

Product Quality Complaint Management in Pharmaceutical Industry – An Overview

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ABSTRACT

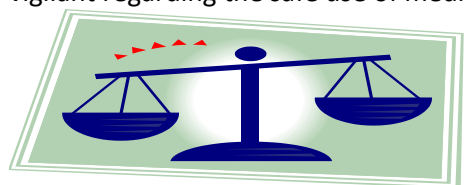
This article covers fundamental basics of product quality complaint. We would learn what product quality is all about, how the product quality complaints are made, processed, investigated and changes implemented. Also we would go through the basics of case processing, how the complaints are classified, categorized based on the priority and then investigated. We would also go through the formal process of responding to the customer and increasing their faith in the company.

A PQP (product quality problem) can be defined as an issue arising due to change in color, odor, appearance, quality, safety and effectiveness of a product. A PQP is a grave concern and is directly related to the efficacy and safety of a drug.

Keywords: Quality Complaint Management, product quality problem, Safety, Pharmaceutical

INTRODUCTION

Safety has been a prior concern for everyman since historical times. Today whatever we buy may it be a simple consumable item or a general medicine, we want to be cent % sure on its effectiveness and safety. Safety and efficacy of a medicinal product go hand by hand. A very efficient product will always carry some degree of precarious nature in it. Times are gone when people used to be the guinea pigs for the safety assessment of medicine. We understand, react and vocalize for the uncomfot we face due to the use of drugs. Therefore this is a need of the hour that every one of us should be extra vigilant regarding the safe use of medicines.



Handling product quality complaints is a serious matter in industries. Complaints should be taken as positive attributes and should be welcomed. There should be nothing like a blame game in handling any complaint. The complainant shows a mirror to the company by complaining about the product and there is always a scope of improvement. It is very important in health care sector that whatever a company is delivering to the consumers, it should be complemented, commented, criticized and suggested for a modification.

Near about 5% of the population using the product will report a complaint and other just take pleasure in gossiping. The product quality complaint department in pharma companies procures extra information on their product disabilities and work on improving them. The complaint management system need to be

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extremely fair and justified. There should be an assurance of confidentiality, an attempt to implement the suggestive action and timely response to the complainant.

WHAT IS PRODUCT DISCREPANCY AND HOW IT IS IDENTIFIED?

Here are some examples of typical product quality complaints generally encountered by the consumers. These may be ignored most of the times but the intelligence says there should be reported either to the regulatory agency or to the manufacturers.

* If the product has organoleptic issues such as}

- Bad taste,
- Bad odor
- Appearance problem

* If the product exhibits lack of efficacy

* If there is suspected contamination

- Any foreign object in the product
- Insect leg in the tablet
- Bug in sealed bottle

* If the product has questionable stability

* If the product has poor packaging and labeling

- Shortage of pills
- Illegible label print
- Broken pills
- Missing desiccant
- 10mg pills found in 20mg bottle
- Empty blister pack
- Blister pack hard to open

* If there is medication error

- Accidental intake of medicine due to resemblance with other medicine

* Formulation errors

- Tablets with disintegration and dissolution issues

- Split tablets
- Air in tube
- Holes in the tablet
- Intact tablets passed in the stool
- Suspension come up with short doses
- Hair hanging out of the pill

* Others

- Burned seal
- Deformed and melted capsules
- Capsules contents spilled in the bottle
- Cartons exposed to moisture
- Cracked and chipped tablets.
- Fiber embedded in the tablets
- Griddy product
- Illegible Logo
- Ink spots on the tablets
- Coating defects-uneven coating and pitting
- Missing applicator tip or Missing insert

HOW THE COMPLAINTS ARE HANDLED

There is always a resolution to every problem, and every mistake can be conquered that should be the adage while handling the complaints. It's quite a complex task to handle but can lead to an astonishing change if handled in a proper way.

There are certain points which help while handling complaints. Improvement in quality will always increase trust in the customers.

1. Understand consumers need
2. Listen to them and react to the situation accordingly
3. Accept appreciation and criticism positively
4. Avoid reoccurrence of mistakes
5. Accept feedback
6. See the complaint as an opportunity for improvement
7. Invite criticism
8. Maintain credibility

HOW THE COMPLAINANT COULD MAKE SURE THAT THE COMPLAINT HAS REACHED THE RIGHT PERSON

For this the companies has there safety website where online complaint can be logged. Most of the companies provide there drug safety contact information for reporting ADE and PQCs directly to the manufacturers. Moreover the consumer/patient can directly contact the pharmacist and then the pharmacist can contact the concerned manufacturer. The consumer participation is very important in the process. The complainant should be kept in loop in the whole process.

HOW ARE THE COMPLAINTS HANDLED IN PHARMACOVIGILANCE DEPARTMENT

While processing a complaint at particular corporations there are certain steps which need to be followed:

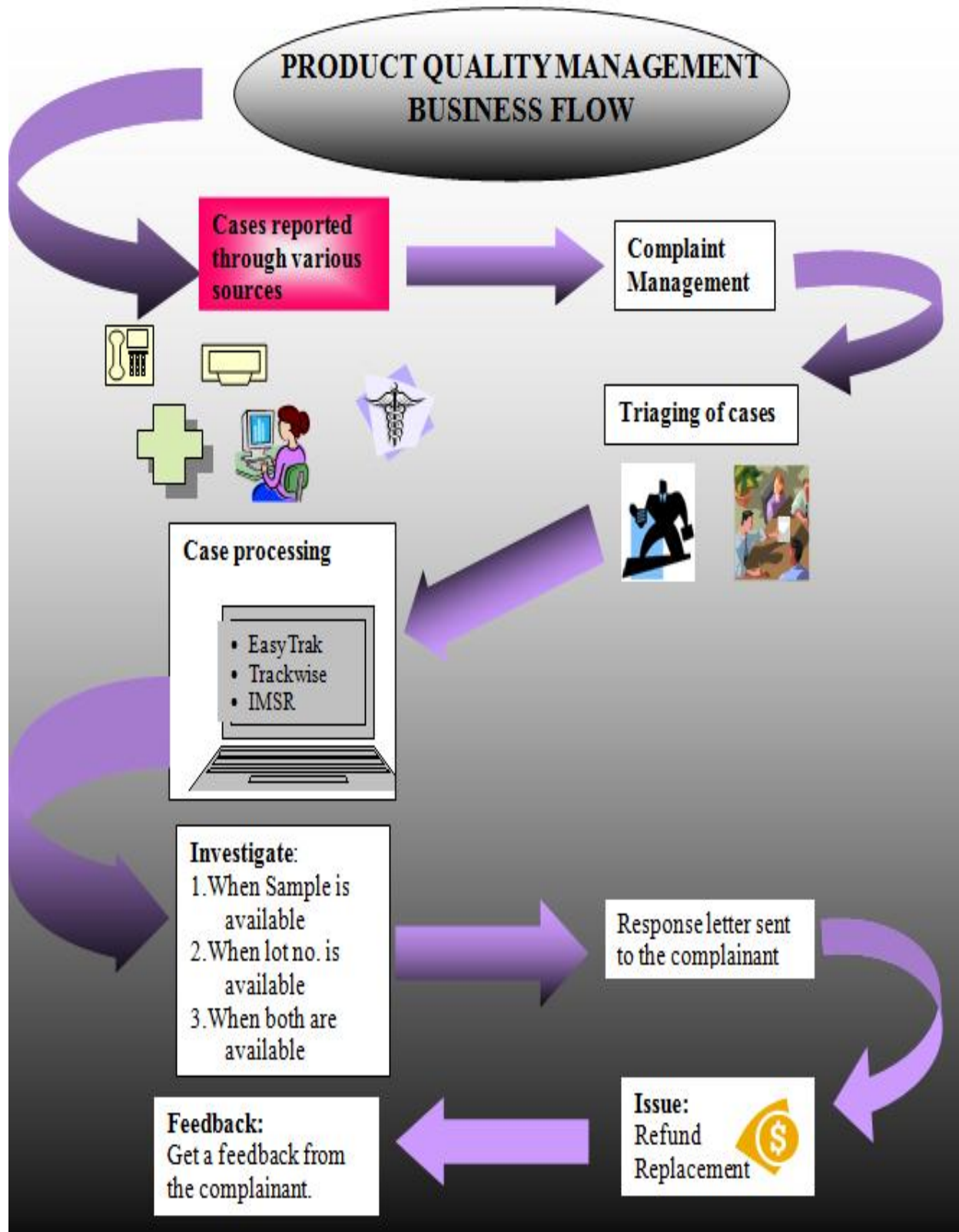
1. A good system to procure complaints 1
 - a) Mails
 - b) Telephone
 - c) Facsimile
 - d) A known person in that company

2. Documenting the complaints on a complaint form
3. Triaging of cases according to priority
 - a) Legal cases
 - b) Cases through regulatory authority
 - c) Serious cases
 - d) Threatened liability
4. Processing of cases in a suitable database
5. Sending acknowledgement letter to the complainant
6. Procuring samples for investigation through 222 form in case the product is a controlled substance.
7. Significant follow ups are also essential
8. Sending sample for investigation
9. Collecting investigation reports
10. Sending the response letter to the complaint.
11. In case of refund/replacement request, the same is done through customer service
12. Requesting feedback from the complainant.
13. Confidentiality and Fairness
14. Medical Evaluation
15. The case should re-open upon request

COMPLAINT REPORTING SYSTEM

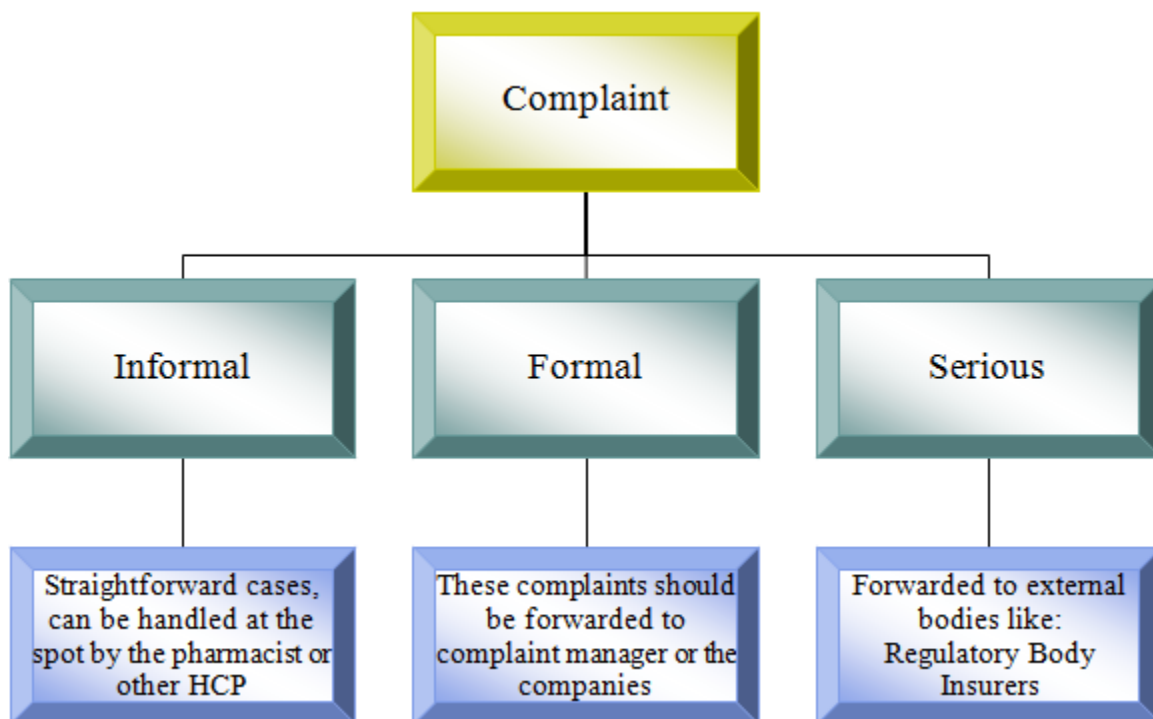
There should be an effective reporting system for every organization. The effectiveness of that system will decide the future of that organization. A good reporting system includes various areas of concern

- The call centre: The Company should have its own call centre (toll free). The consumers should be made aware of that call centre so that they can reach the company easily in case of any emergency. The complaint can be reported through various sources like
 - a) Telephonically
 - b) Fax
- For this, the blister packs should have that no. and other possible contact points like pharmacy, physician for contacting the manufacturer
- A voluntary reporting can be done directly to regulatory authority e.g. MedWatch form 3500A can be used to report a product quality complaint to USFDA.
- When a complaint is made a complaint reference no. should be taken from the person logging the call for future inquiry



TYPES OF COMPLAINT ENCOUNTERED

The complaint classification can be done as



Upon receipt of the complaint it is very important for the complaint manager to triage them correctly. There are varied natures of complainants and more to it varied nature of complaints reported by them. The triaging of complaints should be strictly done on the basis of severity. The following priority levels can be chosen:

- Legal case
- Complaint through regulatory agencies
- Product Quality complaint
- Lack of effect
- ADE associated with PQC

Once the priority is selected the cases are processed on that daily basis. The brief summary of the complaint is triaged on a complaint form along with all the relevant information pertaining to the complaint like

batch no. information; sample information etc. While triaging a complaint the person should make sure of certain points:

- The handwriting should be legible
- The complainant's name and Address should be correct for further correspondence
- The product in question, batch no, expiry date and pack size should be confirmed twice before finalizing
- The documents should clearly mention whether it is a pure product quality complaint, PQC associated with an ADE or whether it is a medical enquiry.
- The date of receipt of the complaint is very important

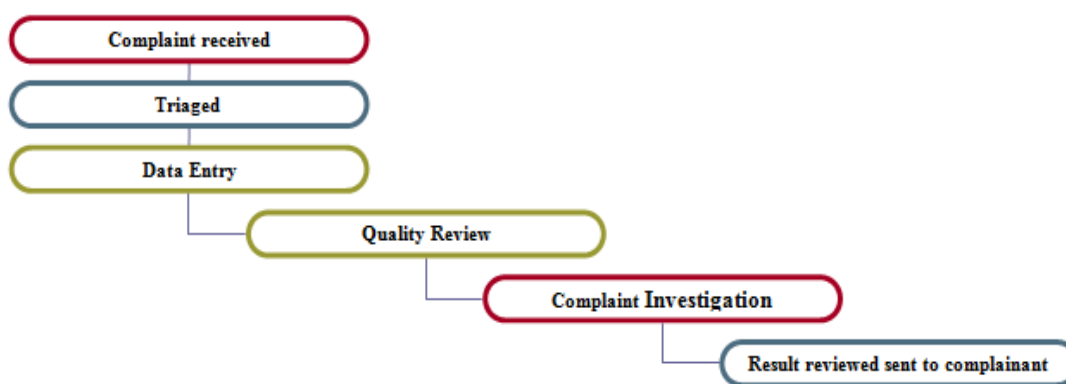
PROCESSING THE CASES IN A SUITABLE DATABASE

The cases received by the drug safety department should make it sure that every complaint received by them should be entered into the database. There are various database used by the companies which utilize them for

managing the complaints effectively. The databases used are:

- EasyTrak
- Trackwise
- MeditTrak

The cases are entered into the database to keep a track of all the complaints received. The cases are entered against the source documents received. The case has to go through various stages in order to get reported. The various stages are



Acknowledging the complaint

After logging the complaint, an acknowledgement letter has to be sent to the complainant referring the complaint reference no. A prepaid mailer should be sent along with the acknowledgement letter for collecting the sample. The following points should be mentioned in the letter

Referring the complaint reference no.

- Brief description of the complaint
- Asking for the complaint sample (un tampered)
- If complaint sample is not available then lot no., expiry date of the sample should be procured.
- Asking to provide the sample within the specified period of time
- Thanking the complainant for taking out their valuable time to report the complaint and using the company's product

According to HIPPA (Health Insurance Portability and Accountability Act) the complainant can deny to provide any personal information. In case the complainant does not wish to provide any contact information, the complaint should be processed but no response should be sent to the complainant.

PROCURING SAMPLES FOR INVESTIGATION

This is a very crucial step in complaint handling. The best result of a complaint can only be obtained when the complaint samples are obtained in perfect shape i.e. without being tampered for e.g. if a suspension has a foreign particle inside, it should not be disturbed and sent as such for investigation. If the sample is transferred to another bottle or if a deliberate attempt has been made to identify the foreign substance the sample shall be considered invalid for investigation.

For procuring the sample a prepaid mailer is generally sent to the complainant. The complainant has to put the sample into the envelope and send it back to the company for investigation. While the samples are sent it should be kept in mind that the samples are delivered to the target site with the same appearance.

In case of controlled substance like Lorazepam, opium tinctures etc a 222 form has to be obtained to request sample from the pharmacy or the packaging unit. This is done in order to keep a strict control on the controlled substances.

SIGNIFICANT FOLLOW UPS

After a case is received it is very important to conduct regular follow ups. This serves various purposes like:

1. The complainant is satisfied as he is being heard and the complaint handling is in progress
2. The information given by the complainant can be of much use and can help further in investigation

RISK ASSESSMENT MATRIX ^[1]

Risk management is an important tool to identify, assess and manage the risk involved in complaint management system. Risk management is not designed to reduce or eliminate risk but it is made to analyze and understand the risk and consciously manage it. After receiving a complaint the first thing is to analyze it and frame the steps to be followed to solve it. The very purpose of the risk management plan is to manage type 3 complaints i.e. serious complaints which need to be notified to the senior management immediately for further necessary action. A certain type of severity assessment coding system should be followed to monitor the complaints and the complaints should be handled according to them. The consequences of an incident have to be matched with the probability of that incident occurring again. A sample seriousness assessment matrix should be framed.

	Serious	Major	Moderate	Minor
Very Frequent	★	★	★	★
Frequent	★	★	★	★
Likely	★	★	★	★
Rare	★	★	★	★
Possible	★	★	★	★

INVESTIGATION TO BE DONE

The investigation is done on the basis of the nature of the complaint. Before initiating an investigation all relevant facts should be collected.

- A detailed analysis of the complaint and associated facts should be studied

- Strategies should be planned for detailed investigation
- A possible conclusion should be made pertaining to the origin of the complaint
- Necessary recommendations should be made for improvements.

· In case of serious complaints the investigation should be initiated as soon as possible before the complaint sample gets destroyed.

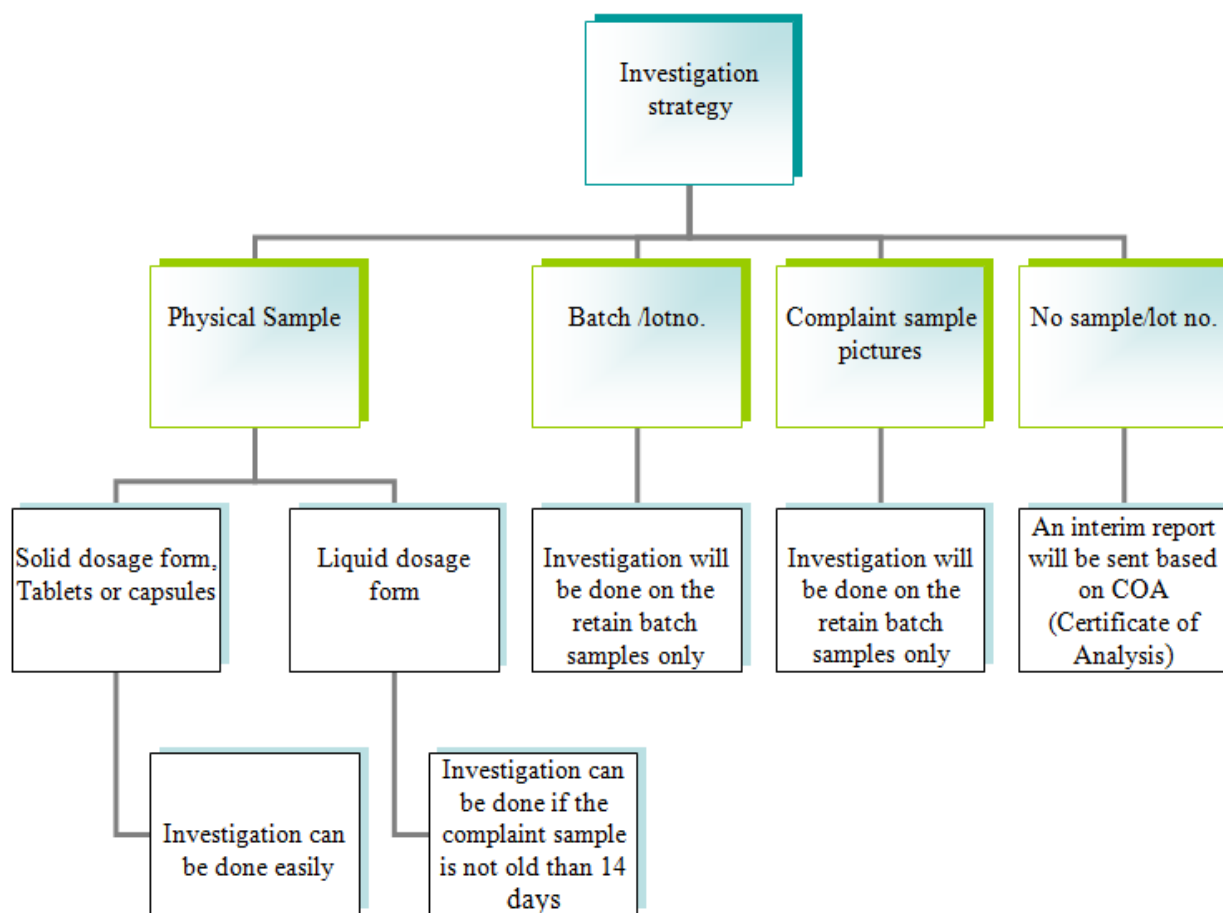
An analysis report is prepared. The investigation is done on following grounds

1. When the complaint sample and Lot no. both are present
2. When only the complaint sample is present

3. When only the Lot no. is present
4. When no sample or lot no. is present.

An analysis report will be prepared even if nothing is present or everything is present. In case initially the lot no. is present and the sample is unavailable but the complaint sample is made available later then the previous report can be updated and sent again.

The drug safety department has to make proper follow ups to get the investigation done on time.



RESPONSE LETTER

Once the investigation report is in hand, it's the time to frame a response letter to the complainant. The salient features of the response letters are:

1. The tracking no. or the complaint no.
2. The details of the complaint
 - When the complaint was logged
 - Where the complaint has been investigated
 - How the physical sample looked.

- The original complaint details
- 3. The body of the letter should pertain to the investigation details
- 4. The summary and conclusion
- 5. The no. of complaints received
- 6. Corrective actions taken to avoid such type of complaints

The response letter decides the impact the complaint would have on the complainant. Based on the summation of the response letter the complainant will give a feedback. The

feedback provides a tool for the companies to improve their activities so that such type of complaints can be avoided in future.

CREDIT/REFUND /REPLACEMENT

Sometimes the complainant desires to have a replacement for the defected product or like to get credited for the amount spent on the medicine which did not work for him. In that case the legal department has to deal with it. The cases involved in replacement or credit needs to be solved immediately.

Below is the table which provides a glance for the important list of things which need to be there for any kind of reimbursement.

DOMAIN	COMPLAINT	REQUIREMENT
Replacement	Consumer bought a strip of tablets but found 2 tablets missing.	The empty strip have to be submitted before asking for any replacement
Credit		Cash memo has to be submitted and account details have to be provided.
Refund		Cash memo. Given through cheque.

Commitment to complainant/Consumer:

After thorough investigation, a response to the complainant is prepared which states the possible reasons for the PQC encountered and the CAPA for the same. It is the responsibility of every pharma company to watch out for complaints and take every possible action to prevent them.

Increasing faith of the complainant in you:
The response to the complaint increases the faith of the consumer in the manufacturing

company. Therefore it is mandatory to close every single complaint appropriately to satisfy the consumer and maintain the level of faith in the product.

CONCLUSION

This article has intended to provide a practical viewpoint of complaint handling to the people engaged in product quality complaint management. It is the need of the hour to take the complaints seriously instead of pretending not to be heard.

↓ REFERENCES

1. Severity Assessment Code, NSW Health Safety Improvement Programme, 2003
2. Complaints Management Handbook for Health Care Services, Australian council for Safety and Quality in Healthcare, 2005.