Technological Progress And The Incorporation Of Technology Into Various Aspects Of Society.

The swift progress of technology poses both prospects and difficulties for quality assurance in the medical sector. The integration of technology such as Electronic Health Records (EHRs), telemedicine, and artificial intelligence into existing systems presents obstacles, despite theirpotential to improve efficiency and patient care.Ensuring the compatibility of different software platforms, addressing data security problems, and guaranteeing the precision and dependability of digital health solutions are crucial matters. In addition, healthcare practitioners must consistently adjust to advancing technologies and revise their quality assurance processes accordingly. Not adopting technology improvements can lead to inefficiency, data breaches, and poor patient care[169].

7.6. Ensuring The Safety Of Patients And Managing Risks In Healthcare.

Ensuring the safety of patients is a vital component of quality assurance in the medical business. Nevertheless, patient well-being remains at significant risk due to healthcare-associated infections, prescription errors, and medical device failures. Effective risk management necessitates the use of strong strategies and proactive actions to identify and mitigate these risks. Moreover, the growing intricacy of medical processes and treatments intensifies the likelihood of blunders and unfavourable incidents. Healthcare providers should give priority to patient safety by implementing thorough training programmes, conducting regular audits, and promoting a cultureof responsibility and transparency[169].

7.7. Limitations on resources and financial pressures

The medical business faces significant hurdles in maintaining quality assurance due to limitations in resources and financial restrictions. Healthcare organisations frequently function with constrained financial resources, which require them to make challenging choices about theallocation and prioritisation of resources.Substantial financial commitments are necessary for investing in quality improvement initiatives, staff training, and state-of-the-art equipment. Nevertheless, the presence of competing priorities such as expenses related to staff, upkeep of facilities, and general overhead costs may restrict the accessibility of resources for quality assurance endeavours.Moreover, reimbursement models that give more importance to quantity rather than quality may discourage the allocation of resources towards enhancing the quality of services. Healthcare providers must find a middle ground between cost-efficient solutions and upholding high standards of service.Enhancing and cultivating the skills and knowledge of employees through workforce development and training[169].

7.8. Enhancement of Human Resources and Education

An adept and well-informed personnel is crucial for ensuring successful quality assurance in the medical industry. Nevertheless, the process of finding and keeping skilled staff members presents considerable obstacles, especially in specific areas like healthcare informatics, clinical research, and regulatory affairs.Furthermore, continuous training and professional development are essential in order to stay up-to-date with improvements in medical technology and regulatory standards. The issues are worsened by restricted access to training programmes, frequent employee turnover, and shortages in the workforce, which ultimately undermine the quality and consistency of healthcare delivery.

8.Future Perspectives:

Understanding the concept of AI chatbots in healthcare is important for obtaining training data for generative AI models, which is relevant to the future of artificial intelligence in QA. The meticulously trained and rigorously tested data produces more resilient and user-focused test cases for healthcare applications, eventually enhancing the quality and safety of healthcare software.

Here are few potential applications of artificial intelligence in the field of Quality Assurance[170, 171]:

1. Progress in artificial intelligence and its influence on testing
According to Forbes, it is crucial for practitioners to comprehend the decision-making process as AI models become increasingly intricate. Hence, the utilisation of XAI approaches will elucidate the rationale behind AI's recommendations for certain test cases, thereby fostering confidence and openness in the testing procedure.

AI algorithms acquire knowledge through the process of trial and error. This methodology reveals concealed software defects and exceptional scenarios by emulating user actions to identify areas that may elude human quality assurance testers.

2. Incorporation of Artificial Intelligence with Other Testing Techniques
Artificial Intelligence (AI) may be smoothly incorporated into DevOps and Agile operations, facilitating uninterrupted testing and feedback loops. The seamless connection will enhance the

speed at which new versions are released and improve the ability to spot bugs at an early stage. Striking a delicate equilibrium between conventional approaches and artificial intelligence can yield the most effective answer.

3. Significance of Ongoing Learning and Adaptation
As healthcare integrates more digital tools, the likelihood of security and data breaches increases. In order to remain effective, AI models must continuously anticipate and outpace the evolving strategies of hackers and attackers. Continuous learning empowers artificial intelligence to effectively detect and mitigate potential risks, hence ensuring the security of software.

Conclusions:

In conclusion, , the incorporation of artificial intelligence (AI) into Quality Assurance procedures in the field of digital healthcare offers both advantages and difficulties. The implementation of this technology can optimise the testing process and improve overall efficiency. However, its widespread acceptance is hindered by the lack of necessary skills, high costs, and the need to comply with regulatory requirements. Ensuring the security and safeguarding of PHI (Protected Health Information) is of utmost importance, necessitating the implementation of robust encryption and anonymization methods. Nevertheless, the future seems optimistic, since generative AI models provide more reliable testing and the ability to uncover previously undisclosed defects and exceptional scenarios. In light of these progressions, it is imperative for the industry to maintain a state of alertness and flexibility, consistently acquiring knowledge and adapting in order to outpace any risks and guarantee the utmost levels of safety and excellence in healthcare software[81].

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