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Quality Assurance and Quality Control in Pharmaceuticals.

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Abstract *:* The Overall worldwide methods for evaluating the concentration of geotaxis impurities residual solvents and different inorganic and organic impurities in medications are briefly reviewed here. Due to national and international requirements, it is now required to disclose both the purity profile and the impurity profile of a certain pharmaceutical product. These elements are explored together with the importance of the efficacy, safety, and quality of medicines, as well as the types, sources, and controls of impurities as well as regulatory issues. One of the requirements for the implementation of any nation's health care system is the availability of important medications in excellent quality, as subpar medications have the potential to cause harm or even death to patients. The goal of quality assurance in the pharmaceutical supply chain is to guarantee that every medication that is given to a patient is safe, efficient, and of a suitable caliber. A thorough program of quality assurance consists both administrative and technical tasks. One crucial function of the pharmaceutical sector is quality control. In order to demonstrate the reproducibility of the procedure, it might also carry out the statistical analysis of the test findings. To find out how successful its test program has been in keeping rejectable products off the market, it examines the product complaints.

Index Terms **-** Quality Control, Quality Assurance, Validation, Accreditation, Callibration.

Introduction: - An important goal of IPCC good practice guidance is to support the development of national greenhouse gas inventories that can be readily assessed in terms of quality and completeness. It is good practice to implement quality assurance and quality control (QA/QC) procedures in the development of national greenhouse gas inventories to accomplish this goal.[1]This guidance establishes good practice consistent with the Revised 1996 IPCC Guidelines for National Greenhouse Gas Inventories (IPCC Guidelines). The QA/QC good practice guidance outlined here reflects practicality, acceptability, cost effectiveness, existing experience, and the potential for application on a worldwide

Quality Assurance:-"The assembly of all planned and systematic actions necessary to provide adequate confidence that a product, process, or service will satisfy given quality requirements" is the definition of quality assurance (QA) as per ISO standards.

Objectives of QA:-

1. Ensure that the good or service satisfies both customer demands and specified quality standards. This is the first goal of quality assurance (QA).
2. Verify that the good or service is appropriate for the intended use.
3. Verify that the good or service satisfies or surpasses the needs of the client.
4. Planned and methodical actions are necessary for quality assurance.

Control of quality:
"Part of quality management focused on fulfilling quality requirements" is how quality control is defined. Quality control is the process of ensuring that the parties involved follow the established guidelines and protocols. There is a verification process in quality control.

Objectives of QC:
1. Finding and fixing any deviations from the set quality standards is the main goal of quality control.
2. Effective utilization of both humans and machinery.
3. Material economy in usage.
4. Lower inspection expenses.
5. A decrease in the price per unit.

ICH Guidelines:-Achievements in quality harmonization include important milestones such as conducting stability studies, defining appropriate thresholds for impurity testing, and a more flexible approach to drug quality based on Good Manufacturing Practice (GMP) risk management.
The ICH topics are divided into the categories below, and ICH topic codes are assigned to these categories.
1. **Quality Guidelines:-**Achievements in quality harmonization include important milestones such as the completion of stability studies, the definition of appropriate thresholds for impurity testing, and a more flexible approach to drug quality based on Good Manufacturing Practice (GMP) risk management..
2. Safety Guidelines:-The ICH has developed comprehensive safety guidelines to address potential risks such as carcinogenicity, genotoxicity and reproductive toxicity. A recent success has been a nonclinical testing strategy to assess liability for QT prolongation, the most important cause of drug withdrawal in recent years.
3. Efficacy Guidelines:-ICH's work under the rubric of efficacy relates to the design, conduct, safety and reporting of clinical trials. It also includes new types of drugs derived from biotechnological processes and the use of pharmacogenetics/genomics techniques to produce more targeted drugs.
4. Multidisciplinary guidelines:-These are multidisciplinary topics that do not fit any quality, safety or efficacy criteria. This includes the development of ICH Medical Terminology (MedDRA), Common Technical Document (CTD) and electronic standards for the transmission of regulatory information.
Good Laboratory Practice (GLP): -OECD Good Laboratory Practice (GLP) principles ensure the production of high-quality and reliable test data related to the safety of industrial chemical substances and preparations. The principles were created in the context of the harmonization of mutual recognition of data (MAD) test procedures.
Content:- Quality in the pharmaceutical industry has become a very important topic. Since then, the world has come together to harmonize their practices and guidelines, and since the FDA launched the current GMP.

Fig-Parameters of Quality Assurance

Quality assurance in the pharmaceutical industry ensures that the products or services of the pharmaceutical industry meet the required quality standards. It aims to build and maintain customer confidence in the product by detecting and preventing defects at an early stage. In the pharmaceutical industry, quality assurance is a continuous process focused on a thorough investigation of customer needs and expectations. Various approaches can be used to support this process, taking into account the importance of minimizing additional costs to the business. In addition, the main goal of pharmaceutical quality assurance is to reduce costs while maintaining high quality standards while complying with relevant regulations and industry formats.

Quality Control: - Quality Control (QC) is the process of ensuring that the products or services you provide meet the standards and expectations of your customers and stakeholders. QC involves setting clear objectives, monitoring and measuring performance, identifying and correcting errors, and implementing improvements.

IPQC (In-Process Quality Control) and Finished Product Quality Control for Dosage Form:-
In-Process Quality Control (IPQC) tests are strongly related to the quality of the final product because checks are made during production to control the process. and adjust if necessary. The key to quality pharmaceutical tablets is to ensure that the product conforms to specification.

Finished product quality control test:-
At the end of the manufacturing process, pharmaceutical tablets undergo finished product quality control (FPQC) tests as defined in the pharmacopoeia to verify that quality parameters are within acceptable limits.

Callibration:-Calibration is a quality control feature that helps ensure all reviewers are on the same page when evaluating an interaction. No matter how well the form is drafted, there can still be differences in interpretation.

Importance of Callibration :-
1. Calibration is responsible for determining the accuracy and quality of the measurement results recorded by any instrument.When starting to work with any instrument, it must be well calibrated to ensure accurate results.
2. Calibration minimizes such uncertainties, ensuring the accuracy of test equipment.
3. By regularly calibrating your instrument, you can eliminatedrift in its early stages, rather than allowing it to build up until it seriously affects your measurements.
4. Calibration helps to quantify and control errors and uncertainties in various measurement processes to an acceptable level.
5. In addition, it helps to improve the accuracy of the measuring device, which in turn improves the quality of the final product.
6. In short, regular calibration allows pharmaceutical companies to have confidence in their results, which they can record, track and control.

Validation:-Validation is the process of obtaining documentation that demonstrates that a procedure, process or activity performed during production or testing maintains the desired level of conformity at all stages..

Types Of Validation: -

1. Prospective Validation:-Validation is performed before the distribution of a new product or a product manufactured according to a modified production process or evidence that the system is doing what it plans to do (e.g. a process validation plan for the first three business batches.)
2. Retrospective validation:-Validation of a process for a marketed product based on accumulated production and verifies data or evidence that the system does what it does based on a review and analysis of existing data (e.g. stability studies).
3.Concurrent Validation:-Tracking critical processing steps of the process and final product, current production testing is about concurrent validation .or proving that the system does what it is intended to do based on data generated during system deployment (e.g. equipment validation.)
4. Process Validation:-It reinforces the documented evidence that provides a high level of confidence that a given process.(eg, the manufacture of a pharmaceutical formulation) will consistently produce a product that meets the given specifications and quality indicators (at optimal costs).

National Accreditation Board for Testing and Calibration Laboratories(NABL):-

NABL is a society registered under the Societies Registration Act, 1860. It functions as an independent agency under the Department of Science and Technology (DST), Ministry of Science and Technology, Government of India. NABL was established to provide government, trade unions and industry in general with an accreditation system for Conformity Assessment Bodies, which includes the assessment of technical

competence in testing by third parties, including medical and calibration laboratories, providers of proficiency tests and producers of reference materials.
NABL provides accreditation services on a non-discriminatory basis. These services are available to all testing facilities, including medical and calibration laboratories, capability providers and reference material manufacturers in India and other countries in the region, regardless of the size of CAB or the applicant's membership in any association or group or number of TAXIS Accredited by NABL.
NABL has established its accreditation system according to ISO/IEC 17011:2004 "Conformity assessment - General requirements for accreditation bodies accrediting conformity assessment bodies".
NABL's accreditation system also takes into account the requirement of Mutual Recognition Agreements (MRAs) of which NABL is a member.

Advantages of accreditation:-
Formal recognition of competence by an accreditation body according to international criteria has many advantages:-
1. Increased confidence in the test/calibration reports given by the laboratory.
2. Better monitoring of laboratory work and feedback to laboratories on whether they have a functioning quality assurance system and are technically competent.
3. Potential business growth due to increased customer trust and satisfaction.
4. Customers can search and identify NABL accredited laboratories according to their specific requirements from NABL website or accredited laboratory directory.
5. Users of accredited laboratories get better access to their products in both domestic and international markets.
6. Saves time and money by reducing or eliminating the need to retest products.

Quality by Design:-
Quality by design is an approach that aims to ensure the quality of medicines using statistical, analytical and risk management methods in the design, development and manufacture of medicines.
Quality by Design (QbD) is a strategic approach used in several industries, including pharmaceuticals, manufacturing and product development, to ensure the continuous delivery of high-quality products.
Elements of QbD:-
1. Define the quality target product profile.
2. Determine the quality characteristics.
3. Perform a risk analysis (assessment).
4. Determine the critical quality indicators and critical process parameters.
5. Determine the design mode.
6. Determine the control strategy.
Objectives of QbD:-
1. The main objective of QbD is to achieve quality products implementation of positive performance testing.
2. Ensures the integration of product and process information obtained during development.
3. Desired attributes can be formed from the information in the information process.

Conclusion:-
To summarize the entire discussion, it clearly shows that quality assurance is somehow related to all departments in the pharmaceutical industry and plays an important role in each department in improving the process of that department. As mentioned in the title, quality assurance plays an important role and is said to be the backbone of the pharmaceutical industry. Ensuring quality, customer satisfaction is emphasized and the instructions given by the authorities are also followed. Because the thalidomide incident happened so long ago, it clearly shows the failure of quality assurance and clinical trials that led to such major disasters that caused teratogenicity (phocomelia). The drug was first invented for morning sickness in pregnant women. Due to lack of proper analysis and quality control, this led to black history, so it also clearly shows that quality assurance plays a very important role in pharmaceutical manufacturing. Quality assurance is not only practiced and emphasized in the pharmaceutical industry, but is emphasized in all industries that touch every emotion.
We understand that quality control is a product-oriented process. When it comes to quality assurance, it is a process-oriented practice. Quality control ensures that the final product meets the quality requirements, but

quality ensures that the production process of the product meets the standards. Therefore, quality assurance can be considered a proactive activity process, while quality control can be identified as a reactive process.

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