INTERNATIONAL JOURNAL OF PHARMACEUTICAL SCIENCES
[ISSN: 0975-4725; CODEN(USA): IJPS00]
Journal Homepage: https://www.ijpsjournal.com

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Review Article

Digital Solutions for Drug Recall and Banned Drug Management

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ARTICLE INFO

Published: 20 Nov 2026
Keywords:
Drug Recall, Traceability, Artificial Intelligence, Blockchain Technology, Recall Notification System
DOI:
10.5281/zenodo.24393711

ABSTRACT

Drug recalls are crucial for protecting public health when pharmaceutical products are found to be defective, contaminated, mislabeled, or unsafe. The traditional drug recall process involve fragmented information systems, manual communication, delayed identification of affected products, and difficulties in tracking products across the supply chain. These can increase the time required to identify, notify, and remove potentially harmful medicines from the market. This study an explores the role of digital solutions for improving drug recall management through different technologies such as blockchain, AI/ML system, serialization, electronic health record, traceability system, recall notification system. Digital platforms can support real-time communication among manufacturers, distributors, healthcare providers, regulatory authorities, pharmacies, and patients. Digital technologies can improve the speed, accuracy, transparency, and effectiveness of drug recalls, while reducing risk of human error. A framework for implementing digital drug recall solutions can strengthen pharmaceutical supply-chain safety and contribute to improve patient protection and public health outcomes.

INTRODUCTION

A Drug Recall is a approach to return the entire batch product due to safety and quality issue or any deficiency in product [1]. The reason for recall can be unapproved drug, microbial contamination in formulation, incorrect information on packaging, visible particulates, suspected to serious risk related to drug [2].

Types of Recall

Class I recall: the situation in which drug cause serious health consequences.

Class II recall: the situation in which drug cause temporary or reversible health consequences.

Class III recall: the situation where drug not cause any health consequences [3].

Level of Recall

Consumer level: these are end user like patients, hospitals, doctors.

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Relevant conflicts of interest/financial disclosures: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Retail level: these are intermediate between wholesale and end user like pharmacies, clinics, dispensing doctors.

Wholesale level: these are distribution between manufacture and retail. Every class I recall is carried out at all the levels of recall, class II recall is carried out at wholesale and retail levels while class III recall is carried out at only wholesale level [4].

Impact on Public and Pharma

On public: Recall increase the patient anxiety, can cause adverse health outcome, also treatment can disturb. This can show in pantoprazole and valsartan recall which had created a temporary gap in medication, which further managed by giving alternating therapies.

On Pharma: Recall can cause drug shortage also may disturb the supply chain, reputation and trust on company may damage, financial and legal liabilities being faced by organization along with the regulatory inspections [5].

Objective of Drug Recall

The primary objective of drug recall is to protect public from defective product present in market. Recall efficiency not only depend on withdrawal rate but also on implementation of corrective action, communication efficiency, traceability in supply chain [1].

Current Drug Recall System

Recall Process

1.Notification and response: the regulatory body is notified about drug, firm explains the reason of recall of drug.

2.Tracking: the drug is recalled at all levels by determining recall strategy across the supply chain. Different means of media and communication is also used for tracking at different levels of distribution.

3.Compliance and Reporting: the regulatory body check status reports to determine effectiveness of recall.

4.Post Recall Procedure: the firm generate final report through recall coordination committee which includes cause, corrective action, effectiveness of recall [6].

Limitations

1.Weak supply chain Traceability: some businesses still depend on manual documentation and traditional systems which make batch identification difficult and slow. This is the major challenge in drug recall process.

2.Lack of Strong legal enforceability: Indian regulatory has limited powers due to which recall execution may delay. The developed countries like USA, other countries have strict law and heavy penalties for any type of non-compliance that is a reason of mandatory recalls.

3.Limited Technological Integration: lack of digital technology integration affects transparency, slow recall communication, reduce regulatory efficiency.

4. Fragmented Regulatory Structure: In India, CDSCO is regulatory authority at center with the coordination of other state authorities. So wherever recall or drug banned is imposed there is communication gap and other enforcement activity results in delayed recall. This is also create problem in recall system.
5. Inadequate Post-Recall Monitoring: Regulatory authorities face this challenge after product withdrawal, the lack of centralized systems of monitoring limited the recall actions evaluation due to which defective drug product are move across the supply chain.
6. Delayed detection and Recall response: In some cases, the recall is initiated after reporting of any adverse effect of drug. This can happen because of inactive inspections, lack of laboratories, poor coordination.
7. Growing challenges due to online medicine distribution: The new age of digitalization has increase the new challenges, the distribution of medicines has become a strong with online era. But the existing recall framework has limited rules and guidelines with online distribution which is not capable of participating in recall monitoring [7].

Pharmaceutical Traceability in Drug Recall

Pharmaceutical track and trace systems (PTTS) is a solution to prevent the false products from entering the market. This system can mandate the scanning of product at every point from entry to dispatch [8]. Track and trace technology helps in tracking the present and

previous locations throughout the supply chain. It has also significance in financial and e-commerce sector, but this technology is not fully adopted across the supply chain [9].

Benefits of Traceability

a. Timely Product Recalls: Product are recalled as soon as possible from clinics, hospitals, patients, through generating digital ID for product which can tagged every information.

b. Cold Chain Monitoring: Temperature sensitive product can be monitored which can also be checked by patient also. These can improve the patient confidence and trust, patients can report if any sub-standard storage of product may happen.

c. Electronic Product Information: Patient can directly access the product or drug information on their hands. Patients can directly access the alerts and notices of recall and product information.

d. Improved supply chain resilience: Companies can tackle the supply chain problem by end-to-end traceability. Industries can make strategies of retrieval and locate the product [10].

DIGITAL TECHNOLOGIES FOR DRUG RECALL

Serialization

Serialization means assigning of unique identifier (serial number) to individual package to product. This identifier can be barcode, 2D matrix or machine readable format which helps in track and trace product through supply chain. While manufacturing the product packaging is printed with unique identifier, the whole serialization data is then uploaded to secure databases. At each stage the product is scanned and verified, ensure authenticity and traceability [11].

AI/ML System

The integration of Artificial intelligence with serialization help in managing recall management.AI and machine learning (ML) can analyze large amount of data to identify unusual patterns and quality problems at early stage. This help industries to detect potential risk associated with patient safety and risk. Techniques such as convolutional neural network and recurrent neural network helps in studying parameters with different factors helps to identify relation with product defect. Machine Learning models such as Natural Language Processing (NLP) can also analyze adverse event reports, investigation documentation, regulatory reports. AI predictive analytics can monitor environmental conditions such as temperature, humidity if any changes occur the system generate the alerts to teams about affected batch. Different ML Techniques, like support vector machines, gradient boosting algorithms, can help in assessing risk associated with individual batches and helping in identifying products that may require testing or investigation [12].

Digital Complaints and Adverse event Integration

Digital complaints of patient help in providing as a source of information. Patients frequently describe their symptoms in normal verbal language rather than standard medicinal terminology. So by integrating digital complaint information with pharmacovigilance or ADR database can provide additional safety information regarding patient health status. It can also help in support continuous drug safety monitoring. Patients complaints can be collected through mobile applications, electronic records, patients portal, and other digital platforms. Natural Language Processing (NLP) which is ML technique, converts raw complaint data into structural information such as drug name, adverse event, severity. These data can be combined with adverse-event database to identify recurring patterns or safety signals [13].

Such example of adverse event database is FDA Adverse Event Monitoring System (AEMS). This is unified platform provide data quality and consistency through disciplined protocols. It has given strength to safety surveillance by optimizing digital tools, special workflow systems. AEMS also serve as centralized platform for managing patient complaints. This platform can help in safety monitoring, trend identification across various drug or formulations, also decision making to protect public health by integrating various data and tools [14].

Real Time Recall Notification System

Whenever concern occurs on marketed product, it is necessary to supply this information to hospitals,

clinics, patients, pharmacists so to action should be taken timely. Despite this, patients and physicians not get timely recall information which leaving the health-care system unable to stop product impact. To solve this problem, FDA had developed the prototype technology for patients and sector so to automatically gives notification of drug recall or banning of drug to health care portals. This allowing the patients, health care professionals, industries to connected with each other and to improve the public health. Whenever firms, manufacturers or FDA initiate the recalls the consumer gets notified about the new recall of batch no., drug name, brand, other information. This system allowed timely, fully automated communication regarding recall [15].

Such example of this technology can be National Institutes of Health-sponsored Informatics for Integrating Biology and Bedside (i2b2) platform which help in identify patient quickly and direct notification to their health care portals that is Electronic Health Records (EHR) [16].

Blockchain Technology for Drug Recall

Blockchain technology is emerging technology in pharmaceutical industry. This technology can solve the problem of security of data and transaction while recalling product. The steps involved in product recall can be:

1.Synergistic decision: The product recall is initiated either by regulatory or manufacturer. The recall strategy is made like level of recall, traceability of product, notification of recall, risk analysis of recall. Recall decisions can be taken by analyze OOS, any adverse effect reported, any packaging defect is identified.

2.Quality issue detection: The smart contract is analytical model which indicated to laboratory about issue. Whatever record are produced that are stored in blockchain network.

3.OOS/OOT investigation: After the completion of OOS/OOT study the smart contract will decide the next decisions should taken on the basis of outcome.

Advantages of this technology:

a. Traceability of product across supply chain

b. Security is improved

c. Increase in confidence of consumer

d. Regulatory Compliance

e. Improvised communication while sharing data [17].

Role of Cybersecurity and Data Integrity

Data Integrity refers to reliability, honesty, consistency and accurate of information generated and processed during pharmaceutical processes. The integrity of data is essential in for ensuring safety, efficacy, quality of product. Failures in data integrity including incomplete batch documentation, manipulated analytical records may compromise in product safety. The increase in digitalization across the pharmaceutical manufacturing is making new issues. Industries must ensure the original, accurate, legible electronic record should be established in relation with data integrity principles. Although these technologies are helping in managing data and efficiency, but it also increases the risk of cyberattacks which can lead to disturb the activities and decisions related to product [18].

Cybersecurity plays a vital role in healthcare infrastructures include medical devices, operating systems, which can expose to security threats. Cybersecurity incompetence may affect device performance, safety risks such problem require updates, corrective action. By strengthening the cybersecurity protocols, medical devices can be protected in complex healthcare systems. Cybersecurity is becoming essential part in safety rather than just technical concern [19].

Regulatory Framework for Drug Recall

The regulation of drug recall comes under Drug and Cosmetics Act, 1940 and Rules 1945. Although there is no standalone statute for drug recall but are different provisions in legal framework to support the recall. The Central Drugs Standard Control Organization (CDSCO) and Drug Controller General of India (DCGI) supervise the recall monitoring. Also State Drug Control Authorities are responsible for enforcement in regional level, the coordination between both central and state authorities are very much important for recall situations. In 2012, CDSCO have introduced "Guidelines on Recall and Rapid Alert System for Drugs" for initiation of recall, recall classification, information regarding product recall. Overall, the

regulatory framework for drug recall has improved over time, but it faces some challenges. Strengthening of recall framework not only for public health but also maintaining confidence in Indian Pharmaceutical products at global level is must [7].

U.S.FDA Recall Framework

US.FDA is one of most followed and strict regulatory in world. Recall framework of FDA is based on risk which applies strategy in all levels of recall. The framework is supported with pharmacovigilance programs such as MedWatch and FAERS. Digital approaches for surveillance like internet search engine are increasingly used in recall signals. Despite this, FDA face criticism over delayed action, improper communication which may compromise with public health and recall procedure [18].

CONCLUSION

Digital Solutions can help in improving and enhancing the drug recall management by providing patient safety through timely recall pharmaceutical product from market. Technologies such as AI/ML, pharmaceutical track and trace system, Blockchain technology, digital complaints, real time recall notification system, help in identifying quality issue, track product throughout the supply chain and notify hospitals, pharmacies and patients quickly, also preparing recall documentation. These technologies and solutions reduce response time, enhance traceability, minimize errors, increase transparency, and regulatory compliance. Adoption of these technologies drug recall gets faster, accurate, efficient which build patient trust on healthcare system.

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HOW TO CITE: Vinay Kamnani, Abhijeet Welankiwar, Digital Solutions for Drug Recall and Banned Drug Management, Int. J. of Pharm. Sci., 2026, Vol 4, Issue 11, 3546-3551. https://doi.org/10.5281/zenodo.24393711