



Libyan International Medical University
Faculty of Pharmacy



COMPLAINT AND RECALL

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Objective

1. **Define complaint.**
2. **List reasons for complaint.**
3. **List complaint records.**
4. **List types of complaint.**
5. **Define recall.**
6. **List reasons of recall .**
7. **List classifications of recall .**

Complaint

- A person should be designated responsible for handling the complaints and deciding the measures to be taken together with sufficient supporting staff to assist him.



Complaint Reasons

- ❑ It gives the company an opportunity to improve the quality of the product .
- ❑ It maintains committed relationship between the customer and company.
- ❑ Improve the safety and performance of devices .



Complaint records should include

- ❑ Name and address of complainant.
- ❑ Name and phone number of person submitting the complain.
- ❑ Complaint nature (including name and batch number of the API) .
- ❑ Date complaint is received .



Types of Complaint

1

Quality complaints

2

Adverse reaction complaints

3

Other medically related complaints

Recall

- A person should be designated as responsible for execution and coordination of recalls and should be supported by sufficient staff to handle all the aspects of the recalls with the appropriate degree of urgency.



Reasons for Recall

- ❑ FDA authorities may order a recall for substandard quality of the finished product or for any other justified reasons.
- ❑ Manufacturer himself may find problems with the product such as: - substandard quality.
- ❑ Accidental damage of the consignment may also happen during transportation In such case product quality may not be questionable .



Classifications of Recall

1

Class I: Recalls for products which could cause serious injury or death

2

Class II: Recalls for products which might cause serious injury or temporary illness

3

Class III: Recalls for products which are unlikely to cause injury or illness, but that violate FDA regulations.

Summary



Complaint A person should be designated responsible.

Complaint Reasons: Improve the safety and performance of devices



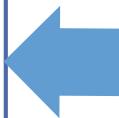
Type of complaint: Quality complaints .

Complaint records: Name and address of complainant



Reasons of Recall :Manufacturer himself may find problems with the product .

Classifications of recall



Recall: A person should be designated as responsible for execution and coordination of recalls

Reference

- ❑ Rules and Guidance for Pharmaceutical Manufacturers and Distributors 2007
- ❑ <https://asean.org/storage/2012/10/ASEAN-TMHS-GMP-Training-Chapter-9-Complaints-and-Recalls-FD-00000002.pdf>
- ❑ <https://www.net/KarishmaMajik/complaints-recalls>
- ❑ <https://injury.findlaw.com/product-liability/fda-recall-types.html>

Thank you

