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Quality Control and Quality Assurance in Pharmaceutical Industry

Gouri Mahesh Sontakke, Shrutika Shriprasad Sakhare, Rasika Dhanaji Chavan
Ganesh Sugriv Dhakne, Vedant Gopichand Hamand
Nootan College of Pharmacy, Kavathe Mahankal, Maharashtra, India

Abstract: *Quality assurance can be defined as "the part of quality management aimed at ensuring confidence that quality must be performed". The trust provided by quality assurance is dual internal to management and external to clients, government agencies, regulators, certification bodies and third parties. An alternative definition is "the complete performance of targeted and organized activities within the framework of a quality method that can be documented to provide assurance that the commodity or service will meet the required quality. Quality assurance is comprehensive and does not have to do with the specific necessity of the product being developed. Quality Assurance (QA), Quality Control (QC), and Good Manufacturing Practice (GMP) are major considerations in the manufacturing, distribution, and marketing of pharmaceutical products to ensure their identification, potency, purity, pharmacological safety, and efficacy and effectiveness. (8) The terms Quality Assurance, Quality Control and Good Manufacturing Practices are defined in most international regulatory documents including WHO, USFDA, MHRA,TGA, MCC, etc. The quality of a pharmaceutical manufacturer's products depends on the fact that up to what satisfactory level of QA, QC and GMP system has been adopted in the process of production, distribution and marketing of products during their total shelf life. The main objective of this article is to demonstrate the fundamental difference between quality assurance, quality control and good manufacturing practice (GMP) and to emphasize their necessity for a pharmaceutical product. (8) This overview describes quality by design and identifies some of its elements. Process parameters and quality attributes are identified for every unit operation. The advantages, opportunities and steps involved in Quality by Design for pharmaceutical products are described. It is based on ICH guidelines Q8 for pharmaceutical development, Q9 for quality risk management and Q10 for pharmaceutical quality systems. It also provides the application of Quality by Design in pharmaceutical drug development and manufacturing.*

Keywords: Quality assurance

I. INTRODUCTION

1.1 Quality Control

QC is the part of GMP convey with sampling, specifications, testing, organization , documentations and release procedures which make sure that the necessary and relevant tests are carried out and that the materials are neither released for use nor products released for sale or supply until their quality has been satisfactory QC is not limited to laboratory operations but must be involved in all regarding to the quality of the product (11)

A. Scope of Quality Control

- **Supply Quality Assurance:** Supplier quality assurance (SQA) is a agreement with the provider of raw materials and components. Under this contract, the manufacturer make sure that incoming materials and parts will be of uniform and reliable quality.
- **In-process control:** Random samples of the product are taken and their quality is measured against predetermined standards of quality during the stage of processing materials. Such tests may tell certain faults in the production process. Primordial steps are taken to make sure that right quality products are manufactured.

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- **Post- mortem inspection:** It is taken after the products are manufactured or completed. It is a technique of classifying the units into acceptable and reject-able class and assessing the quality of a product. Inspection controls are frequently called quality assurance.

1.2 Quality Assurance

Quality Assurance (QA) is a management method defined as "all those planned and systematic activities required to provide reasonable confidence that a product, service or result will meet given quality requirements and be fit for use". (11)

A. Scope of Quality Assurance

Quality assurance means satisfying the quality of the product so that the customer can buy it with confidence and use it with confidence and satisfaction.

In order for a customer to buy with confidence, they must have a sense of confidence in a specific product from a specific company that has a long track record of authentic products. (1)

II. GOOD LABORATORY PRACTICES (GLP)

- "Good laboratory practice" originated in the US in the 1970s due to concerns about the validity of non-clinical safety data submitted to the Food and Drug Administration (FDA) in connection with new drug applications (NDAs). (11)
- In the field of experimental (non-clinical) research, good laboratory practice, or SLP, is a quality management system for research laboratories and organizations to ensure uniformity, consistency, reliability, reproducibility, quality and unity of evolutionary products. Human or animal health (Including pharmaceuticals) through non-clinical safety testing; from physic - chemical properties through acute to chronic toxicity tests. (3)(12)
- GLP principles aim to ensure and assist the safety, uniformity, high quality and responsibility of chemicals in the non-clinical and laboratory testing process.
- GLP is not limited to chemicals and also applies to medical devices, food additives, food packaging, dyes, animal food additives, other non-pharmaceutical products or additives, biological products and electronic products. (11)

III. GOOD MANUFACTURING PRACTICES (GMP)

- Good Manufacturing Practice (GMP) is a system that ensures that products are regularly manufactured and controlled to quality standards. It is designed to minimize the risks associated with any pharmaceutical manufacturing that cannot be eliminated by testing the final product. (22)
- Right down to employee training and personal hygiene, (22) GMP covers all aspects of production from starting materials, premises and equipment. (22)

3.1 cGMP

- The FDA ensures the quality of drug products by closely monitoring how drug manufacturers comply with Current Good Manufacturing Practices (CGMP).
- CGMP controls for drugs contain minimum requirements for the methods, equipment and controls used in the manufacture, processing and packaging of the drug. Regulations ensure that the product is safe to use.
- The process of approving new and generic applications to the market includes checking the manufacturer's compliance with CGMP.

IV. GOOD WAREHOUSE PRACTICES (GWP)

True proper storage is the method of storing supplies so that products are always available, accessible and in good condition, and to ensure that medicines are not damaged during storage.

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Clean and disinfect the storage area regularly. (4) Avoid food, beverages, chewing gum, tobacco , trash cans in warehouse and storage areas. Personal belongings should be kept in designated areas. The temperature of all incoming drugs is recorded. Check all arrivals for spills and packaging condition. If there are seals on the incoming stock, the seal number should be compared to the seal number on the receipt. Empty crates, racks and pallets should be inspected for rodents, insects or odors.

Store supplies in a dry, well-ventilated area and out of direct sunlight. Ensure that water cannot leak into the storage area. Report all spilled and damaged crates, racks, railings immediately to the warehouse manager or manager. (4

V. QSEM – OVERVIEW of ICH GUIDELINE :

Q : Quality guidelines
S : Safety guidelines
E : Efficacy guidelines
M :Multi-Disciplinary guidelines

Quality Guidelines:

Harmonization achievements in the quality area include pivotal milestone such as the conduct of stability, defining relevant thresholds for impurities testing and more flexible approach to pharmaceutical quality based on good manufacturing practices risk management

Safety Guidelines :

ICH has produced a complete set of safety guidelines to detect potential risk like carcinogenicity, genotoxicity and reprotixicity.

Efficacy Guidelines :

The work carried out by ICH under the efficacy headings is concerned with the design, safety, conduct and reporting of clinical trials. it also covers the novel type of medicines derived from biotechnological processes.

Multi-Disciplinary Guidelines:

Those covers the cross cutting topics which do not fit uniquely into one of the quality, safety and efficacy categories.

FDA

The Food and Drug Administration (FDA) is responsible for protecting public health by ensuring the efficacy, safety, and security of human and veterinary drugs, medical devices, biological products, our nation's food supply, cosmetics, and products that emit radiation. .

The Food and Drug Administration (FDA) was established in 1906 and is a government agency subject to the approval of the Federal Food and Drug Act. It is the oldest broad consumer protection agency. FDA certification is mandatory for product placement in the US.

Drug manufacturers must conduct laboratory, animal, and human clinical trials and submit their data to the FDA to obtain FDA approval. The FDA then reviews the data and may approve the drug if the agency decides that the drug's benefits outweigh the harms for its intended use. (5)

USFDA

The United State Food and Drug Administration (USFDA) provides sterile and non-sterile pharmaceutical guidelines for industries. FDA updates guidance for industry from time to time. All FDA-approved facilities must follow these FDA guidelines worldwide

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WHO

On April 7, 1948, (14) the WHO was founded. The first meeting of the World Health Assembly (WHA) was held on 24 July of that year by the agency's governing body. WHO incorporated the assets, personnel and responsibilities of the Health Organization of the League of Nations and the Office for International Hygiene, including the International Classification of Diseases (ICD). WHO has played a leading role in several public health successes, notably the eradication of smallpox, the near eradication of polio, and the development of the Ebola vaccine. (6)

MHRA

Medicines and Healthcare Products Regulatory Agency Ensure that drugs, medical devices and blood components for transfusion meet applicable safety, quality and efficacy standards. Ensure a safe and secure supply chain for drugs, medical devices and blood components. Ensure the efficacy and safety of biological medicines by promoting international standardization and harmonization.

TGA

The Therapeutic Goods Administration is the Australian Government's drug and therapeutics regulatory agency. The TGA regulates the quality, supply and advertising of medicines, pathological devices, medical devices, blood products and most other therapeutics under the Ministry of Health and Aged care. (7)

VI. INTRODUCTION TO THE PRINCIPLES OF DRUG DISCOVERY AND DEVELOPMENT

The drug discovery process ends when one lead compound for a drug candidate is found and the drug development process begins. Once a lead compound is found, drug development begins with preclinical research to determine the drug's efficacy and safety.

PRINCIPLE:-

“Basic principles of drug discovery and development represent the multifaceted process of new drug identification in the modern era, providing a comprehensive explanation of enabling technologies such as high-throughput screening, structured drug design, molecular modeling, pharmaceutical profiling, and translational medicine. areas that have become crucial steps in the successful development of marketable therapeutics. (14)

Investigational New Drug Application (INDA)

An Investigational New Drug Application (IND) is a request by a clinical trial sponsor to obtain approval from the Food and Drug Administration (FDA) to administer an investigational drug or biological product to humans.

New Drug Application (NDA)

A New Drug Application (NDA) provides complete information about a new drug molecule. The purpose of an NDA is to demonstrate that a drug is safe and effective for its intended use in a large population study.

Abbreviated New Drug Application (ANDA)

An Abbreviated New Drug Application (ANDA) contains data that is submitted to the FDA for review and eventual approval of a generic drug. Once approved, the applicant can manufacture and market the generic drug to provide a safe, effective and cheaper alternative to the brand-name drug it refers to.

Central Drug Standard Control Organization (CDSCO)

It carries out regulatory control over the quality of drugs, cosmetics and notified medical devices in the country. It is the Central Narcotics Bureau to perform the functions assigned to the Central Government under the Drugs and Cosmetics Act.

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VII. FUNCTION OF CDSCO

According to the Law on Medicines and Cosmetics, the regulation of the production, sale and distribution of medicines is primarily a matter for state authorities, while central authorities are responsible for approving new medicines, clinical trials in the country, setting standards for medicines, quality control of imported medicines, coordinating the activities of state control organizations medicines and the provision of expert advice in order to achieve uniformity in the enforcement of the Medicines and Cosmetics Act.(15)

The Drug Controller General of India is responsible for approving licenses for certain categories of drugs such as blood and blood products, I.V. fluids, vaccines and serums. The Central Drugs Standard Control Organization is headquartered at FDA Bhawan, Kotla Road, New Delhi 110002 and functions under the Directorate General of Health Services. (15)

VIII. QUALITY ASSURANCE IN REGULATORY AFFAIRS OF PHARMACEUTICAL INDUSTRY :-

Regulatory Matters as mentioned in the title, the first thing that comes to mind when we hear the word regulation is regulation and laws. In this section we are going to discuss how Quality Assurance does is related to Regulatory Affairs Department and how they work hand in hand for the improvement of the particular pharmaceutical industry so that the industry gets better profit. Regulatory Affairs mainly deals with the regulatory aspect of the drug and pharmaceutical industry, in the regulatory aspect also QA documentation to obtain clearance for any related regulatory issues. Job description Regulatory Affairs works closely with authorities to ensure that the product is registered in compliance with the regulation. Documentation is a very important aspect in the regulatory affairs department , these documentations are generally used to register manufactured products in other countries. This documentation should include details of every aspect of the medication; quality assurance details and Certificate Of Analysis (COA) are the main aspects in the drug dossier. The prepared documentation is sent to the authorities of a specific country to register the drug in that country. It will take almost 2 years for the drug to be registered in another country based on export. Every detail of the analysis and analysis that is carried out in the QA department is given in the form as a report that needs to be attached to the drug dossier before it is sent for registration.

IX. METHODOLOGIES AND TECHNIQUES FOR CONDUCTING QA.REPORT:-

Methodologies and techniques for performing quality control the following methodologies and techniques can be used for performing quality control. (10)

1. The interview is to obtain appropriate information from the audit team. In this context, the quality assurance team could ask the audit team for information, listen to and consider their responses, ask follow-up questions and confirm information as needed. An interview technique can also be used to collect information from the auditee
2. Observation is looking at a process or procedure performed by others. (10)It provides evidence for and by this moment that cannot be used to draw conclusions about matters that happened over a period of time.
3. Documentation review is the reading of records or documents either visually or electronically. Examples of records/documentation are correspondence, memoranda, minutes, reports, etc.
4. Re-execution is going through or repeating operational steps. For example, to check the accuracy of efficiency measurements, the auditor may repeat the procedures used to measure efficiency. Replication can help the auditor confirm or deny that a system or part of it is working as intended.
5. A confirmation is a response, usually in writing, to an inquiry, also usually in writing, to confirm information. It can be used to verify that an activity has been performed in the field.
6. Analysis visually or electronically identifies what is the same and what is different between two or more documents, physical objects, or data. There should be analytical evidence
7. Derived by experts/people who are familiar with the matters analyzed and have the ability to make logical conclusions and evaluate judgments from the data collected.
8. Various statistical tools can be used to analyze data or information.
9. Discussion groups are a selection of individuals who have come together to discuss specific issues related to audit topics. They are mainly used to collect qualitative data and information. Focus group techniques are used

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to obtain information about the implementation and impact of government programs based on potential beneficiaries and other stakeholders.

10. Seminars and hearings can be organized for the purpose of gaining knowledge in the professional field, discussion Problems, observations and finding possible solutions. Participants in the seminars can be interested parties, interested parties and experts. (10)

X. VALIDATION

Validation is a concept that developed in the United States in 1978. The concept of validation has expanded over the years to encompass a wide range of activities from analytical methods used for quality control of medicinal substances and medicinal products to computerized systems for clinical trials, labeling or management process, validation is based on regulatory requirements but is not mandated and is best considered an important and integral part of cGMP. (9)

The word validation simply means an assessment of validity or an action demonstrating effectiveness. Validation is a team effort involving people from different areas of the plant. This principle includes the understanding that the following conditions exist: Quality, safety and efficiency are designed or built into the product. Quality cannot be adequately assured by continuous inspection and finished product inspection or testing alone, each step of the manufacturing process is controlled to ensure that the finished product meets all quality attributes including specifications. (9)

XI. NEED OF PHARMACEUTICAL VALIDATION

Validation is an integral part of quality assurance ; It involves the systematic study of systems, equipment and processes aimed at determining whether they perform their intended functions adequately and consistently as specified. (9)A validated process is one that has been shown to provide a high degree of assurance that uniform batches meeting the required specifications will be produced and has therefore been formally approved. Validation itself does not improve processes, but confirms that processes have been properly developed and are under control. (9)

Quality Assurance

Without validation, a process that is well understood and in a state of trust, quality control of the manufactured product cannot be ensured without validation.

Cost Reduction

As each step in validation is constantly monitored, there is less scrap and rework, which would result in effective cost reduction (9)

Government Regulation

Validation is considered an integral part of GMP. Global compliance with validation requirements is essential for obtaining approval for manufacturing and for the introduction of new products.

Scop of Validation

Pharmaceutical validation is a vast field of work and practically covers every aspect of pharmaceutical processing activities, thus defining the scope of validation becomes a really difficult task. However, a systematic view of pharmaceutical operations will highlight at least the following areas of pharmaceutical validation; (9)

- Analytical
- Device calibration
- Process Utility services
- Raw materials
- Packaging materials
- Equipment
- Manufacturing process

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- Product design
- Cleaning
- Operators

Quality By Design

- The product Is designed to meet patient needs and performance requirements.(17)
- The process is designed to consistently meet product quality attributes. (17)
- Influence of raw materials and process parameters on product quality are understandable.
- Critical sources of process variability are identified and controlled.
- The process is constantly monitored and updated to allow for consistent quality over time. (17)

DEFINATION [ICH Q 8(R1)]

A systematic approach to development that starts with predefined goals and emphasizes product and process understanding and process management, based on sound science and quality risk management. (16)(18)

DEFINATION [FDA PAT Guidelines, Sept. 2004]

A system for designing, analyzing and controlling production through timely measurements (i.e. during processing) of critical quality and performance attributes of new and developed materials and processes to ensure the safety of the final product. The concept of "Quality by Design" (QbD) has been defined as an approach that includes a better scientific understanding of critical process and product qualities, designing controls and tests based on the scientific limits of understanding during the development phase and using the knowledge gained during the Product life cycle to work on continuous improvement Environment. QbD describes a pharmaceutical development approach referring to formulation design and development and manufacturing processes to maintain prescribed product quality. Guidelines and mathematical models are used to ensure the creation and use of subject knowledge in an independent and integrated manner. (16)(18)

XII. QbD DEVELOPMENT PROCESS INCLUDE

Begin with a target product profile that describes the product's use, safety, and efficacy.

Define a target product quality profile to be used by formulators and process engineers as a quantitative proxy for aspects of clinical safety and efficacy during product development. Gather relevant prior knowledge about the drug substance, potential excipients , and process operations into a knowledge space. Use risk assessment to prioritize knowledge gaps for further investigation . Design formulation and identify critical end product material (quality) properties that must be controlled to meet target product quality profile (20). Design a manufacturing process to produce a final product with these critical material properties. Identify critical process parameters and input (raw) material properties that must be controlled to achieve these critical material attributes of the final product. Use risk assessment to prioritize process parameters and material attributes for experimental validation. Connect prior knowledge with experiments to create a space for a design or other representation of process understanding (20). Establish a process-wide control strategy that may include input material controls, process controls and monitors, design areas around single or multi-unit operations, and/or final product tests. The control strategy should include expected changes in scope and can be guided by a risk assessment. Continuously monitor and update the process to ensure consistent quality. (20)

XIII. PHARMACEUTICAL QUALITY BY DESIGN

QbD could be a systematic approach to development that starts with predefined objectives and emphasizes product and process understanding and method management supported by sound science and quality risk management (ICH Q8) QbD suggests that devising and developing recipes and manufacturing processes that ensure predefined product quality. (19)(20) So QbD needs an association Understanding and controlling the formulation and production of variable methods affect product quality. The relevant documents from the International Conference on Harmonization of

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Technical Requirements for the Registration of Medicinal Products for Human Use (ICH), ICH Q8, Pharmaceutical Development, together with ICH Q9, Quality Risk Management, and ICH Q10, Pharmaceutical Quality Systems, state on the associated abstract the level, however, of quality ensures the quality of the medicinal product right from the design. ICH Q8 defines quality as "Suitability of either a drug substance or a drug product for its intended use. This term includes such attributes as identity, strength and purity. ICH Q6A emphasizes the role of specifications and states that "Specifications square measure important quality standards that square measure designed and even manufacturer and approved by restricting bodies". Pharmaceutical QbD could be a systematic, scientific, risk-based, holistic and proactive approach to pharmaceutical development that starts with pre-defined goals and emphasizes product and method understanding and process management. (19) It means devising and developing recipes and manufacturing processes to confirm predefined product quality objectives. (19) QbD identifies the properties that are square measure critical to quality from the patients' point of view, translates them into attributes that the medicinal product should have, and determines that important method parameters differ, however.(20)

To systematically produce a medicinal product with the required properties. (19) In order to attempt to do this, relationships between formulation and manufacturing method variables (including drug substance and excipient attributes and method parameters) and product characteristics, square measure and known sources of variability were determined. This information is then used to implement a versatile and robust manufacturing method that can adapt over time to produce a consistent product. (19)(20)

Required Element

1. Pharmaceutical form liquid for injection, solid tablet.(21)
2. Method of administration oral, IV, IM, SC.(21)
3. Independent or clinical administration of a clinical setting.

THE QTPP Leads CQA

Once the QTPP is identified, the next step is to identify the relevant CQAs. CQA is defined as a physical, chemical, biological or microbiological property or characteristic within an appropriate limit, range or distribution to ensure the desired product quality 30. The successful execution of product development exercises to meet the ultimate objectives always depends on the holistic identification of QTPP (21).

Critical quality attributes [CQA] are identified through quality risk management and experimentation to determine the effect of deviations on product quality. A framework for product design and process understanding is achieved by identifying CQA.(21)

TARGET PRODUCT PROFILE (TPP):

The FDA provides guidance for defining a target product profile (TPP). Follow these instructions.(21) The TPP is fully correlated with the drug development program, providing knowledge of the drug during development. In general, TPP is useful for developing links between drug labeling and drug development activities. According to ICH-Q8 (Pharmaceutical Development), pharmaceutical development should include "recognizing the critical quality attributes of a drug product with respect to its intended use as well as the route of administration, and therefore it is essential to consider the intended use and route of administration. (21)

CRITICAL MATERIAL ATTRIBUTES (CMA)

According to ICH, CQA is defined as a quality attribute that includes physical, chemical, biological or microbiological characteristics, and it is desirable that these attributes be controlled (directly or indirectly) to ensure that the resulting product achieves required safety, efficiency, stability and performance. CMAs are key elements that directly affect CQAs. These are defined as physical, chemical, biological or microbiological properties or properties of the input material that should be within an appropriate limit, range or distribution to ensure the required quality of medicinal products. When determining product performance, CQA looks at mechanical variables such as particle size and hardness. So both aspects, i.e. the product determinants of product performance and performance can be explained using TPQP.(21)

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DESIGN SPACE

The design space can be defined as the set of all combinations of method input variables that have been shown to ensure the quality of the data produced by the method. A design space can be constructed for a single unit, multiple or an entire process.(21) Risk assessment, prior experiments, and multivariate factor screening methods are used to identify the criticality of factors and their ranges to create the design space. There may be more than one design space in a pharmaceutical product. Ideally, the design space is generated using experimental design at laboratory/pilot scale and extrapolated to exhibition/commercial scale by establishing a correlation using scale-independent parameters.

CONTROL STRATEGY

Control strategy based on extensive process and product knowledge(21) Includes control over CMA of input materials and intermediates, control of process parameters, quality of final drug product and final packaging. All of these components of a management strategy are included within Process Analytical Technology (PAT).

Reference

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XV. CONCLUSION

As a conclusion of the entire discussion, it clearly shows that quality assurance is somehow related to all departments in the pharmaceutical industry and in each department it plays an important role in improving the process of that department. As the name mentions that quality assurance plays a vital role and is said to be the backbone of the pharmaceutical industry. Quality assurance emphasizes customer satisfaction and also based on the guidelines that have been set by the authorities. As the thalidomide incident that happened a long time ago clearly shows the failure at the quality assurance and clinical evaluation stage that led to such major disasters that caused teratogenicity (Phocomelia).

The drug was first invented for morning sickness problems in pregnant women. It has a dark history due to lack of proper analysis and quality control, which also clearly proves that quality assurance plays a very important role in drug manufacturing. Quality assurance is not only implemented or emphasized in the pharmaceutical industry, but is emphasized in every manufacturing industry that is related to every feeling. As it has been said that QA works on the basis of customer satisfaction, the customer is the main source that gives profit and revenue to any industry. If the product does not have quality, it will be a big failure for the industry. QA It has a role in every part of the industry that is interconnected, QA can create many branch departments “under their umbrella” to increase efficiency and quality standard through means and methods Ever.

A QbD approach for analytical methods that has risk assessment, robustness testing and Resistance testing is much more stringent than the ICH validation requirements (Q2 (R1)). It also includes an assessment Variability of the method compared to the specification limits, which is one of the most important methods attributes to check when deciding whether a tactic is fit for purpose. The approach described here is Indicative of this ICH Q2 (R1), while adding some value, needs to be substantially rewritten to account for risk-based QbD Approaches described in this article. This new QbD process offers the chance for much more regulation Flexibility for the future. Tactical performance criteria could potentially be registered instead the tactic itself. The tactic used can be given as an example of how to achieve the performance of the specified method Criteria. Any changes to the existing method would be covered by internal change control procedures.

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