Technology and Automation: Futuristic Scenario

Position Paper

- Automation
- Robotics
- Data Aggregation & Cybersecurity
- Education & Skill Development
- Pharma Regulation

Presented by Messe Muenchen India and
Indian Pharma Machinery Manufacturers' Association (IPMMA)

Preface

The growth of the pharma industry is closely linked to the development of sophisticated and reliable pharma machinery. Pharma machinery serves as the backbone of the Indian pharmaceutical industry. Much of the pharmaceutical industry's progress and the production of world-class pharma products rely on the use of advanced machineries that are specifically designed to meet the needs of the industry. These machineries hold the key to bringing new and innovative drugs to the market faster, thus improving patient access to new treatments.

Automation and digitization are increasingly adopted in the manufacturing process of various industries. In the pharma industry, these technologies can help increase efficiency, reduce costs and improve product quality through increased accuracy and consistency. In this paper, we discuss the new technologies of automation and digitization and how these are beneficial to the pharma industry. The core of this paper presents five compelling topics: Automation for global competitiveness, robots and COBOTs for innovation, digitization and cybersecurity for data management and protection, education and skill development for digitization and automation, and pharma regulation and technology.

We would like to thank the thought leaders who contributed to this paper on 'Technology and Automation: Futuristic Scenario' by being part of the three-month-long series of consultations across seven cities – Goa, Ahmedabad, Vishakhapatnam, Indore, Bangalore, Chennai and Hyderabad. The consultation seminars were jointly organized by Messe Muenchen India and IPMMA in 2022 and the lively interactions between the stakeholders from pharma and machinery segments served as an extension to the insightful engagements at Pharma Pro&Pack Expo, the leading trade show for pharma processing and packaging.

With this paper, we hope to engage with the pharma and pharma machinery professionals and provide them with invaluable ideas and recommendations for adopting future technologies.

Yours truly,

Bhupinder Singh
Chief Executive Officer
Messe Muenchen India Pvt. Ltd.

Yours truly,

Harshit Shah
President
Indian Pharma Machinery Manufacturers' Association

About Messe Muenchen India

Founded in 2007 as a wholly owned subsidiary of Messe München GmbH, Messe Muenchen India Pvt. Ltd. is one of the largest trade fair organizers in the country today. The company has an extensive portfolio of B2B trade fairs covering a wide range of consumer and capital goods as well as emerging technologies. The company serves the Indian industry and international market with powerful brands such as air cargo India, analytica Anacon India/India Lab Expo, bauma CONEXPO India, drink technology India, electronica India, IFAT India, Indian Ceramics Asia, Intersolar India/The smarter E India, LASER World of PHOTONICS INDIA, MatDispens, Pack Mach Asia Expo, Pharma Pro Pack, productronica India, SmartTech Asia, World Tea & Coffee Expo, and many others.

Messe Muenchen India works closely with industry stakeholders to develop well-researched trade fairs that bring latest innovations to the market and facilitate meaningful business interactions. Headquartered in Mumbai with offices in New Delhi and Bengaluru, Messe Muenchen India connects global competence by bringing professionals together for business, learning and networking.

About IPMMA

Indian Pharma Machinery Manufacturers' Association (IPMMA) was founded in 2001 as a trade association to represent the Indian pharmaceutical machinery manufacturers, including processing, packaging, utility equipment and other ancillary products. Today, IPMMA has already enrolled 300+ members and the association has been recognized by several government, semi-government, and trade councils. It is a great pride for the association that these members already export their products to 80 different countries spread across five continents and therefore the association would put efforts to help other non-exporting members to find business inroads into those foreign countries.

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1.Unlocking India's Potential in the Digital Era

The global pharmaceutical industry is known for its high degree of innovation, research and development following stringent regulatory standards. As the world's third largest pharma industry by volume and the fourteenth largest by value, India plays a critical role in the global pharma manufacturing landscape. The country is known as the 'Pharmacy of the World' as it is among the largest producers of generic drugs and low-cost medicines across the globe. Currently valued at $50 billion, the Indian pharma industry is expected to reach $65 billion by 2024 and $130 billion by 2030.

Covid-19 has tested the resilience and innovative spirit of the Indian industry, and also accelerated its digitalisation through fast adoption of technologies like automation, robotics, and remote data management. Today, there is increasing focus on pharma manufacturing in India through production linked incentives (PLIs), renewed focus on R&D for drug discovery and manufacturing, strong regulatory and compliance framework, and increasing investments in infrastructure like medical device parks and pharma special economic zones (SEZs).

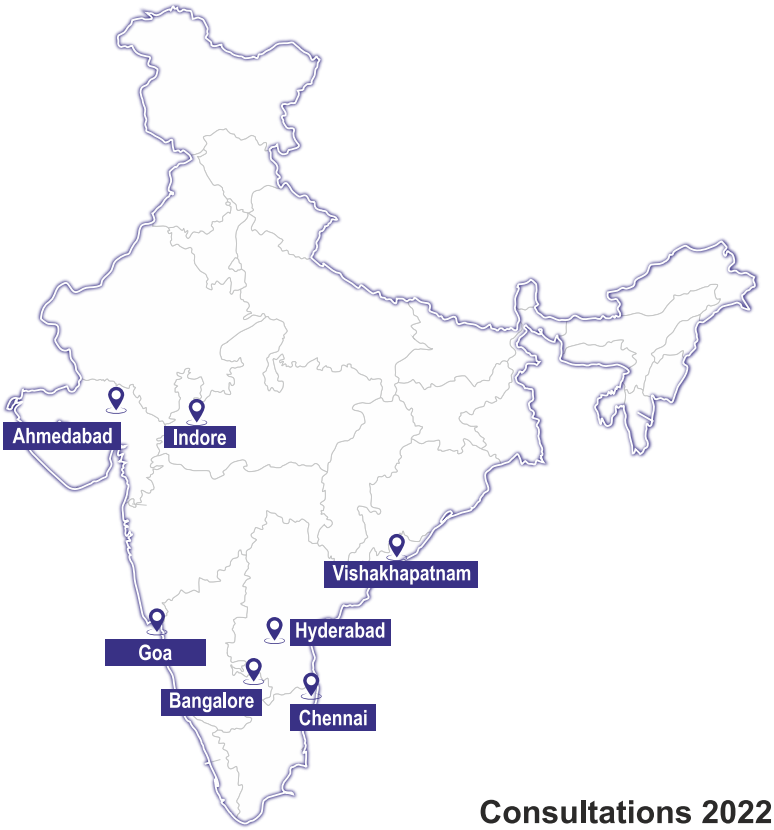
Snapshot of Indian Pharma Machinery Industry

Number of Companies (approx.)	300+
Total turnover	Rs.5000-6000 crores
Main Product Categories	Processing, packaging, utility equipment and other ancillary products
Export turnover	Rs.1000-1500 crores
Number of Export Countries	90+

**Source – IPMMA*

Amidst these positive thrust factors, combined with global technology forces like Generative Artificial Intelligence (AI) and Machine Learning (ML), the Indian pharma machinery industry is proud to present this detailed Position Paper on 'Technology and Automation: Futuristic Scenarios'. This document is the result of a three-month long series of consultations across 7 cities – Ahmedabad, Bangalore, Chennai, Goa, Hyderabad, Indore and Visakhapatnam.

The consultations were jointly organised by the Indian Pharma Machinery Manufacturers' Association (IPMMA) and leading trade fairs management company Messe Muenchen India. IPMMA and Messe Muenchen India are the joint organisers of Pharma Pro&Pack Expo. The key findings of this Position Paper emerged after consulting nearly 30 industry leaders across the pharma processing and packaging value chain.



Consultations 2022

2. Executive Summary

The Indian pharma industry has been one of the earliest adopters of pioneering technologies, enabling Indian-made processing and packaging machines to be exported worldwide. To increase Indian manufacturers' competitive advantage on the global scale and stay ahead of the innovation curve, this Position Paper on 'Technology and Automation: Futuristic Scenario' has put forward the following key observations and policy recommendations.

All observations have been determined after careful deliberation by the Panel of Experts, and categorised under five broad sub-themes:

1. Automation across pharma manufacturing and packaging operations

- The adoption of digitization and automation has taken momentum post-pandemic.
- Digitization and automation improve operational integrity by providing consistency, traceability, and transparency.
- Small and midsize enterprises (SMEs) must implement automation in phases by identifying areas for digitization and automation, building infrastructure, and initiating with the end-objective of integration.
- Automation is mainly witnessed in three areas: warehouse, filling and packaging lines.

2. Application of Robotics and COBOTs

- Robotics and COBOTs are widely used in secondary and tertiary packaging operations. They are used for repetitive tasks which are prone to human errors. Such tasks are more prevalent in warehousing and product filling lines.
- Robotic Process Automation (RPA) is simple to implement. However, the challenge lies in synchronization with batch processes. RPA takes care of all interventions of the line operations.
- Although in a nascent stage today, robotics are the future of pharma processing and packaging.

3. Digitization and cybersecurity

- Currently, almost 50% Indian pharma companies have implemented various systems for secure, time-saving, and paperless documentation management.
- Paperless records help in maintaining logbooks, QA documents, LIMS and support regulatory compliance with minimum data integrity issues.
- Electronic Batch Manufacturing Records (eBMRs) reduce the chance of human errors and gives more time for quality supervision.
- Remote Factory Acceptance Test (FAT) was helpful during the pandemic due to its time and cost-saving benefits. However, going forward a hybrid model is recommended for effective outcome.
- Current challenges in remote inspections are lack of adequate infrastructure, camera resolutions, language barriers, connectivity, and one can only see what is shown. This can be resolved by identifying critical (physical) and non-critical (virtual) areas of activity.
- Data management using tools like AI and ML can help make accurate decisions faster and provide timely recommendations for smooth operations.
- Gathering quality data is crucial to employ AI/ML. Collect, analyse, and act.

- Remote maintenance is possible with Google Eye as it supports breakdown management even in distant places.
- Predictive maintenance supports the smooth running of critical machines.
- This study recommends increased focus on cybersecurity measures like cloud security, hacking and data breach prevention, and installing and monitoring of upgraded firewalls.

4. Education and skill development

- This study recommends upskilling and reskilling of the workforce through continuous training.
- There is a gap between the education curriculum and industry requirements. Overhauling of the curriculum is the need of the hour through industry-academia interactions, industry participation, orientation of teaching faculty, etc.
- Industry-oriented short-term courses are mandatory to bring the workforce upto speed with global best practices in pharma machinery innovations.

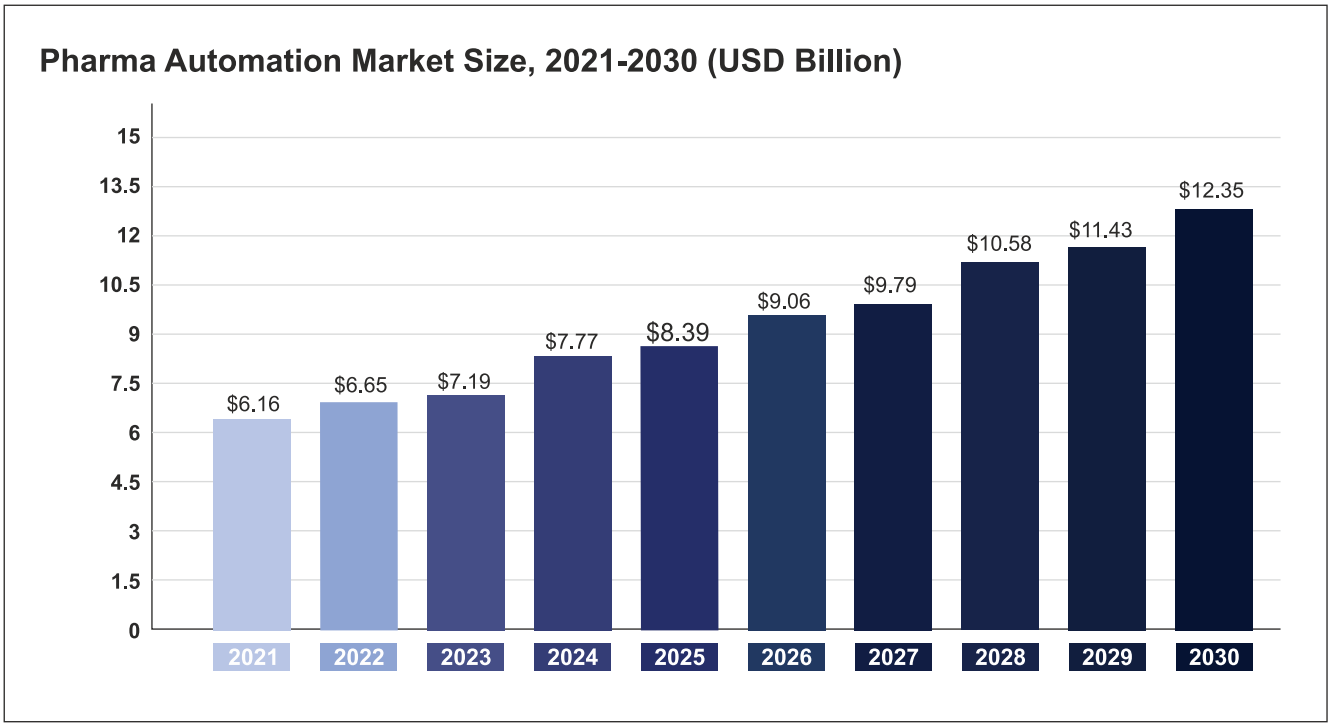
5. Intersectionality of pharma regulation and technology

- Digitization and automation give confidence to regulators about systems and procedures.
- Indian regulators have started accepting digitized systems.
- Machine manufacturers have adequate knowledge about regulatory requirements and can be valuable partners and facilitators for automation projects.

3. Automation holds the key to the Indian industry's global competitiveness

Automation is a critical aspect of the pharma machinery business, especially for equipment used in warehousing, filling and packaging lines. India is one of the largest producers of pharma machinery and has been gradually adopting new technologies through automation to improve efficiency and reduce costs.

Across the world today, the demand for end-to-end automation has replaced traditionally manual operations. Therefore, pharma machinery manufacturers are increasingly integrating automated data gathering, storing, and processing tools for real-time decision-making, regulatory compliance, and growth.



Source: Precedence Research

3.1 Post-pandemic demand trends

Covid-19 has accelerated the adoption of digitization and automation in India. With restrictions on physical movements and gatherings, businesses had to adapt to new ways of operating remotely. The digitization and automation of various processes have played a crucial role in ensuring business continuity and reducing the risk of infection.

3.2 Offsetting human errors through automation

In the world of pharma processing, automation helps in ensuring uniformity in the quality of drugs manufactured and reduces the risk of errors caused by human intervention. Automated systems control temperature, humidity, and other important parameters in the manufacturing process. Automation ensures that the drugs are manufactured under controlled conditions that can improve the quality and safety of drugs and reduce the risk of product recalls.

Automation is also used to handle a wide range of packaging tasks such as filling, labeling and sealing. Automated systems improve the speed and accuracy of packaging solutions. It reduces the need for manual intervention, thus ensuring reduced errors and increased productivity.

Several pharmaceutical companies in India have started adopting automation technologies in their processing and packaging activities. Increasing automation at the global scale is expected to continue to grow exponentially in the coming years, as many companies are seeking to improve their efficiencies, reduce costs, and enhance the quality and safety of drugs.

3.3 Gaining regulators confidence

The global pharmaceutical industry faces challenges like rising inputs costs, government regulations, and the safety of people working at plants, especially Active Pharmaceutical Ingredients (APIs) and formulations. These challenges drive the pharmaceutical industry to implement technologies like process automation and robotics along the filling and packaging lines.

To survive in an increasingly complex and compliance-driven global world order, pharmaceutical companies are fast adopting automated tools for data aggregation and management. Even small and medium sized companies cannot stay behind. They must gradually change to automated processes. Continuous innovation and adoption of new automation technologies will improve the global competitiveness of Indian pharma machinery manufacturers.

The pharmaceutical industry in India is facing several challenges that are driving the demand for automated processes in their system. Competition in the industry is one of the biggest drivers of adopting automation. With the ever-rising competition in the pharmaceutical industry, companies are under pressure of delivering cost-effective products at a faster rate. Automation determines how fast you can bring in new products.

Another driver that makes acceptance of automation in the industry inevitable is the increasing cost of labour. Companies are aggressively seeking ways to replace the workforce.

3.4 Automation to improve quality and productivity

The pharmaceutical industry is a late entrant in automation. Since the industry is more concerned with quality, automation is the future as it eliminates human errors and saves costs in the long run. India is likely to become over $130 billion pharmaceutical market by 2030 and it is aiming as high as $500 billion by 2047. In this journey, pharmaceutical machinery is going to play a very important role. And as the industry goes forward, automation and digital technologies will become more and more engraved in its day-to-day operations.

The cost of manufacturing is going to go high with an increase in wages and therefore it is natural to adopt automation. It makes more sense to invest in capex, which is the equipment to control over Opex. Automation also reduces the risk of product recalls and other costly errors, thus further improving the bottom line.

3.5 Automation to improve operational integrity by providing consistency, traceability, and transparency

There are numerous reasons why the pharmaceutical industry in India must implement automation in its processes. Automation increases capabilities and opens many new possibilities. Automation can help pharmaceutical companies reorganize their operations and increase efficiencies. Automated systems can perform tasks faster and more accurately than humans, which can result in cost savings and improved productivity. Automated systems are programmed to perform tasks consistently, reducing the risk of errors through human intervention, thus ensuring strict quality control.

The pharmaceutical supply chain is complex and includes multiple stakeholders such as manufacturers, suppliers, distributors and retailers. Automation can help companies to easily manage their supply chains and improve delivery times.

3.6 Safety in warehouse, filling and packaging lines

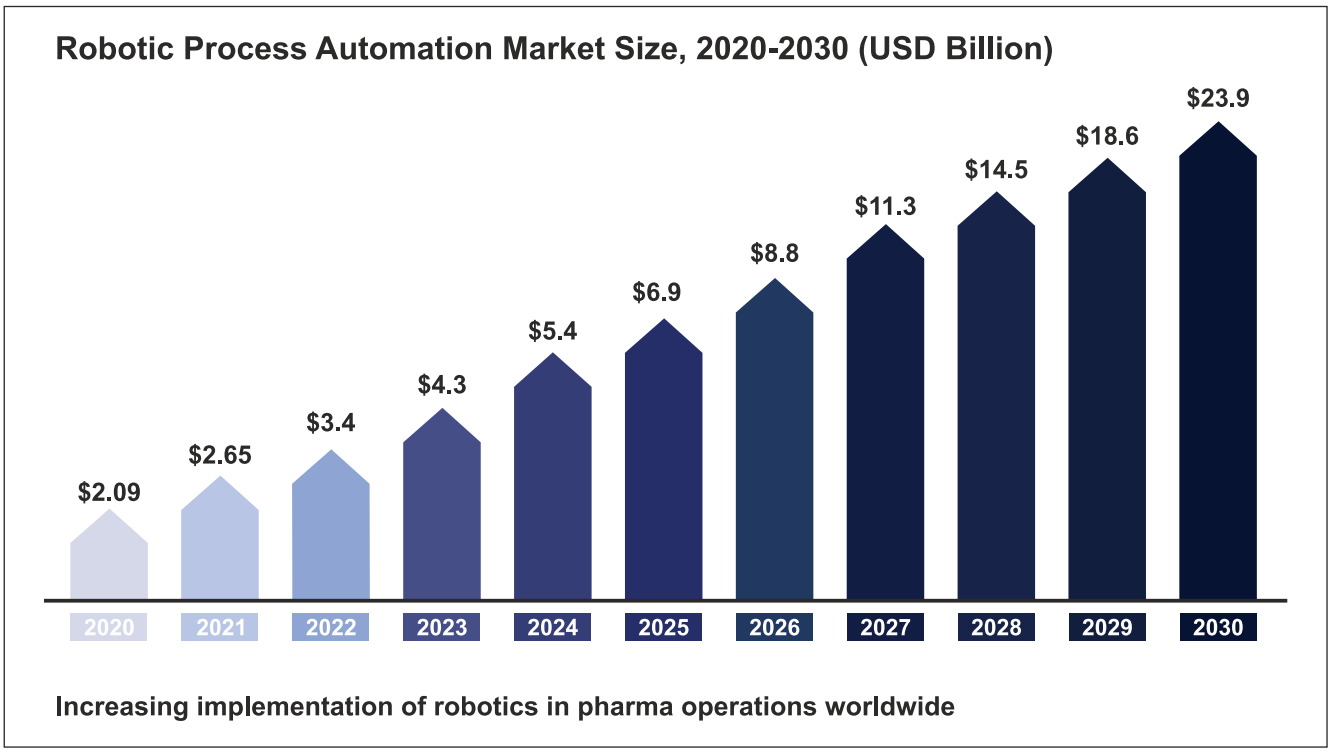
Automation in Indian pharmaceutical manufacturing is widely witnessed in three areas: warehouse, filling and packaging lines. It helps reduce the risk of accidents at a warehouse. Risky tasks, such as handling heavy machinery, toxic materials, etc. that can be dangerous to human lives can be replaced with automated systems to drastically reduce the risk of workplace accidents.

4. Innovation through Robots and COBOTs

The use of robotics and collaborative robots (COBOTs) by Indian pharma machinery manufacturers has been steadily increasing in recent years. Robotics and COBOTs offer several benefits in pharma processing and packaging including increased efficiency, productivity, and accuracy.

4.1 Main areas of application

Robotics and COBOTs are widely used in secondary and tertiary packaging operations. They are also used in warehouses and are recommended for oncology product filling lines. They are used for repetitive tasks which are prone to human errors, time-consuming and require precision such as drug packaging, labelling and assembly. On the other hand, COBOTs are designed to work alongside human operators and can perform tasks that require human-like dexterity and flexibility, such as quality control inspections.



Source: Precedence Research

The pharmaceutical industry is increasingly making use of robotics to automate specific processes in drug development, including drug screening, anti-counterfeiting and manufacturing tasks. Robots are also being used in material transfer operations by industry. Today, processes such as nuclear magnetic resonance (NMR) and high-performance liquid chromatography (HPLC) 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 structures 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 analysed using X-ray crystallography.

4.2 Advantages of robotics and COBOTs

One of the main advantages of using robotics and COBOTs in the Indian pharmaceutical industry is improved quality control. Robots and COBOTs can perform tasks with greater accuracy and consistency than human workers, reducing the risk of errors and improving quality. These technologies increase productivity as they work perform 24/7 without any breaks, thereby reducing production time and costs. Robots can perform hazardous tasks such as handling of toxic materials or working in a sterile enclosure, thereby reducing the risk of injury.

4.3 Robotics for filling, inspection and packaging

The pharmaceutical industry produces millions of tablets each week, all of which must be carefully scrutinised before being packed and shipped to distributors. During this inspection, drug manufacturers must ensure that the correct amount of medication, with the 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 systems. Automation of packaging also requires a system that monitors the operation on a supervisory level, checking for low hopper levels, fallen bottles and low-level supplies. Robotics and machine learning is also applied to ensure that products are packed in the correct bottles and boxes with the correct labelling affixed.

4.4 Robotic Process Automation (RPA)

This software has the ability to transform the global pharmaceutical industry. It improves operational efficiency, saves costs, and accelerates the process of drug development. RPA takes care of all interventions of the line operations.

RPA is increasingly getting popular in the Indian pharmaceutical industry as it helps streamline operations providing consistency, traceability and transparency. The software is capable of interacting with the machinery and guiding it to take decisions, thereby making tedious tasks simpler to manage. This technology is often used to perform repetitive activities and makes complex tasks easier.

RPA is simple to implement for a company. The challenge, however, lies in synchronization with batch processes. The pharmaceutical industry has complex processes that can be difficult to automate using RPA. Companies need to carefully assess which processes are suitable for automation and invest in the right technology accordingly to achieve desired outcomes.

4.4.1 Securing accuracy for repetitive tasks

RPA can be applied to any process of the company from simple tasks like generating an auto-response to complex tasks involving thousands of bots. Some of the common applications of RPA are:

- Administration, tax and finance, accounts payable, payment processing, tax reporting, etc.
- Purchasing: expense analysis, report management, data management, vendor management, etc.
- IT: security monitoring, testing management, server monitoring, etc.
- Supply chain: forecast and demand planning, data management, inventory management, etc.

4.4.2 Boosting productivity through reduced human errors

With RPA, pharmaceutical companies can automate processes to save time and avoid human errors. Below are some of the key benefits of RPA.

- Saves time: RPA performs repetitive tasks with quick robotic speed, thereby allowing employees to spend more time on sensitive and complex tasks.
- Increase ROI: RPA helps improve productivity, thereby impacting positively on ROI.
- Eliminate human error: Automated bots perform 100% accurately and tirelessly, whereas humans cannot be 100% accurate irrespective of how skilled they are.
- Elevate security: RPA guards against security threats by reducing human interactions with sensitive data and information, thereby preventing costly data leaks.
- Increase compliance: RPA adheres to set rules and guidelines. This helps when the industry follows strict regulations.
- Scale productivity: In case of a seasonal increase in demand, RPA achieved projected targets in terms of production.

Currently, robotics is already widely used in the secondary packaging stage, but the coming years will witness massive adoption in aseptic manufacturing environments as well. This implies a deep paradigm shift, in which robot manufacturers will have to adapt to the unique requirements of the pharmaceutical sector (both at the level of robotic solution and supporting testing and documentation), and the pharmaceutical sector itself will be involved in automation and robotics related decision-making to embrace and to thrive with the full potential of Pharma 4.0.

Robotic technologies are at a nascent stage in India. However, India is a thriving market for technology and innovation. Robotics and innovation are inevitable in the future and can significantly boost exports for India's innovative and thriving machinery manufacturing ecosystem.

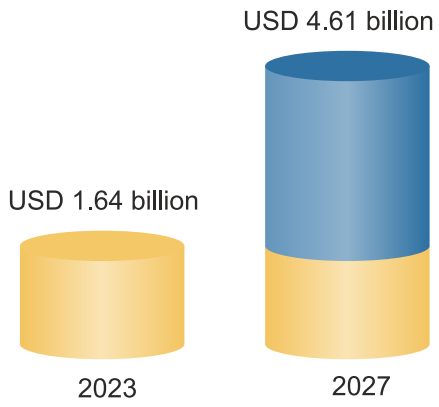
5. Digitisation and Cybersecurity

Researchers and pharmaceutical companies can generate tens of terabytes of data every day through extensive experiments and R&D. This data is a treasure trove for pharmaceutical manufacturing and needs to be accessible, manageable and visible. Collecting, analysing and acting on quality data is crucial for pharmaceutical manufacturing. Hence, pharmaceutical companies must develop innovative data management strategies.

With the adoption of Pharma 4.0, the Indian pharma machinery is undergoing a transformation. The fourth industrial revolution relies on integration of machinery with Artificial Intelligence (AI), Machine Learning (ML), Internet of Things (IoT) and Big Data to access insights from a large volume of data with ease. AI and ML are the key tools in data management in order to take accurate decisions faster and also provide recommendations for smooth operations.

Global AI in Pharma Market

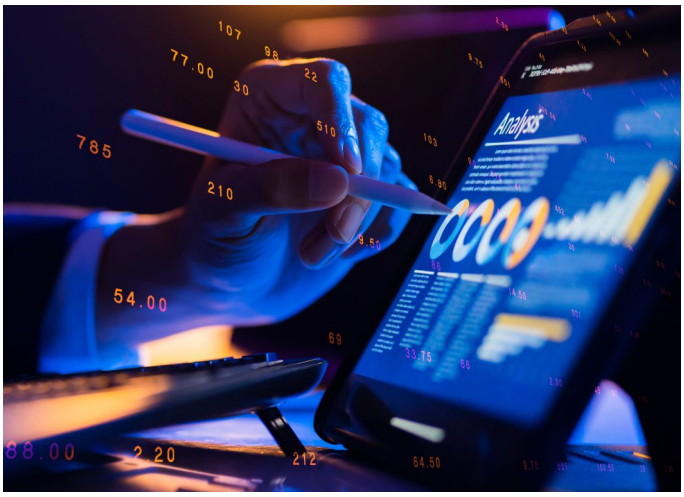
Market forcast to grow at CAGR of 29.4%



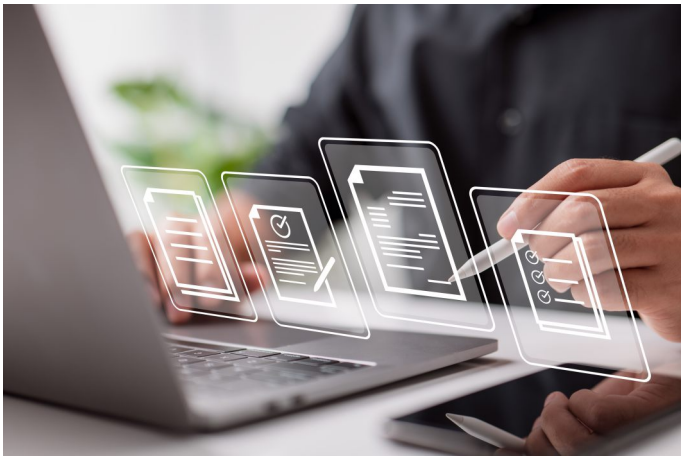
Source: Research and Markets

Key challenges that can make the industry adopt new technologies for data management:

- Achieving marketing speed to reach new emerging markets and get the most out of a product before the patent expires.
- Staying ahead of the competition.
- Attaining organization-wide connectivity in order to align operations with global requirements and improve efficiencies across plants.
- Maintaining competitive pricing.
- Achieving compliant operations.
- Adopting serialization strategy to combat counterfeiting.



5.1 Paperless documentation for speedy decision-making in real time



Challenges such as growing cost pressures, regulatory and safety guidelines and diverse product portfolios are making pharmaceutical manufacturers seek solutions to improve production processes. Currently, almost 50% of companies in India have implemented a paperless documentation management system. The system helps them not just save time but also prevent data manipulation. Accuracy of manual data management is only 91%.

There are several benefits of implementing a paperless documentation management system in pharmaceutical manufacturing, including:

- Paperless records help in maintaining logbooks, QA documents and LIMS (laboratory information management system).
- A paperless system allows for faster and more accurate documentation processing, reducing the time and effort required to manage paper-based records.
- Eliminating the need for paper-based documentation can result in significant cost savings associated with printing, storage, and archiving.
- Digital documents can be stored in secure databases with restricted access, reducing the risk of unauthorized access or loss of sensitive information.
- A paperless system can simplify compliance with regulatory requirements, as all documentation can be easily tracked, audited, and updated.
- Digital documentation can be easily shared and accessed by multiple users simultaneously, improving collaboration and reducing the risk of errors or inconsistencies.
- A paperless system can help reduce the environmental impact of pharmaceutical manufacturing by minimizing paper waste and reducing the need for physical storage space.

5.2 Keeping track of batch manufacturing record with eBMR

Ensuring that each manufacturing batch record meets regulatory compliance can be a daunting task for the pharmaceutical industry. Hence, the electronic batch record (eBMR) system has been developed specifically for the pharmaceutical and biotechnology industries. It is a software that records the manufacturing process of a product. With the use of eBMR, companies can enhance the integrity and accuracy of information. The software has the potential to streamline procedures and boost process efficiencies.

Below are some of the benefits of implementing eBMR system in pharmaceutical manufacturing:

- eBMR reduces the chances of human errors and gives more time for quality supervision.
- eBMR reduces the time for documentation and reporting during the manufacturing process.
- The system provides real-time data and ensures that the manufacturing process is running smoothly and efficiently.
- Ensures that the products are manufactured as per the correct specifications.
- Ensures compliance with regulatory requirements.
- Transparent and treaceable manufacturing process.
- Saves time and effort required for manual documentation.

5.3 Remote FAT in pharmaceutical manufacturing

Remote FAT (Factory Acceptance Testing) became popular in the pharmaceutical processes during the pandemic, which made visits and inspection more difficult. Remote FAT allows customers and manufacturers to perform the testing and inspection process without the need for a physical presence on-site.

In India, Remote FAT has been adopted by many pharmaceutical manufacturers as a way to ensure quality and compliance while also maintaining safety during the pandemic. The process typically involves using video conferencing and other remote communication technologies to allow customers to observe and participate in the testing process.

The use of Remote FAT in pharmaceutical manufacturing in India has several benefits, including reducing travel costs and time, increasing flexibility in scheduling, and allowing for greater collaboration and communication between the manufacturer and the customer. However, there are also some challenges to be aware of, such as ensuring the reliability and security of remote communication technologies, and the potential for technical difficulties or delays during the testing process. Hence, a hybrid model is recommended. A hybrid model requires extensive advance planning and the involvement of a dedicated team.

5.4 Remote inspection at a manufacturing facility

Pharmaceutical manufacturing strives for flawless precision in the construction and operation of machinery. Post-pandemic, the industry involved the use of video conferencing tools, virtual tours, etc. to inspect the manufacturing facilities. Remote inspection has several advantages. It reduces the need to travel, saves time and cost and can improve the effectiveness of inspections. However, there are also several challenges. Some of them are as below.

- Some manufacturing facilities do not have the necessary infrastructure to support remote inspections, such as video conferencing equipment and secure data transfer systems.
- Language barriers: Inspectors and manufacturing facility personnel may not speak the same language, making communication during a remote inspection difficult.
- Connectivity issues: Internet connectivity may not be strong or reliable in some parts of the country.
- Difficulty in assessing: Inspector can only see what is shown to him. Physical inspection in some cases is necessary which can be difficult to do remotely.

5.5 Predictive maintenance through remote sensing

Malfunctions or equipment failures can result in safety concerns, batch contamination and decreased productivity. Hence, the role of predictive maintenance is extremely critical. Predictive maintenance eliminates or lessens the need for corrective pharmaceutical maintenance, which may lead to a loss in revenue. Using appropriate predictive analysis, critical pharmaceutical machinery and equipment can run smoothly. It also helps in management of critical spare parts.

5.6 Preserving data security of the pharma industry

With the increasing use of technology and connectivity in the pharmaceutical manufacturing process, there are various cybersecurity challenges that the industry faces. Some of these challenges include:

- Pharmaceutical manufacturing handles vast amounts of sensitive data, making it vulnerable to cyber-attacks. Data breaches can lead to the loss of confidential information, resulting in reputational damage and financial loss.
- Hackers can gain access to trade secrets, drug formulations, and research data, which can result in the theft of millions of dollars in revenue.
- Ransomware attacks are becoming increasingly common in the pharmaceutical industry, where hackers encrypt a company's data and demand a ransom to release it. These attacks can result in significant financial losses, operational disruptions, and reputational damage.
- Employees with access to sensitive data and systems can pose a significant risk to the cybersecurity of pharmaceutical companies. Malicious insiders can steal data, compromise systems, or introduce malware into the network.
- Pharmaceutical companies often work with third-party vendors, making them vulnerable to cyber-attacks through these vendors' systems. These vendors may not have the same level of cybersecurity measures in place, making them a potential weak point for cybercriminals to exploit.

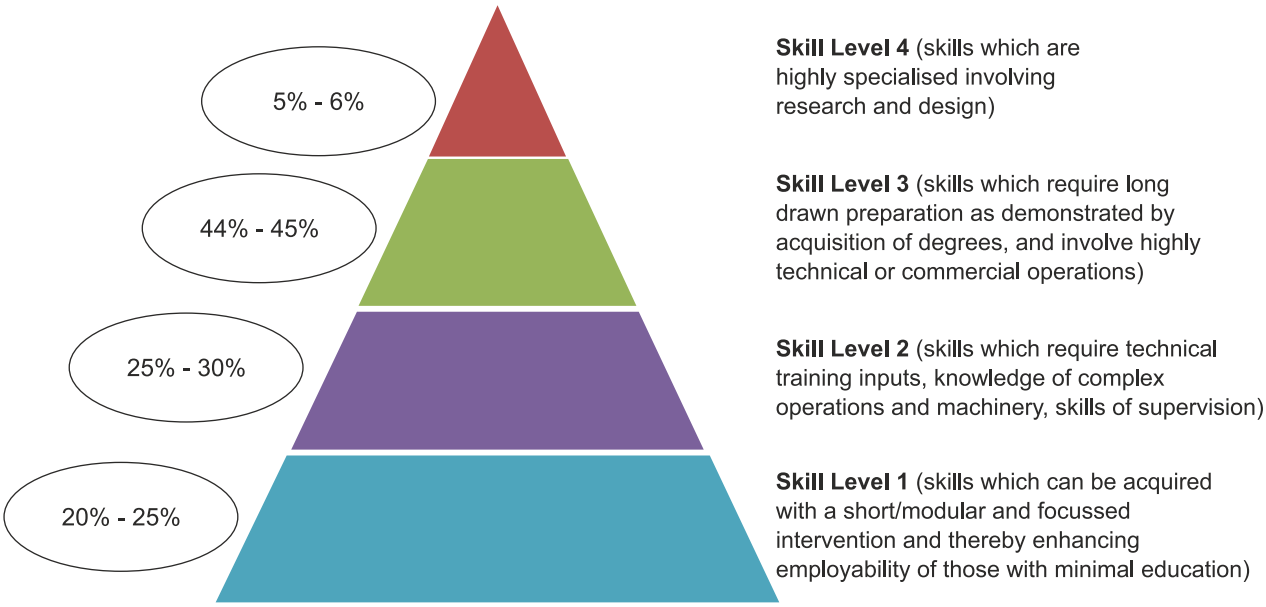
Cybersecurity is an important part of business continuity. To enable security for smooth functioning and collaborations within the organization, it is critical for pharmaceutical manufacturing to adopt and maintain cyber hygiene. Industry shall mitigate the challenges by utilizing firewalls, engaging cybersecurity experts and agencies dealing with these matters, and having proper backup measures in place.

6. Education and Skill Development

Innovation encompassing every aspect of pharmaceutical machinery is changing drastically in Pharma 4.0. Constant skilling and reskilling will be the key to staying relevant in the pharmaceutical machinery ecosystem.

Automation has the ability to replace the human workforce with machines that can perform repetitive command-based tasks. In the era of digitization and automation, the term 'skill' denotes an employee's adaptability to work with and around automated machines. Automation may not lead to a reduction in the workforce. However, skilling the workforce would be the biggest challenge in automation.

The pharmaceutical machinery segment in India, like many other industries, is being transformed by automation and digital technologies. As a result, there is a growing need to skill and reskill workforce in order to ensure they have the necessary competencies to work with these new technologies.



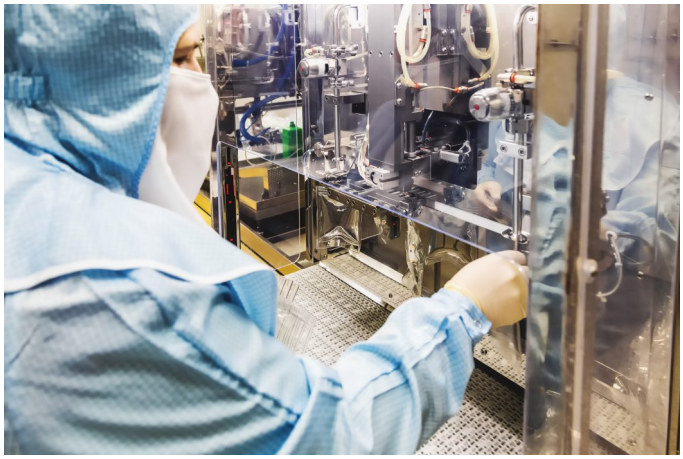
Skills pyramid for the pharma and chemicals industry as per National Skills Development Council (NSDC) of India

6.1 Building a future-ready workforce

The pharmaceutical machinery industry may need to choose from the below four steps to build a workforce in future.

- **Retraining:** This step involves retraining current employees by training them with new skills. This step ensures that the in-house company functions, experience and understanding are preserved by retaining and training the employees on job.
- **Redeployment:** Companies can redeploy employees based on their skill sets.
- **Hiring:** Today the industry does not have enough expertise to guide them to automation. However, once the skill learning takes place, skilled candidates or teams can be hired.
- **Third-party contracts:** Companies can get services from a third-party organization who have a well-equipped and skilled pool of talent.

6.2 Education to power skill development for digitization and automation



Academia needs to identify the skills that are required for automation and digitization in the pharmaceutical industry. This can be done by talking to industry experts, analyzing job descriptions, and looking at industry trends and developing short-term courses. Some of the skills that are likely to be in demand include data analytics, robotics, automation, and programming. Once required skills are identified, training programs can be developed to help students acquire these skills. The training programs can be delivered through advanced degree, diploma and certificate courses in automation engineering.

6.3 Upskilling and reskilling of existing workforce

Employees who are already working can be upskilled or reskilled depending on their profiles. Employees can avail on-the-job training programs like advanced professional courses which is being introduced by associations like IPMMA. Automation and digital technologies are constantly evolving, and it is imperative for employees to stay updated about the latest developments. Companies must provide access to online training programs, encourage to attend industry seminars/conferences, and offer career development opportunities.

6.4 Bridging the industry-academia skills gap

Educational institutions often face the challenge of introducing a curriculum that provides students with skills for digitization and automation. This can be attributed to disruptive new technologies like automation, IoT, big data, etc. being complex and ever evolving. The skills in these fields are highly transferable and changeable. Due to quickly changing skill requirements, reskilling is needed in every few years. Hence, only diploma and degree for students is not the norm anymore. Continued and quick learning and development in a fast-growing digital landscape will be the key for people skilled in automation.

There is often a gap between industry and academia when it comes to the adoption of automation in this industry. Below are some of the strategies with which the gap can be bridged between academia and industry to accelerate the adoption of automation in the industry.

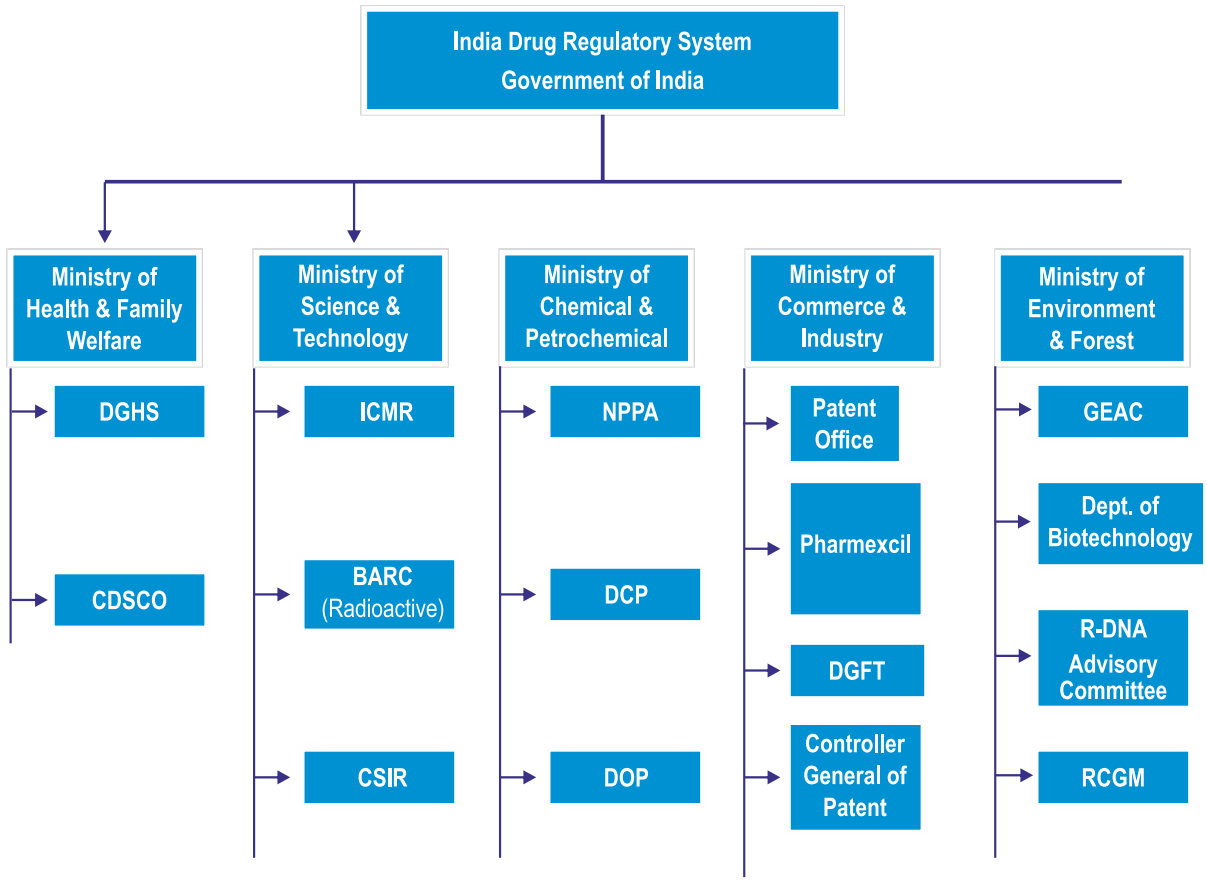
- The pharmaceutical machinery industry can collaborate with academic institutions to conduct joint research on automation in the industry. This research can be used to identify areas that can benefit from automation and to develop innovative solutions to address the challenges in implementing automation.
- The industry can organize workshops and seminars that bring together experts from academia and industry to discuss the challenges and opportunities of automation in the pharmaceutical machinery industry. These workshops can help build a common understanding of the potential benefits of automation and how it can be implemented in the industry.

- The industry can collaborate with universities to offer internship programs that allow students to gain practical experience in the industry. These internships can help students understand the challenges of automation in the pharmaceutical machinery industry and develop solutions to address them.
- The pharmaceutical machinery industry can partner with academic institutions to develop training programs for employees in the industry. These programs can help employees acquire the skills needed to design, implement and maintain automation solutions in the industry.
- Industry can provide funding for academic research that is focused on developing automation solutions for the pharmaceutical machinery industry. This can encourage academic researchers to develop innovative solutions that are relevant to the industry and help bridge the gap between academia and industry.
- There is also a need to collaborate with Government initiatives on skill development through National Skill Development.

Industry associations and manufacturers need to come together to promote skill development. Both sets of stakeholders have potentially critical roles to play in addressing shortages of skills and identifying areas that require training in the era of digitization and automation.

7. Intersectionality of Pharma Regulation and Technology

Global regulatory compliance is constantly changing, providing pharmaceutical machinery manufacturers with many opportunities enveloped with challenges for industry growth. New digitized technologies like AI and automation demonstrate exciting possibilities and provide ample opportunities for the industry to overcome regulatory challenges in the pharmaceutical industry.



Key regulatory bodies in India's pharma industry

7.1 Technology to effectively capture pharmaceutical data

New technologies like AI and ML efficiently capture an enormous amount of data from across multiple channels to be used to improve the performance of machinery. The adoption of automation by drug manufacturers can accelerate the process of drug development whilst bringing down the cost of the drugs for consumers. Technologies such as AI and ML hold a key to capturing data in different types and forms which is known as real-world data (RWD). This data can be then converted using AI algorithms to provide valuable evidence in the form of meaningful data.

7.2 How data captured enables regulatory compliance?

Pharmaceutical machinery can help in capturing data in several ways. Many modern pharmaceutical machines are equipped with sensors and software that can collect and transmit data in real-time. This data can be related to various parameters of the manufacturing process, such as temperature, pressure, speed, and volume.

The data captured by pharmaceutical machinery can be used to monitor the manufacturing process, identify inefficiencies, and improve the quality of the end product. For example, if a machine detects a deviation in temperature or pressure, it can automatically adjust its settings to ensure that the process remains within the desired parameters.

Moreover, pharmaceutical machinery can also help in capturing data related to the raw materials used in the manufacturing process. This data can include information such as the batch number, expiration date, and supplier information. Capturing this data not only helps in ensuring the quality and safety of the end product but also helps in complying with regulatory requirements.

7.3 Regulatory bodies adapt to automation

Pharmaceutical data and technology go hand in hand. The regulatory bodies governing drug regulation are constantly looking out for ways to update their framework in order to accommodate the use of new technologies. This will help them to access and handle data in real-time.

Today, Indian regulators have started accepting digitized systems. Regulatory bodies are adapting to automation in the pharmaceutical industry in a number of ways. Here are a few examples:

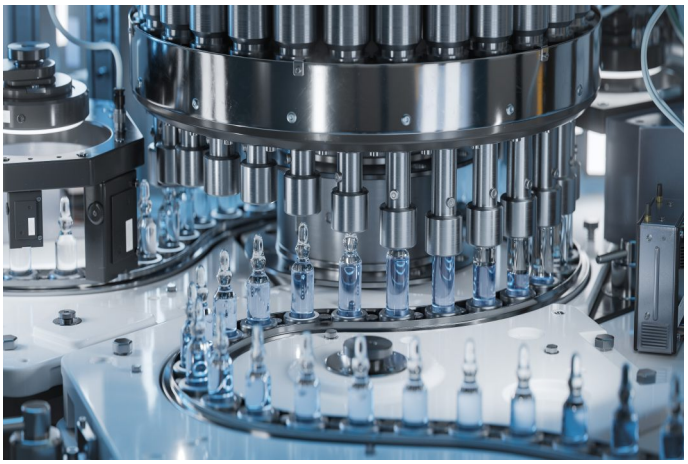
- Regulatory bodies are continuously updating their regulations and guidelines to reflect the increased use of automation and digitization tools in the pharmaceutical industry.
- Regulatory bodies are working more closely with industry to understand the use of automation in pharmaceutical manufacturing and to develop regulatory frameworks that are appropriate for these technologies.
- As automation increases, regulatory bodies are placing more emphasis on quality control. This includes validating computer systems used in manufacturing and ensuring that data generated by automated systems is accurate and reliable.
- Regulatory bodies are also developing new tools and technologies to support the regulation of automation in the pharmaceutical industry.

Regulatory bodies in India like Central Drugs Standard Control Organization (CDSCO) are recognizing the need to adapt to the increasing use of automation in the pharmaceutical industry and are taking steps to ensure that these technologies are safe, effective, and meet regulatory requirements. Digitization and automation give confidence to regulators about systems and procedures.

7.4 Pharmaceutical machinery industry as a technology enabler

The pharmaceutical machinery industry plays a critical role in enabling technological advancements in the pharmaceutical industry. The pharmaceutical machinery provides solutions for manufacturing, processing, packaging, and distribution of pharmaceutical products with state-of-the-art technology. The machinery industry is well-equipped with in-depth industry knowledge to produce cutting-edge automation and robotics solutions that are designed to meet the regulatory compliance requirements of the pharmaceutical industry.

Advances in pharmaceutical machinery technology have made it possible to produce pharmaceutical products with higher precision, efficiency, and quality, resulting in better patient outcomes. For instance, modern pharmaceutical machinery can automate and streamline the manufacturing process, reducing the risk of errors and contamination while increasing productivity.



The use of advanced technologies such as artificial intelligence, machine learning, and robotics in pharmaceutical machinery is also revolutionizing the industry. For example, AI-powered machines can identify defects and anomalies in the manufacturing process, improving quality control and reducing waste.

Machinery that can automate the documentation and tracking of pharmaceutical products can help companies comply with regulations and improve transparency in the supply chain. In addition to complying with regulatory requirements, pharmaceutical machinery industry is addressing key challenges in the industry, such as the need to reduce costs and increase efficiency.

The pharmaceutical machinery industry must consider a wide range of risks as the pharmaceutical industry adapts to new business practices in the wake of changing regulatory compliance and market-driven pressures, some of which include globalization, advancement of technology and stakeholder expectations. From regulatory compliance to customer transparency, the pharmaceutical machinery industry should be well-equipped with adequate knowledge and be a partner and facilitator in automation projects.

8. Concluding Remarks / Recommendations

1. SMEs should start implementation of automation in phases by identifying areas for digitization and automation, building infrastructure, and initiating with the end-objective of integration.

2. Adopting a hybrid model with regards to remote Factory Acceptance Test (FAT). Implementing FAT needs extensive planning and a dedicated team.

3. Current challenges in remote inspections are lack of adequate infrastructure, camera resolutions, language barriers, connectivity, and one can only see what is shown. This can be resolved by identifying critical (physical) and non-critical (virtual) areas of activity.

4. Making extensive use of tools like AI and ML can help make accurate decisions faster and provide recommendations for smooth operations.

5. Increasing focus on cybersecurity measures like cloud security, hacking and data breach prevention, and installing upgraded firewalls.

6. Automation and digitisation give regulators confidence about systems and procedures and thereby maintenance of quality systems at each stage of operations.

7. Pharmaceutical manufacturers must partner in automation projects with machine manufacturers who can be valuable facilitators for smooth implementation.

8. Upskilling and reskilling of the workforce through continuous training programs.

9. Overhauling of the curriculum through industry-academia interactions, industry participation, orientation of teaching staff, etc.

10. Making industry-oriented short-term courses mandatory to bring the workforce up to speed with best global practices in pharma machinery innovations.

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Nationwide Survey

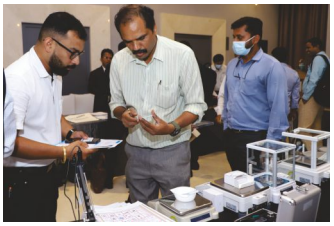
7 Cities | 1250 Delegates | 30+ Speakers

Goa

Ahmedabad

Bengaluru

Indore



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