



A Review Paper On Handling Of Customer Complaints And Managing Recalls Of Marketed Injectables.

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ABSTRACT

A company's force as well as its character largely depends on whether there are complaints about the company's marketable products. Any disfigurement in the injectables can beget serious diminishment to the manufacturing company which has a good character up to now. Once the injectables placed in the request, post-marketing surveillance is an important factor in controlling its adverse goods on the population. The source of the claim can be anything, i.e., shipping, manufacturing and packaging, labeling, breakage of vials, etc. Any error in any of this way can lead to serious problems. thus, dealing with request complaints should be a major task. This critical step requires a single, unified and secure platform for managing product complaints from launch to finish. Request complaints are thus prioritized according to easily defined procedures. In the event of a serious complaint, a root cause analysis should be conducted to resolve the issue and similar injectable products should be removed from the request. The recall system must be so effective that the product can be removed from the request within a specified period of time. The study outlines the typical process for resolving request complaints and product recalls from FDA authorized officer.[1]

KEYWORD:

Complaints, Recalls, Injectables, Defects, Management, PDCA, CAPA, FDA

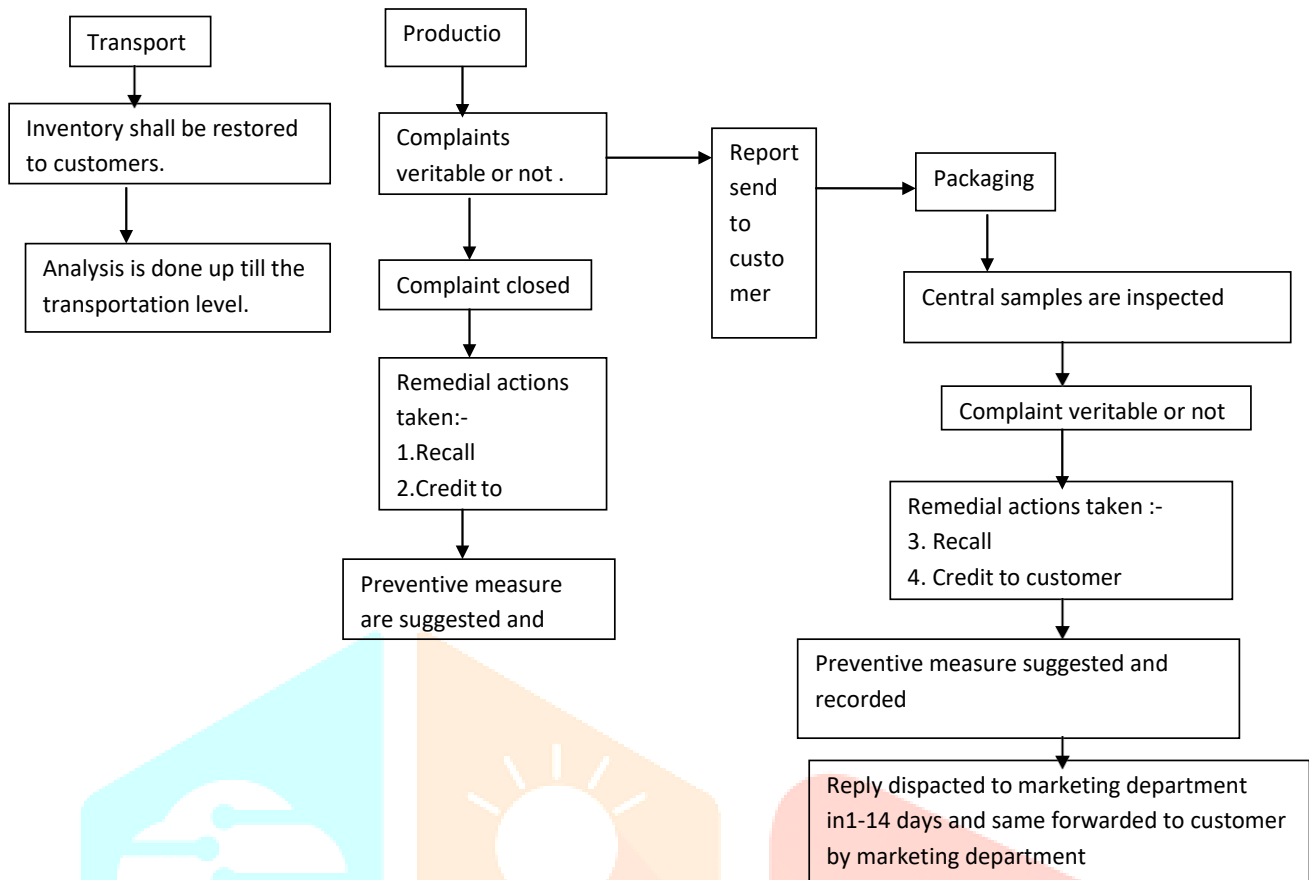
INTRODUCTION

1. The pharmaceutical assiduity launches colorful injectables in the request in order to promote medical inventions. Among the colorful healthcare procedures, injections are extensively honored as one of the most constantly performed. Every time 16 billion injection are administered worldwide, around 90 of which are given in restorative care, 5 are immunisation injections and remaining 5 covers other suggestions including blood transfusion and IV administration of blood and fluids. If these diligence stop launching new exploration ideas numerous conditions will remain undressed. Indeed if diligence develop injectables still there will be numerous problems like injectables complaint.(2)

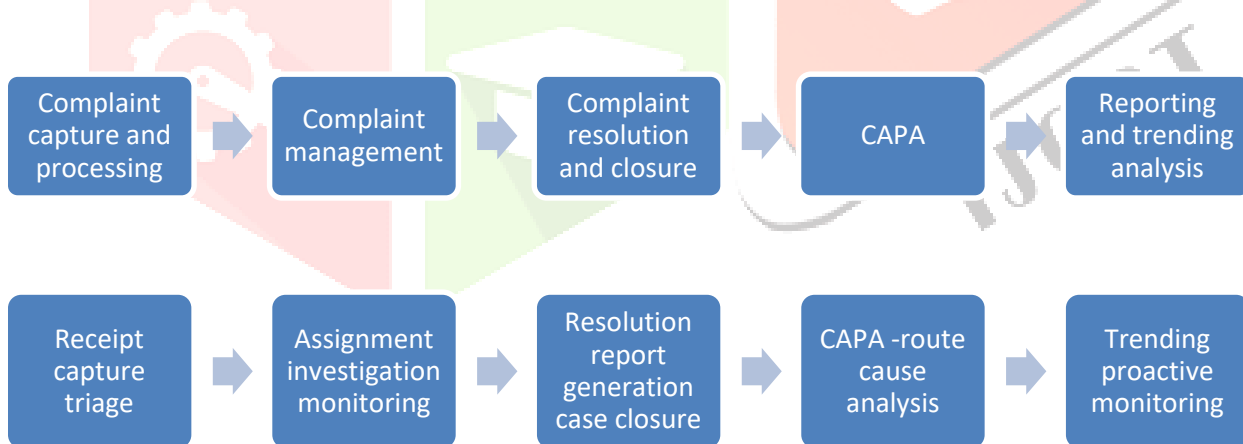
“ A Product Complaint is characterized as an expression indicating that commodity is incorrect or shy in terms of quality or performance. It's any communication, written or verbal entered directly from any client, retailer, distributor or representative of contact giver regarding quality attributes similar as mislabelling, vial breakage or any other matter. This type of complaints is considered as request complaints. In similar cases, the quality and running of pharmaceutical products will be compromised, negatively impacting brand image of establishment. It should of lesser concern to all enterprises to help similar issue from being. To resolve similar issue, recall system is established by the diligence. Proper operation of similar complaints are managed by devoted departments lead by a administrator who should have applicable authority to probe the complaints, together with a sufficient number of inferiors to help him or her. In the pharmaceutical assiduity, dealing with this product complaint is an important issue because if a serious quality problem arises, it can harm the client and also the character of the company. When a product complaint is entered, it's necessary to identify and address the root cause of the complaint. Resolving the root cause helps help the rush of complaints. duly handled complaints can help retain or attract further guests and insure client satisfaction. When serious product quality issues beget implicit detriment to consumers, a product recall must be considered. Complaints handling will have a veritably important place in the pharmaceutical assiduity as this assiduity is directly related to mortal lives. The request product complaints should be handled in an applicable manner.(3)

Procedures for running of complaints regarding injectables(1)

1. The Product Promotion/ Marketing Department receives the complaint from the plaintiff and forwards it to the Quality Assurance Department(QAD).
2. QAD will officially register the complaint with a designated train number.
3. The director of QAD conducts an disquisition through root cause analysis under the supervision of the Head of QAD. Figure 1 below shows the process for root cause analysis of request complaints.
4. This total time frame for transferring renewals to guests should be a outside of 15 days.
5. All periodic complaints are reviewed through the Annual Review of Market Complaints to assess trend diversions.



The basic workflow for product complaint handling in pharma is as:^[3]



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numerous problems like injectables complaint.(2) “ A Product Complaint is characterized as an expression indicating that commodity is incorrect or shy in terms of quality or performance. It's any communication, written or verbal entered directly from any client, retailer, distributor or representative of contact giver regarding quality attributes similar as mislabelling, vial breakage or any other matter. This type of complaints is considered as requestcomplaints.In similar cases, the quality and running of pharmaceutical products will be compromised, negatively impacting brand image of establishment. It should of lesser concern to all enterprises to help similar issue from being. To resolve similar issue, recall system is established by the diligence. Proper operation of similar complaints are managed by devoted departments lead by a administrator who should have applicable authority to probe the complaints, together with a sufficient number of inferiors to help him or her. In the pharmaceutical assiduity, dealing with this product complaint is an important issue because if a serious quality problem arises, it can harm the client and also the character of the company. When a product complaint is entered, it's necessary to identify and address the root cause of the complaint. Resolving the root cause helps help the rush of complaints. duly handled complaints can help retain or attract further guests and insure client satisfaction. When serious product quality issues beget implicit detriment to consumers, a product recall must be considered. Complaints handling will have a veritably important place in the pharmaceutical assiduity as this assiduity is directly related to mortal lives. The request product complaints should be handled in an applicable manner.(3) Procedures for running of complaints regarding injectables(1) 1. The Product Promotion/ Marketing Department receives the complaint from the plaintiff and forwards it to the Quality Assurance Department(QAD). 2. QAD will officially register the complaint with a designated train number. 3. The director of QAD conducts an disquisition through root cause analysis under the supervision of the Head of QAD. Figure 1 below shows the process for root cause analysis of request complaints. 4. This total timeframe for transferring renewals to guests should be a outside of 15 days. 5. All periodic complaints are reviewed through the Annual Review of Market Complaints to assess trend diversions.

Recall Classification:^[1]

1. **Class I recall** -A circumstance in which there is a foreseeable risk that using or being exposed to a prohibited product may have fatal or severe negative health effects.
2. **Class II recall**- A circumstance in which exposure to or use of a prohibited product may have short-term or medically treatable negative health effects, or in which the likelihood of major negative health effects is remote.
3. **Class III recall** - No adverse health effects are likely to be generated in a situation where use or exposure of the infringing product occurs. The aim of this Article is therefore to discuss in detail the main steps taken towards a good complaint redress system which can be easily implemented within the pharmaceutical sector.

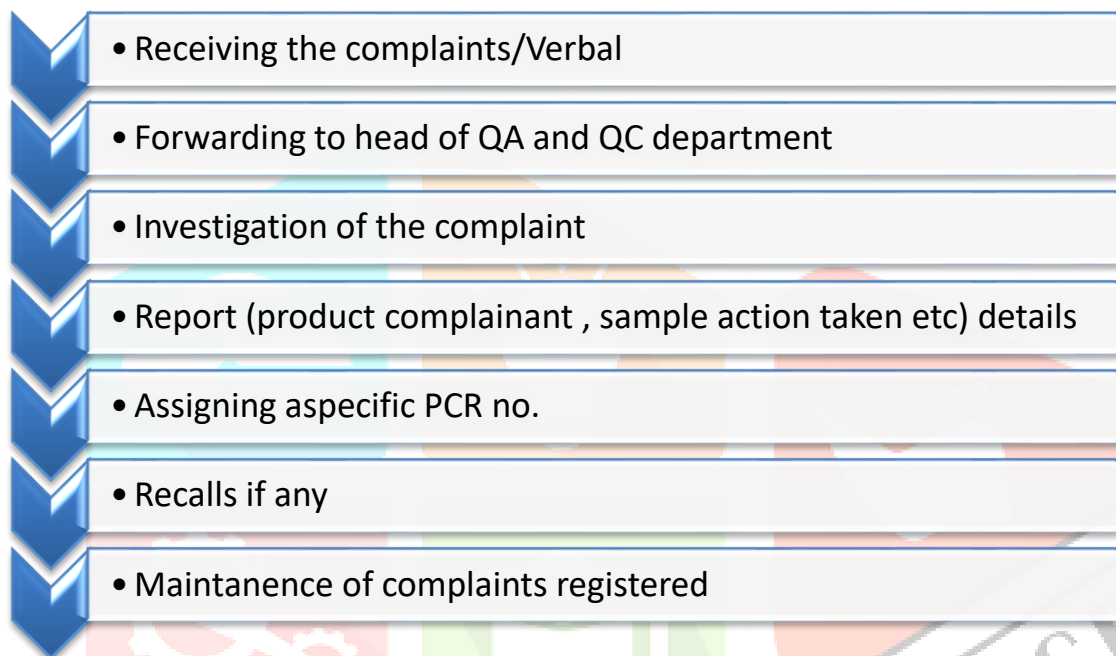
Procedure:^[3]

A Product Recall Coordination Committee is to be set up for the implementation of recalls.

The following shall be members of the Product Recall Coordination Committee:

- i. Managing director
- ii. The head of quality assurance
- iii. Production head
- iv. Director of the Marketing Department.

A final decision on the recall shall be taken by the Managing Director.

**Criteria for recall:^[1]**

The product is recalled by a Recall Coordination Committee appointed by the Regulatory Agencies. The recall procedure must start within 48 hours, and may take up to 14 days from the date of initiation. The product must be withdrawn from the market in a variety of ways, i.e. by advertising and informing the supply chain at various levels, e.g. vendor, distributor, retail or wholesaler as well as user level. It shall be necessary to remove the product from the market for various levels, i.e. buyers, distributors, retailers, wholesalers and users by means of an advertising campaign and placing it on notice in the supply chain. Once the authorised personnel are present, the recalled product must be removed. The recall coordination committee shall be empowered to grant the staff authority for destroying recalls at the site of manufacture.

The documentation of recalled products' destruction is necessary.

Product name :	Date of manufacturing
Brand :	Date of expiration
Batch size:	Quantity destroyed
Recall completed emblem	

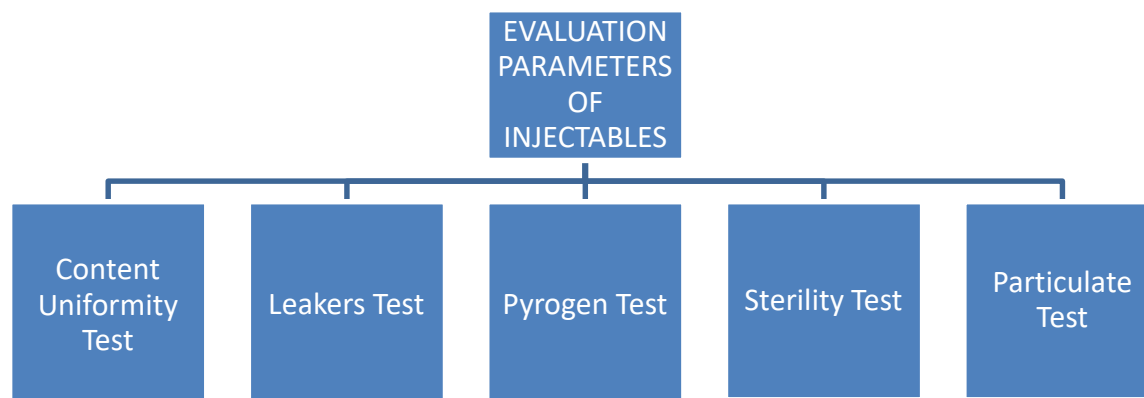
METHODOLOGY

The analysis of complaints and recalls of injectables was studied from FDA site.

Any drug injected into the body is considered an injectable. Since it works against germs by bypassing the body's natural defences, it must be sterile. The manufacturing process for injectables is therefore governed by stringent laws. As a result, facilities that manufacture injectables must be specifically set up for aseptic production. These sterile preparations are also known as parental infusions or implantations. They are manufactured using exacting procedures to guarantee the infusion's sterility and prevent contamination by external substances such as bacterial endotoxins, pathogens, and pyrogens. These medications are difficult to deliver, but their fast absorption by the body reduces the possibility of a first-pass effect.^[4]

A. EVALUATION PARAMETERS:[5]

There are various evaluation parameters for estimation of quality of injectables



1. CONTENT UNIFORMITY TEST:

- Once the contents of 10 unique sterile units have been removed, the weight of each unit is carefully measured once again.
- The empty sterile unit weight is then subtracted from gross weight to determine net weight. If the quantity of the active component falls between 85 and 115.0% of the label claim, the dosage uniformity is fulfilled. The relative standard deviation is 6.0% or less.
- Additional 20 sterile units should be examined if one unit tests outside the range of 85-115.0%, none of the sterile units test beyond the range of 75-125.0%, the relative standard deviation of the resultant is larger than 6.0%, or if both conditions are true.

2. LEAKERS TEST:

- Leaker tests for ampoules are designed to find improperly sealed ampoules so that they may be thrown away to preserve the sterility of the medications.
- The ampoules are placed in a dye solution, such as 1% methylene blue, and subjected to a vacuum of at least 25 inches for at least 15 minutes to perform the leaker test.
- When ampoules are injected into a bath of dye during the autoclave, detection of leaker occurs as it allows for both leakage and sterilization to be performed in one operation.
- A high frequency spark test system that finds the existence of pinholes in ampoules is another method of checking for leaks.
- Due to the flexibility of rubber stoppers, bottles and vials are not subjected to such vacuum tests.

3. PYROGEN TEST:

- This test detects the temperature rise in rabbits after a sterile solution is injected intravenously into the rabbit's ear vein.
- A dose not exceeding 10 ml per kg is injected intravenously over a period not exceeding 10 minutes.
- Test animal of both sexes should preferably be healthy adult rabbits of the same breed.
- Record temperature: thermometer, thermistor

4. PRELIMINARY TEST (SHAM TEST):

- If animals are being used for pyrogen testing for the first time or have not been used in the last 2 weeks, 10 mL/kg of heated pyrogen-free saline should be injected intravenously 1 to 3 days prior to testing for substances. Inject intravesically and condition the animal. Heated to about 38.5°C
- Animal temperatures are recorded for at least 90 minutes prior to injection and up to 3 hours after injection.
- Animals showing a temperature change of 0.6°C or more cannot be used in this test.

5. STERILITY TEST:

- Sterility test means free of viable microorganisms.
- Sterility testing is a microbiological test applied to sterile products to demonstrate that the products have been manufactured and processed according to cGMP specifications.
- Sterility testing is destructive, so it is not possible to test all items for sterility

6. PARTICULATE TEST:

- Particulate matter is made up of foreign, mobile, and undissolved particles (other than gas bubbles) that are not intentionally present in the solution.
- Method A-light obscuration particle count test Method B-microscopic particulate count test.

B. CAPA ^[6]

- CAPA is employed to drive advancements in an association's procedures and is generally carried out to annihilate the root causes of non-compliance or other undesirable circumstances according to legal conditions. The ideal of the corrective and preventative action subsystem is to collect and dissect information, address and probe product and quality-related issues, and apply suitable and effective measures to correct or help them from recreating. It's pivotal to validate and corroborate these corrective and preventative conduct, communicate them to responsible individualities, give material information for operation review, and document these conditioning in order to effectively address product and quality problems, help their rush, and minimize device failures. By conducting a thorough analysis and evaluation, root cause analysis can help identify the underpinning factors contributing to perpetration. Perpetration can encompass colorful issues similar as ministry failure, scarcities in the quality operation system, request or client complaints, or misapprehension of written instructions for task prosecution.

The crucial way and considerations for handling client complaints and managing recalls of retained injectables are(7)

1. Establish a Complaint Handling System

- apply a well- defined and proved process for entering, establishing, and tracking client complaints.
- Assign devoted labor force responsible for managing client complaints and recalls.

2. instantly Respond to client Complaints

- Acknowledge client complaints instantly and give a clear timeline for resolution.
- Gather all applicable information related to the complaint, including product details, lot figures, and client details.

3. Completely probe Complaints

- Conduct a comprehensive disquisition to identify the root cause of the complaint.
- unite withcross-functional brigades, including quality control, product, and nonsupervisory affairs, to gather necessary information.

4. Document Complaint disquisition Findings

- Maintain a detailed record of the complaint disquisition process and findings.
- Document any corrective conduct taken to address the complaint, including changes to manufacturing processes or quality control measures.

5. Determine the Need for a Product Recall

Assess the inflexibility and implicit threat associated with the complaint to determine if a recall is necessary.

Consult nonsupervisory guidelines and involve nonsupervisory affairs labor force to insure compliance with reporting and recall conditions.

6. apply a Recall Strategy

Develop a recall plan that includes clear communication channels, recall objects, and liabilities of all involved parties.

Execute the recall plan instantly, icing the junking and proper disposition of affected injectables from the request.

7. Communicate with Stakeholders

Maintain open and transparent communication with guests, nonsupervisory authorities, and healthcare professionals regarding the recall and its counter accusations give clear instructions for affected guests, similar as returning or disposing of the recalled products.

8. estimate and Ameliorate

Conduct apost-recall analysis to estimate the effectiveness of the recall process and identify areas for enhancement.

Update procedures, as necessary, to help analogous issues from recreating in the future.

C. PDCA CYCLE :[8]

The PDCA cycle is a regular approach to problem- working and enforcing results. Firstly developed in the 1950s by William Deming, the PDCA(or Shewhart) model is grounded on the scientific system and serves as a frame for literacy and enhancement. An indispensable interpretation of PDCA, known as OPDCA, includes a fresh stage of observation to grasp the current condition. The PDCA cycle consists of the ensuing stages

1. Plan This stage involves mapping out the way to address a problem or make changes to a process.
2. Do Next, you test your proposed result or thesis through small, incremental changes that aim to ameliorate processes with minimum dislocation.
3. Check After completing the trial, you review and dissect the results. This stage is essential for assessing the effectiveness of the result and making necessary variations to the plans.
4. Act Eventually, it's time to apply the proven plan. However, this new process becomes the birth for unborn PDCA duplications, If everything went according to plan.(8)

The PDCA process can be applied in colorful scripts, including

1. Exploring and testing multiple results in controlled trials.
2. Avoiding waste by relating and conforming ineffective results before large- scale perpetration.
3. enforcing change and driving nonstop enhancement.
4. Applying Total Quality Management or Six Sigma enterprise.
5. Developing or enhancing processes.

FDA-483(3)

FDA483 is the form used by Food and Drug Administration investigators for examinations. Once the disquisition is complete, the findings must be formally recorded. FDCA requires written examination commentary(\$ 704B(21\$ USC374b)). compliances should be made if the adjudicator finds that the product has been tampered with or has been packaged or reused under conditions not vindicated to the specifications. These

forms will be submitted to operation on the final day of examination. The FDA has given companies 15 days to submit their responses. However, FDA won't consider the response before transferring a warning letter, if FDA receives a response after his 15 business days. FDA- 483 has observed post-marketing issues related to side goods in some non-GMP areas. These are distributed in order of significance. It also includes commentary on certain inferior practices not listed in FDA EIR 483. These were bandied with the company during the examination and noted as similar on the point examination report. There are no commentary on this FDA 483 form regarding marker style, marker content, promotional accoutrements, etc

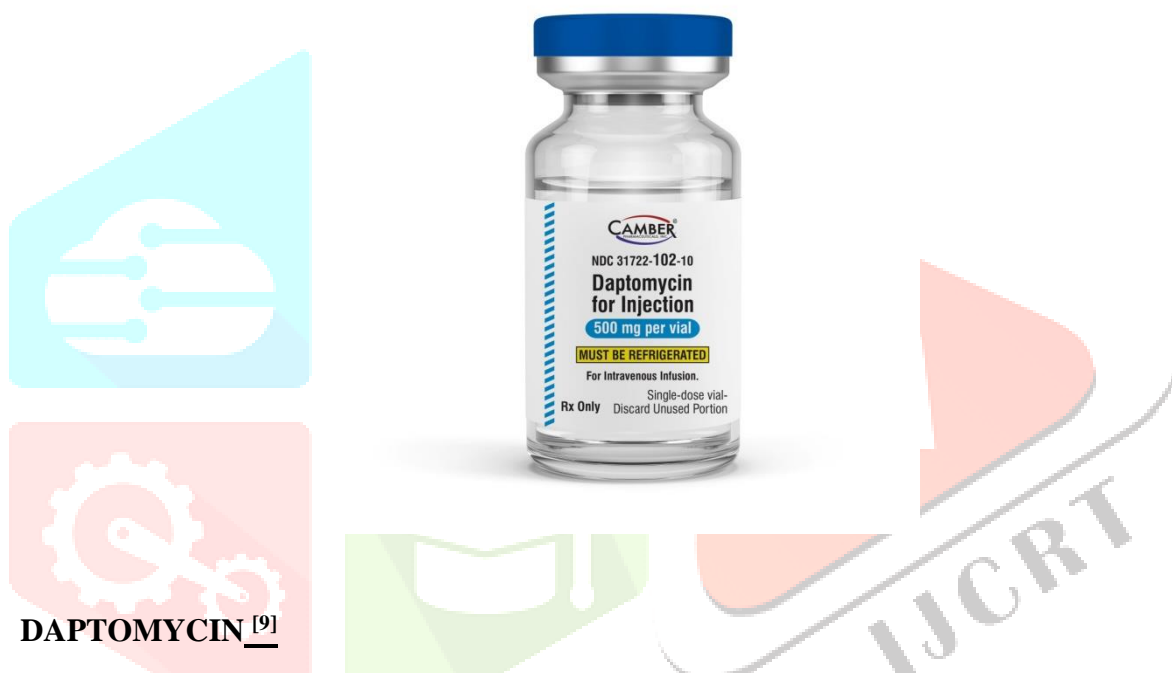
Impact of significant FDA-483:

The effect of both imports and exports of FDA 483 forms is remarkable. For exports, FDA policy stipulates that a Foreign Government Certificate (CFG) will not be issued if the manufacturing facility for the exported product does not comply with Good Manufacturing Practices. For imports, the FDA may permit the rejection of products that appear to be mislabeled, tampered with, or unauthorized without a physical examination.

E. Procedure

Name of drug recalled	Cause of recall	Complaint found by	FDA action taken	Solution
Daptomycin 500 mg	Mislabelling	Healthcare Inc.	Wholesaler and distributors discontinued distribution	-Not Printing labels in advance -Automated quality machine
Vancomycin HCl injection	Presence of visible glass particulates	Hospira Inc. (Pfizer)	Wholesaler, hospital, institutions discontinued uses. Quarantine and notified if further distributed	-Use more robust glass -Upgrade your accumulation equipment
Sodium bicarbonate injection USP	Vial breakage	Exela pharma sciences	Discontinue use and segregate recalled products	To chemically strengthen glass using ion exchange
Injectable antibiotics	Hair in vial	Aurobindo subsidiary	Replacement for recalled product	Machinery vision

Polymyxin B	Hair in vial	Aurobindo subsidiary	Replacement for recalled product	Machinery vision
Bupivacaine Injection and lidocaine injection	Mislabelling	Hospira Inc	Stop administration distribution and quarantine immediately	-Not Printing labels in advance - Automated quality machine



1. **DAPTOMYCIN** ^[9]

Daptomycin is prescribed to patients with complex skin and soft tissue infections (cSSTI) in both adults and children (ages 1 to 17). Adult patients with right-sided infective endocarditis (RIE) caused by Staphylococcus aureus. Professional advice states that when determining whether to apply daptomycin, one should consider the organism's antibacterial sensitivity.

Staphylococcus aureus bacteraemia (SAB) patients in adults and children (ages 1 to 17) Both adult and pediatrics patients who have used bacteraemia should have an association with RIE or cSSTI because bacteraemia use is a risk factor for cSSTI. The only antibiotic effective against Gramme-positive bacteria is daptomycin. When gramme-positive and gramme-negative infections or specific anaerobic bacteria are suspected in mixed cases, daptomycin must be taken concurrer

Fig.1. :Daptomycin injection vial

Reason of recall:

The complaint indicated that vials labelled as "Daptomycin for Injection 500 mg/vial" were discovered in cartons labelled as "Daptomycin for Injection 350 mg/vial". Both the outer carton and inner vial bear the same lot number and expiration date as the "Daptomycin for Injection 500 mg/vial" product.

FDA ACTION TAKEN:

Accord is recalling a product because a hospital pharmacy reported a product complaint. As a result, Accord is taking voluntary action to recall all units of lot #R2200232, Daptomycin for Injection 500 mg/vial. These units may be found in outer cartons labelled as either "Daptomycin for Injection 500 mg/vial" or "Daptomycin for Injection 350 mg/vial". The product can be identified by referring to the provided image of the outer carton and inner vial.

Both Daptomycin for Injection 350 mg/vial and 500 mg/vial were distributed to wholesale suppliers nationwide. Accord has sent or is in the process of sending letters to its Wholesalers and Distributors, notifying them about the recall and arranging for the return of all affected products. Wholesalers and Distributors in possession of the recalled product should immediately stop distributing it

METHODS FOR PROBLEM SOLVING OF COMPLAINTS AND RECALLS : [10]

MISLABELLING: Mislabeling of products and inventory is a major problem that can cost an organization a lot of money and time, regardless of the industry you are in. When it comes to medical devices or pharmaceutical products, where label mistakes can have disastrous results, it is especially risky. Continue reading to find out some of the best ways to prevent mislabeling.

- **Avoid Printing Labels in Advance:** Avoiding printing labels in advance is one way to stop incorrect labeling in manufacturing. Labels should ideally be printed as soon as possible before application. This method will assist in preventing "clearing the work area" issues and "extra" labels that may be lying around.
- **Data Validation:** A crucial step in preventing mislabeling in production is data validation. By ensuring that the data submitted by users is accurate, it eliminates labeling mistakes. Because it requires users to submit data in a certain format, such MM/DD/YYYY, data validation is essential. Because inaccurate data won't be printed, it also reduces waste and time spent.
- **Automated Quality Management Systems:** Mislabeling is an expensive issue that costs some businesses millions of dollars yearly. Although these systems are still in their infancy, automated quality management systems can assist manufacturers in identifying label errors.

2. VANCOMYCIN HCL INJECTION:^[11]

- Vancomycin Hydrochloride is an antibiotic that's specified to treat severe or serious infections caused by methicillin- resistant strains of staphylococci bacteria. It's an effective treatment option for colorful conditions similar as staphylococcal endocarditis, septicaemia, bone infections, lower respiratory tract infections, as well as skin and skin- structure infections. This drug is specifically used in cases who are antipathetic to penicillin or have shown no response to other antimicrobials, including penicillin or cephalosporin agents. also, it's also used for infections caused by vancomycin-susceptible organisms that are resistant to other antimicrobials.



Fig.2. : Vancomycin Hydrochloride injection vial

- Reason of recall
- • Intravenous administration of the product may lead to adverse goods like original vexation or lump, vasculitis/ phlebitis, antigenic or antipathetic responses, and microvascular inhibition, including pulmonary embolism.
- • If the product is taken orally or through a nasogastric tube, there's a possibility of causing gastrointestinal damage. • To reduce the threat, the product marker advises healthcare professionals to visually check it for particulate matter and abrasion before administering it.
- FDA Action Taken
- The administration of Vancomycin injection involves adding a greasepaint to a fluid and delivering it intravenously, generally into a tone. The injection is generally administered sluggishly over a minimum of 60 twinkles, formerly every 6 or 12 hours. still, new- borns babies may admit it every 8 hours.
- The duration of treatment depends on the specific infection being treated. While entering a cure of Vancomycin injection, you may encounter a response, generally during or shortly after the infusion. It's important to instantly inform your croaker if you witness any of the following symptoms dizziness, gasping, briefness of breath, itching, hives, flushing of the upper body, muscle pain, or spasms in the casket and back. Vancomycin injection can be administered either in a sanitarium or athome. However, make sure to use it at roughly the same time each day,
- If you're using it at home. Precisely follow the instructions on your tradition marker and seek explanation from your croaker or healthcare provider regarding any unclear aspects. It's pivotal to use Vancomycin injection precisely as directed, without investing it more fleetly than

instructed. also, don't use more or less of the drug or employ it more constantly than specified by your croaker.styles

- FOR PROBLEM SOLVING OF COMPLAINTS AND RECALLS(12)
- GLASS PARTICULATES – The most frequent reason for recalls of injectables is foreign matter impurity. In fact, between 2008 and 2012, 22 of FDA recalls of sterile injectable medicines were due to the discovery of visible patches. Glass is one of the types of foreign matter impurity that's constantly set up in injectable medicines, similar as vaccines. Four out of the 19 FDA recalls connected to particulate matter in 2014 were caused by glass.
- 1. Glass is the ideal vial material for injectable liquids and lyophilized medicines. Manufacturing Chemist identifies the crucial advantages of glass packaging as follows Low extractable and leachable parcels Chemical idleness for medicine product stability translucency for ease of examination Thermal stability for flexible use and processing Cost
- 2. medicine manufacturers can take a many way to lessen the liability that glass particulate will end up in injectable medicines. Use further robust glass Some vial manufacturers are contributing to the result by creating vials that are more flexible to common disunion. For case, strengthened aluminosilicate glass composition vials are more robust than conventional vials, making them less prone to breaking and dicing. Upgrade your accumulation outfit Any time vials come into touch with one another, glass patches are a concern. This can do both during stuffing and when vials are transferred from mass inflow into a single train, for as when using single- form to feed examination or labelling outfit.



Fig.3. : 8.4% Sodium Bicarbonate injection USP vial

3.SODIUM BICARBONATE INJECTION^[13]

Sodium bicarbonate is constantly employed in the medical field to diagnose or treat acid imbalance in the bloodstream, perform gastric lavage for methanol poisoning, and palliate heartburn. It may beget certain side goods, including headaches, dropped appetite, frequent urination, and mood or internal changes. The mariners present in sodium bicarbonate contribute to the expression of sodium bicarbonate injection.

REASON OF RECALL

The product has a safety issue where the vials may break and glass fractions may fly when the product is pressurized during medication for administration. This poses a threat of injury to the skin, eyes, and other body corridor, which could affect in temporary or endless detriment. Exela has entered five(5) reports of injuries caused by flying glass.

FDA ACTION TAKEN

Exela is waking its guests about the issue through dispatch and pukka correspondence. They're making arrangements for the return and relief of all the recalled products directly from Exela. guests who have the recalled product should stop using it, separate it from other particulars, fill out a recall stock response form and submit it to Exela(indeed if they've no product to return), and keep the product on hold until payload instructions are handed by Exela Styles

FOR PROBLEM SOLVING OF COMPLAINTS AND RECALLS(14)

To chemically strengthen glass using ion exchange

- The result's potassium ions(electronically charged patches) resettle into the glass face and take the place of the glass's original, lower sodium ions. The larger potassium ions bind the glass together as it cools, forming a compressive stress subcaste that gives the glass its tough face.
- Chemically strengthened glass is best suited for touchscreens, appliances, and other high- use operations due to its face durability. Indeed after a small scrape or nick, the glass keeps further of its strength, precluding further cracks and excrescencies.
- Some high- tech spectacles have unique compositions that lessen the liability of this passing, but thesuper-tough face produced by the ion exchange process acts as the first line of defense against common troubles.

4.POLYMYXIN B: [15]

Polymyxin B for injection is a sterile, lyophilized cake or powder with a white appearance, which is employed for the creation of sterile solutions. These solutions are administered via intramuscular, intravenous, intrathecal, or ophthalmic routes to effectively treat infections affecting the urinary tract, meninges (the protective membranes surrounding the brain and spinal cord), and bloodstream. These infections are caused by bacteria strains that are susceptible to the effects of Polymyxin B.

In situations where other drugs with lower potential toxicity are ineffective or not recommended, Polymyxin B

may be prescribed to combat severe infections caused by certain organisms. Specifically, it can be indicated for meningitis caused by *Haemophilus influenzae*, urinary tract infections caused by *Escherichia coli*, and bacteraemia caused by *Aerobacter aerogenes* or *Klebsiella pneumoniae*.

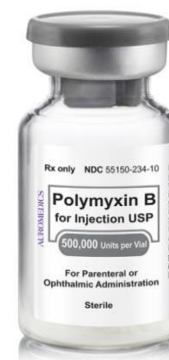
Fig.4. : Polymyxin B USP injection vial

REASONS OF RECALL :

AuroMedics Pharma, a U.S.-based division of the Indian pharmaceutical company Aurobindo, has initiated a voluntary recall of a single batch of the antibiotic polymyxin B due to a customer complaint regarding the presence of a hair in one of the vials. The recall specifically applies to lot number CPB200013 of polymyxin B for injection, which is set to expire in September 2022.

FDA ACTION TAKEN:

The recall notice was published on the FDA's website, and the affected batch was distributed nationwide in the United States. It is worth noting that AuroMedics' voluntary recall follows closely after its parent company, Aurobindo, received a warning letter from the FDA. The warning letter was issued due to Aurobindo's inadequate investigation of batch failures concerning pharmaceutical ingredients and the failure to assess the potential impact of changes on the intermediates and APIs produced at its facility in Telangana, Hyderabad, India.



METHODS FOR PROBLEM SOLVING OF COMPLAINTS AND RECALLS :^[16]

➤ DETECTING DEFECTS IN PHARMACEUTICAL GLASS VIALS

- A glass vial is a crucial part of the initial packaging of pharmaceutical products. High demands are placed on primary packaging like vials by a number of biotechnologically produced medications, highly viscous or low-dosage drug formulations, and a number of oncologic and ophthalmologic medications.

➤ MACHINE VISION ADVANTAGES FOR PHARMACEUTICAL PACKAGING

- Dimensional or aesthetic flaws in pharmaceutical glass vials can be found by vision inspection systems. In order to ensure premium quality, it can also help control the narrow tolerances on vial geometry. Even in the tiniest of defects, 100% vision inspection can find them.

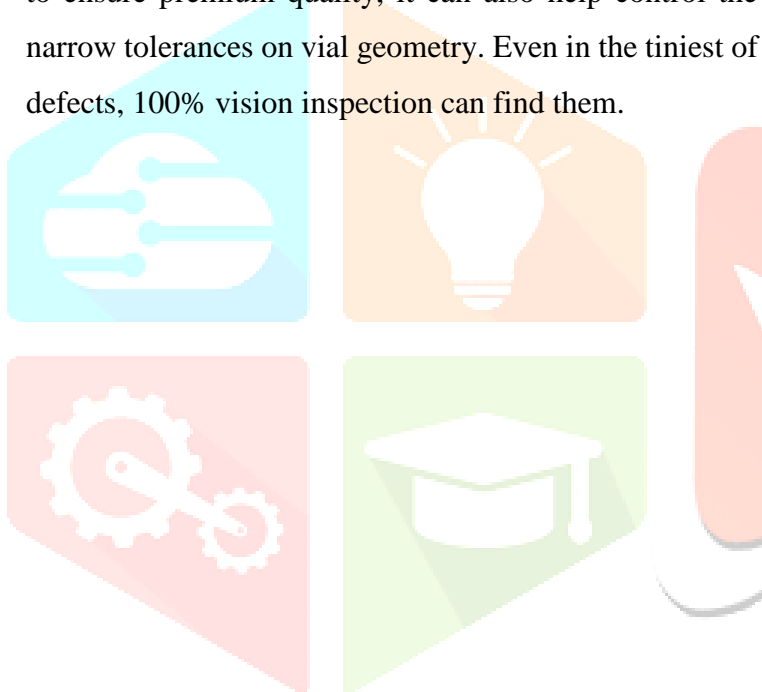


Fig.5. : 0.5% Bupivacaine Hydrochloride injection USP vial

5. BUPIVACAINE AND LIDOCAINE INJECTION ^[17]

"In adults, 0.5% Bupivacaine Hydrochloride Injection, USP is used to generate local or regional anaesthesia or analgesia for various medical procedures including surgery, dental and oral surgery, diagnostic and therapeutic procedures, as well as obstetrical procedures.

The purpose of 1% Lidocaine HCl Injection, USP is to produce local or regional anaesthesia through techniques such as infiltration (e.g., percutaneous injection) and peripheral nerve block techniques (e.g., brachial plexus and intercostal). It can also be employed in central neural techniques (e.g., lumbar and caudal epidural blocks), as long as the established procedures outlined in standard textbooks are followed."

REASONS OF RECALL :

Hospira's evaluation of the potential risk to patients determined that the use of the affected product has the potential to result in moderate to high severity adverse events. If the patient receives 1% lidocaine instead of 0.5% bupivacaine, there is a risk of inadequate dosage, leading to ineffective pain management and failure of surgical anaesthesia. Conversely, if the patient is administered 0.5% bupivacaine instead of 1% lidocaine, an overdose of bupivacaine may occur, resulting in potential consequences such as seizures, respiratory abnormalities (including low oxygen and/or high carbon dioxide levels in the blood, excessive acidity in bodily fluids, and temporary cessation of breathing), heart abnormalities (including issues with contraction and/or relaxation, irregular heartbeat, slower than normal heart rate, abnormal heart rhythm characterized by ventricular quivering instead of normal pumping), cardiac arrest, and cardiac flatline.

FDA ACTION TAKEN:

- Hospira's, Inc. prioritizes the safety of patients and the quality of its products throughout the manufacturing and supply chain process. The company has sent notifications by mail to wholesalers, distributors, retailers, and hospitals, instructing them to arrange for the return of any recalled products.
- Wholesalers, distributors, or retailers who currently have the affected batch in their inventory should halt the administration and distribution of the product immediately and quarantine it. If you have distributed the recalled product to wholesale or retail outlets, please inform any accounts or additional locations that may have received the product from you. [

METHODS FOR PROBLEM SOLVING OF COMPLAINTS AND RECALLS:^[10]

MISLABELLING - Mislabeling of products and inventory is a major problem that can cost an organization a lot of money and time, regardless of the industry you are in. When it comes to medical devices or pharmaceutical products, where label mistakes can have disastrous results, it is especially risky. Continue reading to find out some of the best ways to prevent mislabeling.

➤ **Automated Quality Management Systems**

Mislabeling is an expensive issue that costs some businesses millions of dollars yearly. Although these systems are still in their infancy, automated quality management systems can assist manufacturers in identifying label errors. According to a recent Digi marc survey, manual inspection is still used by 67% of manufacturers. Productivity can also be increased by automation. Rework, scrap, and overtime can be reduced.

➤ Traceability

In manufacturing facilities, incorrect labeling is a frequent problem. It might mean losing money and priceless time. In fact, it's thought that 76% of producers mislabel at least 10% of their products. Therefore, preventing mislabelling is crucial to any manufacturing operation's success. Mislabeling costs businesses \$1.3 million yearly on average.

CONCLUSION

The aim of this Article is to study in detail the main steps taken towards a good complaint redress system which can be easily implemented within the pharmaceutical sector. Plan-Do-Check-Act model gives the implementation on recall of the pharmaceutical product. The classification on the Recall study done by the Analytical head persons of the competitor authority of different sectors. The authority officers of the internal and external auditors committee play important role. The analysis of the complaints done by three teams first of FDA, Drug Inspectors and the external committee officers and third team of the manufacture company.

If any serious issue found in the complaint and also in the analysis for example AuroMedics Pharma, a U.S.-based division of the Indian pharmaceutical company Aurobindo, has initiated a voluntary recall of a single batch of the antibiotic polymyxin B due to a customer complaint regarding the presence of a hair in one of the vials. In such cases whole of the batch is recalled and discarded at once in front of all the authority officers.

If any complaint which not of class I or II and be solved with the proper changes like for improper labelling of the pharmaceutical products, in such cases whole batch was recalled and reprocessed by the proper packaging of the product. This will be done only after the report of the authority body and their decision

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