

A review on implementation of automation in the pharmaceutical industries

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Abstract

Automation is the use of various control systems in industries with little to no human intervention to carry out a variety of tasks. In recent years, automation has migrated to the pharmaceutical sector. Production, packing, labeling, and warehousing departments have all used automation. The use of automated equipment has made the production of customized medications a reality. Using the newest technologies has also had an impact on the R&D sector. The traditional duties of the QA department were restricted to creating SOPs, conducting audits, qualifying, and validating processes and equipment. The deployment of automated technology in the pharmaceutical sector and its effects on the department responsible for pharmaceutical quality assurance are the main topics of this research. The Raman probe and other subjects are covered in this article. Production, packing, labeling, and warehousing departments have all used automation. After the introduction of automated machinery, the creation of customized medications has come to pass. Thus, these systems might be able to take the place of human inspectors. With this technology, you have more flexibility and repeatability for less money.

Keywords: Automation; Packaging; Robotics; Health care system

1. Introduction

Automation means the use of machines and equipments for performing physical and mental operations in a production process in place of human beings¹⁻⁷. Pharmaceutical automation involves the mechanical process of handling materials, distributing medications and manufacturing, packing formulations in industries. Organization learnt the importance of protecting the validity of data generated and in a regulated environment that deviations from process should be investigated and removed. The micro therapeutic research lab incident in March 2017 highlighted the necessity for pharmaceutical organization to ensure the data associated with their organization including data produced by a third party is complaint with industry regulations.

Automation means self-dedicated it is the use of control system such as a computer to control industrial machinery and process reducing the human intervention. Automation greatly reduces the need for human sensor and mental requirements as well as process and System can also be automated⁸⁻⁹.

Eg. Telephone operators have been replaced largely by automated telephone switchboard and answering machine.

Automation means the use of machines and equipments for performing physical and mental operations in a production process in place of human beings.

- It is a system of doing work Where material handling production process and product d designs are integrated through mechanism of thoughts and efforts to achieve a set regulating and controlling system.

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- It is the result of industrialisation driven by the need to increase productivity and to achieve consistent quality products.
- It can be done at various levels of manufacturing system.
- Handling of raw materials semi-finished goods or finished goods
- During production process efficient machines are used.
- Inspections and quality control operations.
- System and operator periodically measure the temperature of liquid. if for example,if the temperature is below the desired value he increases the steam flow by operating the wall slightly. For automatically controlled system a temperature sensitive device is used to produce a signal proportional to the measure the temperature. This signal is fed to controller which compares it with preset desired value¹⁰⁻¹⁵. If the difference exit the controller changes the opening of steam control valve to correct the temperature.

2. What is automation and how it is used in Pharmaceutical Industries

Automation is implementation of machines to carry out most of the repeatable and important functions in pharmaceutical industries for performing physical and mental operations in a production process in a place of human beings¹⁶⁻²⁴. The industries have been developing at a greater pace and in the case of pharmaceutical industries it is nothing different. The regulatory requirements are getting thicker than before. Introduction of machines in to industries can actually save the time. Automated functions can help Industrial Management in keeping up with the ever changing regulatory constraints. Automation greatly reduces the need for human sensor.

The tradition of implementing newer technology that replace human power has been taking place in various industries for various purpose across the world for many years.Now because of this human replacement some worker unions and other communities have always been against to this tradition as the latest technologies can always have a major impact on job opportunities in industries.

Automation is a set of Technologies that result in the operations of Machines and Systems without significant human intervention and achieves performance superior to manual operation.

Lately the use of computer vision systems for Quality assurance purpose has noticeably increased.It is the result that human inspectors could be replaced by the systems.There is advancement in both computer hardware and software.

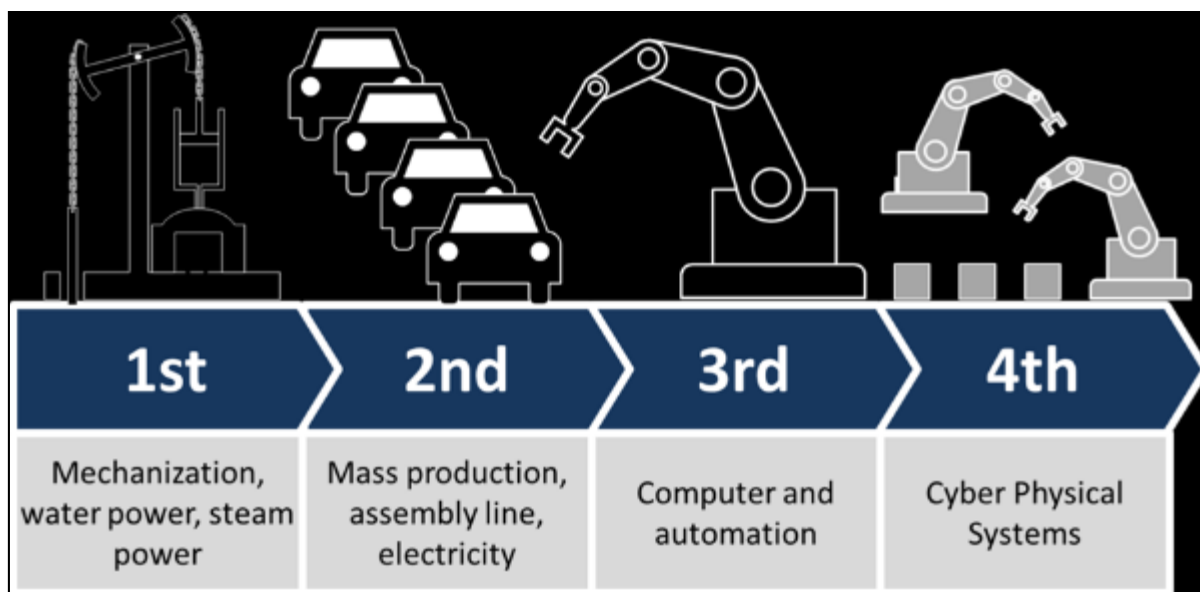


Figure 1 Automation used in Pharmaceutical Industries four stages of manufacturing

The advance in both computer hardware and software Technologies has led to many significant advances.This technology provides a greater level of flexibility and repeatability at relatively low cost. This permits higher plants throughout without compromising with the quality of products²⁵⁻³¹. Currently these systems are being developed as an integral part of pharmaceutical processing plants for online and real-time quality evaluation.

Pharmaceutical companies have been integrating automation into specific process like drug development, sterilization, anti-counterfeiting and more.

The main objective of process automation is to improve a company's workflow. With automation we can reduce costs, time and waste as well as increase productivity³²⁻³³, reduce mistake and control all the processes of the business in real time.



Figure 2 Automation launches an industrious new era in Pharmaceutical industries

2.1. Importance

Automation is the use of different control technologies in sectors with minimal or decreased human interference to operate a range of procedures.

Automation has made its way to the pharmaceutical industries in the recent past. Automation has been implemented in production, labelling and warehousing departments. Production of personalized medicines has become a reality after implementing automated machines. The R&D sector has also been affected by incorporating the latest technologies.

The conventional functions of quality assurance department were limited to preparing SOPs, carrying out audits, qualification and validation of equipments and process. This review focuses on the implementation of automated technologies in pharmaceutical industries and the impact it has had on the Pharmaceutical Quality Assurance department.

2.2. Efficiency

Robots can perform repetitive tasks at greater speed than human workers alone. Automated solutions can also accommodate 24-hour production cycles and are typically easy to implement.

2.3. Accuracy

Automated equipment doesn't need a learning curve to master weighing, blending and tableting of solids or the stirring and filling of liquids. Automation eliminates human error and significantly reduces product defects.

2.4. Visibility

Automation solution facilitate end to end tracking from material Sourcing through to its final delivery electronic batch records, RFID Technologies and workflow management can help in identifying in the efficiencies and correct them anywhere in the supply chain.

2.5. Analytics

Advanced data and analytics can be used to identify market Trends and facilitate accurate forecasting. Analytics can also be implemented to improve processes and predict the effectiveness of potential changes.

2.6. Reduced contamination

With less human interaction during production and handling the risk of product contamination is significantly lessened.

2.7. Return on investment

Automated systems provide energy savings improved product quality and faster production. These positive impacts on the bottom line ensure that the upfront costs of automation Technology will be returned.

2.8. Automation in packing

An increase in the use of robots is particularly significant in dispensing, sorting, kit assemble and light machine trending. The advantages include greater speed and accuracy, more flexibility and more reliability. As the use of robotics in the pharmaceutical industry increases rapidly it's important to consider the benefits of the latest technologies from manufacturers researchers and scientists.

2.9. Filling inspection and packing:

The pharmaceutical industry produces millions of tablet each week all of which must be carefully scrutinized before being packed and shipped to distributors. During this inspection drug manufacturers must ensure that the correct amount of medication with exact chemical composition and weight are precisely packed into the appropriate containers.

Most Pharmaceutical packaging systems use automation to manage bottle orientation, capping, labelling and collation system. Automation of packing also requires a system that monitors the operation on the supervisory level checking for low hopper levels, fallen Bottles and low level supplies.

Until recently, Raman spectroscopy was not widely applied in the pharmaceutical industry. However in the last few years, developments within the industry coupled with improvements in Raman instrumentation have generated increasing interest in the technology. Raman spectroscopy measures the molecular vibration and rotational energy changes of each tablet, ensuring their chemical compounds are corrected before distribution.

This is just one stage of Pharmaceutical inspection. Automation and machine learning is also applied to ensure that products are packed in the correct bottles and boxes with the correct labelling affixed.

2.10. Personalized medicines

Despite differences in genetics, age and gender, most people receive identical medical treatment when diagnosed with the same condition. This is because even the world's best scientist and doctors don't fully understand how individuals develop diseases and respond to treatments. This has resulted in a one-size-fits-all approach to medicine that is based on broad population averages.

More recently the pharmaceutical industry has seen the advent of personalized medicine bringing the industry closer to more precise, predictable health care that is customised to the individual patient powered by our increased understanding of genetics and genomics, more doctors are providing better disease prevention, more accurate diagnosis, safer for drug prescriptions and more effective treatments.

2.11. Robotics in Laboratories

The pharmaceutical industry is increasingly making use of robotic to automate a specific process in drug development, including drug screening anti-counterfeiting and manufacturing task. Today processes such as nuclear Magnetic resonance and high performance liquid chromatography can have sample preparation carried out by robotic arms.

Additionally structural protein analysis can be done by automatically using a combination of NMR and x-ray crystallography. X-ray crystallography is an important technique used in drug Discovery and involves the detailed analysis of crystal structure of protein ligand complexes. This allows for the study of specific interactions between a particular drug and its protein target at the atomic level. This process often takes hundreds to thousands of experiments to create a protein crystal suitable for x-ray crystallography. An automated micropipette machine can allow nearly a million different crystals to be created at once and analyzed x-ray crystallography.

3. Pharmaceutical applications

There are a variety of industry specific applications that greatly benefit from the use of automation technology. Here are some examples

- Processing system (dry granulation, powder blending, high shear/wet granulation, Fluid bed granulation, hot melt extrusion, drying, milling, micronisation)
- Liquid dosing (used in tablet manufacturing)
- Tablet compression and coating
- Encapsulation (solid and liquid dosages)
- RFID labelling (product movement monitoring, quality management)
- Tracking and traceability counterfeit prevention
- Drug delivery systems
- Filling, inspection and packing
- Conveyor and sortation systems (high speed bottle filling, inspection, sorting and grouping, rejection and transferring)
- High investment in general purpose equipment that can be reprogrammed.
- Ability to cope with product variety by reprogramming the equipment.
- Suited to batch production of different product and part styles.
- Lost production time to reprogram and change the physical setup
- Lower production rates than fixed automation.
- Capability to change the sequence of operations through reprogramming to accommodate different product configurations.

3.1. Typical features:

- High investment in Programmable equipment
- Lower production rates than fixed automation
- Flexibility to deal with variations and changes in product configuration.
- Most suitable for batch production
- Physical setup and past programs must be changed between batches
- Efficient use of equipment and manpower
- Increased effectiveness
- Lower costs and high ROI
- Seamless customer experience
- Enhanced cyber security
- Focus critical issues rather than on man work.
- Automation can also be used in the testing of software applications to a process called test automation

In this process computers are programmed with special scripts usually computer programs to run the same test on software that a human would have to do manually.

Test automation provides many of the same advantages as in Industrial Automation including labour reduction, repeatability and waste reduction.

Automobile industry where highly integrated transfer lines are used to perform machine operations on engine and transmission components. The economic of fixed automation is such that the cost of special equipment can be divided over a large number of units produced the resulting unit cost can be lower relative to alternative methods of production.

3.2. Advantages

3.2.1. Reduces cost

One of the top advantage of automation is reduction in manufacturing cost. Instead of having a Floor full of workers you can now have just a few supervisors and have robots to do the job. The initial investment will be a little high, but then the operation cost will reduce, which will be beneficial in the long run. Your expenses will only include maintenance, repairs, and energy. Artificial intelligence and data and Analytics have also helped reduce the production costs by providing insights and information to make the right production decisions.

3.2.2. Increases productivity

Automated productivity lines consists of work stations connected by transfer lines. Each work station takes care of one part of the product process. Robotic process automation can be used to mimic many human actions. The system can be configured to login to applications and take care of administrative work related to the business process. Robot can also be used on the production floor to handle raw material, clean equipment, operate high pressure system and a lot more. For example: In an automobile manufacturing unit auto components are cut and shaped into different press working stations. All the parts are then brought together to one place where a robot puts them together to build the vehicle. Process automation greatly speed up the production process.

3.2.3. Enhances quality

Industrial Automation also helps to increase and maintain consistent quality of the output. In manual process the error rate is around 1 to 1.15%. On the other hand automated machines in the manufacturing industry have an error rate that is as low as 0.00001%. Adaptive control and monitoring helps to check every level of manufacturing process to reduce the margin of errors.

3.2.4. Industrial safety

Huge benefit of automation is has improved safety at the workplace. Using robots for loading and unloading materials (or) transferring huge machine parts has reduced the risk of accidents. Industrial Automation also keep workers from going too close to the assemble line thereby improving safety. Thermal sensors continually check the temperature in the production area. In case if they identify any spike in temperature that the sensors will send an alert, immediately precautions can be taken to ensure the safety of everyone on the production floor.

3.2.5. Accurate results

Data automation is based on accurate data integration and connectivity. When accurate information is used in the production process you can be assured of precise results. Artificial Intelligence and machine learning solutions help you get detailed data that can be analysed using data analytic tools to get accurate information.

Deep learning algorithms are used to build self healing digital grids that use data analytics and intelligent energy forecast to manage energy generation. Machine learning app have been used to build a self learning quality control system for assembly line. Machine learning and artificial intelligence solutions are scalable and self learning. Both these features ensure that the automated systems deliver accurate results every time without fail.

3.2.6. Better working conditions and value addition

One of the best benefits of Industrial Automation is that it ensures consistent production and results. Computers robots and automated machine work at steady pace. It allows you to have a better grip on the production rate.

Automation not only deliver consistent production but also consistent quality. In a flexible manufacturing system the tools processing machines and material handling robots are connected and controlled by a central computer system. Once the entire process is computed the production goes on continuously without any drop in the pace or the result.

Flexible automation process let you design or reconfigure a machine to suit a different product measurements or new product. In tradition production process it may take days or weeks to train employees. Another problem is that it can be difficult for workers to get used to the new process which could cause production delays or quality issues. On the other hand reprogramming a machine or a reboot is easier and takes up less time plus after a few trial you will be ready to go into full production.

Automation frees up employees from working on tedious and repetitive task. This means that they can focus on other areas where they can do a value-add. They can help with research and process development also workers can effectively use robotic tools and machines to deliver faster and quicker result. Employees also experience the feel good factor of doing positive..

3.2.7. Industrial communication:

Without industrial communication, industrial automation can be near impossible. The communication system helps monitor and operate entire production lines, manage power distribution and control machines. The most popular protocol for industrial communication are fieldbus, profibus, ether cat, etherNet/Ip.

Industrial communication allows for faster data analysis and real time decision making.

3.2.8. Monitoring and predictive maintenance:

A huge benefit of industrial automation is that it helps in monitoring and predictive maintenance. Production lines and production floor can be continuously monitored using sensors. These sensors track temperature, acoustics, time-frequency, oil pressure and other parameters related to the production process. If the sensors detect any change in these parameters they will immediately send an alert, when the alert is received the technicians can immediately identify the cause for the change. If it is noted that the changes in parameter may cause equipment problems or issues in the production process, then immediate services or repairs can be done. Automation can help identify possible issues before they blow up into huge problems that can result in production downtime.

3.2.9. Equipment monitoring

An automated equipment monitoring system helps to observe the working condition of all the equipment in the manufacturing unit. Sensors, cameras and network can be used to observe the equipment from a far. The monitoring system also helps diagnosis any issues in the equipment and do the necessary repairs and services. This automated solution can be effectively used in petrochemical plants, manufacturing units and other industries where large and complex machines are used. The automated system enhances safety, reduces the number of operators on the floor and improve machine performance and life span.

3.3. Disadvantages of automation

3.3.1. Worker displacement

The most significant disadvantage of automation is the displacement of human labour. This is because a computerized task can be executed faster with greater accuracy than that can be achieved by a human

For example.

Disney World has been using self driving Cars for years to transport guests around the park many people are afraid that this will result in a few hour jobs for human.

3.3.2. Needs large capital expenditure

Automation has been a staple of industry for many decades. However there are some unintended consequences that manufacturers have to take into account before making the switch to automation. One of these consequences is the need for large capital expenditure to maintain and service automated systems. These systems are also more susceptible to cyber-attacks than manual systems would be, which can leave companies vulnerable if their infrastructure is not properly protected.

3.3.3. Can become redundant

Automation is a convenient solution to many problems. However this convenience can be redundant in situations where change is introduced that requires the automation to be modified. These types of changes will only serve to increase the workload of the company and might cost them precious time and resources.

3.3.4. Still requires human intervention:

While the overall benefits of automation have been proven there are still certain tasks that requires human intervention. We shall consider the above example of self driving cars. These machines can detect most obstacles on the road and can

be programmed to stop. However some specific conditions can cause these machines to misinterpret information and produce undesire effects such as driving through a barrier that is not clearly visible to the car sensor.

4. Conclusion

Automation would theoretically offer several benefits to the pharmaceutical sectors, including increased productivity for technologists, lower radiation exposure, and improved overall image quality. The effectiveness of the QA department will be improved by using computer-based QA algorithms to identify and quantify QA defects, obtaining QA data to develop global QA norms, and creating structured databases. Considering the near term and long term impact of automation, the paper trails in the industries will vanish and the drug development will move to the virtual world, this on the other side benefits the QA department as the window for making errors and overseeing deficiencies will get narrower. QA department will play a crucial role in developing automated technologies as their expert knowledge will be needed by the engineers to manufacture an efficient automated system that does not affect the product quality.

Compliance with ethical standards

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Disclosure of conflict of interest

The authors declare that they have no conflict interests.

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