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Quality Control and Quality Assurance

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***Abstract:** This brief review presents the international approaches to assessment of the content of geotaxis impurities (residual solvents and various inorganic and organic impurities) in pharmaceuticals. Nowadays, it has become necessary to provide not only purity profile but also impurity profile of a particular pharmaceutical product because of national and international regulations. The supply of essential medicines of good quality has been identified as one ofthe pre-requisites for the delivery of health care system of any country as poor quality medicines can harm or even kill consumers. The presence of unwanted chemicals in a particular medicine, even in extremely small quantities, may influence its efficiency and safety. Unlike in other industries, a medicine is a dynamic product whose color, consistency, weight, and even chemical identity can change between manufacture and ultimate consumption. Impurities in pharmaceutical products are of great concern not only due to the inherent toxicity of certain contaminants, but also due to the adverse effect that contaminants may have on drug stability and shelf-life. In pharmaceutical and drug products, impurities are the unwanted chemicals (organic, inorganic and residualsolvents) that remain with the active pharmaceutical ingredients (APIs), or develop/added during formulation, or upon aging.*
***Keywords:** Quality control, Quality assurance*

I. 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.

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 basis. The outcomes of the QA/QC process may result in a reassessment ofinventory or source category uncertainty estimates. For example, if data quality is found to be lower than previously thought and this situation cannot be rectified in the time frame of the current inventory, the uncertainty estimates ought to be re-evaluated.

A. Quality Systems

The Good Laboratory Practice (GLP) is a quality system concerned with the organizational processes and the conditions under which non-clinical health and environmental safety studies are planned, performed, monitored, archived and reported. The ISO/IEC 17025: 2005 Standard, replacing the previous standards (ISO/IEC Guide25 and EN 45001), contains all of the general requirements for the technical competence to carry out tests, including sampling, that laboratories have to meet if they wish to demonstrate that they operate a quality system, and are able to generate technically valid results. It covers analytical tasks performed using standard methods, non-standard methods, and laboratory-developed methods, and incorporates all those requirements of ISO 9001and ISO 9002 that are relevant to the scope of the services that are covered by the laboratory's quality system. The OECD Good Laboratory Practice (GLP) GLs and the ISO/IEC Standard focus on different fields of activities, but they have been developed simultaneously, and they are specifyingbasically the same requirements in terms of AQC.

B. QA/QC

Quality Control (QC) is a system of routine technical activities, to measure and control the quality of the inventory as it is being developed. The QC system is designed to provide routine and consistent checks to ensure data integrity, correctness, and completeness and to identify and address errors and omissions.

Quality Assurance (QA) activities include a planned system of review procedures conducted by personnel not directly involved in the inventory compilation/development process.

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II. PRACTICAL CONSIDERATIONS IN DEVELOPING QA/QC SYSTEMS

Implementing QA/QC procedures requires resources, expertise and time. In developing any QA/QC system, it is expected that judgments will need to be made on the following:-

1) Resources allocated to QC for different source categories and the compilationprocess
2) Time allocated to conduct the checks and reviews of emissions estimates
3) Availability and access to information on activity data and emission factors,including data quality
4) Procedures to ensure confidentiality of inventory and source categoryinformation, when required
5) Requirements for archiving information
6) Frequency of QA/QC checks on different parts of the inventory
7) The level of QC appropriate for each source category
8) Whether increased effort on QC will result in improved emissions estimatesand reduced uncertainties
9) Whether sufficient expertise is available to conduct the checks and reviews.

III. ELEMENTS OF QA/QC SYSTEM

The following are the major elements to be considered in the development of a QA/QC system to be implemented in tracking inventory compilation:-

1) An inventory agency responsible for coordinating QA/QC activities
2) A QA/QC plan
3) General QC procedures
4) Source category-specific QC procedures
5) QA review procedures
6) Reporting, documentation, and archiving procedures.

IV. INVENTORY AGENCY

The inventory agency is responsible for coordinating QA/QC activities for the national inventory. The inventory agency may designate responsibilities for implementing and documenting these QA/QC procedures to other agencies or organizations. The inventory agency should ensure that other organizations involved in the preparation of the inventory are following applicable QA/QC procedures.

A. QA/QC PLAN

A QA/QC plan is a fundamental element of a QA/QC system, and it is good practice to develop one. The plan should, in general, outline QA/QC activities thatwill be implemented, and include a scheduled time frame that follows inventory preparation from its initial development through to final reporting in any year. Itshould contain an outline of the processes and schedule to review all source categories.The QA/QC plan is an internal document to organize, plan, and implement QA/QC activities.

Once developed, it can be referenced and used in subsequent inventory preparation, or modified as appropriate (i.e. when changes in processes occur or on advice of independent reviewers). This plan should be available for external review. In developing and implementing the QA/QC plan, it may be useful to refer to thestandards and guidelines published by the International Organization for Standardization (ISO), including the ISO 9000 series. Although ISO 9000 standards are not specifically designed for emissions inventories, they have been applied by some countries to help organize QA/QC activities.

V. QUALITY ASSURANCE REVIEW PROCESS

The QAR process ensures that a comprehensive review is carried out in accordance with international standards. Generally, it involves the standard four phases i.e. planning, conducting, reporting, and follow-up.

1) Planning Phase

Planning

a) Understand the OAGN or Audit environment
b) Define QAR
c) Objective & scope
d) Identify key areas for QAR

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e) Select appropriate audits for QAR Decide
f) Methodology
g) Define roles and responsibilities
h) Estimate resources including time
i) Prepare QAR plan

2) Conducting Phase

In the second phase, the review team conducts the review using the QAR plan to guide the gathering of evidence.
Conducting of QAR
a) Conduct entry meeting
b) Gather information
c) Record and analyze information
d) Discuss QAR findings with audit team

3) Reporting Phase

The third phase is where the review team uses the outputs (preliminary findings and recommendations) of the conducting phase as inputs to prepare a draft QAR report.
Reporting of QAR
a) Prepare draft QAR Report
b) Conduct exit meeting with
c) Finalize QAR Report

4) Follow-up

The final phase is where the review team uses the action plan prepared by the audit line functions as inputs, and assesses the extent of implementation of the QAR recommendations and reasons for non-implementation, if any.
Follow up QAR
a) Management
b) Implements Action Assess
c) Implementation of action plan
d) Prepare follow-up QAR Report

VI. METHODOLOGIES AND TECHNIQUES FOR CONDUCTING Q. A.REPORT

Methodologies and Techniques for Conducting QA Review Following methodologies and techniques can be used for conducting Quality Assurance Review:

1) Interview is seeking appropriate information from the audit team. In the context, quality assurance team could ask audit team for information, listen to and consider their responses, ask follow-up questions and corroborate information, as appropriate. Interview technique can be also used to collectthe information from the audited entity
2) Observation is looking at a process or procedure being performed by others. It provides evidence for that point in time and by them, which cannot be usedto draw conclusions about matters that have occurred over a period of time.
3) Documentation review is reading records or documents either visually orelectronically. Examples of records/documentation are correspondences,memorandum, minutes, reports, etc.
4) Re-performance is walking through or repeating operational steps. For example, to check the accuracy of efficiency measures, the auditor may replicate procedures used to measure efficiency. Replication can help theauditor confirm or deny the system or some part of it works as claimed.
5) Confirmation is a response, ordinarily in writing, to an enquiry, also ordinarily in writing, to corroborate information. It can be used to verify thatan activity was carried out in the field.
6) Analysis visually or electronically identifies what is the same and what is different between two or more documents, tangible items or data. Analyticalevidence should be derived by experts/people who are knowledgeable aboutthe matters analyzed and have the ability to make logical inferences and value judgments from the data collected. Different statistical tools can be used to analyze data or information.

7) Focus group discussions are a selection of individuals brought together to discuss specific issues on audit topics. They are primarily used to collect qualitative data and information. Focus groups techniques are used to obtain information on the implementation and impact of government programs based on the prospective of the beneficiaries and other stakeholders.

8) Seminars and hearings can be organized to obtain knowledge of specialist area, discuss problems, observations and find out possible solutions. The participants of seminars may be interested parties, stakeholders and experts.

VII. CONCLUSION

As a conclusion on the entire discussion it clearly shows that quality assurance is somehow related to all the departments in a pharmaceutical industry, and it plays animportant role in each department to enhance the process of that particular department.

As how the title mentions that the quality assurance plays vital role and it is said as the backbone of a pharmaceutical industry. Quality Assurance they emphasize on customers satisfaction and also based on the guidelines which have been set up by the authorities.

As the thalidomide incident which took place long ago it shows a clearly failure in the quality assurance and the clinical trial phase which lead to such a big disasters which caused teratogenicity (Phocomelia). The drug was first invented for morning sickness problem in the pregnant women's. Due to lack of proper analysis and quality check it has cause a black history, thus this also clearly proves that the quality assurance has a very important role in production of medication.

Quality assurance is not only implemented or emphasize in pharmaceutical industry whereas it is emphasize on every production industry which is related to every feel. As it was said that QA works based on customers satisfaction, customer is the main source which gives profit and revenue to any industry. If the product doesnot have qualities then it will a big failure to the industry. QA has its role in every partof an industry which is inter-related, QA can form many branches of department "under their Umbrella" to increase the efficiency and the standard of the quality by every means and methods.

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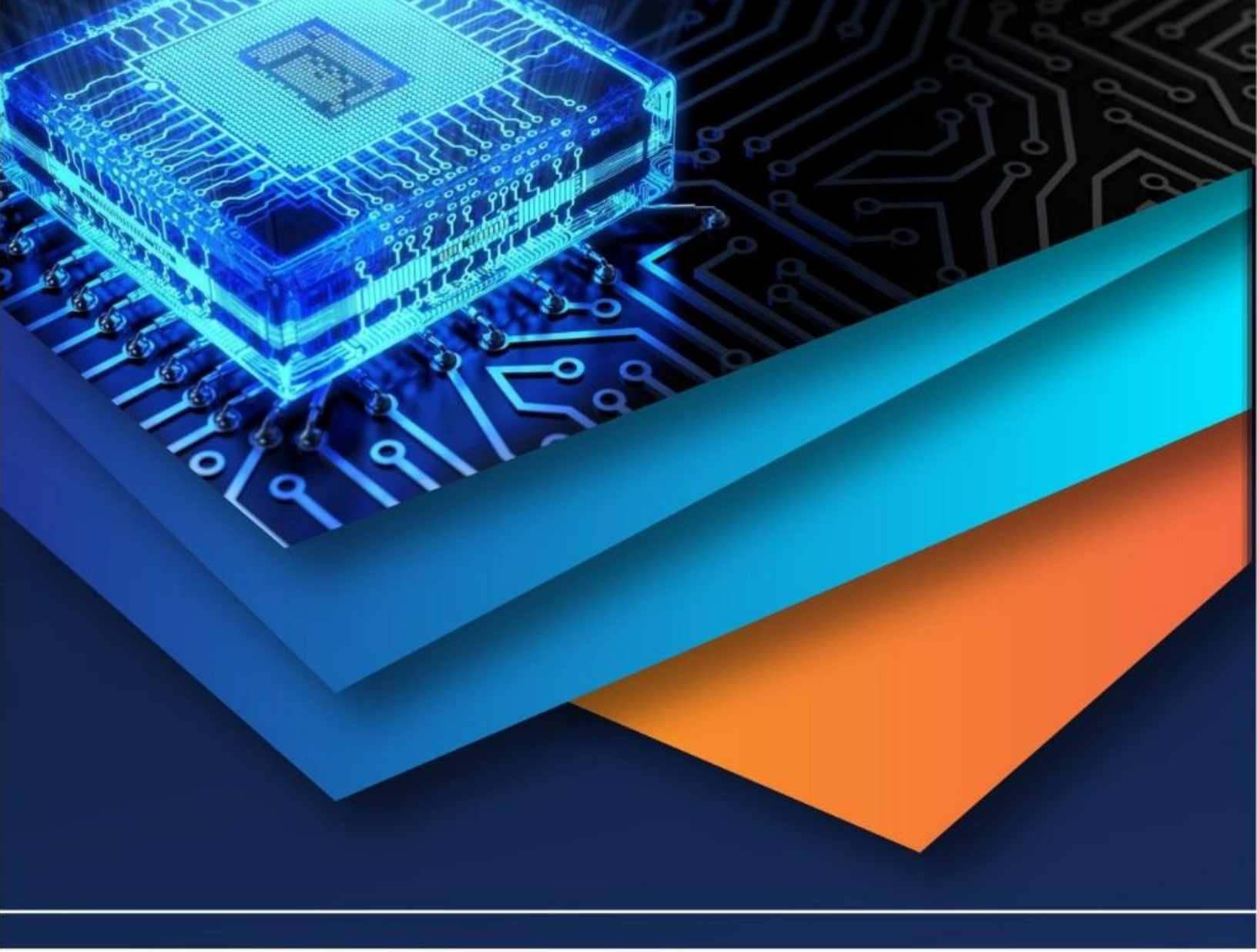

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