Study of Indian Drug Product Recalls in US Market

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Abstract:

An attempt was made to review the reason/s of drug recalls of Indian Pharmaceutical products since last 15 years in US market. It was observed that from 2010 to 2025, India's pharmaceutical industry underwent significant transformations, solidifying its position as the "Pharmacy of the World." Known for providing affordable medications to over 200 countries, India houses more USFDA approved manufacturing sites than any country outside the U.S. However, this period also saw a rise in drug recalls, predominantly due to contamination, inaccurate data, and noncompliance with current Good Manufacturing Practices (cGMP). This review explores the reasons behind these recalls, highlighting improvements in India's regulatory landscape and quality assurance frameworks. Initially, many Indian manufacturers struggled with cGMP adherence, resulting in companies like Ranbaxy and Aurobindo faced scrutiny for data handling and contamination issues. However, between 2017 and 2023, Indian companies began to embrace proactive quality measures like Quality by Design (QbD) and Quality Risk Management (QRM). The government updated regulations to align with WHO and EU standards, emphasizing cleaner manufacturing environments and stringent procedures. The recalls followed three main trends: early recalls were largely contamination issues, the emergence of nitrosamine-related impurities led to major global recalls in 2018, and labelling issues contributed to Class II and Class III recalls. While Class II recalls raised concerns without immediate life threats, they highlighted ongoing issues within quality systems. The impact of these recalls was profound, affecting laws, the economy, company reputations, and most importantly, patient trust. High-profile cases, like the 2013 sanctions against Ranbaxy, prompted significant overhauls in compliance and quality processes across the industry. In summary, through regulatory enhancements and a shift in quality culture, the Indian pharmaceutical industry is working to restore global confidence and enhance patient safety.

Keywords: *Pharmaceutical quality assurance, USFDA drug recalls, Indian pharmaceutical industry, Good Manufacturing Practices (GMP), Quality by Design (QbD), Data integrity and regulatory compliance, Nitrosamine impurities, Manufacturing reforms and digital transformation.*

Introduction:

The USFDA defines pharmaceutical quality as making sure that every drug product meets safety, efficacy, and performance standards, as well as other appropriate QBD (Quality by Design) standards, throughout its entire life cycle[1]. The end of the process doesn't just determine quality; it also comes from building a system that combines science, risk management, and regulatory oversight. The USFDA says that pharmaceutical quality is "the suitability of either a drug product or drug substance to meet its intended purpose[1]."

The most important thing about pharmaceutical quality is following current Good Manufacturing Practice (cGMP)[2]. cGMP sets rules that a regulating body must follow to make sure that drugs are made in a safe way. These rules cover everything, from making things and controlling materials to testing, storing, and releasing them. The USFDA is looking at factories to make sure they are following the rules. If they don't, they will send warning letters or alerts about imports[2]. It does say, though, that just following the rules isn't enough; the product should be made with quality in mind. The Quality by Design (QbD) principle makes this idea official by saying that an API has quality built in[3]. QbD makes the formulation, process parameters, and manufacturing equipment scientifically understood and controlled in order to cut down on variation and the chance of failure[3]. The FDA believes that Quality Risk Management (QRM) is very important for making sure that drugs are safe and effective[4]. Quality Risk Management (QRM) is the process of finding possible threats to product quality, figuring out how important they are, and making controls to deal with them. The agency backs a science- and risk-based approach, which is what ICH Q9 (R1) says it should[4]. The data must also be correct, which is very important. The FDA says that all data about manufacturing and testing must follow the ALCOA principles, which stand for Attributable, Legible, Contemporaneous, Original, and Accurate[5]. They stress how important it is to keep the quality high throughout the product's life, even after it has been approved. The FDA says that there are three steps to process validation: designing the process, making sure it works, and checking it over and over again[6]. They also talk about how technologies like continuous manufacturing and Process Analytical Technology (PAT) can help keep an eye on things in real time to ensure the quality of the product[7]. The FDA thinks that drugs should be of the same quality everywhere in the world. The International Council for Harmonisation (ICH) is one of the programs that does this by setting standard quality requirements[8]. Finally, everyone who works in the pharmaceutical industry, including regulators, manufacturers, and healthcare professionals, is responsible for the quality of drugs. To keep patients safe, this makes a culture of quality and constant improvement[8].

The state of the Indian pharmaceutical industry:

The Indian pharmaceutical industry is a big part of the country's economy and healthcare system. People call it the "Pharmacy of the World"[9]. This industry has changed a lot in the last few decades. It used to be all about making things in the area, but now it's a well-known place for research and production all over the world. Right now, the Indian pharmaceutical market is worth more than $50 billion. About 20 billion of that comes from sales in India, and almost 70% of that comes from exports[10]. India is known for sending medicines to more than 200 countries, including the US and the UK, which are two of the biggest markets, as

well as many developing countries[10]. It also makes the most vaccines in the world, which is about 60% of what the world needs[11]. The Indian pharmaceutical industry is doing well because it can make drugs that work well for a low price. A strong production system, skilled workers, and advanced technology make this possible.[12] The Indian Patent Act of 1970 had a big effect on the pharmaceutical industry because it let companies patent processes instead of products[13]. This method helped local businesses find cheap ways to make patented drugs, which lowered the cost of medicines for everyone. The TRIPS agreement made product patents possible in 2005. This led to more innovation and partnerships with drug companies all over the world[14]. As a result, Indian companies like Sun Pharma, Dr. Reddy's, Cipla, and Lupin expanded their businesses around the world, and many of their facilities met strict global standards set by regulators like the USFDA[15]. India has more factories that have been approved by the USFDA than any other country outside the U.S. This shows how much it cares about safety and quality[15]. In the fiscal year 2024–2025, Indian pharmaceutical exports reached $30.47 billion, an increase of more than 9% from the year before[16]. Biologics, vaccines, bulk drugs, and formulations were all part of the exports. Formulations made up about 75% of the total value. The U.S. is India's biggest market, followed by Europe, Africa, and Latin America[16]. In India, the pharmaceutical market is mostly made up of anti-infectives, cardiovascular medicines, gastrointestinal agents, anti-diabetics, and nutritional supplements[17]. The ₹15,000 crore Production Linked Incentive (PLI) Scheme is one of the ways the government is helping the pharmaceutical industry grow[18]. This program helps India make more bulk drugs and lessens the need to buy drugs from China. So far, 55 businesses are getting help, mostly with high-tech APIs and speciality drugs[18].

India's pharmaceutical industry is strong because it makes the most generic drugs in the world[19]. Indian companies make about 20% of the world's generic medicines by volume[19]. India is a popular partner for international pharmaceutical supply chains because it has low costs, follows the rules, and can make a lot of things at once[20]. India is also becoming more interested in biotechnology, biosimilars, and complex generics[21]. This shows that the country is moving toward growth based on new ideas. The rise of contract development and manufacturing organisations (CDMOs) and contract research and manufacturing services (CRAMS) has made India's role as a global outsourcing hub for drug development and production even stronger[22]. The Indian pharmaceutical industry still has to deal with a number of long-term problems, even though it has had some successes. One of the biggest worries is that the industry still gets its active pharmaceutical ingredients (APIs) and other raw materials from China[23]. This puts the industry at risk of supply chain problems and geopolitical risks[23].

There have also been ongoing worries about quality compliance and regulatory oversight, especially after cases of contaminated or low-quality medicines that have gotten a lot of attention around the world[24]. It is very important to have strict quality control, better ways to test things, and be open about how things are made[24]. Low profit margins, high prices in the generic market, and little investment in research and development make it hard to stay in business for a long time[25]. India still spends a small amount of its revenue on research and development compared to other developed countries[25]. India needs to close this gap if it wants to move from a generic-led model to one that is led by innovation[25]. The Indian pharmaceutical industry has also gone digital in the last few years, using AI, automation, and data analytics to help with drug discovery, manufacturing, and managing

the supply chain[26]. These new ideas have made things work better, made fewer mistakes, and improved the quality of the products. The domestic healthcare market is also growing quickly because people are making more money, getting more insurance, and the government is providing healthcare[27]. This is a great chance for more growth. The market for Indian pharmaceutical companies has grown because people are more interested in wellness products, lifestyle-related disorders, and non-communicable diseases[27].

Recalls of products:

The US Food and Drug Administration (USFDA) says that a drug recall is when a company or distributor takes a product off the market because it breaks FDA rules[28,29]. The main purpose of a recall is to keep patients safe and make sure that only safe, effective, and high quality drugs are sold to the public. Drug recalls are a key part of the larger system that regulates drugs. They are very similar to the ideas behind pharmacovigilance, quality assurance, and current Good Manufacturing Practices (cGMP)[1,3,6]. Problems with drugs can sometimes only be found after they are on the market, even though drug development, production, and quality testing are very strict. These problems could be caused by contamination during production, incorrect labeling, incorrect potency, adulteration, the presence of impurities, or not meeting safety and stability standards[29,30]. If these kinds of problems aren't fixed, they could put patients' safety at risk, make treatment fail, or even have serious health effects in the worst cases.

The USFDA says that drug recalls are not just administrative actions; they are an important way to keep patients safe in the pharmaceutical ecosystem[28]. Two ways to lower the chance of getting bad products are to follow the rules and do quality control. But recalls are a very important way to fix problems that happen after a product is sold[29,30]. By taking unsafe products out of the supply chain, recalls lower risks and keep people from being exposed to drugs that could be harmful. This process shows that the FDA is serious about keeping people safe. If a manufacturer finds a problem with one of their products, they can start a recall on their own. If the manufacturer doesn't do the right things, the FDA can ask for a recall or order one[28,31]. The FDA watches recalls to make sure that bad products are taken off the market and that patients are told when they need to be. The FDA, the manufacturer, the distributors, and the healthcare providers all need to work together to make sure the recall process goes smoothly and on time. There are more reasons to recall drugs than just making sure patients are safe right away. They also show that the pharmaceutical industry and government agencies are working hard to keep people trusting medicines[32]. A good recall system shows that businesses care about the quality of their goods and are willing to fix any problems that come up after they are sold. Recalls also give manufacturers important information that helps them find problems in their production, quality control, or supply chain processes. This helps them avoid problems in the future[30,33]. In this way, recalls are both ways to fix problems and ways to stop them from happening in the first place in the pharmaceutical quality system. The FDA does not see a recall as a sign of failure; instead, it sees it as a necessary step to improve safety and quality[29,32]. Problems can happen in an industry that makes a lot of drugs and ships them all over the world. The FDA's rules make sure that any problems that come up are fixed right away to keep people safe[31,32]. This proactive approach helps the FDA reach its main goal of protecting public health, making sure that safe drugs are available, and keeping the drug supply safe[28,29,31]. The recall process also shows how important it is to be honest and talk to each other. If a

product is recalled, it's important to tell healthcare providers, distributors, and, if necessary, the public about the problem, the risks it poses, and how to return or fix it[33]. This open communication helps people understand and ensures that patients and healthcare systems can do the right things to lower risk[33].

Not only are drug recalls important for safety and quality control, but they are also a great way for companies to learn[29,30,31]. Each recall shows where there might be problems with making things, managing the supply chain, or following the rules[30,33,34]. Manufacturers can figure out what went wrong with recalls and then fix the problems so they don't happen again[29,31,34]. This will make all of their products better. This constant feedback loop makes the pharmaceutical quality system work better and stops the same problems from happening in new products[28,32,33]. A drug recall is a planned, corrective, and preventive step to make sure that drugs that are unsafe or of poor quality are taken off the market[28,29,30]. It is a key part of the pharmaceutical industry's rules, quality, and drug safety system[32,34]. The main goal is to protect patients, make sure drugs are safe and work, follow the rules, and get people to trust medicines. Manufacturers and regulatory bodies work together to make sure that healthcare is safe and reliable by doing drug recalls the right way[28,31,33,34]. This shows that they care about patient safety and high standards of pharmaceutical care[29,32,34].

Drug Product Recall: Various Types, Levels, and Classifications

A drug product recall is when a drug company or the government takes back or fixes a drug that is being sold, but is against the rules or could be bad for your health[35,36]. Drug recalls keep the public safe, make sure that companies follow the rules, and ensure that drugs are always of high quality[36,37].

Recalls are an important part of the drug quality assurance system because they show that the company is following current Good Manufacturing Practices (cGMP)[1,3,38]. If there is a problem with making, labelling, or storing a product, it may need to be recalled to protect people's health[36,39].

There are two main ways to group drug recalls: by who starts them and why. It's important to know the different types for regulatory compliance and good risk management[40,41].

Voluntary Recall:

Definition: The manufacturer, distributor, or importer starts the process when a product is found to be broken or possibly dangerous[42].

Purpose: to protect public health, keep the company's good name, and show that the company is following the rules[42,43].

Reasons for a voluntary recall:

1. Contamination (chemical, microbial, or particulate)[44].
2. Errors in labelling or packaging[44,45].
3. Wrong amount or mix[45].

4. Reports of negative reactions or signals from pharmacovigilance[46].
5. Issues with storage or stability[44,46].

Regulatory Context: A company should do a voluntary recall because it shows that they are following the rules[42,43].

For example, a batch of oral antibiotics is recalled before it can do any harm because it has the wrong amount of active ingredient[45].

Recall what is needed:
Definition: Regulatory bodies like the USFDA and CDSCO order a company to recall a faulty product when the company doesn't do it on its own[35,47].

Legal Basis: Required by laws that protect public health and safety; not following the rules can lead to fines, license suspensions, or the seizure of goods[48,49].

For example, the FDA orders a recall for consumer safety because a company doesn't pay attention to reports of contaminated sterile injectables[35,47].

Leaving the market:
Definition: Removing a product from the market because of small problems that are not likely to be a serious health risk[43,50].

Key Features:
Usually started by the maker
Some problems aren't safety-related, like problems with labels or packaging[50,51].

For instance, a small error on the drug packaging or a label with the wrong font size that doesn't change the dose[51].

Getting Back to Stock:
A preemptive recall from distributors or wholesalers before the product gets to stores or consumers[52].

Purpose: To stop bad products from getting into the market[52,53].

For instance, a batch of syrup that unusually changes colour because of problems in the manufacturing process is taken out of warehouses before it is sent out[53].

Drug Recalls by Risk Level:

The USFDA decides how drugs are recalled based on how dangerous they are to people's health. CDSCO has a risk-based classification system that is similar to the WHO's[36,55].

Table 1. Types of recalls according to risk levels

Type of Recall	Risk Level	Description	For instance	Recall Time
Class I	Very high	Things that could seriously hurt your health or even kill you. We need to do something right away to fix the problem.	Drugs that have needles in them or the wrong active ingredient in them to save lives	Within 24 to 72 hours
Class II	Not a lot	Things that could make you sick for a short time or for good. There is a small chance of a big risk.	Tablets that are only a little bit different in strength, have a little bit of contamination, and don't hurt anyone badly.	Within 10 days
Class III	Not very high	The goods probably won't hurt your health. Most of the time, the problems are with the labeling, packaging, or administration.	Wrongly printed expiration dates, small mistakes in the packaging	Within 30 days

Types of Recalls on the risk level[58-64].

Levels of Drug Recall (How far the action goes in the supply chain):
The level of recall shows how far the recall action goes down the chain of distribution. It is important to know levels so that you can plan operations and follow the rules[56.57].

Remember at the Store Level:
Definition: Items are taken from pharmacies, hospitals, and stores[58].

Use: This is usually used for Class I or Class II recalls, especially if the product is already with customers[59].

For example, local pharmacies had to take back tablets that had germs on them[60].

Remember at the wholesale level:
Definition: Products are taken back from wholesalers or distributors, usually before they get to stores[61].

Use: Stop moderate-risk problems or mistakes before they are sent out[62].

Tablets with small errors on the labels were sent back to the warehouse stock before they were sent to stores[62].

Consumer Level Recall:
Definition: High-risk products are taken back directly from customers, usually after someone reports bad effects[63].

Example: A life-saving injectable drug is recalled after a toxic impurity is found[64].

USFDA Drug Product Recall of Indian Manufacturer (2010–2025):

2010–2013:

Some Indian companies, like Ranbaxy, Sun Pharma, and Aurobindo, had to take their products off the market because of quality issues like contamination, labeling mistakes, and the presence of foreign tablets[35,65].

Aurobindo took Zolpidem tablets off the market because they had foreign tablets in them[66].

Ranbaxy's products were pulled from the market because they broke CGMP and data integrity rules. This caused import warnings for a number of plants[35,67].

2014:

In January 2014, Dr. Reddy's took back 58,656 bottles of Lansoprazole because they had germs in them[68].

Ranbaxy recalled 64,626 bottles of atorvastatin calcium tablets in January 2014 because the doses inside the bottles were not the same[67,68].

Sun Pharma took 2528 bottles of Metformin ER tablets off the market because they had foreign tablets in them[66,68].

2015:

Before the 2013 bans, Wockhardt voluntarily pulled several drugs made at their *Waluj* and *Chikalthana* plants because the FDA was worried about them[69].

2016:

Cadila Pharma got back 6 kg of Ondansetron API because it had microbes in it[70].

Alkem took back 1,739 bottles of Metformin Hydrochloride tablets because they found tablets that weren't supposed to be there[71].

Par Pharmaceutical took back more than 242,000 bottles of Travoprost eye drops because they were worried about how clean they were[72].

2017:

Dr. Reddy's took back 5,904 bottles of Olanzapine tablets because they had an impurity that made them less stable[68,73].

Aurobindo pulled back 29,800 vials of Pantoprazole Sodium Injection because they had changed color[66,70].

2018–2019:

A lot of drugs were recalled because Indian companies like Aurobindo, Sun Pharma, and Cipla made ARB drugs like valsartan that had nitrosamine impurities (NDEA, NDMA)[74,75].

The FDA sent out warning letters about recalls that were caused by problems with manufacturing[35,36].

Sun Pharma took back 400,000 bottles of different drugs because they had problems with contamination and labeling[68,76].

2020 to 2023:

Aurobindo Pharma had to recall Irbesartan products several times because they had NDEA in them[74,77].

Glenmark took back 73,056 units of Carvedilol and 22,656 bottles of Theophylline ER tablets because they had nitrosamine impurities and didn't dissolve properly[78].

Dr. Reddy's took back 13,752 bottles of Eszopiclone tablets because they were not pure or had broken down[68,73].

Sun Pharma took back 2,088 vials of Decitabine for Injection because they didn't meet CGMP standards[35,36,68].

Zydus took back 8,784 bottles of Entecavir tablets because they weren't pure[79].
UniChem took back 230 bottles because the labels were wrong[66,71].

2024–2025:

Glenmark, Alembic, Sun Pharma, Zydus, Granules India, and UniChem all recalled several products because they had problems with how they were made. For example, they had nitrosamine impurities that were higher than FDA limits, aluminium contamination, and they didn't meet dissolution specifications[74,77,78].

Glenmark had to take back 55,560 Carvedilol tablets and 17,496 bottles because they had nitrosamine impurities and other issues[78].

Sun Pharma took back 11,328 bottles of Spironolactone tablets because they had aluminium in them[68,76].

Indian drug companies recalled millions of doses in 2025. Most of the time, these recalls were Class II, which means they could be harmful to health for a short time or even permanently[35,36,65,80].

In March 2025, Dr Reddy's recalled 1,000 infusion bags of Levetiracetam because the labels were wrong and could cause an overdose[68,73]. Glenmark took back more than 1.4 million bottles of Atomoxetine because they were worried about impurities[78,80].

Most of the recalls from Sun Pharma, Zydus, and Glenmark were because of impurities that could cause cancer, microbial contamination, and mistakes on the labels[74,75,78].

Table 2. Yearly data on drug recalls

Year	Business	Item	Units and Lots	Why	Date of Recall
2014	Dr. Reddy's	Lansoprazole capsules	58656 Bottles	Microbial Contaminations	January 2014
2014	Ranbaxy	Pills of atorvastatin	64626 Bottles	Putting different doses in the same bottle	January 2014
2017	Aurobindo	Vials for Pantoprazole Shots	29800 vials	Switching colors	February 2017
2024	Dr. Reddy's	Eszopiclone tablets	13752 Bottles	Impurities or degradation that didn't work	June 2024

2024	Sun Pharma	Decitabine Injection in Vials	2088 Vials	Changes to cGMP	July 2024
2025	Glenmark	Carvedilol tablets	73056 units	Impurities of nitrosamines that are too high	From March to April 2025
2025	Glenmark	Theophylline Extended-Release Tablets	22656 bottles	Not being able to dissolve	March to April 2025
2025	Sun Pharma	Spironolactone pills	11328 Bottles	Pollution from aluminum	2025
2025	Dr. Reddy's	Bags for Adding Levetiracetam	A Thousand Bags	Wrong labeling (risk of overdose)	March 2025

The USFDA's yearly data on drug product recalls from 2010 to 2025[35-37,65-80].

A detailed examination of US FDA drug recalls involving Indian manufacturers from 2010 to 2025, encompassing issues related to production and regulatory compliance:

The US FDA has been increasingly recalling drugs from Indian manufacturers between 2010 and 2025 due to worsening quality and compliance issues[35,65,81]. A trend analysis shows that the number of recalls has risen sharply, particularly since 2017, driven by stricter regulations and heightened scrutiny of manufacturing processes[74,75,82]. Prominent companies like Glenmark, Sun Pharmaceutical, and Dr Reddy's have faced multiple recalls for various products, including those used for cancer and high blood pressure[78,80,83]. These recalls often stem from violations of Good Manufacturing Practices (cGMP), which are designed to ensure drug safety and quality[1,2,36]. Common issues include inadequate cleaning procedures, contamination problems, failures in sterility, and labelling errors that can confuse patients and lead to unsafe usage[68,70,84]. For instance, several drugs were recalled due to serious impurities, including cancer-causing substances[74,75,78].

The rising recalls have serious implications for these businesses, leading to financial losses and eroded trust from patients[81,82,85]. To address these ongoing challenges, Indian drug companies must strengthen their quality assurance practices. This includes investing in better training, cleaning protocols, and technology to enhance documentation and problem detection[86,87]. Being proactive through internal audits can help prevent regulatory actions and maintain compliance[1,2,36]. Such steps are crucial for restoring confidence in the industry while ensuring patient safety[65,81].

To fix these problems with manufacturing and rules:

Between 2010 and 2025, Indian pharmaceutical companies went through a major transformation in how they manage quality and manufacturing[82,88]. These changes came in response to increasing inspections from the US FDA and stricter global regulations, pushing companies to upgrade their systems and reduce the risk of product recalls[74,75,82].

To meet international expectations, Indian firms began adopting stronger quality standards based on WHO GMP, EU GMP, and US FDA guidelines[2,36,89]. The revision of Schedule M further reinforced the need for strict Good Manufacturing Practices[90]. Companies also became more careful about where they sourced their raw materials, creating systems for supplier qualification and regular audits. By ensuring that only approved vendors were used and checking materials for purity, potency, and traceability, they greatly reduced the chances of contamination or variations during production[88,91]. At the same time, the industry invested heavily in better testing and manufacturing facilities[86,87,92]. Modern analytical laboratories equipped with advanced instruments and real-time monitoring systems helped companies maintain consistency and catch problems early[87,92]. Clean rooms, improved HVAC systems, and continuous environmental monitoring became standard, especially in facilities producing sterile or biological products[89,93].

Digitalisation changed how quality assurance worked[94]. Many companies started using digital Quality Management Systems to ensure accurate documentation, secure data handling, and smoother audits[95]. Alongside this, regular employee training on GMP, deviation handling, and data integrity built a stronger culture of responsibility and quality across every level of manufacturing[2,36,87].

Regulatory bodies and the government also played a key role by updating policies and encouraging alignment with international organisations like PIC/S[90,96]. At the same time, the adoption of new technologies such as artificial intelligence, blockchain, and Process Analytical Technology helped improve process control, transparency, and supply chain safety[87,94,97]. By combining technology, stronger regulations, and a culture of continuous improvement, the Indian pharmaceutical industry has built a more reliable and globally respected quality system[81,88,97]. These efforts have not only helped reduce manufacturing problems and recalls but also strengthened India's position as a trusted player in the global pharmaceutical market[82,86,88].

Ideas:

Between 2010 and 2025, Indian pharmaceutical companies made major strides in strengthening their quality assurance (QA) systems and manufacturing processes[81,82,98]. These reforms were driven by the need to comply with global standards and reduce product recalls, especially under the scrutiny of the US FDA and other international regulators[25,36,82,99].

To improve quality, companies adopted advanced global benchmarks such as WHO GMP, EU GMP, and US FDA guidelines[2,36,100]. The revised Schedule M placed a stronger focus on stricter Good Manufacturing Practices (GMP), process validation, cleanliness, and

proper documentation—all essential for maintaining compliance[90,101]. At the same time, firms built robust supplier qualification systems to ensure raw materials met the highest standards[91,102]. Regular supplier audits, approved vendor lists, and continuous checks for purity, potency, and traceability became standard practice, minimising contamination and product variation[81,91,102].

Analytical laboratories were upgraded with cutting-edge instruments and modern testing methods for raw materials, in-process samples, and finished products[92,103]. Real-time monitoring tools like Process Analytical Technology (PAT) helped maintain process stability and detect issues early[97,104]. Massive investments were also made to modernise facilities—adding clean rooms with HEPA filters, improving HVAC systems, and installing advanced environmental monitoring systems to control microbial and particulate contamination, especially in sterile and biologic production[93,104].

Digitalisation and automation brought further transformation[94,105]. Many companies adopted digital Quality Management Systems (QMS) to improve data integrity, ensure accurate recordkeeping, and stay prepared for audits[95,105]. Alongside these technological upgrades, continuous employee training on GMP, deviation management, and documentation built a strong culture of accountability and shared responsibility for quality[2,87,105]. The Indian government supported these efforts by introducing updated regulations, including the new Schedule M, and by aligning domestic standards with international frameworks such as PIC/S. These initiatives enhanced India's reputation for regulatory reliability and strengthened global confidence in its pharmaceutical products[81,88,97].

Embracing Industry 4.0 technologies such as artificial intelligence, blockchain, and PAT further improved real-time process control, data transparency, and supply chain traceability[87,106]. Companies began adopting risk-based quality management and rigorous internal audits to identify and prevent quality issues before they occurred[106]. Continuous improvement through feedback and data analysis ensured manufacturing processes remained strong and compliant[81,82,88]. Looking forward, India's pharmaceutical sector aims to build an even more resilient quality ecosystem by focusing on digital transformation, sustainability, and continuous manufacturing[105,106]. These advancements—combined with strict regulatory oversight—will continue to reduce manufacturing errors, enhance global trust, and safeguard patient health worldwide[81,82,98,106].

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