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# Development of Automated Quality Assurance Systems for Pharmaceutical Manufacturing: A Review

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**Raksha Ranebennur1, Shailesh Thirumaleshwar1*, Hemanth Kumar Somareddy1, Rajvi Desai2, Sandeep DS2**

1Department of Pharmaceutics (Pharmaceutical Quality Assurance) JSS College of Pharmacy, JSS Academy of Higher Education and Research, Mysore, Karnataka-570015

1*Department of Pharmaceutics (Pharmaceutical Quality Assurance) JSS College of Pharmacy, JSS Academy of Higher Education and Research, Mysore, Karnataka-570015

2Department of Pharmaceutical Regulatory Affairs, NGSM Institute of Pharmaceutical Sciences, Nitte (Deemed to be University), Deralakatte, Mangalore-575018

## Corresponding author's email:

shailesht@jssuni.edu.in

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## Abstract

Automation has revolutionized the pharmaceutical manufacturing industry, with various applications such as High-Quality Risk management, Quality by Design (QbD), Process Analytical Technology (PAT), Anti-counterfeit technologies and so much more. In this abstract, we highlight real-time industry examples of automation in pharmaceutical manufacturing, including in-situ analysis in integrated continuous manufacturing systems with PAT, data-rich experiments using automated lab reactors and in-situ sampling, and tamper-evident packaging solutions utilizing deep learning and machine vision foil inspection. The potential for personalized medicines and drug discovery has also been enhanced through automation, allowing for faster and more precise analysis of data, resulting in the development of tailored treatments for individual patients. Automated filling, packing, and labeling processes have improved accuracy and reduced the risk of counterfeit products in the market. Automated continuous manufacturing has enabled real-time monitoring and control of the manufacturing process, leading to higher product quality and reduced production time.The utilization of data-rich experiments and in-situ sampling in automated lab reactors has sped up faster data analysis, leading to improved process optimization and reduced development time for new drug formulations. The implementation of automation has also transformed the roles and responsibilities of quality assurance systems in the pharmaceutical industry. These now comprise digital data handling and interpretation, automated data collection, , electronic batch records, and ensuring confidentiality and data integrity. In conclusion, automation has transformed the pharmaceutical manufacturing industry by enabling high-quality risk management, process analytical technology, personalized medicines, and anti-counterfeit technologies. Automation has also enhanced drug discovery, filling, packing, labeling, and continuous manufacturing processes, leading to improved product quality, efficiency, and patient safety in the pharmaceutical industry. The roles and responsibilities of quality assurance systems have evolved to include digital data handling, automated data collection, and maintaining data integrity.

## 1. Introduction:

Despite the fact that the sector has generally been based mostly on human processes, the pharmaceutical industry in India is progressively adopting automated technologies. To be successful and competitive in a linked world, implementing new automated operational technology (OT) and information technology (IT) is critical as well as important. Challenges like quality issues, inconsistency due to manual manufacturing processes, cost aspects, human errors, global competition which is increasing on a large scale, and regulatory compliances can be overcome by continuous innovation by adopting automation techniques which will in improve the quality systems of pharmaceutical manufacturing.(1) Furthermore, Robotics and Cognitive Automation (R&CA) rollouts require validation to ensure that systems are suitable for their

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intended use, just like any information technology (IT) project that could have an impact on the quality of products, patient safety, or data integrity. R&CA validation, however, can present a difficult task.(2)

### 1.1. Automation:

Automation is the use of machinery to complete most repeatable and significant tasks in the pharmaceutical industry. There has been a faster rate of industry development overall, and the pharmaceutical sectors are no exception.(3) Regulations are becoming more stringent than before (3,4). Automated processes can aid industrial management in adhering to the constantly evolving regulatory requirements. In many industries around the globe, replacing human power with newer technologies has become the norm over the past few decades. Since the newest technologies can always have a significant effect on job opportunities in industries, work unions, and other communities have always been against this tradition.(5) Recently, there has been a noticeable rise in the use of computer vision tools for quality control. As a consequence, these systems might take the place of human inspectors. There have been numerous important advancements as a result of improvements in computer hardware and program technologies.(6) This technology offers more freedom and repeatability for a relatively inexpensive price. This enables increased factory throughput without affecting product quality. These systems are currently being developed as a crucial component of pharmaceutical processing facilities for online and real-time quality assessment.(7)

### 1.2 Automated Quality assurance systems:

#### 1.2.1 High-Quality Risk Management (QRM)

Quality risk management is an organized, systematic, risk-based method of quality management. The method includes the evaluation, communication, control, and review of quality risks. It is particularly important in the pharmaceutical sector because product quality has a significant impact on customer health and safety.(8)

It offers an efficient method for identifying, discovering, objectively evaluating, and regulating possible quality risks. It supports ongoing process and product quality development throughout the product life cycle.(9) Quality by Design (QbD) is a method for managing the life cycle of a product. It is a multipurpose feature designed to increase efficiency and productivity. Hence, minimizing patient risk through understanding. It is a process defined by document and regulatory requirements.(10) Basic design documents include Quality Target Product Profile (QTPP), Summary of Control Strategy, PPQ Reports, Ongoing Process verification Reports (CPV), and Risk assessment Reports.

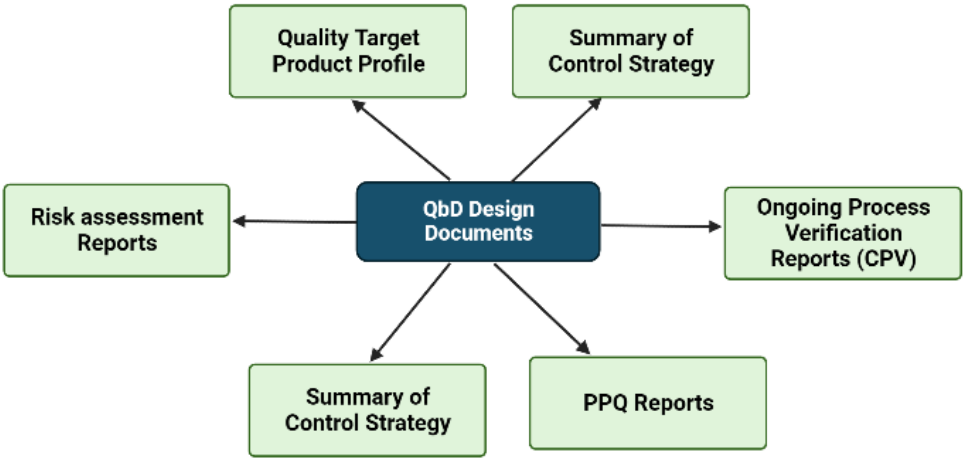


**Figure 1:** QbD Design Documents

This technique is employed to identify a functional design (MODR) for spectrophotometric development and fluorimetric methods for Darunavir measurement, as well as to enhance the standard of products and processes, particularly in the automotive industry.(11–15)

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### 1.2.2 Process Analytical Technology (PAT)

According to the FDA, process analytical technology (PAT) is a method for designing, analyzing, and controlling pharmaceutical manufacturing processes through the measurement of crucial process parameters that have an impact on an active pharmaceutical ingredient's crucial quality characteristics. (API). It includes three main tools:

- Multivariate data acquisition and data analysis tools;
- Process analytical chemistry tools of inline and online analytical instruments include biosensors, spectroscopy, fiber optics, and others;
- Continuous improvement or knowledge management tools.(16)

It is an essential aspect of Pharmaceutical Current Good Manufacturing Practices (CGMPs) for the 21st Century-a Risk-Based Approach, which the FDA declared in August 2002 in an effort to advance and modernise the production of pharmaceuticals. With the ultimate aim of improving the quality of the finished product while also reducing production costs, process analytical technologies (PAT) are used to provide and appreciate timely analysis of key quality parameters, significantly assisting the pharmaceutical industry in the manufacturing sector. Process analytical technologies (PAT) are used to produce suitable finished goods with acceptable quality and purity by using immature material properties, process monitoring, production parameters, and chemical techniques.(17)

- **PAT and Automation**

A PAT system has to evaluate product quality in real-time, without causing restructuration, in order to measure important quality characteristics. To do this, spectral instrumentation like Near Infra-Red (NIR), Raman, UV-Vis, or other kinds of spectrometers are frequently used. One or more multivariate prediction models are needed in order to "calibrate" these devices and transform the spectrum reactions into quality values. These models, which are statistical mathematical operations, can assess the data and forecast the worth of a product's qualitative characteristics in real-time.

The use of "traditional" laboratory analysis is needed to design these calibration models during the development stage; however, once the calibration models have been built, the need for traditional analysis is greatly reduced. Once the models have been built, one can run additional experiments to learn more about the process mechanics, or how the input product and process factors impact product quality. This is where the scientific and logical way of process understanding is put to build the quality of the product with the help of automation.

With this process understanding, it is possible to create control programmes and then manage the process to produce a product that is reliable and of high quality. Compared to conventional process management, this robotic and automated strategy is entirely different. Process completion is when "Quality by Testing" is implemented. Traditional process control is based on experimentally determined control equations and presumed raw material traits. With PAT-based control, quality is guaranteed at the conclusion of the process because the control methods are based on real-time quality metrics that can account for raw material and process variability.(18)

### 1.2.3 Potential of Personalized Medicines

Patients these days are treated in a one-size-fits-all treatment despite having a variety of hereditary variations. Due to their success in treating illnesses, personalised medications have gained recognition in the medical community. Automation is essential for personal medications to become a fact or to realise their full potential. Drug discovery may be more effective and faster with more advanced methods. It is possible to use a variety of current computational technologies to conduct numerous experiments to determine the ideal drug mixture and dose. It is challenging to develop personalised medicines in a world with such a diverse populace, and with the current traditional techniques, the concept of personalised medicines can be viewed as impractical. As a result, the world of medicine can benefit greatly from advancements in technology. The potential of modern medical care can be focused to achieve optimum effectiveness and assist outpatients in remote regions of the globe in receiving the finest medical care. For instance, everyone in the world is distinct due to diverse genetics. Because of this, the medical care they need will also differ. Automated systems can manage complicated genetic

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data and assist the R&D section in developing effective therapy options. Grouping those with comparable genetics will be the first step, after which the production of medicines just for them will be the main goal. With further technological advancements, specific medications for people could be created based on how well they would respond to the drugs. Depending on the quantity needed, the production methods can be readily optimized to produce drugs in a variety of concentrations. Because of the way conventional and contemporary production processes are set up, different medication concentrations cannot be produced as and when needed.(4,19) At this point, after a production cycle is started, it must finish before being approved for the start of a new batch with a different concentration. Automated equipment will be efficient in regulating process variables to create medicines with the necessary concentration in the required amounts as and when needed. Therefore, the production of personalised medications for patients around the world is the only application for this specific mechanisation benefit.(4) Another example which can be considered is Invetech and Argos Therapeutics, two biopharmaceutical partners, develop an automatic manufacturing system for personalised immunotherapy based on Argos' Arcelis Technology, employing two robotic limbs and five axles. Dendritic cells are created on cell processing machinery using ribonucleic acid (mRNA) taken from a patient's tumour as a marker. Mobile devices automate the treatment of white blood cells while they are being produced, regulating dendritic cell development and growth. These cells create the necessary proteins, which when administered to the patient will trigger the production of killer T-cells by the patient's immune system that will specifically target metastatic cells.(20,21)

### 1.2.4 Automated Filling, Packing and Labelling

In each of the various pharmaceutical sectors, millions of dosage forms are manufactured, and before each one leaves the facility, it must be thoroughly inspected for safety. Many manufacturers deal with a variety of tasks using automatic systems, including filling capsules, vials, and containers, inspecting dosage forms and their corresponding containers, etc. All the automated procedures are under the control of a single machine. The centralized computers effectively keep track of all the crucial process variables to maintain the consistency of product quality. Automated filling devices are also efficient at filling capsules, containers, and bottles. They have the ability to inspect the fill level of vials and containers and can successfully reject any goods that haven't been filled. Such automated systems can be used to carry out such tasks in a large-scale manufacturing centre. The automatic systems are so effective that they practically eliminate the QA/QC department's problem. Since information about the batches is continuously logged in the computer memory, all the batches with noncompliance problems can be readily recognised.(4,22) The packing system employs various equipment types for labelling, shrinkage, animation, wrapping, closing, case and tray construction, assembly, cooling and drying, feeding, pouring, picking, and installation (robotic systems), cleaning and disinfection, as well as diagnostic and diagnostic tools. The process of packaging involves a variety of techniques. Theoretical fixed atmosphere packing (MAP) reduces oxygen levels and consumes carbon dioxide levels. The sophisticated wrapping that she is in should be used by those with sharp sensibilities.(21)

Pathogen and contaminant identification and monitoring are used in packaging that is based on nanotechnology. Fighting fraudulent medicine goods requires anti-fraud technology.(23–25)

Anti-Counterfeit Technologies can be used in the following three ways:

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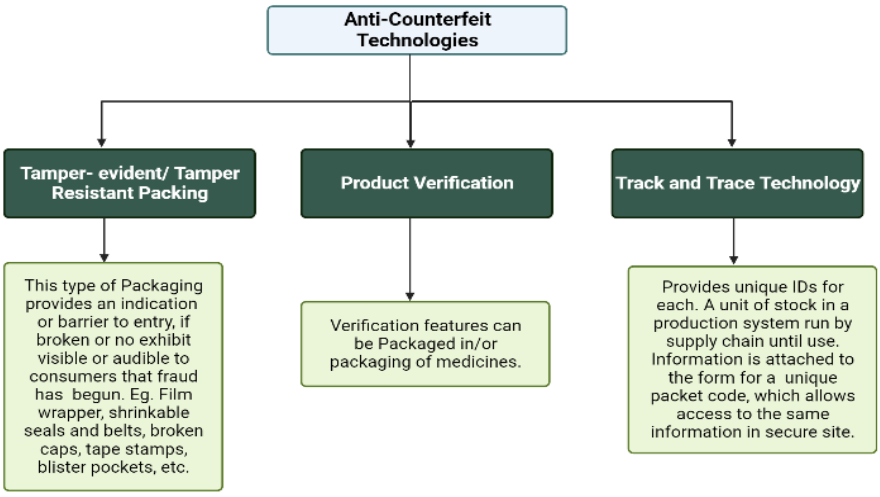


**Figure 2:** Anti-Counterfeit Technologies(26,27)

### 1.2.5 Digitalization and Automation in Quality Control and Quality Assurance Systems

When it comes to quality assurance and quality control, quality management is fundamental. Checks on the market and experiments show that it is a successful procedure, which is supported by manufacturers of pharmaceutical products. The International Conference on Harmonization (ICH) Q10 model, which is founded on the International Organization for Standardization (ISO) Quality principles, including Good Manufacturing Practices (GMP) with frequently used to refer to pharmaceutical quality control. International Conference on Harmonization (ICH) "Q9 Quality Risk Management" and the International Conference on Consensus (ICH) "Q8 Drug Development".(28)

The International Conference on Harmonization (ICH) Q10 has three Main objectives

• Achieving product fulfillment.

• Establish and maintain a control environment

• Facilitate further development.(29)

### 1.2.5 Automated Continuous Manufacturing

Until there is a technical malfunction, industrial robots can operate constantly for very extended periods of time. It only requires a constant electricity source and routine upkeep. As a result, these ongoing procedures can help industries financially. There are certain limitations, such as the employees' physical and emotional health situations, when it comes to requiring people to work extended hours. Machines are exempt from this, so there is no issue. All the equipment will operate smoothly and without any hiccups for a very long time with appropriate upkeep. This could be immediately blamed for the jobless rate. The working society would not want this to occur, so manufacturers and authorities will need to investigate this. The industries may be impacted by this. Automated continuous and uninterrupted manufacturing can be seen as an advantage in manufacturing.(30)

### 1.2.6 Application of Automation and Robotics in Laboratory

In the pharmaceutical sector, robotics is widely used for drug research, drug screening, different manufacturing procedures, etc. Most analytical tools can be mechanized, which simplifies the laborious analytical processes. The QC department's burden is greatly decreased. when there is greater output. The automated systems can step in to assist if the analytical section is unable to receive its findings on schedule. Robotics and automated systems are incorporated, which makes prompt sampling and testing of all the quantities possible. There would be very little risk of losing any batches thanks to the ongoing testing. The analytical tools are developed in a way that ensures proper handling or storage of all test findings. Since most systems never change the data, they adhere to the FDA's rules for keeping data security. For instance, an automated HPLC system would be able to gather the samples, analyse them, and send the findings to the central computer instantly. A QC team's participation in this situation is not required. In this manner, the

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laboratory systems of the pharmaceutical sectors can greatly benefit from automation and automated systems.(31)

### 1.2.7 Automatic Control

At each stage of the process, a variety of integrated sensors are accessible to detect the factors, keeping the system under control and reducing mistakes. The automated systems are so advanced that they can even be set to close or start recording if a group is found to be non-compliant. The sensors are positioned all over the automated systems so that they can be used to constantly watch the process variables. On the other hand, this data is sent to the computer, which examines it and then decides important issues like rejecting groups or closing down the system. Human involvement will be minimal in such circumstances because all that is required is that the various systems engaged function correctly. The staff would have an advantage in adjusting to automation if they had a thorough grasp of the automated processes.(32)

The WFI systems, pure steam systems, air handling units, and production systems are among the essential systems that some sectors incorporate. This has the benefit of allowing for the control of all quality-related attributes. The staff is informed in the event that any kind of problem arises with any of the tools. In the production of parenteral, etc., where great care must be taken because even a small deviation from the necessary conditions has an effect on the product's quality, such combined systems are crucial.(33)

## 2. Industry Examples:

### 2.1 PAT Provides In-Situ Analysis in Integrated Continuous Manufacturing System

The batch-wise production method that is widely employed in the pharmaceutical sector is fraught with challenges, from technological drawbacks to problems with quality control to supply chain weaknesses. Recently, interest has grown in integrated continuous manufacturing (ICM), which employs a number of integrated unit processes to streamline output. Model-based management systems with a variety of Process Analytical Technology (PAT) features are used by ICM systems. The design and development of an end-to-end ICM pilot manufacturing facility that makes tablets of a commercially available generic medication as well as active pharmaceutical ingredients (API) are described in this study.

In four of the six processing units, PAT probes were installed to provide real-time testing and confirm conformance to quality goals. The chord length distribution (CLD), reactant concentration, and reaction output were measured in the reactive crystallizer using ParticleTrack (FBRM) and ReactIR in-situ sensors. To ascertain the distribution of API crystal chord lengths and the number of reactants and solvents in the slurry, FBRM, and IR were equally positioned in the resuspension unit. Other PATs in the system included near-IR sensors to assess API content consistency in the polymer melt and measure residual solvent amounts following drum drying. In two distinct locations, Raman probes helped determine the crystal form and crystallinity, and after drying, an API particle size distribution was determined using a laser diffraction device.

The prototype plant's success in producing API and tablets to specification shows how real-time PAT can be used with integrated system management to increase productivity, minimize energy usage, cut down on inventory levels and lead times, and lower capital investment. (34)

### 2.2 Data-Rich Experiments Using Automated Lab Reactors and In-Situ Sampling

This study makes a strong case for the use of data-rich experimentation (DRE) to completely characterize reactions in later phases of pharmaceutical development while minimizing the impact of possibly conflicting goals. To precisely describe responses and processes, DRE makes use of technologies currently in use that offers comprehensive, real-time analytical data combined with modeling tools. Since reactions frequently develop non-linearly, gathering time-referenced analysis data over the course of a trial offers a more precise picture of reaction development. Automated, in-situ sampling reduces the weight of the experiment, making it simple for researchers to gather this information and increase the quantity of knowledge obtained from each experiment.

In this research, a cyclization reaction's late-stage process characterization studies were supported by an automatic benchtop reactor (EasyMax 102 synthesis workstation) and companion autosampler (EasySampler 1210). A 24-full factorial design of experiment (DoE) was used to organize the data-rich

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tests, with 12 reaction samples being collected at regular times throughout each 22-hour trial. While EasySampler automatically removed, quenched, and diluted reaction samples for HPLC analysis, EasyMax automatically controlled reactor parameters. The information was then used to simulate time-dependent competing conditions and trade-offs required for obtaining high yield and reaction stability, as well as to create dynamic response surfaces for each response variable.(35–37)

### 2.3 Tamper Evident Packaging:

- **Deep Learning and Machine Vision Foil Inspection Solution**

This application demonstrates how analytical machine vision and deep learning technologies can be used to create and effectively implement a hybrid surveillance system in the field. The system's assets are successfully combined to achieve high detection accuracy for defect traits, whether they are clearly specified or not. One such method for various goods was successfully implemented in many locations. The technology correctly identified major seal defects while maintaining a low false failure rate. A key area for process optimization was identifying differences in cap torque based on seal integrity and completeness. Using the ongoing process data, the cap torque was adjusted to produce better closures and reduce product failures.

Using thermal imaging, liquid on the lid and container was discovered as well, which could cause problems with subsequent processes like labeling. The general level of excellence increased as a consequence. Additionally, even rare defects like fractured caps that would have gone undetected were successfully detected by the algorithm.

In order to considerably better a critical manufacturing process, this programme deftly combines cutting-edge imaging techniques and analytical tools. It is crucial to employ tried-and-true industrial thermal imagery methods as well as a unique fusion of deep learning and discrete vision tools. The result is an extensive solution with wide industrial utility.(37)

- **Hybrid Imaging**

All pharmaceutical OTC goods are mandatory to come in in tamper-evident packing, as per FDA regulations following a malicious product contamination incident in the 1980s. To help guarantee a product's excellence, food and beverage makers have followed that example. The development of a full and robust seal is impacted by capping processes, resulting in under- or damaged seals that are concealed by a plastic cover.

The seal is heated by induction, which causes it to adhere to the container rim. The ultimate closure quality greatly depends on the foil temperature. In this instance, the plastic cover post-induction heating procedure allowed a thermal camera to capture an image of the foil's thermal signature. The thermal images can plainly show some flaws, but others are more ambiguous and challenging to measure. The effective examination method uses "hybrid" imaging analysis, which blends analytical vision tools with deep learning.

The system, which was implemented in different manufacturing facilities, correctly detected significant seal flaws while minimizing the false failure rate. Better cap torquing was achieved as a result of the identification of critical process development areas using defect seal data that had been preserved. Lower reject rates and better seal quality were the outcomes of this.[38]

## 3. Roles and Responsibilities of Quality Assurance Department After Implementation of Automation in Pharmaceutical Industry:

The quality assurance department will have to adapt to the most recent technological advancements. The life of quality assurance employees has undoubtedly become simpler than it used to be with all the most recent technologies accessible for guaranteeing the standard of goods and procedures. The personnel must have enough new updated skills to keep up with the automated systems.

### 3.1 Digital Data Handling and Interpretation

In an automated world, all data is digital, so personnel need to have the necessary skills to manage and understand it. The process of analyzing material to draw a well-informed assessment is known as information interpretation. Data are given significance through interpretation, which also establishes the implications of the material. It goes without saying that analysis is important, which is why it must be done properly.

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### 3.2 Automated Data Collection

Automation tools can be used to collect data from various networks and systems, including Enterprise Resource Planning (ERP) systems, testing apparatus, and production equipment. The standard of pharmaceutical products can be improved by looking at this data's trends and patterns.

### 3.3 Automation and Quality Control

To ensure that the products are produced in accordance with quality standards, the production process can be monitored and controlled using automation tools. Automated quality control systems have the ability to identify errors, and detect the defects in real-time, enabling prompt correction.

### 3.4 Electronic Batch Records

The manufacturing process, including each stage involved in the manufacturing of pharmaceutical products, is documented using electronic batch records (EBRs). EBR development and administration can be automated, reducing the possibility of mistakes and assuring legal compliance.

### 3.5 Designing better Automated systems

The personnel must be ready and educated enough to create effective, trouble-free automatic systems. The QA team will be able to place the required probes and sensors needed to watch the same since they have sufficient knowledge of the key quality characteristics. The experts working on developing the automated systems will require their expertise. Additionally, having a thorough understanding of the procedure can help in designing the tools in a specific manner to ensure that the manufacturing processes go smoothly.(38)

### 3.6 Confidentiality

The security of these data is a concern as more and more data are becoming computerised. Because the automated systems are up to date with legal requirements, the data is kept in a way that prevents its transfer without the appropriate permission. The relevant personnel is properly taught to prevent them from taking any actions that could result in a server data leak. Therefore, concerns about keeping data confidentiality after adopting automated systems can be postponed.(4)

### 3.7 Data Integrity

Data integrity questions can come up in the same way that data security questions can. The makers are responsible for ensuring that the automated methods used comply with 21 CFR PART 11. It outlines the significance and specifications for computerised data capture in the food and pharmaceutical sectors. Data integrity is a major area of worry for the examiners during quality checks. The automated system will keep data in the appropriate computers, but this will not be sufficient on its own. All these data must be accessible by a small group of people who are also in charge of managing the data with care. The information should not be accessible to or editable by anyone from the business. The information should not be accessible to or editable by anyone from the business. Every system that complies with CFR 21 Part 11 is even able to keep track of how frequently data is updated or altered. Since CFR compliant technology would be used, data integrity would not be an issue; however, it is up to the QA management to ensure that the data are only available to authorized staff. The QA staff engaged in the same must have completed CFR 21 part 11 instructions. As a result, there will be no possibility of data integrity in a completely automated factory.(38)

Since most modern tools gather data digitally, all the industry's paperwork will become unnecessary. Digital data collection methods will need to be taught to the QA division.

The amount of work required by staff will be significantly decreased once all the paperwork is gone because it will be simpler to maintain comprehensive documentation.

Automation itself may not have a significant impact on the roles of QA personnel in the pharmaceutical industries, but there is a good chance that in the near future, as technologies advance and different industrial revolutions occur, there will be less of a need for manual QA personnel.

## 4. Conclusion:

The Quality Assurance systems in the pharmaceutical manufacturing sector have been experiencing significant digitalization and automation in recent

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years. The drive to enhance the effectiveness, timeliness, and caliber of the drug manufacturing and distribution processes is what prompts this trend. Processes are being streamlined and mistake rates are being decreased by using sophisticated statistical tools, sensors, and robotic technologies. Recent technologies like robotics, automatic control, development of personalized medicines, automated filling packing and labelling, the development and impact of automation with the tools of Quality by Design (QbD) and Process Analytical Technology (PAT) are playing a major role in the expansion and evolution of technology in pharmaceutical manufacturing. Furthermore, there are so many current examples that show the growth of automation in this sector. These examples include tamper-evident packaging, in situ analysis in continuous manufacturing and data-rich experiments. The pharmaceutical industry can collect and analyze a lot of data from different sources by means of digitalization and automation, which can be used to speed up the drug development process and enhance patient results. Data analytics, for instance, can be used to track patient safety and drug effectiveness as well as identify patient groups most likely to profit from a given medication.

Digitalization and automation are also being used to enhance telemedicine, personalized medicine, electronic health records, and other facets of the healthcare system in addition to medication creation and delivery. The development of automation in Quality Assurance systems is developing onto a stage that ultimately aids in the right delivery of healthcare.

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