REVIEW ARTICLE

# Impact of Automation in Pharmaceutical Industry on Roles and Responsibilities of Quality Assurance: A Review

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**ABSTRACT**

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, packaging, labeling, 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 (QA) department were limited to preparing standard operating procedures (SOPs), carrying out audits, qualification, and validation of equipment and processes. This review focuses on the implementation of automated technologies in pharmaceutical industries and the impact it has had on the pharmaceutical quality assurance department. This article covers topics such as the Raman probe and the different ways it has been made use of in the pharmaceutical industries. The conventional role played by the QA department has also been enlisted while also mentioning how they change with the implementation of automated technologies.

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

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## INTRODUCTION

### What is Automation?

Automation is the implementation of machines to carry out most of the repeatable and important functions in pharmaceutical industries. The industries have been developing at a greater pace, and in the case of the pharmaceutical industries, it's nothing different. The regulatory requirements are getting stricter than before.[1] Automated functions can help industrial management in keeping up with the ever-changing regulatory constraints. The tradition of implementing newer technologies that replace human power has been taking place in various industries across the world for many years now. Work unions and other communities have always been against this tradition as the latest technologies can always have a major impact on job opportunities in the industries.[2]

Lately, the use of computer vision systems for quality assurance purposes has noticeably increased. As a result, human inspectors could be replaced by these systems. The advances in both computer hardware and software technologies has led to many significant advances.[3] This technology provides a greater level of flexibility and repeatability at relatively low costs. This permits higher plant throughput without compromising with the quality of products. Currently, these systems are being developed as an integral part of pharmaceutical processing plants for online and real-time quality evaluation.[4]

## SIGNIFICANCE OF AUTOMATION IN THE PHARMACEUTICAL INDUSTRIES

### Automated Filling, Inspection, and Packaging

Millions of dosage forms are produced in their respective pharmaceutical industries, and all of them must be carefully checked for safety before being sent out of the facility.

Most manufacturers use automated systems to manage many activities like filling of capsules, vials and containers, an inspection of dosage forms and their respective containers, etc. A centralized computer is assigned to monitor all the automated processes. The centralized computers efficiently monitor all the critical process parameters to keep the quality of the products consistent.

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Filling of capsules, containers, and vials are also effectively carried out by automated filling machines. They are capable of inspecting the level of filled containers and vials and can effectively reject the particular products that haven't been filled.

In a large scale production facility, such automated systems can be utilized to carry out such activities. The automated systems are so efficient that the headache of the QA/QC department is literally nullified. All the batches with non-compliance issues can be identified easily as the data regarding the batches are continuously logged in the computer memory.[5]

**Making Personalised Medicines a Reality**

In the current scenario, despite having a lot of genetic indifferences, people get treated in a one-size-fits-all approach. The medical field has realized the importance of personalized medicines due to their effectiveness in curing ailments. For personal medicines to become a reality or reach their actual potential, automation is very necessary. More sophisticated systems can pave the way for more efficient and quicker drug discovery. Various modern computational technologies can be incorporated to run multiple tests to identify the perfect combination of drugs and their dosages. In a world, with such a diversified population, it's difficult to come out with personalized medicines and with the existing traditional methods, the idea of personalized medicines can be termed as impossible. Hence the improvements in automation can see a lot of advances in the medical world. The potential of modern medical treatment can be targeted to get maximum efficiency and help outpatients in far corners of the world to get the best possible medical treatment. For example, diversified genetics make every individual in this world unique. As a reason, the medical treatment required by them will also vary. Automated systems can handle complex data related to genetics and help the R and D department to come up with efficient treatment methods. It'll begin with grouping the people with similar genetics and then focusing on producing drugs specifically for them. With further advances in technologies, medicines can be produced for individuals based on their adaptability to the drugs. The manufacturing processes can be easily optimized to manufacture different concentrations of drugs based on the required amount. The traditional/ current manufacturing practices are such that they cannot be modified to produce various concentrations of drugs as and when required. Currently, if a manufacturing cycle is run, it has to run its full cycle before being cleared for the next batch with a different concentration. Automated machines will be effective in controlling the process parameters to produce the required concentration of drugs in required quantities as and when required. So this particular advantage of automation can solely be utilized to produce personalized medicines for patients across the globe.[6]

**Involving Robotics in the Laboratory**

Robotics is being used extensively in the pharmaceutical industries for drug development, drug screening, various manufacturing processes, etc. most of the analytical instruments can be automated and hence makes the tedious analytical procedures simpler. The workload on the QC department is reduced considerably. In cases where the production is more. The analytical department is not able to get their results on time; the automated systems can come to help. Incorporation of robotics and automated systems, facilitate timely sampling and testing of all the batches. Due to the continuous testing, chances of missing out on batches would be very less. The analytical systems are designed such that all the test results are stored or handled properly. In most systems, the data is never modified and hence falls in line with the FDA guidelines for maintaining data integrity. For example, an automated HPLC system would be capable of automatically collecting the samples, analyzing them, and transferring the results to the centralized computer. In this case, the involvement of a QC team isn't necessary. This way, the robotics, and automated systems can make a tremendous impact on the laboratory systems of pharmaceutical industries.[7]

**Continuous, Uninterrupted Manufacturing**

The industrial robots can work continuously for very long periods until any technical failures occur. All it'll need is a continuous power supply and regular maintenance. Thus, such continuous processes can bring in financial benefits to the industries. When it comes to asking humans to work for long hours, there are certain constraints like the physical and mental health conditions of the workers. In the case of machines, this isn't a problem. With proper maintenance, all the machines will work efficiently without any kind of hiccups for very long periods. This could straight away be seen as a culprit for unemployment. Manufacturers and regulators will have to look into this aspect as the working community wouldn't want this to happen. This could also affect economies. Continuous, uninterrupted manufacturing can be seen as a boon for the manufacturers.[8]

**Automatic Control**

A number of integrated sensors are available to sense the process variables at every step, keeping the processes in a controlled system with minimized errors. The automated systems are so sophisticated that they are even capable of shutting down or recording in case a non-compliant batch is identified. The sensors are placed throughout the automated systems so that they can be used to monitor the process variables continuously. This data, on the other hand, is transferred to the computer, which analyses the data and then makes important decisions like rejecting batches, shutting down of the system, etc. In such cases, human intervention will be minimum, as they would only need to see to it that the various systems involved are working properly. Proper understanding of the automated systems would give the personnel an upper hand in coping up with automation.[9]

In some cases, industries integrate all their critical systems, i.e., the WFI systems, pure steam system, air handling units, and the manufacturing systems. This is advantageous as every quality-related attribute can be kept at check. In case

of any kind of issue with any of the systems, the personnel is alerted. Such integrated systems are of importance in the manufacturing of parenteral, etc. wherein lots of care must be taken because even a small variation from the required conditions has an impact on the quality of the product.[10]

## DISCOVERY OF THE BREAKTHROUGH TECHNOLOGY IN CONTINUOUS MANUFACTURING TECHNOLOGY

### Raman Probe

Raman spectroscopy is the measurement of molecular scattered light wavelength and intensity. The Raman sample detects many organic and inorganic chemicals in the media surrounding the sample using Raman spectroscopy. The sample uses guided laser light from a sapphire window. It leads molecules to vibrate distinctly when the light hits the sample, producing a "fingerprint." The fingerprint is caught and transferred to an analyzer via fiber optic cables, where it is compared to recognized signals. Open-path Raman spectroscopy can detect a broad variety of vapor, fluid, or strong phase chemicals. The detection limits rely on the route length (i.e., the distance between the light source and the sapphire detector) and the wavelength of excitation used, as well as the individual chemical. Typical limits for detection range from low ppm to percentage concentrations.[11]

Raman spectroscopy is emerging to become a popular analytical tool for various pharmaceutical applications.

### The Benefits of Raman Probe Include

*Product Authentication*

Falsification of drugs has become a major issue. Falsified drugs range from those using inaccurate ingredients, no active ingredients (e.g., sugar pills), or inadequate pharmaceutical active ingredients. The latter are the most difficult since the sample can be passed as the real item by a straightforward compositional assessment. Pfizer's Viagra ®, used in the therapy of erectile dysfunction, is one of the most frequently reproduced drugs. A major factor for Raman's evaluation is the blue dye, the indigo carmine aluminum lake used in the coating of these tablets. Dye coatings are often used in combination with size and shape to ensure that the item is unique, allowing pharmacists and consumers to easily recognize it. In the case of the Viagra ®, Raman spectra evaluated using laser excitation of 785 nm produces fluorescence that obscures the Raman spectrum's low wavenumber end. This is unfortunate because the distinction between authentic products and fake Viagra ® is important in this region. Using excitation of 1064 nm can overcome this interference. An optimal solution is the introduction of Raman dispersive-based spectrometers using the longer laser wavelength. The counterfeit spectra of drugs indicate extra peaks at 381 and 438 cm-1 that can readily be used to distinguish counterfeits from the originals. The main component analysis can be used to illustrate further this capability of Raman spectra to separate authentic ones from the counterfeit ones.[12]

*Product Shelf Life*

The shelf-life or expiry date is based on the moment a medication retains a potency of more than 90%. The Raman spectrum of medicines is unique and the spectral assessment of prepared mixtures makes it possible to identify with an error of less than 1% and thus analyze drug degradation effectively.[13]

*Drug Development*

The method for synthesizing the drug is developed once a possible new drug is recognized. Raman spectroscopy is suitable for monitoring concentrations of reactants, intermediates and products, pathways, kinetics, procedures, endpoints and yields for a variety of reaction types such as Diels-Alder, Fischer esterification, Grignard, and hydrogenation**.** FT-Raman analyzers provide the required x-axis stability for hour-long, temperature-controlled reactions, immune optics, or the inclusion of an x-axis.[14]

*Drug Quality*

Quality by design in drug production begins with controlling the purity of raw materials and ends with the quality of the product. The latter requires assurance that the active ingredients, excipients, and other additives contain the correct amount of the product. Raman spectroscopy was used to monitor mixing in mixers and check individual products before delivery. An Excedrin ® tablet comprises of three APIs of 44, 44, and 12%, respectively, aspirin, acetaminophen, and caffeine. This composition can be determined by mixing a Raman variety measured with the natural API spectra, and the result can be equal to 100%. Tablets can give erroneous results from a single point measurement. For example, a single spot measurement of 300 microns of diameter showed 45% aspirin, 22% acetaminophen, and 33% caffeine composition. Several techniques have been developed to fix this wrong result. These include mapping of the samples using a raster approach or pattern, using a large Raman transmission to spin the tablet. Note that you don't need to map the entire pill.[15]

### The Role of Raman Spectroscopy in the QA/QC Laboratory

The function of modern QA/QC laboratory has evolved into one where there is almost any issue. Product analysis is performed using a variety of scientific instruments, some destructive and some non-destructive. Specificity and sensitivity are key elements of any analytical tool that can be used in this environment. In this webcast, we will discuss the role Raman micro- and macro-spectroscopy can play in simplifying and streamlining the assessment and packaging of products. Furthermore, the usefulness of Raman spectroscopy will be evaluated to detect product defects due to inclusions of foreign bodies, content faults, or deviations from expected content uniformity.[16]

The present wet chemistry analysis off-line, destructive quality control technique is a bottleneck in manufacturing because comprehensive sample preparation is required. Raman spectroscopy, on the other hand, is a non-destructive method of identification that does not require sample preparation. Raman

spectroscopy, on the other hand, is a non-destructive method of identification that does not require sample preparation as depicted in Figure 1. In the pharmaceutical industry, the use of Raman spectroscopy as a quality control tool needs capital investment and thorough calibration. However, Raman spectroscopy dramatically decreases the time and labor costs of preparing, conducting, and analyzing tablets 'active ingredient structure while improving the amount of tablets tested and hence the amount of confidence.[11]

Raman spectrometers will continue to decrease in size, integrate into other analytical equipment, and provide an incredible means for the analysis of pharmaceuticals. Such benefits can explain the impact this tech can have on the QA/QC departments of the pharmaceutical industries. Emerging technologies, a vibrant regulatory landscape, and the latest scientific obstacles continue to increase Raman spectroscopy's applicability and usefulness as a process analytical technology (PAT) in pharmaceutical production. Raman transmission technological innovations allow the non-destructive and quick assessment of bulk tablets or capsules. Transmission Raman is mainly used for off-line content uniformity measurements. It has been shown that Raman spectroscopy enables real-time process corrections for API response surveillance or secondary pharmaceutical procedures. Since the 1990s, Raman's extension to ongoing production settings has been proved and is expect to see more applications in this setting. Raman is a precious PAT for tracking and controlling the bioprocess of fermentation or cell culture. Simultaneous in situ measurement of nutrients, metabolites, and cell concentration is an attractive feature of Raman.[16]

## CASE STUDY

Figure 2 below shows the process flow for a freshly implemented method in the plant at a very high level. This method is the basis of the case study on PAT and scalable automation. The process flow is typical of biotherapeutic facilities and consists of numerous discrete steps, including dissolution, filtration, chromatography, ultrafiltration/diafiltration (UF/DF), nanofiltration, followed by (not shown) formulation, filling, and freezing. The heart of the process is the chromatography and the skids of UF/DF. Furthermore, there are numerous vessels, tanks, pH adjustment carts, and temperature control modules (TCMs) combined in the "process balance" environment. The CIP system and the WFI system are two other critical components in the process. The CIP system is typically a skid-based system, such as chromatography and UF/DF. Probably the most important ancillary system in the process is the WFI System. The CIP system and the WFI system are two other critical components in the process. WFI is used in the overall production process for about 50% of the time. Information is collected at each stage of the process during ordinary manufacturing, and the findings of each step are critical to the ordinary sequential processing of the product. Typically in their operation, chromatography and UF/DF skids are all automated and controlled locally with local operator interface. Until now, in the industry, the conventional approach has been to buy chromatography, UF/DF, and CIP skids from various vendors, usually with proprietary and differently configured/documented control systems installed on each skid.

In addition to leading itself to arduous data collection, communication between the skids is a huge and expensive challenge for operational and process control. Furthermore, with so many different control platforms controlling the same process, it has become very difficult to understand and reduce variability in the overall process.

An online reporting tool was deployed within the scope of the case study that provides a real-time comparison of parameters across multiple batches, also referred to as "golden batches" fingerprinting. It enables the department of quality assurance to compare information over various batches regarding moment, process step, or batch-ID, which significantly promotes process monitoring and comprehension. The centralized automation infrastructure is completely utilized in this reporting implementation. This technology can be used to identify the "Golden batches"– golden batch is the one that performs ideally concerning cycle times, yield, and quality. The aim is to identify the characteristics of this golden batch and to control the interest parameters in order to fit the golden batch values. In order to understand all the dynamics of each process, it is necessary that the parameters are compared over time, from batch to batch, and then to correlate these parameters with others to analyze the different interactions within the process. Having a centralized idea of automation provides a strategic benefit to quality assurance in attaining this objective.[17]

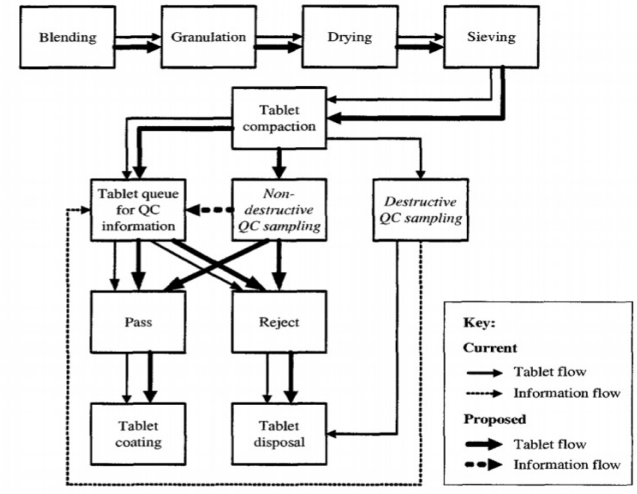


**Figure 1:** Flowchart depicting the implementation of non-destructive QC sampling into the conventional tablet manufacturing process

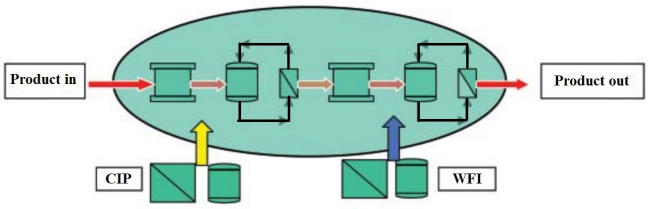


**Figure 2:** Diagrammatic representation of process flow in a typical bio-therapeutic plant

With the implementation of the latest automated technologies in the facility, it has become easy for the quality assurance department personnel to collect all necessary data regarding the complex processes being carried out. The dependency on a dedicated manual analytical department is reduced as all the data are readily available in the digital form. The automated systems are efficient in collecting and recording data at every step in the process. The importance of QA personnel in the pharmaceutical industries

Like the food industry, compliance with global quality standards is also essential for the pharmaceutical industry. A key reason for the same is the direct correlation between product quality and government health/safety. Deficiencies in pharmaceutical medicines also increase the danger of compromising customer health and life.[18] Effective quality assurance enables organizations create greater credibility and consumer confidence, as well as keeping compliance with FDA regulations and enhancing effectiveness in manufacturing. Therefore, in the pharmaceutical industry, quality assurance provides tremendous advantages in terms of increased revenues and a better reputation.[19]

## CURRENT ROLES OF THE QUALITY ASSURANCE DEPARTMENT

The discrete QA department is a new trend in the industries.

- This is an overview of roles played by QA in the pharmaceutical industry:
- In the development stage, it is essential to verify the quality of the raw material provided from suppliers during research and development, validate test techniques, carry out document control, and prepare working processes. They also play a significant role in recruiting and training staff, information recording, clinical trials, and API batch formulation.
- In the Manufacturing Stage – The few instances of the role of the QA departments in production are:
- Preparation, approval and implementation of important papers such as quality policies and goals, quality manuals, validation master plan, etc.
- Carry out various validation and qualification programs.
- See to it that all the aspects related to the industry are within specifications.
- Make sure that proper training procedures are carried out, and related documents are maintained.
- In case of deviations, the QA team has to take up the responsibility to document and analyze the same.
- Handling of customer complaints by carrying out necessary follow up actions. i.e., supervise the investigation to find the root cause and provide an investigation report to the customer.
- Regulate and document market returns.
- To train the internal audit team of each department on interacting with auditors during external audits.
- Review all the associated QC data prior to clearing a batch for release into the market.

## ROLES AFTER IMPLEMENTATION OF AUTOMATION IN PHARMACEUTICAL INDUSTRY

The quality assurance department will have to cope with the latest technologies. With all the latest technologies available for ensuring the quality of products and processes, life of quality assurance personnel has definitely become easier than what it looked like some time ago.[20]

The personnel must be equipped with new skills to keep up with the automated systems.

The new skills include:

### Digital Data Handling and Interpreting

All the data in the automated world are digitalized and hence the personnel must have adequate knowledge to handle and interpret the same. Information interpretation relates to the execution of procedures by which information is analyzed to reach an informed conclusion. Interpretation of data gives meaning to the information and determines its meaning and consequences. The significance of interpretation is obvious, and that why it needs to be done correctly.[21]

### Innovative Thinking to Design Better Automated Systems

It is necessary that the personnel be prepared and knowledgeable enough to design efficient, hassle-free automated systems. Since the QA team have adequate knowledge regarding the critical quality attributes, they'll be able to position the necessary probes and sensors needed to monitor the same. Their knowledge will be needed by the engineers involved in constructing the automated systems. Also, having enough knowledge about the process can help in designing the equipment in a particular way so that the manufacturing processes happen without any hassles.[22]

### Develop Computer Handling Skills

The personnel must have the necessary computer handling skills. The personnel must have adequate knowledge about handling computer software necessary for data handling and monitoring the automated systems.[24] Adequate training must be provided for the personnel so that they can cope up with the changing work environment. Various software used includes ProcessPro, Batchmaster, Response Pro, Ceecom manufacturing, etc. Since most complicated functions are taken care of by this software, having enough knowledge to handle them will give the QA personnel an advantage in coping up with the automated systems.[23]

### Confidentiality

With all the data getting digital, the questions regarding the confidentiality of these data to arise. The automated systems come compliant with the latest regulatory requirements, and hence the data are stored such that they cannot be transferred without proper authorization. The related personnel are well trained so that they don't perform actions that could lead to a breach in data from the servers. Hence, the queries regarding maintaining the confidentiality of data after implementing the automated systems can be put off.

### Data Integrity

Just like how the confidentiality of data can be questioned, queries related to data integrity can also arise. The manufacturers must see to it that the automated technologies implemented are 21 CFR PART 11 compliant. It states the importance and requirements for electronically recording data in food and drug industries. During quality audits, one main spot of concern for the auditors is data integrity. The automated machine store data in the respective servers, but this alone won't be enough. The personnel having access to all these data must be limited, and they must be responsible for the careful handling of data. The data should not be such that anyone from the industry can access it and make changes to it. All the CFR 21 part 11 compliant systems are even capable of recording the number of times data has been changed or modified. Hence, as such, data integrity would not be a problem with the implementation of CFR compliant equipments, but it relies upon the QA management to see to it that the data are only accessible to responsible personnel. The QA personnel involved in the same must have undergone training in CFR 21 part 11. This will ensure that the chances of data integrity in a fully automated plant is nullified.

Since most of the latest technologies use digital data collection, the need for all the paper-work in the industry will get nullified. The QA department will have to be trained to use digital data collection systems.[24]

In the absence of all the paper-work, the personnel work will be drastically reduced as the extensive documentation becomes easier.

Automation as such may not have a drastic impact on the roles of QA personnel in the pharmaceutical industries but, in the near future wherein the technologies may further develop and various industrial revolution can come across there is every possibility that the dependency on manual Q.A personnel will reduce.[25]

## CONCLUSION

In the pharmaceutical industries, automation would give a number of theoretical advantages such as enhanced productivity of technologists, reduced radiation dose, and enhanced general image quality. Developing computer-based QA algorithms to detect and quantify QA deficiencies, deriving QA information to create universal QA norms and structured databases will enhance the QA department's effectiveness.

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.

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