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Change Control from Initiation to Implementation in the Pharmaceutical Industry: A Comprehensive Review

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Abstract

Change control plays a role in cGMP, just as all aspects of quality management should continually strive for enhancement. It works with a prior mechanism that empowers designated personnel across fields to assess, as well as having permission to authorize proposing or doing modifications that would impact the status that was prevalidated for the process system, including facilities, systems, and equipment. Change management involves overseeing changes in staff, protocols, operations, and product standards. These changes can occur in areas such as manufacturing, quality control, quality assurance, engineering, research and development (R&D), and marketing. Depending on their significance, changes may be categorized as critical, major, or minor; they may also be classified as emergency, planned, or unplanned based on their nature. Effective change management encompasses the coordination of personnel resources along with protocols to ensure consistency in operations and product excellence. It is a component of GMP compliance, as regulatory bodies mandate companies to demonstrate proficiency in managing changes. The process entails initiating a change request, followed by evaluating its impact on the product before devising an action plan for implementation, ultimately culminating with the Change Control Board (CCB) making decisions regarding the proposed changes.

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INTRODUCTION

In the context of board spectrum method developmental and process validation phases in the pharmaceutical field, change control plays an important role in upholding the quality of the product. The concerned parties are highly responsible for proposing or introducing changes to an existing methodology. These changes are thoroughly examined, determined, recorded, and finally practically validated for approval[1,2]. According to EU GMP Guidelines, Annexure 15, Change control is "a formal system by which qualified representatives of appropriate disciplines review proposed or actual changes that might affect the validated status of facilities, systems, equipment, or processes. The intent is to determine the need for action that would ensure and document that the system is maintained in a validated state"[3]. Change control is a systematic

approach to managing alterations in manufacturing processes, equipment, materials, quality control, engineering, quality assurance, research and development, and documentation. This review focuses on how a change proposal moves through internal company processes and then potentially into regulatory processes, based on change's nature and its impact. It ensures that changes should be implemented with traceable, documented, and controlled manner and build up the basic of quality management systems. Robust change control procedures are crucial now more than ever as industries struggle to innovate while upholding strict quality and safety standards[4]. From the min-20th century, the concept and theory of change control placed their roots in the pharmaceutical sector, evolving alongside the growth of complex manufacturing systems and the increasing focus on quality assurance[5,6]. It is now an essential part of industry-specific legislation and a number of international standards, such as ISO 9001 and Good Manufacturing Practices (GMP). Change control encompasses a series of interconnected processes that involve change initiation, risk assessment, approval, implementation, and post-implementation review[7]. Together, these procedures guarantee that changes are properly considered, carried out with caution, and recorded with great care[8]. By doing this, organizations can reduce operational disruptions while preserving product quality, ensuring regulatory compliance, and promoting continuous improvement.(Figure 1)[9]

Figure 1 Structure of Change Control

Categories of Changes:

On the basis of the impact, three types of Changes are found.

1. ***Minor Changes***: Changes that have little to no effect on the final product, procedure, or system. Minor changes often refer to changes or enhancements that have no appreciable impact on the product's safety or quality. For example, changing the product labels' text size[10–12].
2. ***Major Changes:*** Changes that significantly impact the final product, procedure, or system. To maintain the consistent and standard quality of the product, major changes might need to be carefully considered and validated. For example, changing the manufacturing method[10–12].
3. ***Critical Changes:*** Changes that might significantly impact a product's efficacy, safety, or quality are referred to as critical adjustments. Critical Changes can need thorough evaluation, verification, and regulatory clearance. Example changing API for pharmaceutical product[10–12].

Beside the above-mentioned categories, the changes are also classified into the following three distinct categories, and it is entirely dependent on the specific nature of the changes.

1. ***Emergency:*** An emergency change is a change that must be implemented immediately to address an urgent issue that could significantly impact product quality, patient safety[10,13].
2. ***Unplanned:*** An unplanned change arises unexpectedly and necessitates immediate intervention. Deviations are categorized as unplanned changes; hence, it is imperative to the possession of a robust strategy in place to efficiently address them when they affect the effectiveness, safety, and quality of a product[10,13].
3. ***Planned*** A planned change is a calculated, deliberately analysed, and meticulously executed adjustment to facilities, equipment, processes, materials, or documents. These changes adhere to the usual change control process and are carried out on an established timeline[10,13].

Table 1 Grading of Changes

	Critical changes	Major changes	Minor changes
Significant changes	Significantly impact a product's efficacy, safety, quality	Influences product quality or process reliability	Little to no effect on the final product, procedure, or system
Possible measure	Exhaustive testing, Validation Regulatory approval	Review, Validation Regulatory communication	Amendment Review Documentation
Examples	Changing API for pharmaceutical product	Changing manufacturing process	Changing the size of the font on product labels.

Table 2 Area of changes

Particular Area	Changes
Production/Process changes	Supplier of raw material and specification of raw material Manufacturing process parameter, scale up/scale down Technology transfer(TT) implementation Replacement and modification of equipment Verification, Calibration, qualification, and In-Process testing procedure
Quality Assurance	Sampling technique and quantity of Samples. Documentation and Standard operating procedures(SOPs). Validation Protocols Equipment Calibration and Maintenance Qualification of equipment
Quality control	New Analytical Techniques New reagent and solvent Stability Protocols Storage Conditions Environmental Monitoring Program New reference standard Quality testing parameter
System-Engineering	Validation of Equipment Equipment qualification and Commissioning Parts of equipment HVAC system and AHU system Design layout and Working Pharmaceutical water system and Pure steam Compressed air and nitrogen system Software/ Hardware or Change in any program
Research and Development	Addition or elimination of steps of Manufacturing process Raw materials addition or omission Specifications(Raw materials, intermediates, and final product) Quantitative aspects(raw materials & finished products) Storage environment and Manufacturing factors Validation and testing procedures

Grading the Changes:

Various changes procedures may need to be used as a basis, depending on the area of consideration based on approval and validation. Since these changes can be easily standardized and happen rather frequently in practice, many companies handle changes to the material used for packaging, such as labels, boxes, and information leaflets, according to change control procedure. In these situations, the criteria and the sequences that are employed are deliberately matched to complement

and work in tandem rather than being separate. Many companies utilize lists and flow charts as examples for grading changes, but these cannot and should not take the place of an individual's appraisal of the change, especially when it comes to the associated risk assessment[14].Various organizations adopt different and elaborate grading categories. Additionally, some companies have extensive and detailed lists of potential changes, along with their respective grades. The example presented in Table 1 demonstrates just one approach to grading changes[15].

Area of Changes:

The following table indicates the different areas of changes It includes the changes in different areas listed in Table 2[14,15]

Change Control Regulatory Requirements:

1. EudraLex Volume 4, GMP:

The EudraLex Volume 4 GMP is the responsible authority to provide guidelines to EU producers of human and medical products on interpreting Good Manufacturing Practice (GMP) principles[16]. In Chapter 4, Section 4.29, the necessity of defined procedures and protocols in the change control process is emphasized[17]. Verification of any changes to manufacturing techniques, tools, or materials that can affect process repeatability and product quality is mandated by Chapter 5, Section 5.25. In order to prevent unanticipated results [18]. Annex 15, Section 11, describes the significance of quality risk management in evaluating the plan of change and its affectivity on the quality of products[19].

2. EU 1252/2014

EU 1252/2014 is applicable to any company that manufactures and/or distributes active substances for medicines, including manufacturers of medicinal products. Article 14 concerns manufacturing process change control standards and mandates manufacturers evaluate the effect of such changes on an active ingredient's quality before implementation [20].

3. FDA 21 CFR Part 211:

This is the prime principle for completed pharmaceutical items [21]. According to 21 CFR 211.22, the Quality Unit allows for approval or rejection of changes. The organization holds the responsibility for supplying the quality control professionals with the resources and facilities needed [22].21 CFR 211.100 provides guidelines to establish the written procedure as well as the process control mechanism. It also adopted the variations when they were implemented. Only authorized personnel who are satisfied by authorized individuals and approved Quality Unit ,are responsible for developing this procedure. Suitable justification and proper documentation must be present for any kind of variation, excluding the prescribed process[23].21 CFR 211.160 Outlines the criteria for documented procedures in a laboratory environment.[24].

4. **ICH Q10**

The ICH Q10 is a set of guidelines for a successful quality management system in pharmaceuticals. According to Section 3.2.3, the change control procedure must ensure that the changes will have no unexpected consequences, and the proposed changes should be assessed using quality risk management[25].

Multiple types of changes impact multiple regulatory areas concurrently, such as GMP requirements, authorization requirements, and employee occupational health and safety(Figure 2). Quality-related changes might impact many departments within an organization, such as R&D, marketing, engineering, manufacturing, regulatory affairs, and quality control. As a result, the entire company must be included in the control process[26].

CHANGE CONTROL PROCESS:

The Change Control Process involve following steps

1. *Change Request Initiation*:

In the first stage of change control, a change request form is completed under the change control procedure that has been defined by the company to identify and formally document the proposed change. When creating the actual change request documents, the companies can group changes by type and priority. Depending on how the change is classified as minor, major, or critical and according to company criteria and internal procedures, changes can be introduced. It may not be a big process change for minor changes in the application. While major and critical changes need more evaluation before they can be introduced[27,28].

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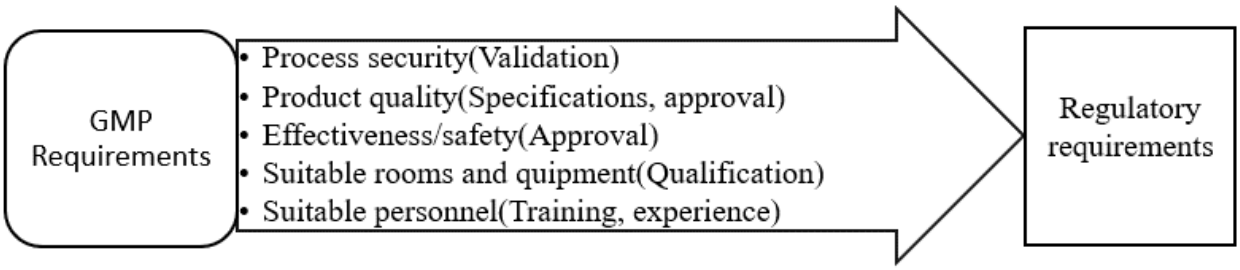


Figure 2 Impact of changes from GMP to Regulatory requirements [26]

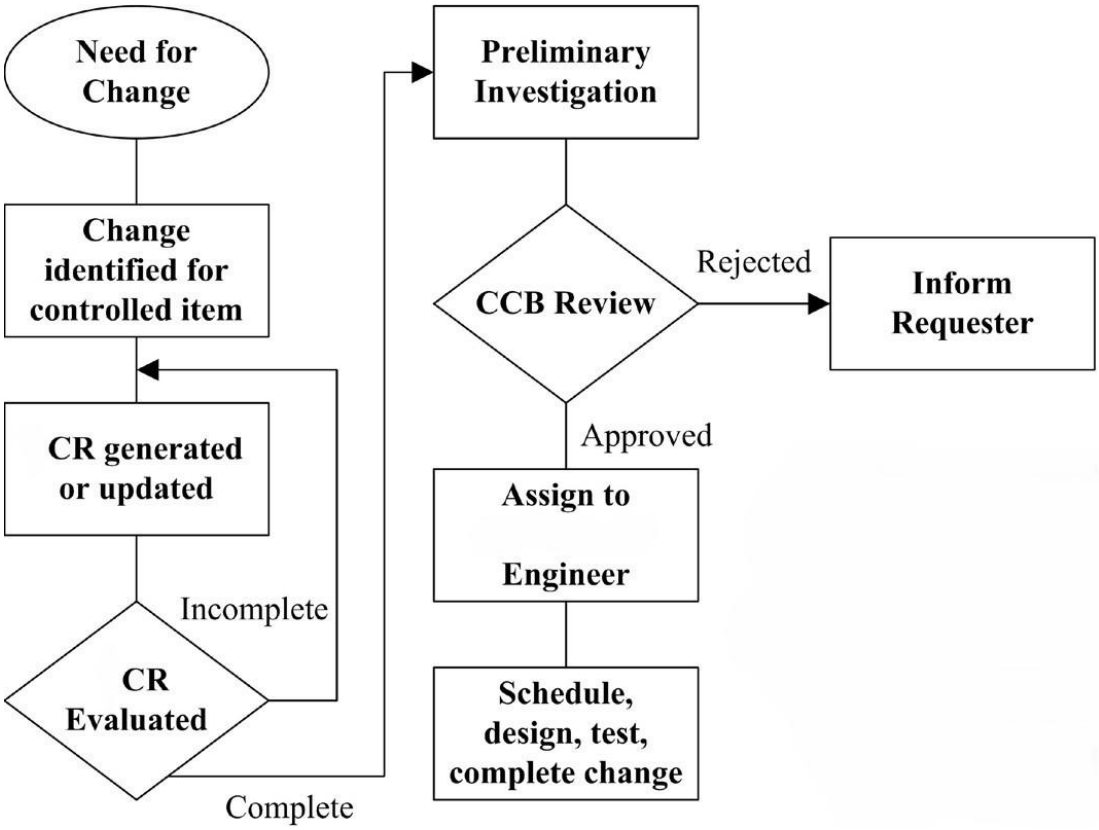


Figure 3 Flowchart of Change Control Process

2. Review change:

After the initiation of the change request, a review is conducted. In other words, the proposed change is reviewed with respect to how it will affect product quality, safety, efficacy, and regulatory compliance with legal requirements. Additionally (quality risk assessments) could be executed for isolation potential possible risks related to the change[29].

3. Evaluation Change:

The change request is rigorously evaluated by professionals who have the appropriate qualifications and experience. At this point, all relevant information and data are extensively examined and evaluated[30,31].

4. Approve Change:

After the evaluation and review of the change request, the QA department approves or rejects the change request plan. Approvals may be required from QA head for Major and Critical changes[32].

5. Implement Change:

After getting approval from concerned regulatory authorities, the preplanned changes are now implemented in a systematic way and controlled manner. The changes require the adjustment of equipment through documentation, noticeable period. and more over the efficacy of change methodology[32].

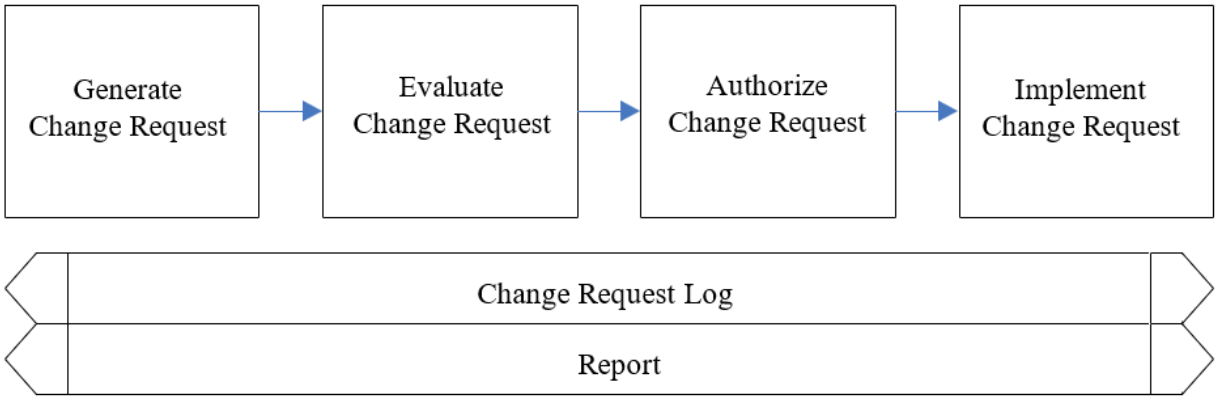


Figure 4 Change Request Process Flow [36]

Change Description		
Project Name:	Change Name:	Number:
Requested By:	Contact:	Date:
Description of Change:		
Reason for Change:		
Priority : 1. High 2. Medium 3. Low		
Impact on Deliverables:		
Impact of Not Responding to Change (and Reason Why):		
Date Needed:	Approval of Request:	Date:

Change Impact
Tasks/Scope Affected:
Cost Evaluation:
Risk Evaluation:
Quality Evaluation:
Additional Resources:
Duration:
Additional Effort:
Impact on Deadline:
Alternative and Recommendations:
Comments:

Sign Offs	
1. Accepted 2. Deferred 3. Rejected 4. More Info Requested	
Comments:	
Project Manager Signature:	Date:
Decision Maker Signature:	Date:

Figure 5 Change Request Form[39]

6. ***Action plan:***

Using the change investigation report, the initiator, evaluator, or Quality Assurance manager prepares an action plan. The initiator may cancel the record, providing supporting evidence if necessary. After the initiator completes a document-based action item, it proceeds via departmental review before being reviewed by Quality Assurance using the change control record. If verification fails, QA alerts the initiator and provides supporting documentation. Upon acceptable examination, QA closes the action plan and returns the record and report to the initiator[32,33].

7. Change Effectiveness monitor:

After implementing the changes, the effectiveness produced is under evaluation. Once the change is implemented, these follow-up checkups are important for assessing the impact and degree of success of the change implementation. The effectiveness is then continuously monitored and evaluated post-implementation. Such follow-up necessitates an effectiveness check to determine the change's impact and degree of success. This monitoring will be able to isolate potential issues and indicate the area in which the change has brought about the desired effect. These regulatory phases are key determinants for the isolation of deviations from expected outcomes, as well as preventive measures[32,33].

The steps of change control process that are described above are mentioned in Figure 3 as a Flowchart[34].

CHANGE CONTROL MANAGEMENT PLAN:

Change Request(CR) Process:

The submitter fills out a Change Request (CR) Form and sends it to the Change Manager for pre-review. The CR is reviewed by the project personnel to ascertain the effort involved with respect to implementing of the change suggested and in turn develop a detailed solution proposal for change[35]. The change request is accessed by the concerned authorities and after it found appropriate, it gets approved to proceed with the implementation of that project or product. If approved, the code is altered to apply the requested change. The submitter and everyone involved are then updated on the CRs progress and status. The CR Log is also updated by the Change Management to log down all of the it Change Order details. On the full CR lifecycle, it updates its status to reflect where we are at any given time and any new developments there may be(Figure 4) [36].

Change Request Form:

This form is filled out by the change requester and approved by the change control board[37,38]. Change request forms include a description of the change, the change request number, the reason for the change, the impact on cost and risk, and the priority level of the change(Figure 5)[39].

Evaluating Change Requests:

Following priority level are used to evaluate the Change Request(CR)[40,41].

Change Control Board (CCB):

The Change Control Board (CCB) makes sure that a defined procedure is followed to evaluate suggested changes and integrate them with the predetermined release of a product, representing program and project management's interests [41,42].

Table 3 Description of Priority type and level

Priority	Description
High	High priority is given to the CR by Change Control when the CR is critical or emergency that requires immediate attention.
Medium	Medium priority is given to the CR by Change Control when the CR is for Major change.
Low	Low priority is given to the CR by Change Control when the CR is for Mimor change.

Table 4 Description of personnel acting as the Change Control Board (CCB)

Role	Name	Contact	Description
Chairperson	-	-	Conduct CCB meetings and decide on changes in the end.
Project Manager	-	-	Manage the Schedule of meeting and provide resources
Technical Lead	-	-	Evaluation and review of CRs
Quality Assurance	-	-	Maintain Quality standards of CRs
Stakeholder	-	-	Represents the interests

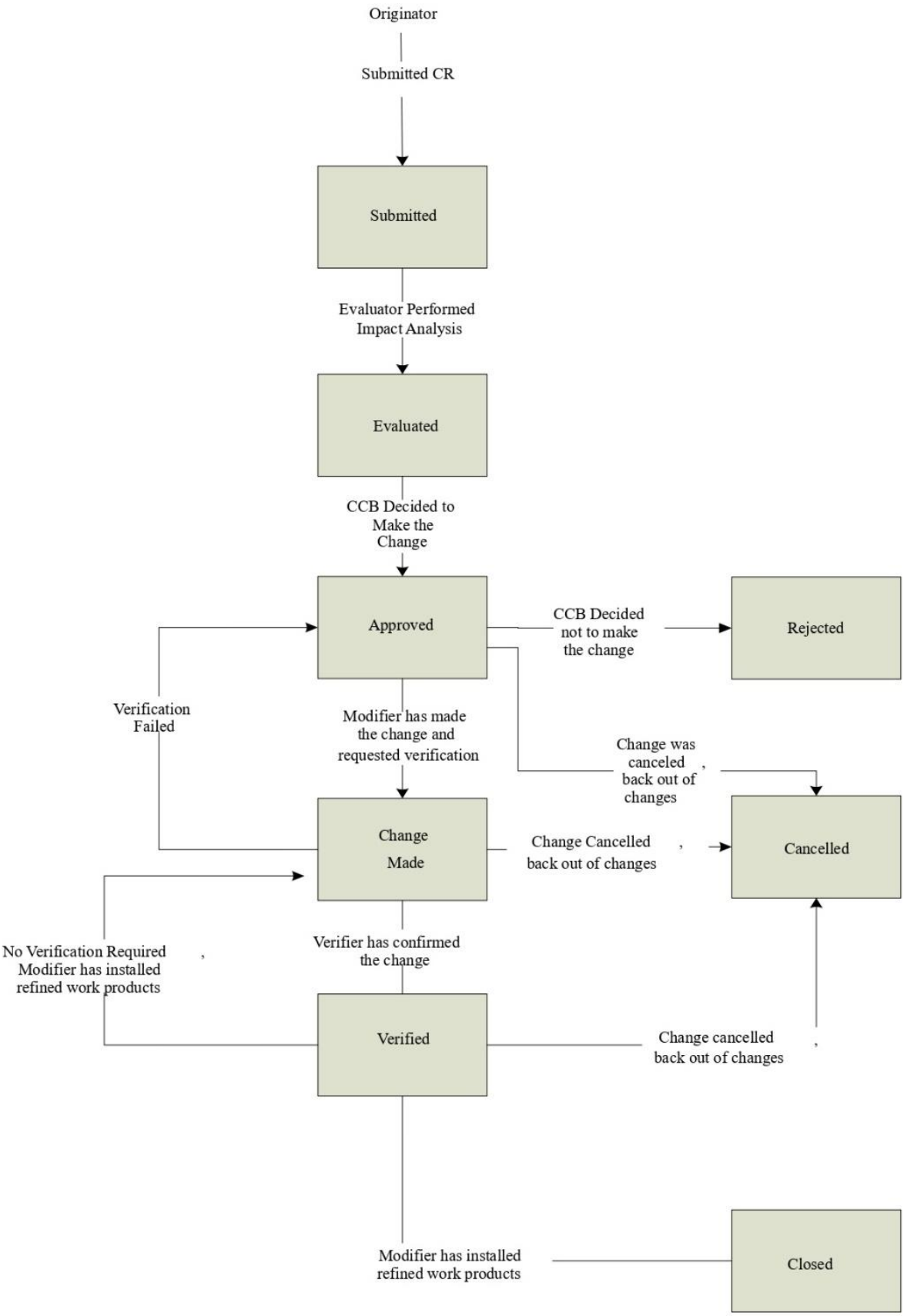


Figure 6 Flow of Change Control Management[47]

Table 5 Process Summary[48]

Input	Process	Output
Informal Proposal Change Suggestion Program and CCB Approved Work Products Project Blueprint Risk Evaluation User Specifications Valid Change Request (CR) Submitted in Standard Format	Proposal of Change Review and Approvals Performance of Work Indicated Evaluation of CRs Modification of policies, processes, and systems Verification any approval change	Final Report Review of Report Necessity of Filing Type of Submissions Change Management Log Documentations Status Reports

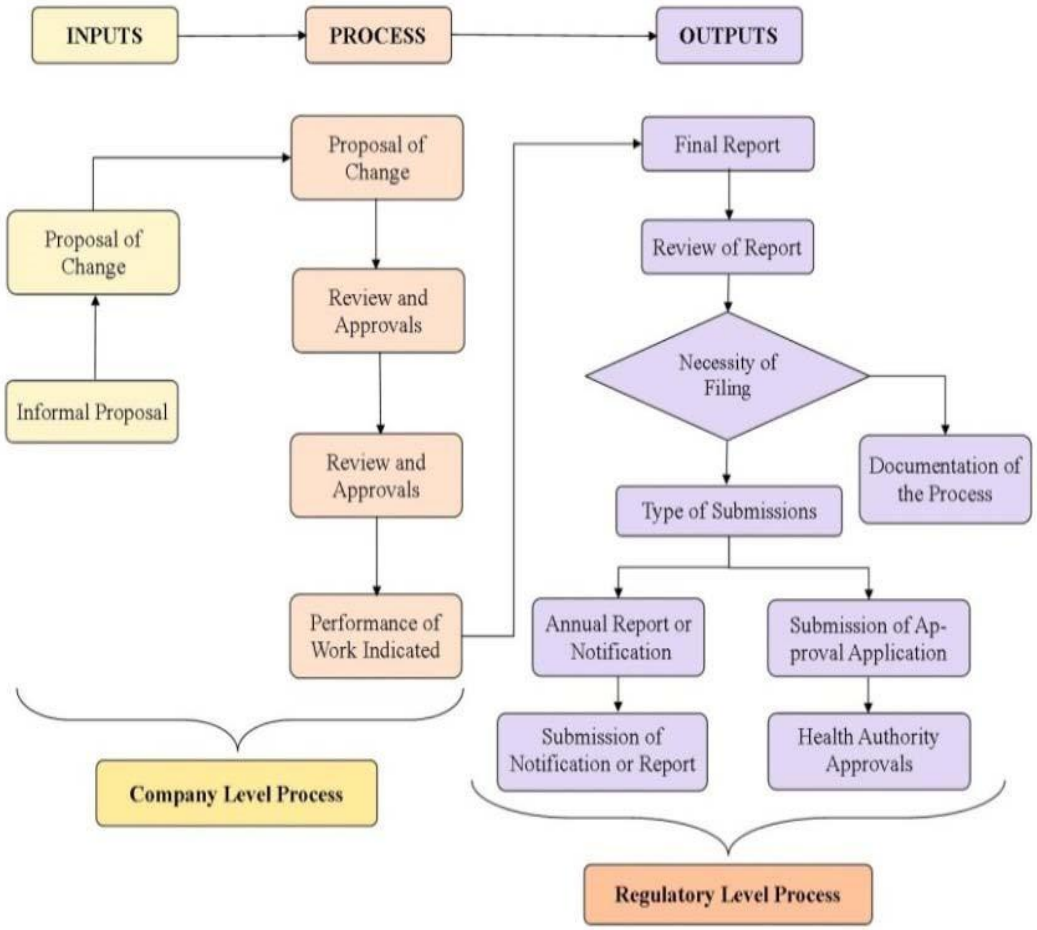
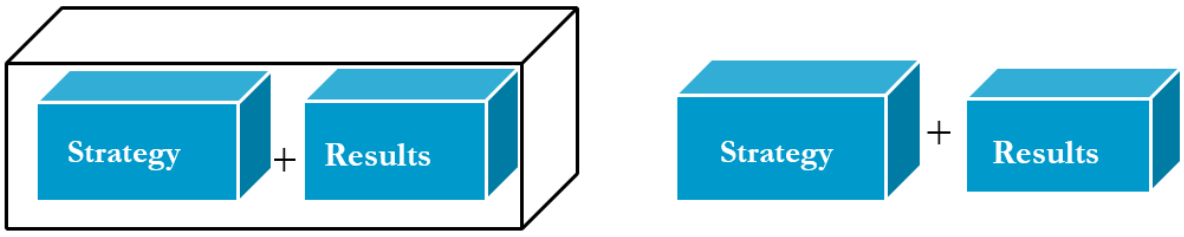


Figure 7 Process Summary[48]



Evaluation of a proposed variation as a 'whole' (Strategy + Results)

Step 1: Submission of a Change Management Protocol

Step 2: Reporting of implemented change

Figure 8 Post Approval Change Management

The CCB is responsible for reviewing change requests, requesting impact analyses of proposed changes, making decisions, and informing impacted parties and persons of those choices, as shown in Table 4[43–45]

CHANGE CONTROL MANAGEMENT:

An originator submits a CR to begin the procedure. If the status of the CR becomes “Submitted,”. The CR is changed to "evaluated" status once an impact study is completed by an evaluator. Whether to implement the change is decided by the Change Control Board (CCB). If accepted, the status changes to "Approved.” It enters the "rejected" state if it is refused. The change becomes effective and enters the "Change Made" state if authorized.[46] Verification is then necessary; in the event that verification is successful, the status is reverted to "Approved" for changes. It can move straight to the "closed" state if no verification is necessary, or it can become "verified" if it is confirmed. The change installs enhanced work items and enters the "closed" state following verification.(Figure 6)[47]

Process Summary:

This shows how a change proposal moves through internal company processes and then potentially into regulatory processes, based on change’s nature and its impact. It highlights the importance of both internal reviews and potential regulatory requirements in implementing changes(Table 5, Figure 7)[48].

POST APPROVAL CHANGE MANAGEMENT:

This methodology outlines the changes in a specific area that an organization hopes to make and how they will be prepared and validated during the product's lifespan[49]. It is a methodical approach to change assessment that ensures an early assessment of the strategies of changes and a subsequent data analysis utilizing the standard tools and techniques(Figure 8)[50]. Since the marketing authorization holder requires approval from the regulatory agencies to implement the suggested strategy for testing to confirm the change made an impact on product efficacy. It is anticipated that such a step-by-step approach would result in a more rapid, accurate and stable change implementation following approval[51].

Written Procedure and Documentation:

Writing processes should be located in the appropriate location to describe changes that permit improved quality of product related material, equipment, and methods of manufacturing or testing conditions. The SOPs and maintaining records of documents for Change Control is mandatory for this documentation.[52] The Change Control Form (CCF) in Change Control is a product-related form that includes a change request for the initiating department, proposed change details, and QA Head's comments, Changes category, supportive documents, management review form, and CCF assessment.[53]

CONCLUSION

This review specifies the requirements for a change control process, various change factors, regulatory requirements, and the protocol required for performing change in the pharmaceutical industry. This study also confirms that, change control involves systematic control of changes to ensure they do not negatively impact product quality, safety, efficacy, purity, or potency. The change control system manages the changes at the end-to-end level in terms of initiating, reviewing, evaluating, implementing, approving, and conducting continuous effectiveness verifications. The steps below form a solid and unimpaired change management system that can be used by any organization to manage the transformation into continuous improvement: Conclusion Change control in the pharmaceutical sector is not typical regulatory compliance, but rather an essential aspect of product quality, patient safety, and operational effectiveness. The change control management plan includes making a change request, filing a change request form, evaluating the change request based on priority level, and obtaining approval from the change control board (CCB).In post-approval change control management, there are too many brainstorming meetings, and the toughest task for the change control committee is to acquire advanced technology, knowledge, excellent troubleshooting skills, a unique style, and strategies for this phase. Post-approval change control management has a significant impact on its market authorization and regulatory approval, so it should be planned accordingly with proper scheduling in compliance with GMP as well.

Ethical Approval

No ethical approval was necessary for this study.

Author Contribution

All authors made substantial contributions to the conception, design, acquisition, analysis, or interpretation of data for the work. They were involved in drafting the manuscript or revising it critically for important intellectual content. All authors gave final approval of the version to be published and agreed to be accountable for all aspects of the work, ensuring its accuracy and integrity.

Conflict of Interest

The authors declare no conflict of interest, financial or otherwise.

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