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Q. A. and Q. C. Documentation and Regulatory Authorities of Indian Pharmaceutical

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Abstract: *The notion of documentation is significantly more important in the pharmaceutical sector, as it helps to comprehend product quality standards, safety requirements, etc. In a nutshell, the document communicates the finished result. There are several guidelines, including GLP, GMP, and cGMP, to preserve product quality. The industry's Q.A. and Q.C. departments inspect and guarantee that the final Bach product meets criteria. Even though ICH is a reputable institution, it does not maintain global harmonisation. I attempted to introduce some of the documentation needed for such a body that should be kept on file by the maker organisation for emergency situations in this review piece. Additionally, the idea of IPQC (In Process Quality Control) verifies that quality is maintained throughout the production process, from the raw materials to the finished product. Several regulatory organisations that create and uphold the professionalism of our pharmacy profession were introduced in this article. Various papers, including BMR, MFR, SOPs, a quality audit plan, and reports are included in this article. Common Technical Document and Electronic Common Technical Documentation submission materials for regulators were examined. The discovery and development of drugs, the introduction of clinical trials, investigational new drug applications, new drug applications, the SUPAC approach, and the many stages involved in product registration to the CDSCO and USFDA are also crucial.*

Keywords: Documentation

I. INTRODUCTION

The quality of data collecting and reporting for supporting research, registrations, commercialization, and life-cycle management of pharmaceutical products is crucial [1]. Adhering to the GDPs ensures preventing mistakes that may otherwise have an influence on product quality, patient safety, the status of manufacturing facilities, and associated activities when manufacturing and during the analysis of pharmaceutical goods. The US and European regulatory agencies, including the FDA's CFR and EMA, demand adherence to GDPs. In addition to the general chapter "1029" published by the United States Pharmacopeia, the World Health Organization [3], Health Canada, and EudraLex [5] have all released detailed guidelines about GDPs. However, GDP plays a significant role in US current good manufacturing practises (cGMPs). In addition to meeting regulatory requirements, it is crucial to keep accurate records of all activities in the pharmaceutical industry for business reasons. This allows for critical evaluation of internal processes for the improvement of processes and products and saves time by not having to repeat studies from scratch if necessary.

II. CONCEPT OF QUALITY CONTROL

There isn't a single definition of quality. Regardless of how the word "value" is used, quality control refers to the process by which goods and services are examined and evaluated to determine if they adhere to set standards. Using this technique, a business may evaluate, maintain, and improve the quality of its products.

To preserve the brand's reputation, quality control is essential for maintaining quality in product and to increase groth of it. It ensures that the company examines evidence-based data and research rather than anecdotal perceptions in order to ensure that the services and items fulfil the requirements. [1]

In order to preserve product quality throughout the production process and in the finished product, quality control is the practise of testing the product at each stage of the process. This idea was developed through testing of Raw materials to the final product.

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Ultimately, it help to control and to ensure to get the product is uniform as possible and to minimize the error that occurs during processing.[1]

III. CONCEPT OF QUALITY ASSURANCE

In order for a client to confidently purchase and utilise a product, quality assurance entails guaranteeing its quality. A buyer must have faith in a certain product from a specific firm that has a track record of producing trustworthy items for a long period in order to be able to make a purchase with confidence. It's important to assure design quality and that the product functions exactly how the consumer wants it to in order to develop this type of trust. A contract between a manufacturer and its customer is analogous to quality control. Top leaders must create clear rules that apply to everyone in order to deliver real quality assurance. the divisions in charge of planning, design, production, market research, and post-sale assistance. [2,3]

The goal of quality assurance is to provide confidence that the standards for quality will be reached. It belongs to the quality management system. Each functional department should have a distinct responsibility in the quality assurance function, which involves cross-functional planning and analysis of quality. [2]

Methods Of Q.A.:

Quality assurance utilizes one of three methods:

Failure testing entails regularly putting a product through its paces to see if it breaks or malfunctions. For physical goods that must withstand stress, testing the product under harsh circumstances like heat, pressure, or vibration may be essential. Software products may need to be put through rigorous load or heavy use tests as part of the failure testing process.

At Bell Telephone Laboratories and Western Electric Company in the 1920s and 1930s, Walter Shewhart created the statistical process control (SPC) methodology. This methodology use statistical methods to oversee and control the production of the product. [3,4]

Total quality management, or TQM, employs quantitative methods as the foundation for continual improvement. TQM employs facts, data, and analysis to support product planning and performance assessments.[2,3,4,5]

IV. GOOD LABORATORY PRACTICE

4.1 Aim of GLP

GLP aids in lowering the incidence of studies producing misleading negative results. False negative results for toxicity studies suggested that the test object was not harmful when in fact it was.

GLP also lessens the possibility of erroneous positives. In research on non clinical safety, the outcomes incorrectly suggest that a test object is harmful or not.

GLP encourages the acknowledgement of research data on a global scale. The acceptance and trustworthiness of the data are acknowledged at the international level with OECD member states when studies are carried out in accordance with OECD GLP criteria. [5]

Due to the subpar and dishonest laboratory practises in the early 1970s, GLP was created. Inaccurate test systems and accounting, as well as incorrect equipment calibration, are examples of bad lab procedures.

GLP, according to Valcarcel M., is a collection of guidelines, operational processes, and practises put in place by an organisation to guarantee the high quality and accuracy of the reliability and accuracy of a laboratory's findings. The specified organisation establishes the rules in this practise, and the laboratory work is planned, run, monitored, and reported. [5]

4.2 GLP Principle

Organizational needs are outlined in the GLP principles. The quality control of non-clinical safety investigations is governed by GLP. The regulation's goal is to motivate researchers to design and carry out their investigations in a manner that enhances the reliability and validity of the test findings. GLP handles the following problems:

- The facilities that the organisation offers.
- Effective and knowledgeable staff.
- The calibre of approved tools and substances.

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- A predetermined research plan.
- SOPs, test protocols, and process validation.
- The accuracy of the findings.
- Quality assurance programme and Quality assurance laboratory (QAL) (QAP).
- Results that have been documented and stored.[5,6]

Businesses must meet all requirements in order to offer all the amenities for ideal laboratory practise. Staff should be sufficiently knowledgeable about the guiding concepts and operation of the procedures.
For accurate findings and to keep the lab's standards high, the regulatory organisations' standard rules for testing and assessment laboratories should be followed.[6]

4.3 Fundamental of GLP

A. Resources

1. Organization and Management

Management is ultimately in charge of implementing sound organisational and scientific practises inside their institutions. Proper experimental design definition, understanding of scientific concepts, recording of experimental and environmental factors, thorough findings evaluation, and reporting of results are all components of good science. In contrast, a competent organisation should offer enough facilities, infrastructures, effective planning and conducting of investigations, as well as a method for verifying the study outcomes. [6]

2. Personnel

Every member of the institution's personnel should have a thorough record kept of their time there. The documents contain each individual's comprehensive curriculum vitae, training history, and job descriptions. These records, which must be kept in accordance with GLP guidelines, are used to demonstrate that every member of staff is qualified to administer tests thanks to their education, work experience, and training.

3. Availability of Facilities

To ensure the validity of a studies, the institution and administration should provide enough facilities with cutting-edge infrastructure. The site plan's documentation, upkeep, and cleaning should all adhere to the rules.

4. Equipment Accessibility

The organisation must have access to adequate equipment for the study. The management should guarantee the equipment's appropriateness and the accuracy of the instruments.

B. Characterization

It includes:

a. Test Items: They might be a substance that is an active component of a drug, a pesticide, a food additive, a vaccination, an industrial chemical, biomass, or a plant extract. Analytical characteristics of these goods include chemical identification tests, solubility, stability, and others. To prevent contamination, the test items should be maintained appropriately.
b. Test Systems: Test systems may include plants, animals, bacteria, cells, and other biological entities. They might occasionally also be analytical tools. test systems should be operated in a way that complies with both the national animal welfare law and GLP principles.

C. Rules

a. Research Protocols: The research protocol or plan specifies the study's framework and methodology.. The anticipated timeline for the study should be included in the plan.
b. Written procedures are sometimes referred to as SOPs (Standard Operating Procedures). SOPs include guidelines on how to carry out each technical operation and guarantee that the study, environmental factors, and data are well organised.

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D. Results

It covers data archiving, final reporting, and raw data.

Raw Data: It is important to record both the original record and the data required for the reconstruction. What was done, how it was done, when it was done, and who did it should all be included in the raw data. The procedure by which the data was captured should be made clear, and it should be confirmed that the process was carried out in accordance with the rules and SOPs.

V. ICH (INTERNATIONAL CONFERENCE OF HARMONIZATION)

The three countries that have decided to harmonise regulatory standards are the United States, Europe, and Japan. The International Meeting on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use was established as a result of the WHO meeting on Drug Regulatory Authorities that took place in Paris in 1990. (ICH).

The formalisation of the harmonisation idea was started to benefit the pharmaceutical sector and regulatory organisations. To ensure safety and efficacy for testing, the ICH guidelines minimised the use of animals and discouraged repeating clinical studies. By accelerating the regulatory procedure for novel pharmaceutical applications, the concepts also reduced the amount of time needed for development and increased the amount of resources available. Since then, the ICH has embraced technology and given priority to a paperless application process and the exchange of real-time information among stakeholders.

The International Conference on Harmonization (ICH), a global organisation, develops guidelines for the safety, efficacy, and cross-disciplinary needs of the harmonisation process. members of the founding organisations should be included (the European Union, the European Federation of Pharmaceutical Industries and Associations, the Ministry of Health, Labour and Welfare of Japan, the Japan Pharmaceutical Manufacturers Association, the Food and Drug Administration of the United States, Pharmaceutical Research and Manufacturers of America, Swissmedic, and Health Canada). The International Federation of Pharmaceutical Manufacturers and Associations, which participates and serves as a non-voting member, is the WHO's representative.

Work Products offers downloadable recommendations for interdisciplinarity, effectiveness, quality, and safety. Stability studies, analytical validation, pharmacopoeias, quality risk management, and other topics pertaining to acceptable manufacturing practises are all included in the Quality Guidelines (GMP). The safety recommendations showing genotoxicity, reproductive toxicity, and other safety evaluations. The effectiveness guidelines include a wide range of clinical trial design, conduct, safety, and reporting topics. Additionally, it encompasses the development of novel medicines using biotechnological techniques, as well as the application of pharmacogenetics and pharmagenomics to provide more specialised, targeted drugs. [8]

5.1 Quality Guidelines of ICH

Important accomplishments in the Harmonization area's focus on quality include the execution of stability studies, the creation of acceptable impurity testing criteria, and a more adaptable strategy for pharmaceutical quality based on GMP risk management. [6,8]

In the quality Guidelines their is series of guidline as:

Q1: Guidlines for Quality.
Q2: Validation of Analytical methods/ techniques/ machines
Q3: Impurities
Q4: Pharmacopoeias
Q5: Biotechnological Product quality
Q6: Specifications
Q7: Good Manufacturing Practices
Q8: Pharmacutical Development
Q9: Quality Risk Management
Q10: Quality System of pharmaceutical's
Q11: Development and Manufacturing of Drug Substance

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Q12: Lifecycle Management
Q13: Continuous manufacturing of Drug Substance and Drug Product
Q14: development of analytical procedures. [6,8]

5.2 Safety Guideline of ICH

To identify possible concerns including carcinogenicity, genotoxicity, and reprotoxicity, the ICH has created a thorough set of safety criteria. The non-clinical testing approach for determining the QT interval prolongation liability, which has emerged as the primary driver of medication withdrawals in recent years, has made substantial strides.
S1: Carcinogenicity study
S2: Genotoxicity study

5.3 Regulatory Authorities

FDA: (FOOD AND DRUG ADMINISTRATION)

The Food and Drug Administration is the US federal government's oldest comprehensive consumer protection branch. Since 1848, the federal government has utilised chemical analysis to keep an eye on the safety of agricultural products; in 1862, the FDA and the Department of Agriculture took over this duty.
Since then, the FDA has evolved alongside societal, political, economic, and legal developments in the US. Examining the history of these developments highlights the growth of the FDA's role in protecting public health and also offers insightful information when we evaluate the current regulatory issues.
The FDA was in charge of regulating $2.7 trillion worth of food, pharmaceutical, and cigarette goods as of 2021. 46% and 54% of its budget, respectively, are provided by the federal government.
The FDA is a government agency that certifies and controls the production of goods that have anything to do with the general public's health. This company offers products that are secure to the general public.
It controls all items using a set of regulations created by the FDA with the participation of the nation. FDA certification ensures a high-quality product.
Among the goods governed by the FDA are food, pharmaceuticals, medical devices, radiation-emitting equipment, vaccines, blood products, biologics, animal and veterinary products, cosmetics, and tobacco products.

CTD (COMMON TECHNICAL DOCUMENTS)

A set of guidelines outlining the structure and data that should be included in a dossier for an application to register a new drug product that could be used in all three areas were created in 2000 by representatives from the European Medicines Agency (EMA), the United States Food and Drug Administration, and the Ministry of Health, Labour, and Welfare in Japan. Since they were created under the aegis of The International Conference on Harmonization, these suggestions have joined the family of ICH recommendations (ICH). The CTD had a single, clear objective: to create a standard format for technical documentation that would raise demand for electronic submissions and significantly reduce the time and resources needed to combine applications for the registration of human pharmaceuticals. Thereafter, regulatory assessments and significantly reduce the time and materials needed to put together applications for the registration of human medications. Additionally, regulatory examination and A standard document having same parts would make it easier to communicate with the applicant, and it would also make it simpler for regulatory agencies for data shearing.
1. The ICH has released four recommendations for the CTD as well as four publications with questions and answers. In 2002, the initial batch of ICH CTD guidelines were published. Since July 2003, NDAs submitted to the FDA in the EU and Japan must be in the CTD format, which is also strongly advised. After being accepted by the EU, the USA, and Japan, the CTD structure has gained support in a number of other nations, including Canada and Switzerland.
2. The electronic CTD (eCTD), which has been required for the centralised process in the EU since 2010, will take the place of the paper CTD.

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5.3 General Principles

Similar to how it should be in other papers, material should be presented in the CTD in an understandable and transparent manner. According to the ICH M4 advice document on the CTD1's structure, text and tables should be created with margins that allow the document to be printed on both 8.5 x 11" and A4 paper (EU and Japan) (USA). It is advised to use Times New Roman 12-point for narrative text. 3 Every document that is a part of the CTD should have a page number. "1 of n" stands in for "n," the total number of pages in the document.

A document's unique header or footer that briefly describes each page's topic matter is required on all of them (e.g. an abbreviation of the full section number and title, i.e. 2.7 Clinical Summary). The M4 guidelines1 enable a condensed numbering string in order to prevent fifth, sixth, etc. level subheadings inside a document. In this situation, the page header or footer should include the document number and name (e.g., 2.6.6 Toxicology Written Summary), followed by a short section numbering system.

Overall organisation of the CTD.

The ICH M4 guidelines1 thoroughly outline the CTD's overall layout and provide guidance on where to insert documents and how many pages should be in each one. This granularity information is especially beneficial if the dossier has many indications or different components of the investigational pharmaceutical product (IMP). Along with the M4 criteria, a list of queries and responses is also provided to address the most common worries voiced.

The CTD dossier is divided into five main modules

Module 1: prescribing information as well as administrative information

Module 2: Overviews and Summaries of Modules 3–5.

Module 3: Quality

Module 4: Non-clinical reports

Module 5: clinicaltrials reports.

5.4 Guidelines for the Common Technical Document:

The majority of countries utilise the CTD format. Therefore, CDSCO has also decided to adopt CTD format in order to comply with technical criteria for registration of pharmaceutical goods for human consumption. The framework for CTD preparation for marketing authorization of medicines for human use other than biological goods is outlined in this guideline document, and the same has been the case for biological products since 2009. It is obvious that the full and logical information contained in this organised application would help the CDSCO review and handle the situation more effectively. It would also make it simpler to prepare electronic submissions, which the CDSCO may begin to accept in the near future. served as the basis for the development of this advice by CDSCO. Drugs & Cosmetics Act of 1940 and its implementing Rules, as well as M4, Step 4 version, dated January 13, 2004.

5.5 Scope

According to Rule 122E of the Medications & Cosmetics Rules, new drugs are classified as completed pharmaceutical goods, and this guideline is relevant to their importation, manufacturing, and marketing clearance. In addition to new dosage forms, new chemical entities, new indications, updated release forms, and new administration methods, new medications, etc. This recommendation does not offer advise on the layout of the studies needed for product registration; rather, it identifies the right format for submitting the collected data. The "content requirements" for each form of submission are specified in the Drugs and Cosmetics Act and Rules established there under; as a result, this guidance paper must be read in conjunction with those documents.

5.6 The Electronic Common Technical Document (e CTD)

There is an interface and a global specification for the transmission of regulatory information from the pharmaceutical industry to authorities. The Common Technical Document (CTD) format served as the foundation for the standard, which was created by the Multidisciplinary Group 2 Expert Working Group of the International Council for Harmonization.

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Purpose

Sponsors and applicants are given technical advice in this guide about the standardised electronic submission format for INDS, NDAs, ANDAS, BLAS, and master files. The Guide aims to facilitate and improve communication between sponsors, applicants, and the FDA's electronic submission support team. It is not meant to take the place of sponsors and applicants speaking with support personnel directly about implementation strategies or problems with electronic submissions, though. It is challenging to pinpoint every potential problem that might arise in connection with the creation and transmission of electronic submissions due to the inherent heterogeneity among studies and applications. Sponsors and applicants should thus speak with the relevant center's electronic submission support staff, which is CDER, before submitting any inquiries.

e-CTD Submissions

1. Create entries that are eCTD ready.
   - To develop submission-ready papers, prepare material using standardised templates and style standards.
   - Control and handle source documents
   - Provide several eCTD templates for various submission types (initial, reports, and amendments)
   - To assure submissions of the highest quality, prepare and process papers.

2. Compile, disseminate, and verify contributions
   - Develop submission modules using the best eCTD tools available.
   - Create properties particular to submissions. Create a PDF from the finished papers with links.
   - Examine and put modules together for submittal.
   - Place documents in a specific area of the eCTD modular architecture.
   - Organize PDF files including metadata and lifecycle instructions to make sure information is sent correctly and is simple to find for agency reviewers.
   - To check that technical criteria are satisfied, run the validation tool.
   - Verify the papers' quality to make sure the requirements for agency validation are satisfied.

3. Send agency a submission and carry out lifecycle management
   - Use the safe electronic submission channel provided by the FDA to submit applications.
   - Manage the whole submission lifecycle.

5.7 General Instructions

The broad parameters for any additional information that may be included in an eCTD v4.0 message are outlined in the following subsections.

Requirements of the Submission

Although there are no character limits for the optional title 9 of the submission unit, only the first 128 characters will be seen to reviewers. In order to distinguish between comparable sorts of submission units or sequences, The goal of the submission should be briefly described in the value entered for the submission unit title.

Replace the cover letter with a title that does not respond to FDA queries, contains information that is significant or needs to be evaluated, or provides information that is needed to determine whether an application will be approved or accepted. Conclusion

The study offers proof of the significance of the CTD and eCTD. It is evident that CTD has assisted several nations in not only creating their own registration procedures but also actively participating in the creation of new ICH recommendations. One of the sectors with the highest regulation is the pharmaceutical business.Around the world, regulatory governing bodies (authorities) have been established to guarantee that drugs intended for human use meet the highest standards of quality, efficacy, and safety. FDA, TGA, CDSCO, EMEA, and others are a few examples. In order to guarantee that the joint efforts of drug development team results product that is accepted by regulatory authorities, regulatory affairs' responsibility is to establish and implement regulatory strategies. Drug regulatory affairs, which

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includes information from Common Technical Documents (CTD) Regulatory Dossiers, is a dynamic field that includes both the scientific and legal aspects of drug development.

5.8 Drug Discovery

A drug development programe begins when an illness or clinical condition exists for which there are adequate available medical remedies, and this unmet clinical need acts as the project's primary driving force. An early hypothesis that the inhibition or activation of a protein or pathway could have a pharmacological impact in a disease state is developed using research that often takes place in academic settings. In order to assist a drug discovery endeavour, this activity results in the choice of a target that needs more confirmation before going on to the lead discovery stage. When a lead is identified, a thorough search is conducted to identify a biological or small molecule treatment that is connected to a drug, will enter preclinical testing if successful, will enter clinical testing, and will subsequently be developed into a marketable drug. [11]

The discovery of screening hits, medicinal chemistry, and optimization of those hits to increase their affinity are necessary for modern drug development. After a molecule that meets each of these requirements has been discovered, drug development can go forward. If successful, clinical investigations are developed. [12]

5.9 Pathway for the Development of Drug:

Since drug development has become more sophisticated over the past 40 years, significant clinical testing, an IND application, and the preclinical stage of drug research are all required before an FDA marketing approval. Applications for new drugs or licences for biologics are frequently carefully reviewed before approval. Drug performance is then once more submitted to regulatory agencies for post-marketing research after receiving approval. Following a thorough medical review, the main goal is to offer patients safer, more efficient therapies as soon as possible.

There are five essential steps in the U.S. FDA drug development process, and each one has several phases and sections. We will go over each step and different phases of drug development so that we have a complete understanding of the entire procedure. the following stages of medication development:

Step first: Discovery and Development
Step second: Preclinical Research
Step third: Clinical Development
Step four: FDA Review
Step Sixth: FDA Post-Market Safety Monitoring.[13]

VI. INVESTIGATION NEW DRUG APPLICATION

Any pharmaceutical corporation can use the Investigational New Drug (IND) programme to continue for human clinical studies and send a trial Drug all around of the state boundaries (often to clinical investigators) drug has been authorised befor the marketing application. Data demonstrating that it is rational to start testing a novel medicine on people must be included in an investigational new drug (IND) application. Additionally, a sponsor might proceed to the clinical trials phase of medication research using an IND application.

Technically, the IND application is how the sponsor obtains this FDA exemption.

IND APPLICATION TYPES

- investigator's Application of IND
- Emergency Application of IND
- Treatment Application of IND
- Screening Application of IND

6.1 Investigator's Application for IND

In this case, a doctor who begins and oversees the inquiry and whose direct supervision the experimental medicine is supplied or distributed submits the application. A doctor could propose the following research in a research IND application:

- An unpermitted drug,

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- An approved product for another indication or
- An approved product in a new patient locality

Emergency Use IND Application:
According to 21CFR, Sections 312.23 or 312.20, the FDA may utilise an experimental medicine in an emergency if the FDA receives this application and there is not enough time to submit an IND application.

Treatment Application of IND

- During the course of the FDA assessment and final clinical work, this application is submitted for investigational medications that have shown positive report of clinical testing for serious or immediately life-threatening illnesses.
- Patients with significant or immediately life-threatening illness conditions may be receiving a medicine that is not yet licenced for marketing if there is no equivalent or effective alternative treatment or other therapy available.
- A medicine may be made instantly accessible for treatment usage before phase III, but normally not before all clinical trials have been completed, if a condition poses an immediate threat to life.

Screening Application of IND
In order to screening for the preferable formulations, it is filed for a number of closely comparable compounds. A separate IND may be used to create the chosen chemical. It may also be used to screen various salts, esters, and other drug forms that are pharmacodynamically related but chemically distinct. [14]

New Drug Application
The objectives of NDA include giving FDA reviewers enough information to determine the following:

- Drug efficacy and safety,
- Risks outweigh benefits,
- Is the proposed labelling (package insert) for the medicine suitable, and what information should it include?
- Are the processes utilised to make the medicine and the quality controls in place sufficient to maintain the drug's identity, power, quality, and purity? Risk Advantage. [14]

SUPAC - (Scale up and post approval changes)
For scale-up and approval after modifications necessary for the immediate release product / emergency product known as SUPAC, the FDA and the American Association of Pharmaceutical Scientists supplied the scientific basis.
It offers guidance for the following post-approval modifications:

- Components,
- compositions,
- production location,
- process, and machinery

General Stability Consideration
Analyzing the possible effects of SUPAC changes on the stability of the pharmaceutical product is crucial. Broad guidelines for conducting stability studies may be found in Submitting Documentation according to FDA Guidline for the Stability of Human Drugs and Biologics.
The following points for SUPAC submitting should also be considered:

1. With the exception of those requiring data of scale-up,stability from pilot size batches will frequently be adequate to handle the recommended alteration.
2. In situations which show the stability data a propensity for greater loss of potency or degradation under increased circumstances, it proposed that historical increased stability data from a typical sample batch be submitted for the comparison

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3. It also advised, in instances the supplement include all of the long-term data on test batches that are currently accessible from ongoing investigations.
4. The examination and acceptance of the addition would be facilitated by the submission of previous expedited and readily accessible long-term data.[15]

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