HANDLING OF RETURNED PRODUCTS

Drugs are an important component of Health Care System

Definition of Finished Product:

A Product that has undergone all stages of Production, including Packaging in its final container and Labeling.

Returned Good / Product.

The Finished Product sent back to the manufacturer

Disposal of Finished Product from Factory Premises

Storage at Depots

Sales and Distribution

A Returned Drug Product is the Distributed F.P. that has been returned to the manufacturing following reasons,

COMPLAINT

DAMAGE

EXPIRATION OF VALIDITY.

A Salvaged drug product is that product which has been subjected to improper storage conditions like extremes of Temperature, Humidity, Smoke, fumes, radiation, fire accidents or equipment failure but may be reprocessed or recovered after laboratory validation to meet the approved specification laid down for that product.

CLASSIFICATION OF RETURNED DRUG PRODUCTS

- Drug products that still comply with all acceptable standards according to investigation by quality control department.
- Drug products which can be reprocessed to comply with appropriate specifications.
- Drug products which are Un-acceptable.

DISPOSITION OF RETURNED DRUG PRODUCTS

- returned drug products shall be counter checked at the Security and informs the concerned department –i.e. Warehouse
- Receiving bay then records amount and identification of returned drug products
- Returned drug products are handed over to In – charge ware house
- Returned drug products shall be kept in QUARANTINE area
- Q.A. shall come for Physical Verification
- Holds in place until further decision

To be **RECOVERED** – QA & Validation dept. for reprocessing

To be **DESTROYED** – Destruction shall be done in the presence of QA officer and Excise Official

Destruction shall be done in such a way that No Pollution hazards shall be caused and prior approval from ETP (Effluent Treatment Plant) and Biomedical Waste Dept.

Records of Returned Drug Product & Destruction Details:

A. Name of Product
B. Batch No.
C. Label Claim
D. Dosage Form
E. Qty & Date Of Receipt
F. Origin of returned goods
G. Storage conditions
H. Transportation

A Destruction Certificate shall be signed and commented by warehouse person and QA person.

This certificate should be a part of the batch document.

QUALITY REVIEW

The prime motto of any Pharmaceutical industry, as a vital segment of health care system, should be of producing a product of good quality in terms of safety, purity and efficacy.

NECESSITY FOR QUALITY PRODUCT

As all the countries are marching towards globalization. This globalization in turn forces the companies to produce a product which meets the quality specifications set by the respective countries, and because of increasing complexity of modern Pharmaceutical manufacturing arising from a wide variety of unique drugs and dosage forms. The Pharmaceutical company has set a department called quality assurance (QAD) in order to install the quality aspects in each and every product.

It is the responsibility of the QAD to install all the quality aspects of a product in each and every product with the help of the other departments like production, quality control dept, stores and maintenance. It does it duty by reviewing various steps involved in manufacturing of products.

QUALITY REVIEW

Quality means purity, safety and efficacy, whereas review means counter checking.

As a whole, quality review in a Pharmaceutical company, represents counter checking each and every step starting from acquiring raw material to releasing finished products, including market complaints.

QUALITY REVIEW TEAM

A systematic and effective review team includes knowledgeable, professional and experienced persons from each and every department. A typical QR team includes:

Quality assurance -1 person

Production -1 person

Quality control-1 person

Regulatory affairs -1 person

Supply chain management -1 person

Team leader – Generally president or vice president (tech)

OBJECTIVES OF QRT

To minimize the errors those arise during various stages involved in production and to minimize the market complaints and mainly to install safety, purity and efficacy in each and every product.

RESPONSIBILITIES OF QRT

In the way to achieve the objectives, QRT will take various variables into consideration for reviewing, which includes

A. **Raw material review**
B. **Production records review**
C. **Packaging and Labelling review**
D. **Finished product record review**

A. RAW MATERIAL CONTROL REVIEW

Quality review team will take decisions for the approval of quality of raw material from a vendor by auditing the manufacturing premises of vendor and documenting the auditing reports and then the reports will be sent to QRT leader for final approval of vendor to supply the raw material.

B. PRODUCTION RECORD REVIEW

B1. Dispensing: In dispensing, each and everything has to be documented like r/m name, batch no., quantity, A.R.N., approval signature.

B2. In process checks: The number of units assayed at the end of the process is not likely to be representative of more than a small portion of the actual portion and so as to minimize batch to batch and within batch variation, it is important to ensure that finished products have uniform purity and quality within batch and between the batches.

This is accomplished by identifying critical steps involved in manufacturing process like checking parameters of tablets (hardness, weight , thickness , friability , DT) and pH adjustments in case of parenterals.

Each and every thing in process checks has to be documented for further reviewing.

C. PACKAGING AND LABELING RECORD REVIEW

After manufacturing a product, QA member will check that correct labels have been used for correct products and see that no mix-ups had occurred, and the approved labels should be attached to the BMRs.

D.FINISHED PRODUCT RECORD REVIEWS

Final testing of f/p is done in Quality control dept. The finished product is tested for compliance with predetermined standards prior to release of product for packaging and subsequent distribution. All the tests and results should be documented. QRT will review the documents before approving for market release.

This finished product testing along with in process checking assures that each and every unit contains the amount of drug claimed on the label, that the entire drug in each unit is available for absorption, that the drug is stable in the formulation in its specific final container, and that dosage units themselves contain no toxic foreign substances.

FREQUENCY OF QUALITY REVIEW

It varies from company to company starting from once in a month to quarterly reviewing, in some instances emergency reviewing.

COMPLIANCE TO Q.R.

Compliance with respect to quality review department can be achieved only by following standard operational procedures by concerned officials of respective departments. I.e. they should document each and everything they do and do as per given in SOP.

RESPONSIBILITY OF QUALITY REVIEW DOCUMENTS

Quality assurance dept will take the responsibility of all the quality documents concerning quality aspects of products