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Review

Quality Control & Quality Assurance in Pharmaceuticals: Essentials to Ensure that Products meet the Required Standards for Safety and Efficacy



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	<p>Abstract</p>
<p>Published on: 12.12.25</p>	<p>The pharmaceutical industry is renowned for its stringent quality standards, and ensuring medication effectiveness and patient safety. In order to achieve these objectives, quality control and assurance are crucial. Quality assurance and control are components of quality control.</p>
<p>Published by: Futuristic Publications</p>	<p>The use of Quality assurance is essential in all It takes experience to manage quality in the industry. of Total Quality Management and Six Sigma, Out of Specifications (OOS), Out of Trend (OOT), and Corrective & Preventive Measures (CAPA) and ICH compliance rules perfectly. The emphasis of quality assurance is fulfilling quality requirements, while quality Assurance aims to provide reassurance that The quality standards are fulfilled. Products and services are not the only focus of management. quality as well as the methods used to attain it. To progress Industrial product and process quality, especially The automotive sector has also embraced them. by the Food and Drug Administration (FDA) of the United States for Drug discovery, development, and manufacturing.</p>
<p>2025 All rights reserved.</p>  <p>Creative Commons Attribution 4.0 International License.</p>	<p>Keywords: Quality Management, Six sigma, TQM, OOS, OOT, CAPA, ICH, FDA.</p>

INTRODUCTION

Quality refers to be the ability of a product or service to meet its purpose or consumer need. Quality Management (QM) serves as the overarching system used to achieve and manage quality. Quality Management (QM), the overarching umbrella that includes both QC & QA, refers to the administration of systems design, policies, and processes that minimize, if not eliminate, harm while optimizing patient care and outcomes. It entails a more Comprehensive approach to not only maintaining quality but also improving it. It utilizes quality control and quality assurance in addition to other quality

management models, such as total quality management (TQM) or continuous quality improvement (CQI). The meaning of the quality could be understood from two perspectives: 1. Manufacturer's perspective 2. Consumer's perspective From the manufacturer's perspective, the quality is to conform to the specifications. The consumer's perspective is to consider quality characteristics with price considerations. Getting maximum quality features while having a price the motto of maximum consumers.

DIFFERENCE BETWEEN QUALITY CONTROL (QC) & QUALITY ASSURANCE (QA)

Quality Control (QC)	Quality Assurance (QA)
QC is that part of GMP which is concerned with sampling, specifications, testing documentation and release procedures which ensure that necessary and relevant tests are carried out.	QA is the sum total of organized arrangements made with the objects of ensuring that product will be of the Quality required by their intended use.
QC is lab based	QA is a company based.
QC improves the development of specific product or service	QA improves the process that is applied to multiple product that will ever be produced by a process.
QC implements process.	QA helps to establish process
QC Focuses in the product to find the defects that remain after development.	Focuses on processes and procedures improve quality, including training, documentation, monitoring and audits.
QC has reactive approach.	QA has proactive approach
QC's Testing team engaged in the software testing.	QA's whole team is engaged in the process.
QC is part of SDLC	QA is a separate process.

It is totally of the arrangement made with the object of ensuring that pharmaceutical products are of the quality required for their intended use. QA is then heart and soul of quality control.

$$QA = QC + GMP + GLP + GCP$$

Good Manufacturing Practices

A fundamental tenet of GMP is that quality must be incorporated into each product batch at every stage of the production procedures as opposed to being examined in a batch. Its goal is to lessen any production-related hazards connected to medications that testing is unable to remove the completed item. Inadvertently added toxic substance

may be found in subpar pharmaceuticals. A drug won't function as planned if it contains very little or none of the ingredient listed.

Example:

Tragic events were brought about by tainted pediatric paracetamol syrup in Haiti in 1996. This had 26% ethylene glycol in it. Acute kidney failure claimed the lives of 59 children. The majority of nations will only permit the import and sale of medications produced in accordance with globally accepted GMPs. Governments can encourage the exports of pharmaceuticals from their nations by requiring GMP in all pharmaceutical production and providing GMP training to their inspectors. Every elements of production, including the raw materials, the workspace, the machinery, the personnel's personal hygiene, training and comprehensive written protocols, is crucial for every step that could have an impact on the final product's quality. Systems that can offer documented evidence that the right procedures are regularly followed at every stage in the manufacturing processes every time a product is made. GMP guarantees that pharmaceuticals are consistently produced and controlled to the quality standards appropriate for their intended use and as stipulated by the product specification. GMP is also known as cGMP or — “Current Good Manufacturing Practice.”

GMP Guidance:

1968 saw the adoption of the first GMP draught text by the WHO. The WHO GMP was acknowledge as a crucial component of the WHO certification scheme in 1969 when the world health assembly recommended the first version of the scheme to assess the quality of the pharmaceutical products entering the global market. The expert committee on biological standardization (ECBs) adopted a supplementary annexe on biological medicinal products in 1991. This Annexe lays out the general methodology for the quality control of the biological medicines, which encompass a range of products including vaccines, blood and blood products, antigens, cell and tissue therapies, and others.

CONCEPT OF GMP:

- Appropriately qualified and trained personnel, Adequate premises &space
- Suitable equipment and services. Correct materials, containers and labels.
- Approved procedures and instructions.
- Instructions and procedures are written in an instructional form in clear and unambiguous language, specifically applicable to the facilities provided.
- Operators are trained to carry out procedures correctly.

Good Laboratory Practices (GLP)

GLP concerns with organizational process and conditions with which the laboratory studies are planned, performed, recorded and reported. The term "good laboratory practice," or GLP, refers to a set of guidelines designed to guarantee the caliber and objectivity of non-clinical laboratory studies used to support governmentregulated product research or marketing authorizations. The pharmaceutical business and the obligatory non-clinical animal testing that must be carried out before new therapeutic products are approved are most frequently linked to the term GLP. Nonetheless, a wide range of additional nonpharmaceutical substances are covered by GLP, including food additives, color additives, food contamination thresholds, food packaging, and medical devices. In 1972, GLP was initially implemented in Denmark and New Zealand. In response to instances of fraud discovered in toxicity lab data that pharmaceutical corporations had submitted to the FDA, GLP was implemented in the United States. The most famous instance involved Industrial BioTest Labs (IBT), where thousands of safety tests for chemical manufacturers were either

fraudulently claimed to have been completed or of such poor quality that police investigators were unable to piece together the work that had been done. Despite IBT's superficial delivery of the test results as stipulated by their contracts with the manufacturers.

Essential Requirements of GLP for efficient working • Technical Competence

- Well Equipment
- Good Internal Organization
- Co-ordination of Activities Of Various Section Of Lab
- Good distribution of work
- Validation of materials, sub materials

Laboratory Requirements as per GLP

- Procedure for sampling
- Distribution of sample
- Methods of recording observations
- Checking of worksheets
- Recording of technical data
- Care of apparatus Sig Sigma

The Six Sigma

Quality assurance methodology and approach have established a standard for excellence. It has been accomplished by merely using a systematic quality management approach and raising the bar for quality. The Six Sigma Quality approach has generated a lot of excitement in nearly every area, including BPO, retail, healthcare, and so on. These cutting-edge techniques are created specifically for the purpose of testing important goods and services. to make sure that they are successfully meeting the expectations of the customers about the items and that they are meeting the necessary requirements. Six Sigma quality management has become an organization's top priority for survival and profitability due to the global demand for high quality products.

Aim of Six Sigma concept

1. Process improvement
2. Improved methodology
3. Improved quality
4. Customer satisfaction
5. Reduction in process variation
6. Reduction in costs

7. Fewer defects to achieve the goal

8. Continuous quality improvement

Six Sigma DMAIC

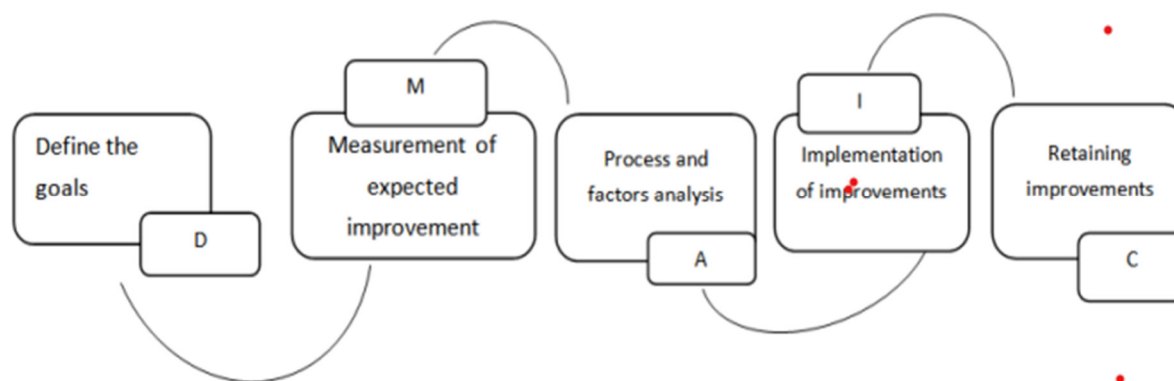
1. **Define:** Define is the first and most difficult step of sigma approach. The basic step of aim is defining the problems and objectives. 'Define' explains project, aim goal, difficulties, target magnitude and time span to achieve the improved process.

2. **Measure:** this is the process of collecting expected future data. The data will help to understand the magnitude of improvement and will answer either the expected improvement can be measured or not. The data is not necessarily quantitative.

3. **Analyze:** this process includes the analysis of the whole process and helps to understand the factors of influence. This is nothing but the analysis of raw data to establish a correlation between input variables and possible output that implies critical quality attributes (CQAs).

4. **Improve:** the next step is improvement of the process that has been outlined in the define step to achieve the expected outcome and result. The principles, specifications and process outflow selected in the first step should be improved and incorporated in the lifecycle with fewer defects.

5. **Control:** the improvement done in the last step should be retained and additional procedures may be included in the workflow.



Out of specifications (OOS)

When an analytical or test result of any batch or material is out of prescribed and predetermined limits or specifications, it is called as OOS. OOS may be raised in the case of stability testing, analysis of in process, test of raw materials, intermediates and finished goods (API). A drug or drug product must be tested as it is being developed and as it approaches completion to make sure it functions as anticipated and within the bounds listed in the compendia, drug master file, or drug application. The methods for conducting an investigation in the event that an OOT or OOS is traced are outlined in the pharmaceutical company's standard operating procedures (SOPs). If any sample test results deviate from the predefined standards, the Quality Control (QC) staff will be the first to report the issue. When an OOS result occurs, the laboratory supervisor should respond objectively and timely manner. - The laboratory supervisor should first examine the analysis results, as this can reveal errors in the production process or analytical procedure. - Next, it is important to inspect the real samples, glassware, tools, and analytical equipment. - To verify the analyst's accuracy, the lab supervisor should confer with the analyst. He needs to double check the reports and chromatograms. - He ought to confirm the computations. - Verify the equipment's and instruments' functionality. He should ascertain that all of the reagents, solvents, and standard solutions utilized in the test that produced an OOS were in compliance with quality control requirements. - To guarantee the validity of the analytical procedure, the analytical method should be confirmed and data given.

Historical information about the analytical process, tool, and apparatus should be acquired to

Scope of out of specifications (OOS)

The purpose of OOS investigation is to determine cause of the OOS result, The designated personnel classify the OOS as either assignable cause or non-assignable cause. The source of the OOS result should be identified either as an aberration of the measurement process (laboratory error) or an aberration of the manufacturing process. Each OOS is identified with a unique identification number, for example, OOS/RM003/2020. The meanings of the letters and numbers in this identification number format are : OOS is Out of specification, RM is Raw Material department and the 003 is OOS case number for year 2020.

OOS Software

OOS software solution helps laboratories to manage OOS investigations from start to finish. The entire business may be impacted by OOS incidents, so it's critical to be able to swiftly link investigations with other quality processes like change management, non-conformance, CAPA, and others. Softwares makes it easy to see how an issue is connected to other quality processes. OOS software provides features and support for consistent identification and management for OOS results within the text of quality management system (QMS). The software determines if the reason is assignable or nonassignable, which helps with OOS classification. When an OOS occurs, the analyst is supposed to alert the quality control manager, and the senior manager will also insist that the QA provide the analyst an OOS form. EX- simpler QMS software.

Phase 1 The first phase in the investigation is to analyze to determine if there was a laboratory error, such as:

- Dilution error of standard and sample solution
- Errors in the method of analysis
- Malfunction of the equipment
- Errors in calculation If there is no assignable cause or error discovered during phase 1 of the investigation, then phase 2 should be initiated

Phase 2 In this phase of the investigation, an evaluation of the manufacturing processes, sampling procedures, and other laboratory tests which may have caused the error is carried out. Retesting and Hypothesis are two of the additional laboratory tests performed.

Retesting: Finding errors that may have happened throughout the analysis or dilution process is the aim of retesting. To guarantee a precise examination into the error's cause, the retesting sample needs to come from the same original batch. Should the retesting findings likewise go outside of the specified range, the batches ought to be retested, and the inquiry ought to be expanded to encompass further connected batches and items.

Hypothesis:

Examining a specimen from any more units gathered during the initial sampling or from a fresh sample drawn from the same batch is required to test the hypothesis. Errors resulting from a wrong hypothesis help to support the original theory. Because of this, the company needs to develop a new protocol.



OOT (Out- Of- Trend)

Out of trend is defined as a result of a sequence of the analytical results which conform to the specifications but not in the expected trend with respect to the initial or expected result. OOT indicates that there might be an issue with the production process or the analysis. Establishing a process for handling out-of-trend outcomes in active raw materials, completed products, stability studies, environmental monitoring, and water trend in the pharmaceutical industries is the primary goal of OOT. Pharma and biotech industries place a high value on managing out-of-trend (OOT) situations. Stability tests should be conducted on a regular basis by biotech and pharmaceutical companies to determine the condition of bulk products, finished products, in-process materials, and raw material samples. During a stability study, OOT results are time-dependent or stability results that fail a statistical process control criterion or fall outside of a prediction interval. A time dependent result which falls outside a prediction interval or fails a statistical process control criterion. A trend is a series of temporal processes, such as those used in the production of various product batches. Two categories of trends exist: When analyzing process data or in a situation where no trend is anticipated, such as in production, everyone assumes that the data are subject to statistical control. In the other scenario, a pattern is anticipated. Stability testing is a common example of this, where one anticipates that the amount of contaminants will increase over time or that the content of the API will decrease over storage.

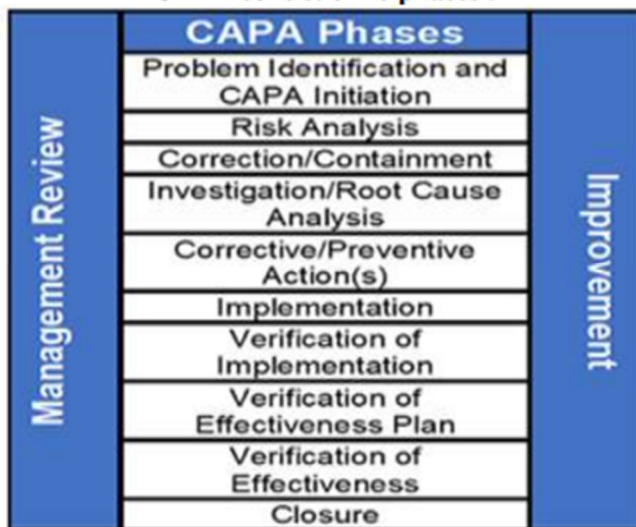
Purpose – To lay down the procedure for conducting an investigation of out of trend (OOT) results observed during laboratory testing of samples.

Responsibility – Officer quality control – to notify the Executive/ Asst. manager QC about the OOT result. Head quality control – to authorize the for the reanalysis.

CAPA (Corrective Action & Preventive Action) Corrective Action and Preventive Action, or CAPA, is a framework for identifying, resolving, and averting problems. In addition to outlining steps to address the problem, it examines its root cause in order to stop it from happening again.

1) Problem Identification and CAPA

CAPA consist of 10 phases :



2) **Initiation** : In order to start the CAPA process, the problem identification and initiation phase requires documenting the issue. Included in the description should be all the pertinent details such as who, what, when, where, why, and how many.

2) **Risk Analysis** : Depending on the risk to the patient, user, business, or compliance, a risk analysis should be done. CAPA timelines ought to be determined by the risk analysis's findings. The distinction between high-risk and low-risk issues in terms of urgency should be clear.

3) **Correction/contamination**: To prevent further production and distribution, correction and containment should be completed as soon as possible. The organization should conduct a review of related processes and products to determine if there are any larger issues. In the event of a product defect, a field correction and/or recall may be required. Correction and containment activities are an attempt to mitigate the short-term impact.

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4) **Investigation/Root cause Analysis**: Among the most commonly used tools/methods for conducting investigations to determine the root cause of a problem are, but are not limited to:

- Brainstorming
- The 5 whys
- Flowcharting

- Fishbone diagrams
- Affinity diagrams
- Is/Is Not
- TRIZ (Theory of Inventive Problem-Solving)
- Physics of Failure

5) Corrective/Preventive Action(s): Corrective and preventive actions are long-term solutions to resolve or eliminate the cause of a nonconformity or potential nonconformity. A corrective action is one that is taken to eliminate the source of a nonconformity and prevent it from recurring. A preventive action is one that is taken to eliminate the source of a potential nonconformity or other undesirable situation. A correction is an action that is taken to remove a detected nonconformity.

6) Implementation: Corrective and preventive actions are initiated and implemented during the implementation phase to address the root cause or causes of a nonconformity. Procedure updates, training, and process modifications are some examples.

7) Verification of Implementation: Verification is defined as confirmation of specified requirements through the provision of objective evidence. The verification of implementation phase certifies that corrective and preventive actions were carried out. The verification of implementation (VOI) and verification of effectiveness (VOE) phases of a CAPA are frequently confused, but they are separate and distinct phases. VOIs are used to ensure that corrections, containment, corrective actions, and preventive actions were carried out as planned and promised.

Examples of VOIs:

- Procedures, work instructions, forms, and/or templates were updated
- The suspect parts were sorted
- The suspect parts were reworked
- The suspect parts were quarantined

8) Verification of Effectiveness Plan (VOEP): The effectiveness plan phase is used to establish and define predetermined criteria for determining the effectiveness of corrective and/or preventive actions. George T. Doran is credited with first using the term SMART:

- Specific — Is the VOEP unambiguous, clear, and focused?
- Measurable — Is quantifiable data being used to assess the VOEP?
- Achievable — Is the VOEP feasible or practical?
- Relevant — Is the VOEP appropriate for the level of risk?
- Time bound — Does the VOEP have a realistic deadline?

9) Verification of Effectiveness (VOE): Reviewing and documenting the predetermined criteria established in the verification of effectiveness plan is part of the verification of effectiveness phase. A successful verification of effectiveness should show that the true root cause of the problem was identified and that the corrective and/or preventive actions were effective.

10) Closure: This is the final stage of the CAPA procedure. A CAPA should only be closed once the effectiveness verification has been completed successfully. If a CAPA is found to be ineffective, I recommend starting a new one while referencing the old one.

ICH

(International Council for Harmonisation of Technical Requirements of Pharmaceuticals for Human Use) The International Council for Harmonisation of Technical Requirements of Pharmaceuticals for Human Use (ICH) is a unique harmonization organisation involving regulators and the pharmaceutical industry. • Launched in 1990 by the US, EU, and Japan. The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use, or ICH, is a trailblazing pharmaceutical initiative that brings together regulatory bodies and industry stakeholders to forge consensus on technical guidelines. ICH was founded in 1990 with the goal of harmonizing the often disparate approaches to drug development and regulation around the world, fostering a more efficient and streamlined pathway for pharmaceutical product approval and postapproval processes.

History and mission:

The International Conference on Harmonization (ICH) was founded on the realization that inconsistencies in regulatory requirements hampered the development and approval of pharmaceuticals on a global scale. ICH's mission is to achieve greater harmonization in the interpretation and application of technical guidelines in order to improve global collaboration and ensure the safety, efficacy, and quality of pharmaceuticals around the world. This collaborative effort is critical for addressing the challenges posed by pharmaceutical research, development, and marketing's global nature. The organization follows a well-defined structure that is guided by a Management Committee and supported by the ICH Secretariat. Expert working groups comprised of representatives from regulatory agencies and the pharmaceutical industry are critical in the development of guidelines. This collaborative approach enables the pooling of diverse expertise, resulting in guidelines reflecting a consensus-based understanding of scientific and technical issues.

Development of ICH Guidelines:

The ICH guidelines cover a wide range of subjects, including quality, safety, efficacy, and multidisciplinary aspects of pharmaceutical development. The development process entails rigorous review and discussion within expert working groups, which results in recommendations approved by the ICH Assembly. The guidelines are dynamic, evolving in response to advances in scientific knowledge and technology, and they serve as the foundation for regulatory submissions and approvals.

Quality Guidelines:

The ICH quality guidelines address critical aspects of pharmaceutical manufacturing in order to ensure product consistency and quality. Stability testing, impurities, and specifications for biotechnological and pharmaceutical products are among the topics covered. ICH facilitates global acceptance of manufacturing practices by establishing common standards, allowing for efficient production and supply chain management.

Efficacy Guidelines:

Guidelines for pharmaceutical efficacy provide a framework for the design, conduct, and reporting of clinical trials. Clinical safety, statistical principles, and data management are covered, ensuring that studies are conducted ethically and generate robust data to support new drug registration. Adherence to these guidelines encourages the generation of high-quality evidence, which improves the credibility and reliability of clinical trial data.

Impact and Global Adoption:

ICH's influence extends beyond its organizational boundaries. The ICH guidelines have been widely adopted by regulatory authorities around the world, contributing to a more cohesive and efficient global regulatory landscape. ICH facilitates the acceptance of regulatory submissions across multiple jurisdictions by providing a common language and framework for the evaluation of pharmaceutical data, reducing duplication of efforts and expediting the availability of new medicines to patients.

FDA (Food & Drug Administration) The U.S. Food and Drug Administration (FDA):

Safeguarding Public Health through Regulatory Excellence The United States Food and Drug Administration (FDA) is a cornerstone of public health protection, playing a critical role in ensuring the safety and efficacy of a wide range

of products that touch the lives of millions of Americans every day. The FDA, which was founded in 1906, has grown into a globally recognized regulatory authority, setting standards and overseeing the development, manufacturing, and distribution of foods, drugs, medical devices, biologics, and veterinary products. This note delves into the FDA's many responsibilities, regulatory processes, and critical role in maintaining public health.

Historical Evolution and Mandate:

The FDA can be traced back to the Pure Food and Drug Act of 1906, which was enacted in response to public outcry over unsafe and mislabeled food and drug products. Legislative expansions, such as the Food, Drug, and Cosmetic Act of 1938, have broadened the FDA's scope and authority over the years. Today, the FDA is part of the Department of Health and Human Services (HHS) and is charged with protecting public health by regulating a wide range of products.

Regulatory Functions:

Food safety, drug development and approval, medical device regulation, biotechnology products, blood transfusions, radiation-emitting devices, veterinary products, and other regulatory functions are all overseen by the FDA. The agency uses a science-based approach to evaluate product safety and effectiveness, balancing innovation with public safety.

Drug Approval Process:

The FDA's primary responsibility is to approve new drugs. The drug approval process includes rigorous scientific evaluation, clinical trials, and data review by manufacturers. The FDA ensures that a drug's benefits outweigh its risks, and after approval, it continues to monitor its safety in the post-market phase. The agency's dedication to patient safety is demonstrated by its risk evaluation and mitigation strategies (REMS), which address known or potential risks associated with specific drugs.

Medical Device Regulation:

Medical devices are regulated by the FDA to ensure their safety and effectiveness. The level of regulatory scrutiny is determined by the classification of devices, which ranges from low-risk (Class I) to high-risk (Class III). The premarket approval process for Class III devices entails a thorough examination of scientific data. Through post-market surveillance mechanisms, the FDA also monitors the safety of marketed devices.

Biotechnology and Advanced Therapies:

Biotechnology advancements have resulted in the development of novel therapies such as gene and cell therapies. The FDA is critical in regulating these innovative treatments, balancing the need for innovation with the need to protect patients. Patients with unmet medical needs benefit from accelerated pathways to promising therapies, such as breakthrough therapy designation and accelerated approval.

Food Safety Oversight:

The FDA is in charge of ensuring the safety of the American food supply and working to prevent contamination and outbreaks. The agency's mandate spans the entire food production and distribution chain, from inspecting food facilities to establishing and enforcing food labeling standards. The Food Safety Modernization Act (FSMA) of 2011 was a significant legislative milestone that empowered the FDA to prevent foodborne illnesses proactively.

Global Impact and Collaboration:

The FDA has an impact outside of the United States. borders, as numerous other nations rely on it for regulatory directives. Understanding the worldwide scope of the food and pharmaceutical sectors, the organization works with counterparts around the world to unify regulatory strategies. Partnerships with Health, the European Medicines Agency (EMA), Canada and other regulatory bodies enhance information sharing and international regulatory coherence.

Challenges and Future Directions:

The FDA faces ongoing challenges, such as adapting to rapid technological advances, dealing with emerging public health threats, and navigating the complexities of globalization. The agency is constantly working to streamline regulatory processes without jeopardizing safety. Initiatives like the FDA's Digital Health Center of Excellence demonstrate the agency's commitment to fostering healthcare technology innovation.

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