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Review

Role of Atomization in Pharmaceutical Industries

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Abstract:

Automating processes involves various control systems in industries with little to no human intervention to complete a variety of activities. The pharmaceutical industry has seen an increase in automation recently. Departments involved in manufacturing, packaging, labeling, and storage have all used automation. Manufacturing of specialized drugs is now possible thanks to automated equipment. Using the most recent technologies has had an impact on R&D as well. The SOP creation, auditing, qualifying, and equipment validation were the only conventional responsibilities of the QA department. The main focus of this study is relating to the use of automated technology in the pharmaceutical industry and how it affects the division in charge of pharmaceutical quality assurance. The Raman probe and other subjects are covered in this article. sDepartments involved in manufacturing, packaging, labeling, and storage have all used automation. The development of personalized pharmaceuticals has occurred as a result of the development of robotic devices. Therefore, these systems might be able to replace human inspectors. You can achieve greater accuracy and customization for a lower cost with this kind of technology.

Keywords: *Automation, Qualification, Quality assurance (QA), Research and development (R&D), Validation.*

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Introduction:

Automation is the substitution of machines and equipment for humans in a production process to carry out physical and mental tasksh1–7. Pharmaceutical automation refers to the mechanical handling, distribution, and packaging of ingredients in various industrial settings. Organizations have discovered the value of safeguarding the accuracy of data produced and the need to identify and correct process abnormalities in regulated environments. Automation is the use of an auto- mated system, such as a computer, to operate industrial machinery and processes while minimizing the need for human involvement. Automation means self-dedicated. Human sensor and mental requirements are significantly reduced by automation, and processes and systems can also be automated.

Automation is the employment of machinery and technology in place of employees to carry out mentally and physically demanding tasks throughout a production process:

- 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.
- It is a final result of industrialization, which was motivated by the need to boost production and produce items of consistently superior quality.
- It is possible at different manufacturing system levels.
- Working with raw materials, semi-finished products, and completed items.
- Machines that are productive are employed during the manufacturing process.
- Processes for quality control and inspection.

What is automation?

Automation is the use of technology to execute the majority of repeatable and significant tasks in pharmaceutical manufacturing so that they can undertake mentally as well as physically processes throughout a production process instead of humans. The pharmaceutical industries are not any exception to the quicker pace of growth within industries. Regulations are becoming more intricate than they once were. Industries can actually save time by introducing machines. Automated procedures can aid Industrial Management meet given the constant change legal requirements. Human sensors are much less necessary thanks to automation. In numerous businesses and for numerous reasons around the world, it has become tradition to replace workers with newer technology. Now, because of this human replacement, certain labor unions and other groups have always been against this practice because new technology capable of having a major effect on employment chances in industries. Automation is a group of technologies that allows machines and systems to operate with little or no human involvement and to perform better than manual operation. More and more often now, control of quality uses computer vision technologies. Systems might eventually replace inspectors with humans as a result.

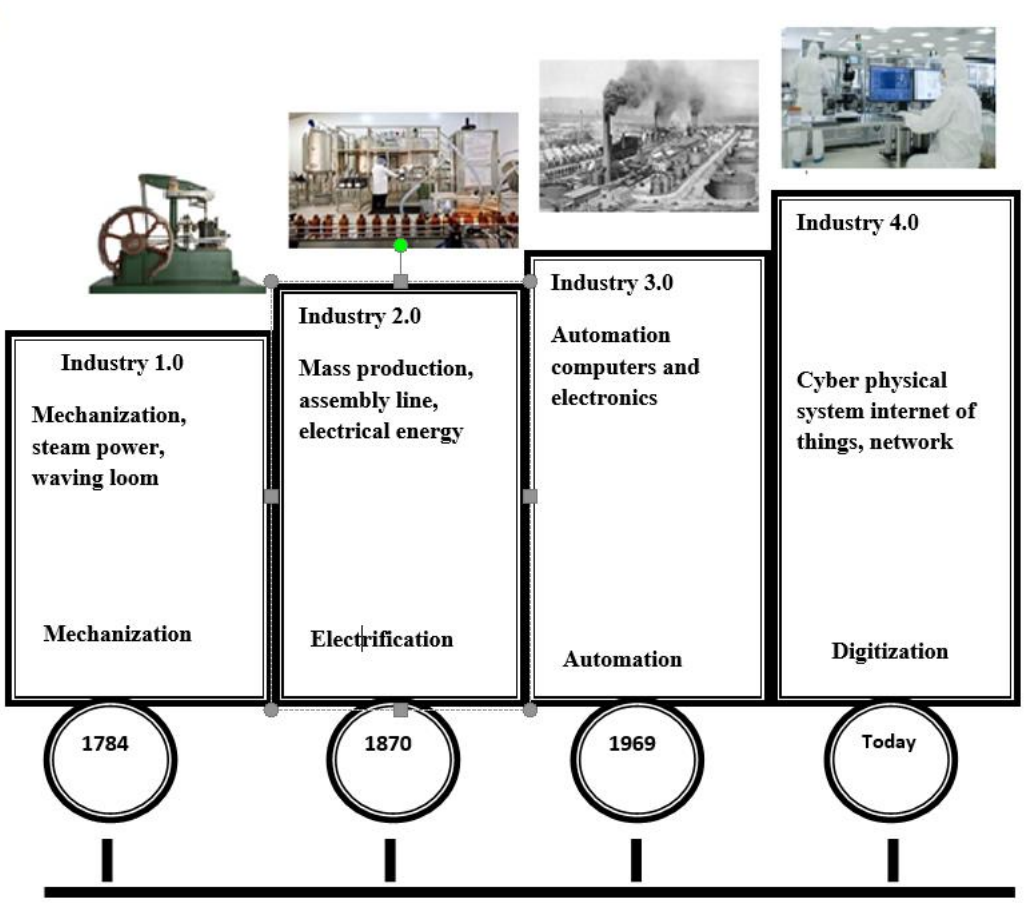


Figure 1: Automation used in Pharmaceutical Industries four stages of manufacturing

Both computer hardware and software have improved. Numerous important advancements have resulted from the development of computer equipment and software technologies. This technique offers both adaptability as well as consistency at a lower cost. This densities throughout without lowering a quality of product. These technologies are currently being created as an essential part of pharmaceutical processing facilities for online and continuous quality assessment. Pharmaceutical firms have been incorporating automation into a variety of processes, including medication discovery, sterilization, and anti counterfeiting. Process automation's primary goal enables higher plant is to streamline a business's workflow. With automation, we can boost productivity [12–13], cut down on errors, and maintain real-time control over all company operations while also cutting expenses, time, and waste.

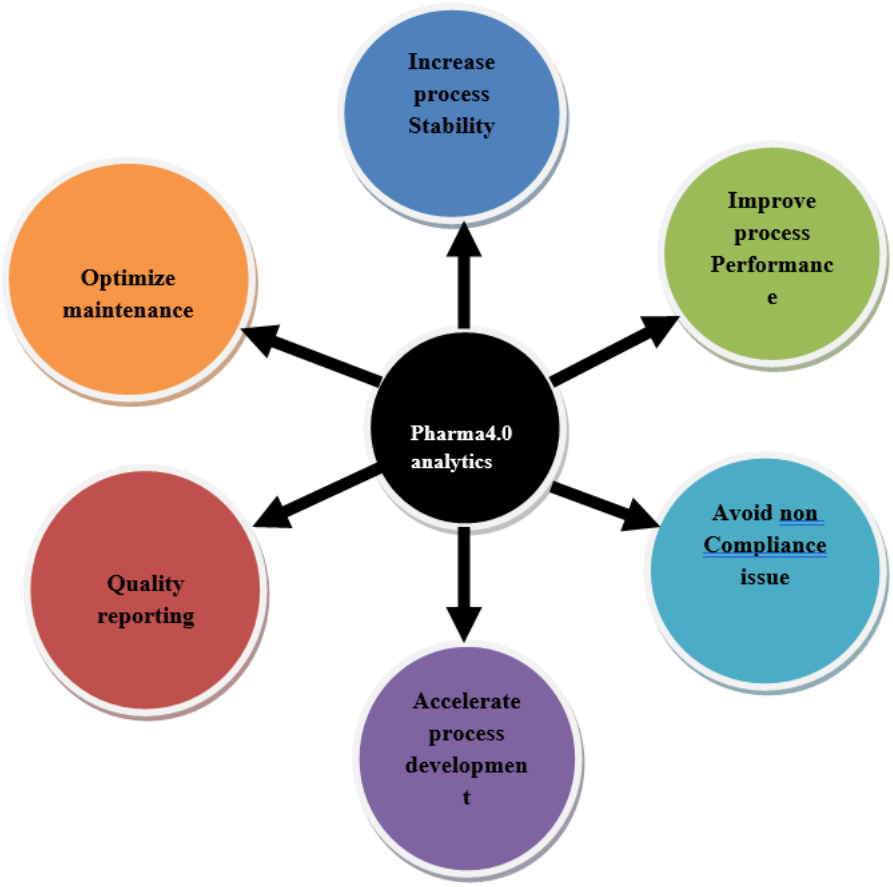


Figure 2: Automation launches an industrious new era in Pharmaceutical industries

Automation in pharmaceutical Industries:

- **Importance:**

Automation is the use of various control systems in industries with little to no human intervention to carry out a variety of tasks.

The pharmaceutical sectors have recently embraced automation. Production, labeling, and storage facility sectors all have automation in place. After implementing computerized equipment, the production of customized medications has become a reality. The application of modern innovations has also had an effect on the R&D sector.

The traditional duties of the quality assurance department were restricted to creating SOPS, conducting audits, and qualifying and validating processes and equipment. The deployment of automated technology in the pharmaceutical sector and its effects on the Pharmaceutical Quality Assurance department are the main topics of this research.

- **Efficiency:**

Robots can complete monotonous tasks more quickly than just human labor. 24 hour production intervals can be accommodated by automated technologies, which are often simple to deploy.

- **Accuracy:**

Weighing, mixing, and tablet of solids, as well as stirring and filling of liquids, are tasks that automated equipment can perform with ease. Automation minimizes imperfections in goods dramatically and prevents errors made by people.

- **Visibility:**

Automation solutions allow for end-to-end tracking of materials from their sourcing to their final delivery. Electronic batch records, RFID technologies, and workflow management can assist in finding inefficiencies and fixing them anywhere in the supply chain.

- **Analytics:**

It is possible to discover market trends and enable precise forecasting using cutting-edge data and analytics. Additionally, analytics can be used to enhance procedures and foresee how successful possible modifications will be.

- **Reduced Contamination:**
- The risk of product contamination greatly decreases with less human involvement during production and handling.
- **Return on Investment:**

Automated systems boost product quality, speed up manufacturing, and save energy. The initial investment in automation technology will be repaid thanks to these advantageous effects on the bottom line.

- **Automation in Packaging:**

Robotics usage is rising, which is especially relevant for dispensing, sorting, kit assembly, and light machine trends. The benefits include increased reliability, flexibility, and speed. It's crucial to take into account the advantages of the newest technologies from manufacturers, researchers, and scientists as robots utilization in the pharmaceutical sector expands quickly.

- **Filling Inspection and packaging:**

Millions of tablets are produced each week by the pharmaceutical industry; each one must undergo stringent inspection before being packaged and delivered to distributors. Drug producers must make sure that precisely the right amount of medication, with the proper chemical composition and weight, is packed into the right containers before this check.

Automated bottle orientation, capping, labeling, and collating system are used in the majority of pharmaceutical packaging systems. In order to automate packing, a system that supervises the process is necessary. This system must look for dropped bottles, shortage levels, and low feeder levels.

- .**Personalized Medicines:**

Despite variations in genetic makeup, age, and gender, the majority of patients who are diagnosed with the same illness receive the same medical care. This is so because even the smartest scientists and medical professionals in the world still don't fully comprehend how different people acquire diseases and react to treatments. This has led to a universal medical strategy that is based on general population averages.

Recent advancements in genetics and genomics have enabled more doctors to provide better disease prevention, more accurate diagnosis, safer drug prescriptions, and more effective medication, bringing the pharmaceutical industry closer to providing more precise, predictable health care that is tailored to the individual patient.

- **Robotics in Laboratories:**

The pharmaceutical business is progressively using robotics to automate several steps in medication development, including manufacture and counterfeiting protection tasks as well as drug screening. Automated arms can now prepare data for approaches like nuclear magnetic resonance and high performance liquid chromatography.

- **Manufacturing that runs without interruption:**

The ability of industrial robots operate perpetually for extremely long times before experiencing any technological difficulties. It only requires ongoing power and scheduled maintenance. Thus, such ongoing operations can assist the industries financially. There are several restrictions, including those related to the workers' physical and psychological well-being when asking them to work additional hours. Nothing to worry about exists because machines are exempt from this. If the equipment receives the proper maintenance, it will run flawlessly and trouble-free for a very long time. Immediately, one might attribute unemployment to this. The working class would not want this to occur, so manufacturers and regulators will need to look into this. The economies may be impacted by this. Manufacturing that is ongoing and unbroken can be viewed as advantageous for producers.[8]

- **Automatic Management:**

To sense the process variables at each stage and maintain a controlled system with a low error rate, a number of integrated sensors are available. Because of their sophistication, the automated systems can even be programmed to stop working or begin recording if a batch is found to be non-compliant. The automated systems are so advanced that they can even stop working or start recording if a batch that is not compliant is found. The sensors are dispersed throughout the automated systems to enable continuous process variable monitoring. Instead, this information is sent to the computer, which examines it before making crucial decisions like rejecting batches or shutting down the system. Human involvement will be minimal in such circumstances because all that is required is that the various systems involved function properly. The workforce would have an advantage in adjusting to

automation if they had a thorough understanding of the automated systems.9 The WFI systems, pure steam systems, air handling units, and manufacturing systems are just a few examples of the critical systems that some industries integrate Integrated systems provide the advantage of controlling all quality-related attributes. This means that various aspects of the production process can be monitored and adjusted as needed to ensure product quality.[6]

- **Utilizing robotics in the lab:**

For the creation of medicines, their evaluation, various manufacturing procedures, etc., the pharmaceutical industry makes extensive use of robotics. The majority of analytical instruments can be automated, which simplifies the laborious analytical procedures. The QC department's workload is greatly decreased. when there is greater production. The QC department's workload is greatly decreased. when there is greater production. Utilizing robotics and automated systems makes it easier to sample and test all of the batches on time. Chances of missing batches would be extremely low due to the ongoing testing. The design of the analytical systems ensures that all test results are handled or stored in a proper manner. The majority of systems follow the FDA's guidelines for maintaining data integrity because they almost never change the data. An automated HPLC system, for instance, would be able to gather the samples, conduct the necessary analysis, and send outcomes to a single computer without any human intervention. A quality control team is not required in this situation. In this way, automation and machine learning can have a significant impact on the pharmaceutical industries' testing structures.[7]

- **Development of the game-changing technology in continual manufacturing technology:**

Raman spectroscopy measures the wavelength and power of molecularly scattered light. Raman spectroscopy is used by the Raman sample to identify numerous organic and inorganic chemicals in the related media. Guided laser light from a sapphire window illuminates the sample. As a result, the sample's molecules vibrate noticeably when the light strikes it, leaving a "fingerprint." Fiber optic cables are used to capture the fingerprint and send it to an analyzer, where it is contrasted with signals that are known to exist. Open-path Many different types of vapor, fluid, or strong phase chemicals can be found using Raman spectroscopy. Distance traveled, which is a measurement of the separation between a light source and a sapphire detector, the chosen excitation wavelength, as well as the specific chemical being detected, all play a role in the detection limits. Low ppm to percentage concentrations are typical detection limits.[11] An increasingly common analytical device for use in numerous pharmaceutical applications is raman spectroscopy.

The Raman Probe's Advantages Involve:

- **Authentication of Products:**

A significant problem now is drug falsification. Falsified medications can have insufficient pharmaceutical active ingredients, inaccurate ingredients, or none at all (such as sugar pills). The latter are the trickiest because an easy compositional analysis can pass the sample off as the real item. One of the most frequently falsified medications is Pfizer's Viagra®, which is used to treat erectile dysfunction. The blue pigment indigo carmine aluminum lake used to coat these tablets is a key component of Raman's evaluation. In order to make an item distinctive and make it simple for customers and pharmacists to identify it, dye coatings are frequently used in conjunction with size and shape. In the case of Viagra®, luminescence is produced in the Raman spectra when they are evaluated using laser excitation at 785 nm, which hides the low wave number end of the Raman spectrum. This is unfortunate because it's crucial in this sector to distinguish between genuine products and imitations Viagra ®.This interference can be removed by using 1064 nm excitation. The introduction of Raman-based spectrometers using the longer laser wavelength is the ideal remedy. The counterfeit drug spectra show additional peaks at 381 and 438 cm-1 that are easily distinguishable from the real thing. It is possible to use the main component analysis to further demonstrate how Raman spectra can distinguish between genuine and fake products.[12]

- **Product Lifespan:**

When a medication retains more than 90% of its potency, that is when the shelf-life or expiry date is determined. Because each medication has a distinct Raman spectrum, spectral analysis of prepared mixtures enables accurate identification with an error rate of less than 1% and efficient analysis of drug degradation.[13]

- **Developing new drugs:**

Once a potential new drug has been identified, a method for synthesizing it is developed. Raman spectroscopy has been used to study a variety of reactions, including Diels-Alder, Fischer esterification, Grignard, and hydrogenation. is suitable for monitoring reactant, intermediate, and product concentrations, pathways, kinetics,

procedures, endpoints, and yields. The x-axis stability Immune optics, temperature-controlled hour-long reactions, or the inclusion of an x-axis are all provided by FT-Raman analyzers.[14]

- **Drug Superiority(Quality):**

Controlling the efficacy of raw materials is the first step to quality by design in the production of pharmaceuticals, which leads to high-quality products. The latter calls for confirmation that the product's active ingredients, ingredients, and other additives are present in the appropriate quantity. Before delivery, each product was examined using Raman spectroscopy to ensure that it had been thoroughly mixed. The three APIs that make up an Excedrin® tablet are aspirin, acetaminophen, and caffeine, each of which has an API of 44, 44, and 12%, respectively. By combining a Raman variety measured with the natural API spectra, this composition can be ascertained, and the result can be 100%. The results of one single point of measurement on a tablet can be inaccurate. By combining a Raman variety identified by natural API spectrum measurements, this composition can be ascertained, and the result can be 100%. The results of one single point of measurement on a tablet can be inaccurate. It is possible to correct this incorrect result using a number of methods. Using a raster approach or pattern to map the samples is one of them, as is spinning the tablet with a sizable Raman transmission. It should be noted that you don't have to map the entire pill.[15]

- **The Role of Raman Spectroscopy in the QA/QC Laboratory:**

The role of a modern QA/QC laboratory has changed to include almost any issue. A variety of scientific tools, some damaging and some not damaging, are used for product analysis. Any analytical tool that can be applied in this setting must have both specificity and sensitivity. In this webcast, we'll talk about how Raman spectroscopy, both small and large can simplify and streamline product evaluation and packaging. Raman spectroscopy's value in identifying product flaws like foreign body inclusions, content errors, or deviations from expected content uniformity will also be assessed.[16]

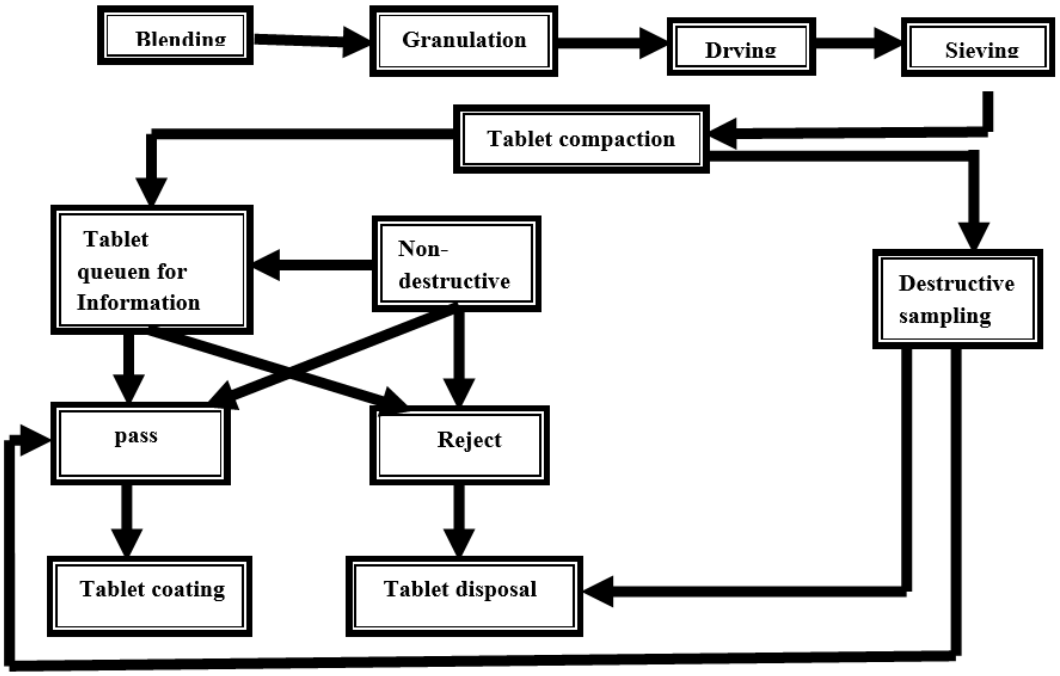
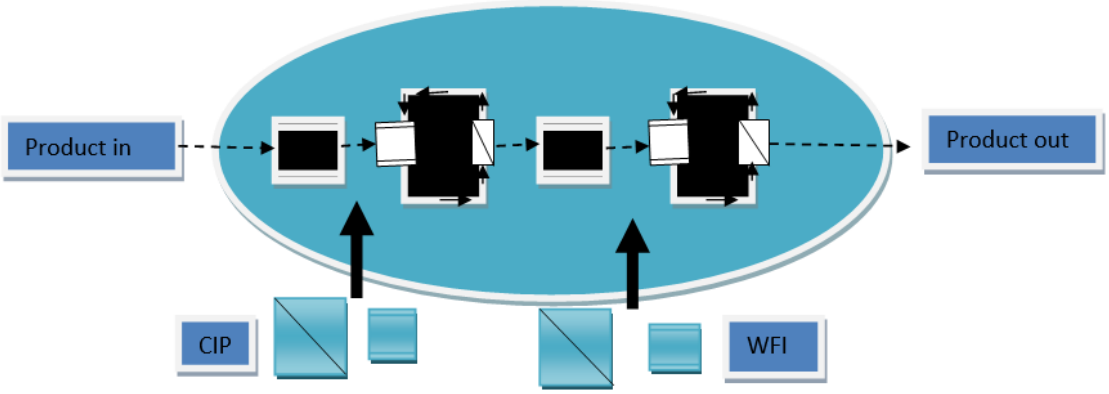


Figure 3: Flowchart showing how non-destructive quality control sampling is integrated into the standard tablet manufacturing process

Within the context of the case study, an online reporting tool—also known as "golden batches" fingerprinting—was implemented that allows a real- parameter comparison over time for different batches. This reporting implementation makes full use of the centralized automation infrastructure. The "Golden batches"—those that perform best in terms of cycle times, yield, and quality—can be found using this technology. Having a centralized concept of automation helps quality assurance strategically achieve this goal.[17]



Roles in the pharmaceutical industry following the implementation of automation:

The quality assurance department will need to change to keep up with new technological developments. With all the most recent tools at our disposal to guarantee process quality and products, Quality Control Personnel lives have undoubtedly become easier than they were in the past.[20] In order to keep up with automated systems, the staff needs new skills. The new abilities include:

- **Interpreting and manipulating digital data:**

In a world where everything is automated, employees must be able to handle and interpret digital data Information meaning is the method of examining data to reach a well-informed conclusion. Data are interpreted to give them meaning, and this process also establishes the implications of the information. Without a doubt, interpretation is significant, which is why it must be done correctly.[21]

- **Creative Design to Create Better Automated Systems:**

The team must be equipped with the necessary skills to develop efficient, problem-free automated systems. Because they have an in-depth comprehension of these critical quality attributes, the QA team will be able to put in all the probes and sensors necessary for monitoring them. The engineers working on building automation systems will require their knowledge. Additionally, having sufficient process knowledge can be useful in designing the equipment in a specific way to ensure that the manufacturing processes go smoothly.[22]

- **Increase your proficiency with computers:**

The staff must possess the required computer handling abilities. The staff needs to be competent in using the computer programs required for handling data and keeping an eye on the automated systems. In order for the staff to adapt to the shifting work environment, adequate training must be offered. Process Pro, Batch master, Response Pro, Ceecom Manufacturing, and other programs are used. Since this software handles the majority of complex tasks, having the necessary skills to manage them will help QA staff members adapt to the automated systems.[23]

- **Confidentiality:**

Questions about the confidentiality of this information are starting to arise as more and more data are becoming digital. The automated systems adhere to the most recent legal requirements, and as a result, the data are stored in a way that prevents their transfer without the necessary authorization. The relevant staff is properly trained to prevent them from taking any acts that could result in a server data breach. Therefore, concerns about maintaining security of information after implementing automated systems can be postponed.

Data reliability:

The same problems that arise with regard to data privacy also occur with regard to data integrity. The technologies that are automated must adhere to 21 CFR PART 11 requirements, and the manufacturers must ensure this. In the food and pharmaceutical industries, it outlines the necessity and importance of electronic data recording.

Pharmaceutical Application:

Applications unique to different industries gain a lot from the usage of automation technology. Here are a few instances:

- High sheer/wet granulation, fluid bed granulation, hot melt extrusion, drying, milling, and dry granulation and micronization are examples of processing systems.
- Liquid dosing (used in the production of tablets)

- compressed and coated tablets
- Encapsulation (liquid and solid dosages)
- RFID labeling (quality control, tracking goods movement)
- Prevention of counterfeiting by tracking and traceability
- Devices for delivering drugs
- Filling, examining, and packaging
- Systems for sorting and conveying materials (high speed bottle filling, inspection, grouping, rejecting, and transferring)
- High investment in reprogrammable general-purpose machinery
- Ability to program the machine to handle product variety.
- Suitable for batch manufacturing of various product and part styles.
- Production time lost while the physical setup and programming were changed
- Reproduction rates compared to stationary automation.
- Reprogramming ability to alter the order of processes to accommodate various product configurations.

Typical Features:

- High investment in Programmable equipment.
- Fewer outputs per hour than with fixed automation.
- The capacity to be adaptable to modifications and adjustments in product configuration.
- most appropriate for batch manufacturing
- Physical setup and previous programs need to be updated between batches.
- Effective use of resources (equipment and personnel).
- Higher effectiveness.
- Lower expenses and higher return on investment
- Scandal-free client experience.
- Enhanced cyber protection.
- Pay attention to important issues rather than manpower.
- Additionally, automation can be utilized in a procedure known as automation of tests for testing.

During this process, computers are programmed with specialized scripts, typically computer programs, to conduct the same software test that would otherwise need to be done manually by a human.

Many of the benefits of industrial automation can also be used to test automation, including labor savings, repeatability, and waste reduction.

Highly integrated transfer lines are used in the automotive sector to execute machine operations on engine and transmission components. Fixed automation is more cost-effective than other types of manufacturing because it allows for the distribution of special equipment costs across a large number of units produced.

Advantages:

- **Improves quality:**

Additionally, industrial automation contributes to improving and sustaining production quality. The average mistake rate in a manual processes is between one and one and one-half percent. On the other hand, automated machines in the industrial sector have an error rate of just 0.00001%. Adaptive control and monitoring aid in checking each stage of the production process to lower the margin of error.

- **Lowers expenses:**

Automated offers many benefits, one of which is lower manufacturing costs. Now, you only need a few controllers and a few computers can do the work in place of a workplace full of employees. Although the initial expenditure will be rather high, operating costs will eventually drop, which will be advantageous over the long term. Only upkeep, repairs, and energy will be included in your costs. By giving producers the knowledge and information, they need to take the most efficient manufacturing options, artificial intelligence, data, and analytics have also contributed to lower production costs.

- **Boosts productivity:**

Workstations are linked with transfers lines to form automatic production lines. Each workstation handles a certain step in the production process. Automation of robotic processes can be used to simulate a variety of human actions. System configuration options include the ability to log into apps and handle business process administration.

Along with handling raw materials, cleaning equipment, operating high pressure systems, and many other tasks, robots are frequently used on the production floor.
For instance: In an automobile assembly line, auto parts are chopped and formed into various press working. Sta tions.For instance: In an automobile assembly line, auto parts are chopped and formed into various press workin g. The machine next assembles each component to create the vehicle after it has been collected in one location. The production cycle is significantly accelerated by process automation.

- **Industrial security:**

Automation has significantly increased worker safety, which is a huge advantage. Accident risk has been decreased by using robots for the purpose of lifting goods or move massive machine parts. Additionally, industrial automation prevents workers from walking too close to the assembly line, enhancing safety. The ambient temperature in the production zone is continuously monitored by thermal sensors. The factory floor may all be kept secure by taking fast safeguards in the event that the sensors detect any temperature spike and give out an alarm.

- P**recise outcomes:**

On precise data incorporation and interaction, information automation is built. You may be assured that the manufacturing process will produce exact outcomes when reliable information is utilized. You can obtain precise information by employing data analytics tools and machine learning, as well as AI, technologies to gather specific data.

Self-healing digital grids that regulate power production through data analytics and intelligent energy forecasting are created using deep learning algorithms. A self-learning quality control system for a manufacturing line has been created using machine learning software. Technologies based on machine learning and AI are adaptable and self-learning. These two aspects guarantee that the automated systems consistently produce reliable results.

- **Improved circumstances for employees and value addition:**

Industrial automation guarantees constant output and findings, which is one of its greatest advantages. Computers, robotics, and automated equipment all operate steadily. You can control manufacturing pace better thanks to it. Consistent production and quality are both delivered through automation.

A centralized computer facility combines and administers the material handling robots, tools processing machines, and other equipment in a flexible production system. Once the complete process has been calculated, production continues constantly without any decrease in the speed or outcome.

Flexible automation processes enable you to set up or repair a machine to accommodate new or changing product specifications. Training staff might take days or even weeks in a traditional production process. Another difficulty is that it may take employees some time to become used to the new procedure, which could result in a production lag or poor quality. Reprogramming a machine or performing a reboot, on the other hand, is simpler and takes less time, and after a few trials, you'll be ready to start full-scale production.

Employees are freed from doing boring, repetitive job thanks to automation. This allows them to concentrate on other fields which they can bring value. Workers can efficiently employ robotic tools and equipment to offer better and quicker results, and they can assist with research and process improvement. Additionally, employees benefit from doing well on a foot-by-foot b

- **Industrial communication:**

Automation in the manufacturing industry may be nearly impractical without industrial communication. The communication system aids in managing power distribution, operating machines, and controlling and monitoring entire lines of manufacturing. The most widely used industrial communication protocols are ether Net/IP, field-bus, profi-bus, and ether Cat.

Real-time data analysis and decision-making are made possible via industrial communication.

- **Observing and anticipatory maintenance:**

The fact that automated machinery facilitates monitoring and preventive maintenance is a major advantage. Sensing devices can be used to continuously monitor production lines and the production floor. These sensors monitor several production-related characteristics, including temperature, acoustics, time-frequency, oil pressure, and others. The sensors will promptly send an alert if they see any change in these parameters, and when the warning is received, the technicians can quickly determine what caused the change. If it is determined that changes in parameters could result in machinery failures or troubles with the production process, prompt servicing or

repairs can be performed. Before they grow into major concerns that could cause production to stop, automation can assist spot potential problems.

- **Equipment surveillance:**

The efficiency of all the equipment in the manufacturing unit is monitored by an electronic monitoring system. Devices can be observed from a distance using sensors, cameras, and networks. The monitoring system also aids in discovering potential problems and performing the required maintenance and repairs. Petrochemical plants, manufacturing facilities, and other sectors that use huge, complicated machines can all benefit from using this automated solution. The automated system improves safety, decreases the number of people needed on the floor, and increases the efficiency and longevity of the machines.

Disadvantages of automation:

- **Requires significant initial investment:**

For many years, automation has been a mainstay of industry. Manufacturers must take into account a few expected implications before making the automation move, though. One of these effects is the requirement for significant capital investments in order to maintain and service automated systems. Additionally, these systems are more vulnerable to cyber attacks than manual systems would be, which might make businesses less resilient if their infrastructure is not adequately secured.

- **Becoming unnecessary:**

Numerous issues can be easily solved by automation. But when change is introduced and the automation needs to be changed this benefit can become useless. These kinds of adjustments could end up costing the organization time and money while merely serving to increase workload.

- **Displacement of employees:**

Automation's biggest drawback is that it eliminates jobs for people. This is because computerized tasks can be completed more quickly and accurately than they can done by a human.

For example: Many people worry that the use of self-driving cars at Disney World, where visitors are transported around the park for years, will eliminate the need for human workers.

- **Still needs human intervention:**

  Even if the general advantages of automation have been shown, some tasks remain dependent for human involvement. We'll take the self-driving automobile example from before as an example. The majority of road obstructions may be identified by these vehicles, which can also be instructed to halt. However, under certain circumstances, these computers may interpret data incorrectly and result in undesirable outcomes, such as driving through a barrier that is not clearly visible to the automobile sensor.

Conclusion:

Automation in the pharmaceutical industries would theoretically have a number of benefits, including increased productivity for technologists, reduced radiation exposure, and improved overall image quality. The department's effectiveness will be improved by creating computer-based algorithms to identify and measure deficiencies, information extraction to generate global databases that follow rules. Engineering teams will require the QA division's professional expertise to create an effective automated system that doesn't compromise product quality, so their involvement in the development of automated technologies is crucial.

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