QUALITY REVIEW

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QUALITY REIVEW

QUALITY REIVEW is the prime Moto 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, and this globalization in turn forces the companies to produce a product which meets the quality specifications set by the respective countries.

- 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 (QA) in order to inspect the quality aspects in each and every product.

It is the responsibility of the QA to instill all the quality aspects of a product in each and every product with the help of other departments like production, quality control, stores and maintenance.

It does its duty by reviewing various steps involved in manufacturing of products.

Quality means purity, safety and efficacy

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 REIVEW TEAM

A systematic and effective review team includes knowledgeable, professional and experienced persons form each department.

Team Leader- Generally President or Vice-president

Quality Assurance – 1 person

Production - 1 person

Quality Control - 1 person

Regulatory Affairs - 1 person

Supply Chain Management - 1 person

Objective of QRT

- ✓ To minimize the errors those arise during various stages involved in production
- ✓ To minimize the market complaints
- ✓ To instill safety, purity and efficacy in each and every product.

Responsibilities of QRT

1. Raw material review
2. Production records review
3. Packaging and labeling review
4. Finished product record review

1. **Raw material review**

Quality review team will take decisions for the approval of quality of raw materials 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.

2. Production records review

a) **Dispensing** : In dispensing, each and everything has to be documented like raw material name, batch no. quantity, approval signature etc.

b) **Inprocess checks** : The number of units assayed at the end of the process in 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 batches.

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

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

3. # Packaging and labeling 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 Batch Manufacturing Records.

4. Finished product record review

Final testing of finished product 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.

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This finished product testing along with the 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 (during market complaints).

COMPLIANCE TO QUALITY REVIEW

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 every thing 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.

THANK YOU