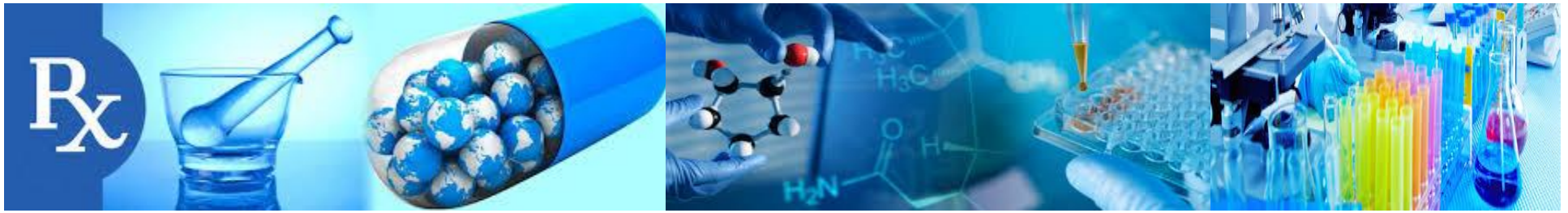
SNS COLLEGE OF PHARMACY AND HEALTH SCIENCES

Affiliated To The Tamil Nadu Dr. MGR Medical University, Chennai
Approved by Pharmacy Council of India, New Delhi.
Coimbatore -641035

COURSE NAME: INDUSTRIAL PHARMACY-II

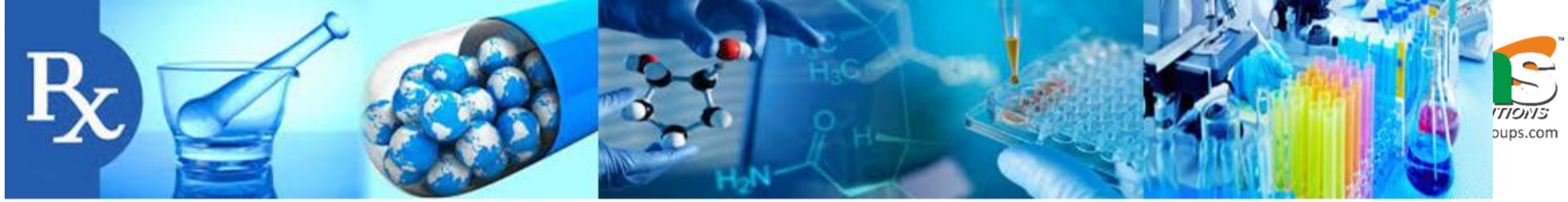
(BP 702 T) IV YEAR / I SEM

TOPIC: CHANGE CONTROL



CHANGE CONTROL

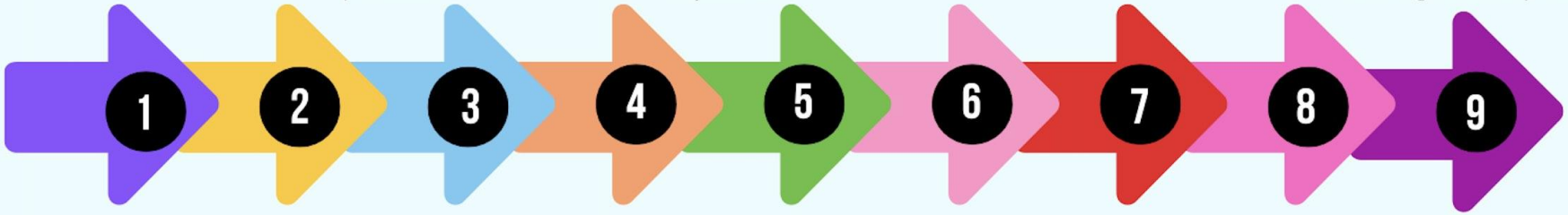
ICH World Health Organization



CONTENTS/OBJECTIVES OF PRESENTATION:

- What is Change and change control
- Importance of Change control System
- How it is Proceed in our company

Change Control Flowchart in Pharma



Stage 1: Identification of Change

The change control process in pharma begins when a change is proposed.

Stage 2: Justification for Change

This step of the change control pharmaceutical procedure acts as a gatekeeper, ensuring that changes are not made hastily or without proper reasoning

Stage 3: Preliminary Assessment/Review

Review stage serves as the initial screening phase in the change control pharmaceutical process.

Stage 4: Detailed Evaluation

If the change is approved for further consideration, a detailed evaluation is performed.

Stage 5: Approval or Rejection

Based on the detailed evaluation, the change may be approved or rejected.

Stage 6: Communication

Throughout the process, effective communication is essential in change control pharmaceutical process

Stage 7: Implementation

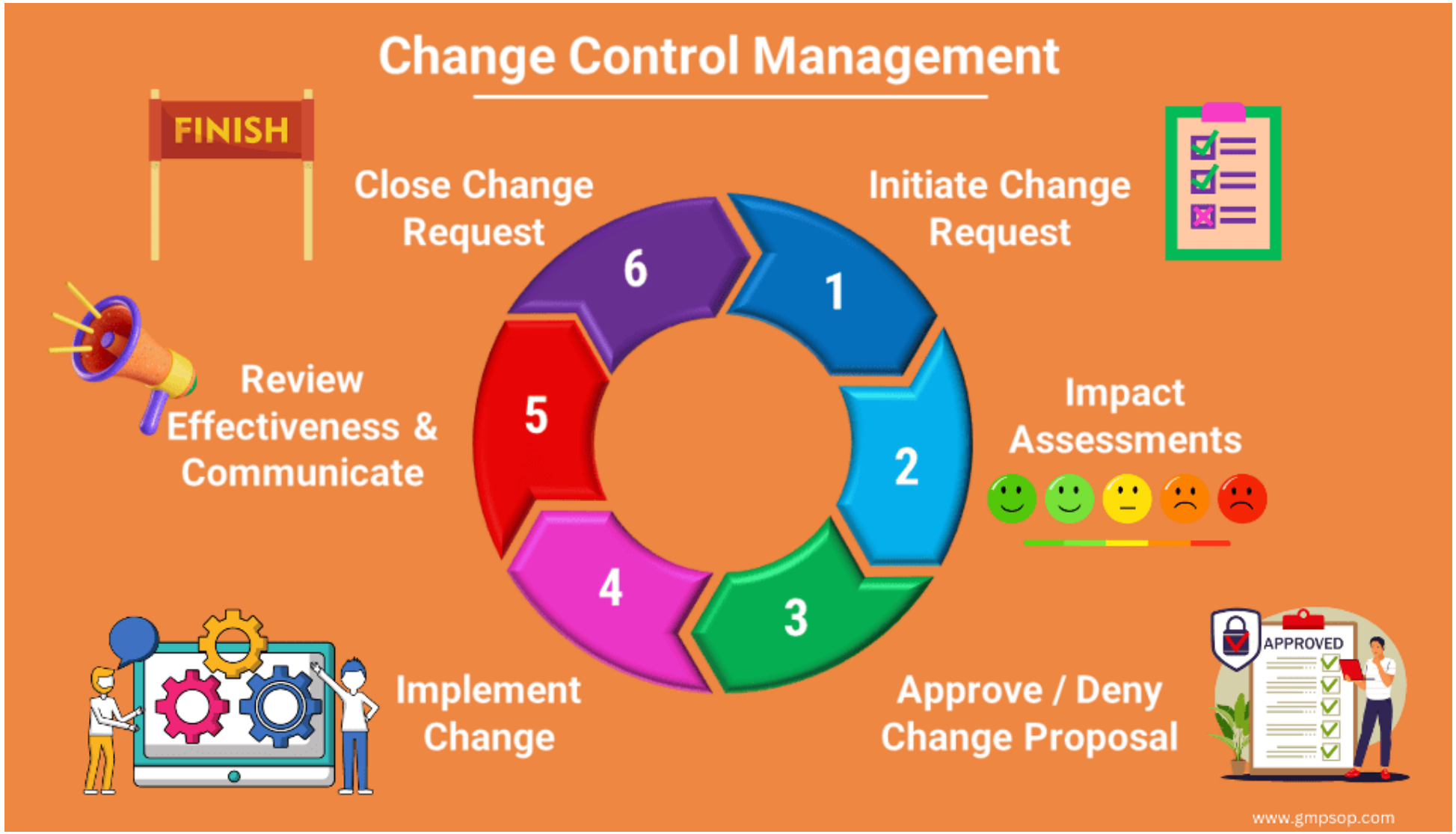
Properly executing this stage is crucial for ensuring the integrity of the change and maintaining the standards .

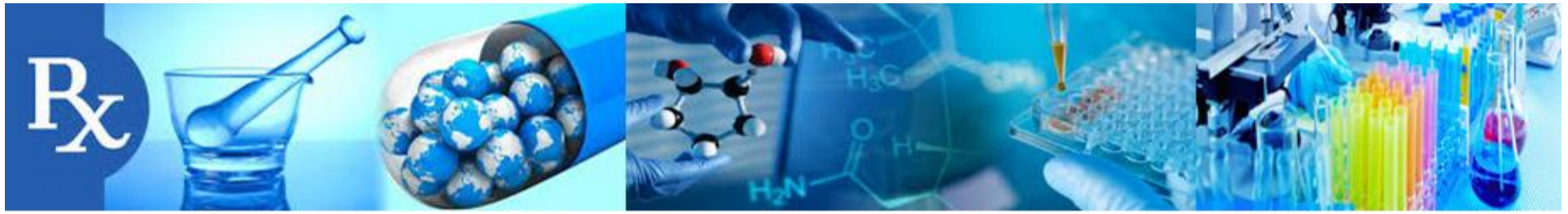
Stage 8: Verification

After the change has been implemented, it's crucial to verify that it was executed correctly and that there are no unintended consequences

Stage 9: Closure & Review

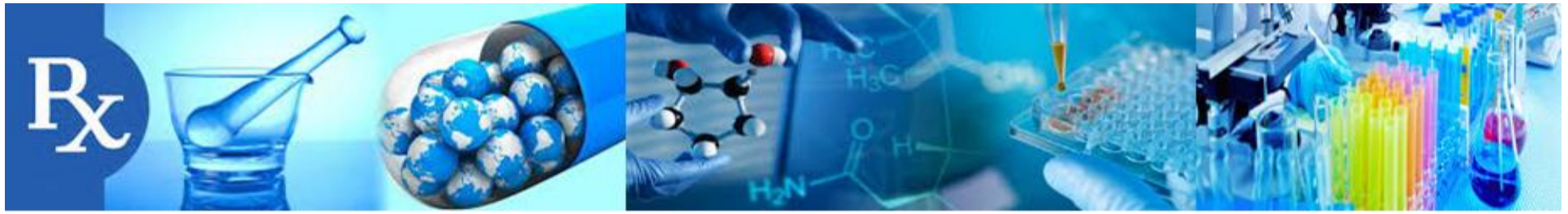
The final step in the change control process is to formally conclude the initiative and reflect upon its long-term implications


Change Control Management
FINISH
Close Change Request
Initiate Change Request
Review Effectiveness & Communicate
Impact Assessments
Implement Change
Approve / Deny Change Proposal
APPROVED
1
2
3
4
5
6
www.gmpsop.com



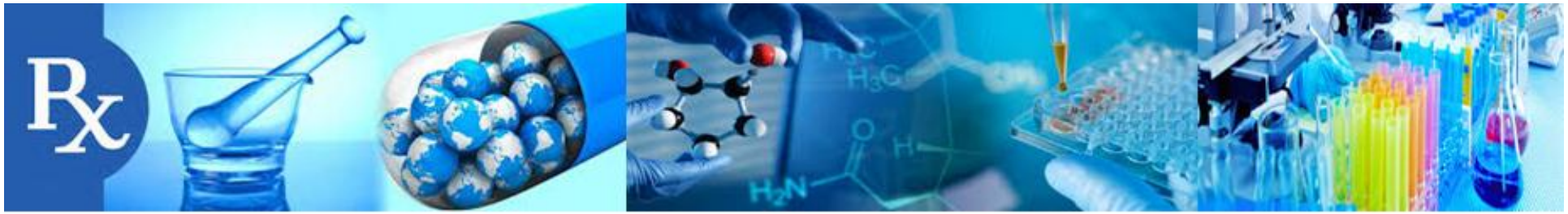
WHAT IS CHANGE?

Any Amendment in the approved Process , Specifications , SOP's, Vendor, Batch Size etc which effect the Product quality attributes (Safety, Efficacy and Potency) or Regulatory, statutory or ISO requirements whether minor or major will be considered as CHANGE

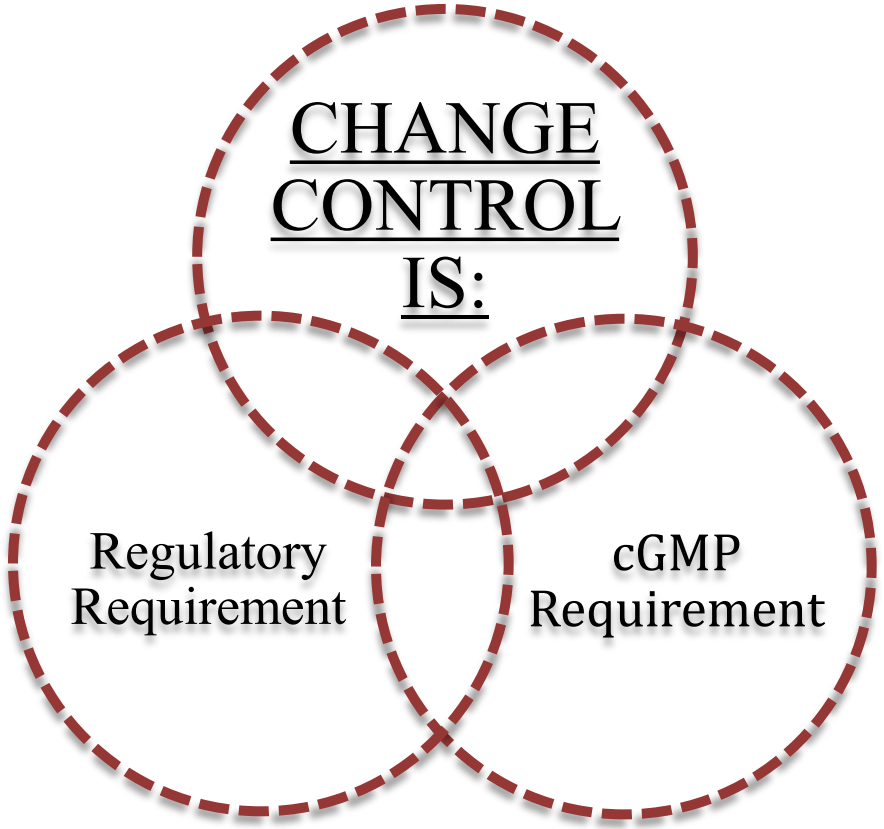


CHANGE CONTROL:

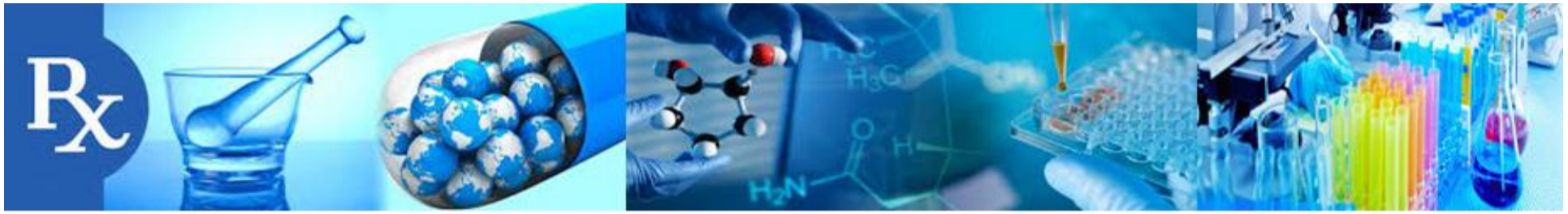
A Process that ensures that changes to materials, methods, equipment, software etc are properly documented , reviewed , approved and traceable is known as Change control



WHY IT IS IMPORTANT



If change is not controlled , not implemented properly then any Product hazard may occur



EFFECTS OF SINGLE CHANGE ON SEVERAL AREAS AT SAME TIME

GMP REQUIREMENTS

REGULATORY REQUIREMENT

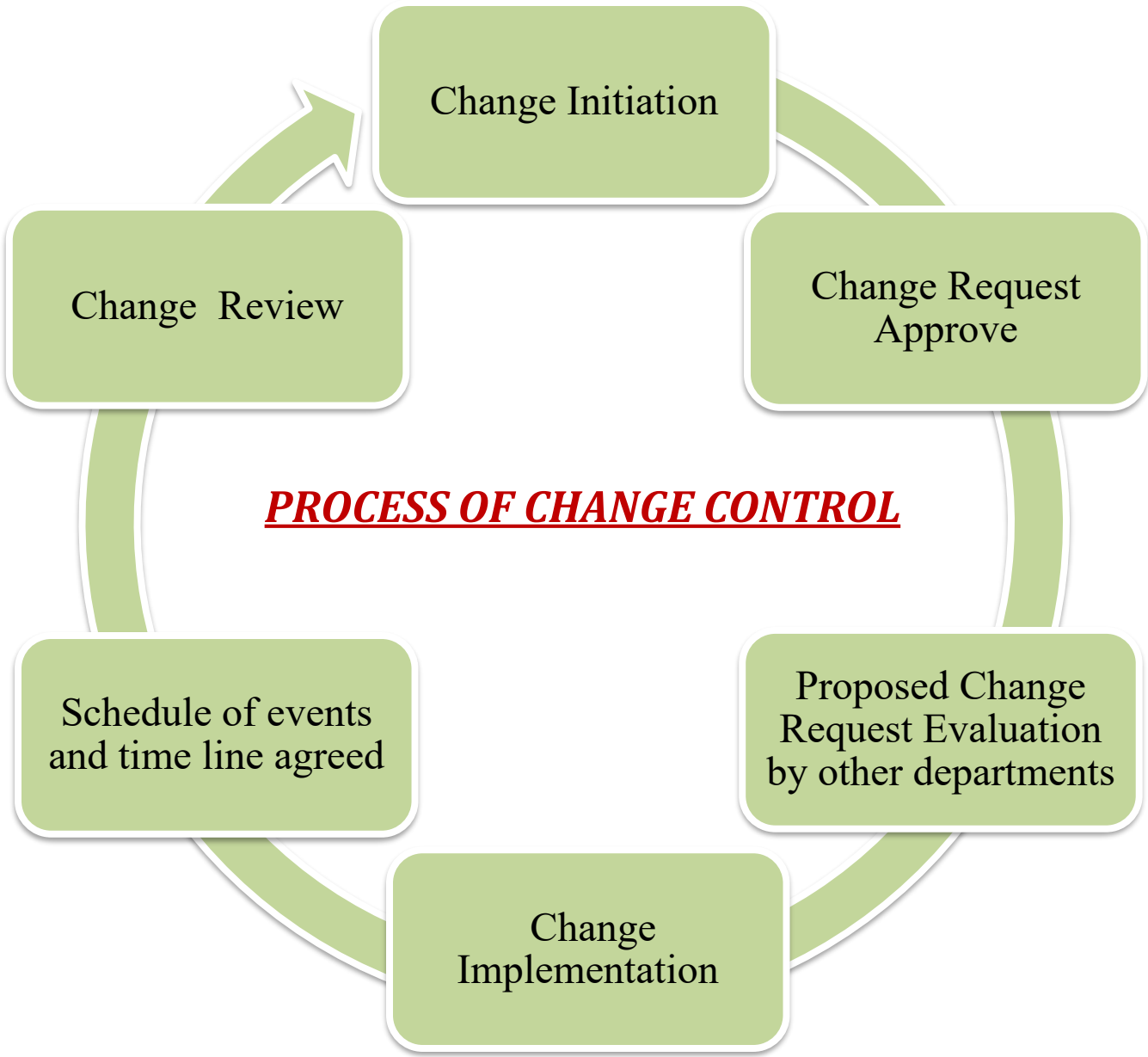
Suitable personnel (training, experience

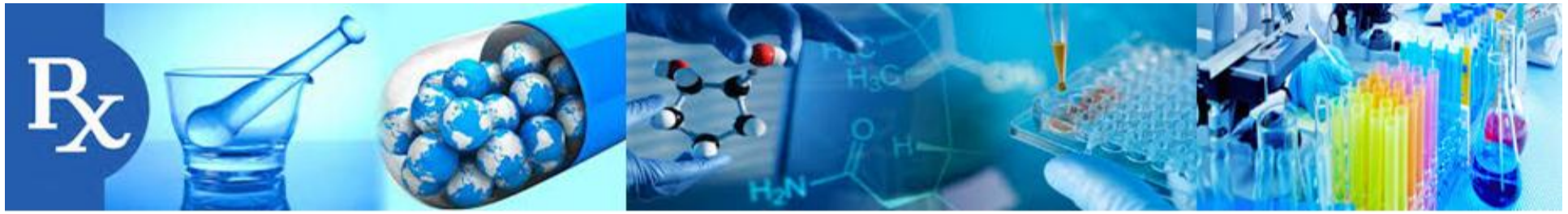
Suitable rooms and equipment (qualification

Product quality (specifications, approval

Effectiveness / safety (approval)

Process security (validation


Change Initiation
Change Request Approve
Proposed Change Request Evaluation by other departments
Change Implementation
Schedule of events and time line agreed
Change Review
PROCESS OF CHANGE CONTROL

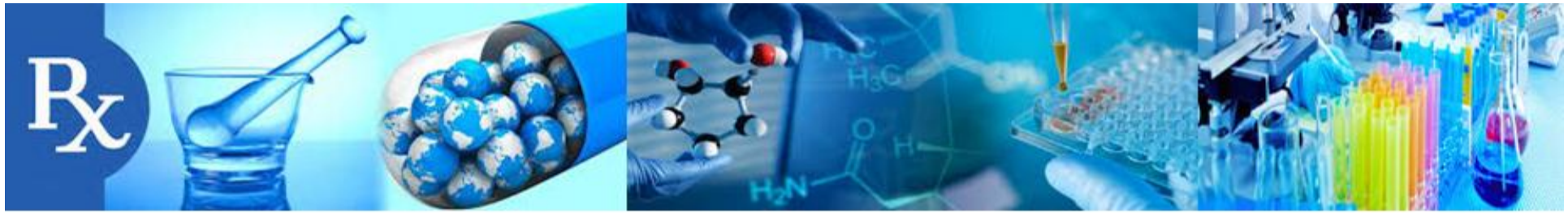


1. CHANGE INITIATION

a) INITIATOR INFORMATION:

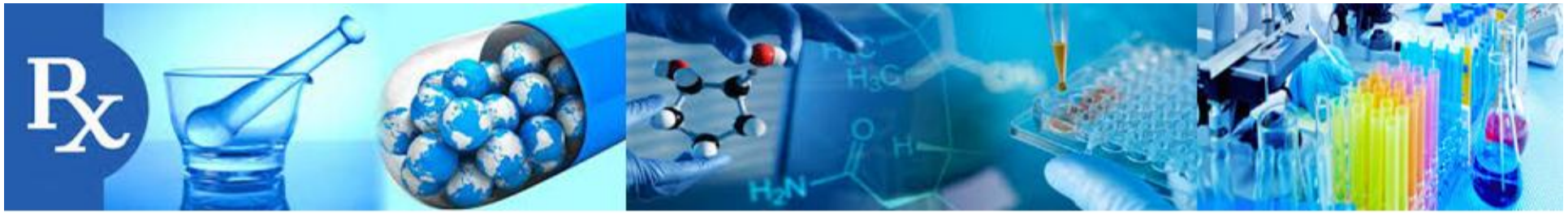
a) :

- Name
- Department
- Date, CCF no. etc



b) CATEGORY OF CHANGE (WHERE THE CHANGE IS REQUIRED):

- Composition
- Equipment and Facility
- Process and Art Work
- Materials and Vendor
- Analytical Method
- Batch Size etc.

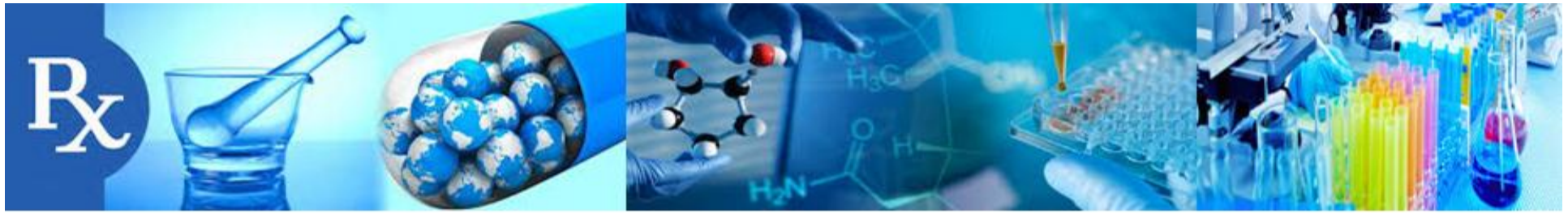


c) DESCRIPTION OF PURPOSED CHANGE:

Initiator will provide full description of required change along with related information

World Health Organization

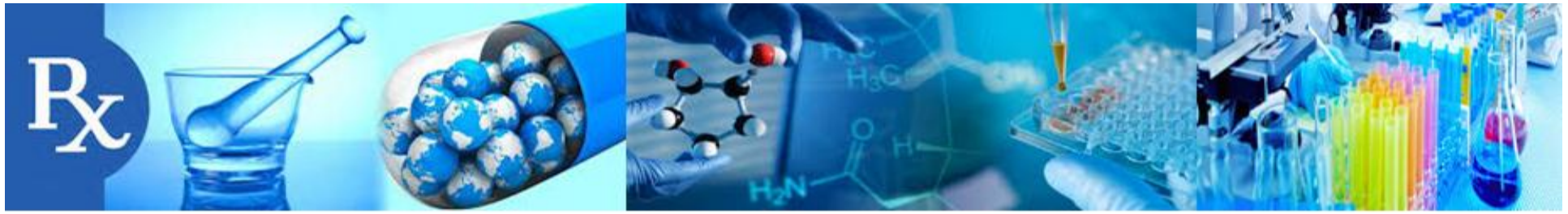
ICH



D) REASON FOR CHANGE:

The initiator will provide the:

- Reason for change
- Consequences if change is not implemented.
- The existing/ Current Situation

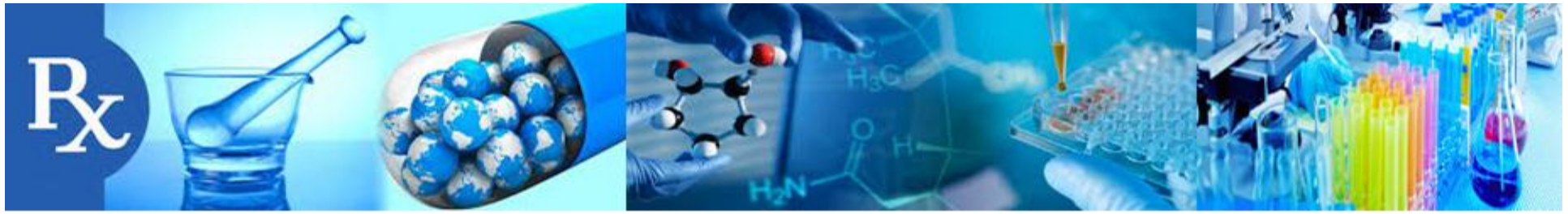


E) RECOMMENDED ACTION PLAN.

The Initiator will:

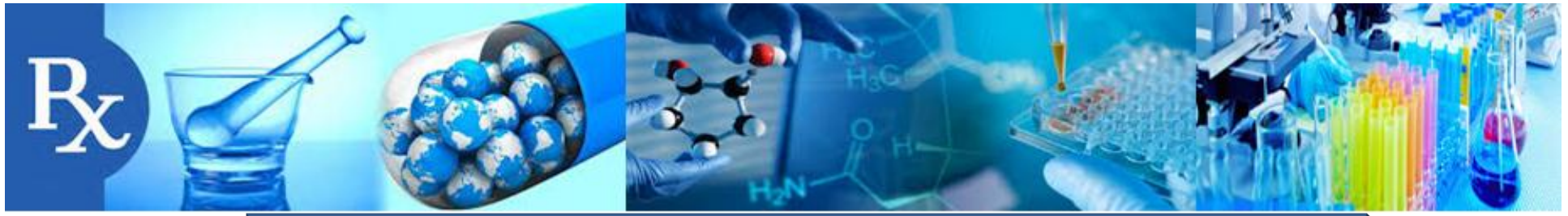
1: Specify implementation action plan and target date.

2: Specify the batch number of product from which change if, approved will be implemented



2- CHANGE REQUEST APPROVE:
(INITIAL REVIEW BY QUALITY ASSURANCE)

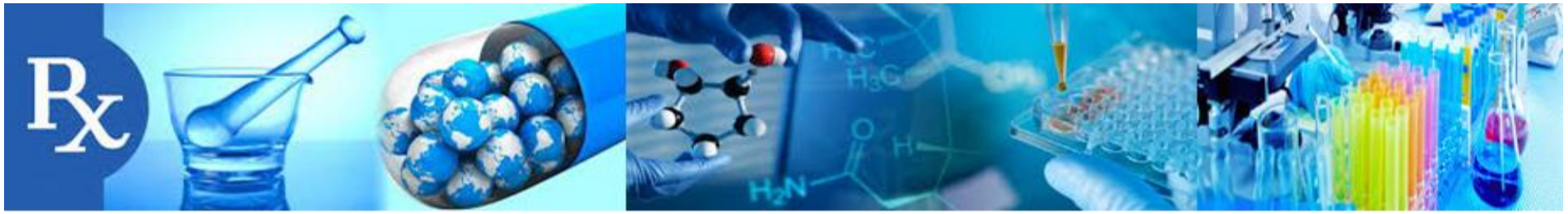
- The Change request form will be Logged by Quality Assurance department.
- Quality assurance Manager will Consider the nature of change either major or minor.



- Quality Assurance Manager will review that the proposed change may have impact on:

Regulatory	Yes	No
EMS	Yes	No
cGMP	Yes	No
Technical	Yes	No
Others	Yes	No

- Q.A Manager will also Review the Proposed change for Risk management.
- The quality Assurance Manager will approved/reject the Change Control Request along with his Comments.



4. SCHEDULE OF EVENTS AND TIME LINE AGREED:

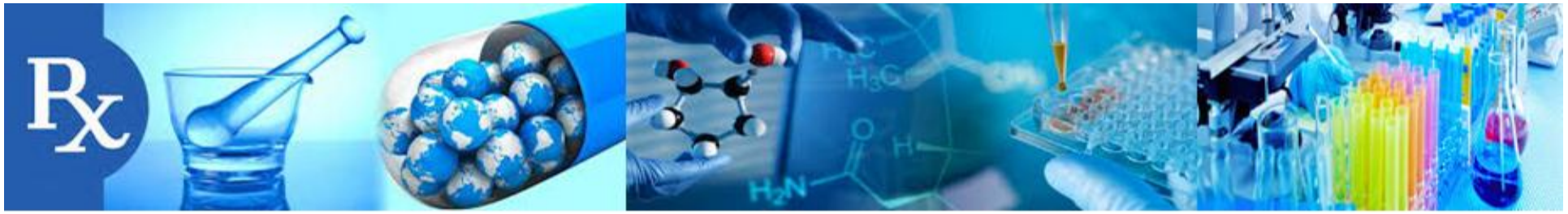
Quality assurance department will schedule the events for implementation

5. CHANGE IMPLEMENTATION:

Quality Assurance department will checked that the Change is implemented

6.CHANGE REVIEW:

Quality Assurance Manager will review the implemented change in order to access the impact of Change

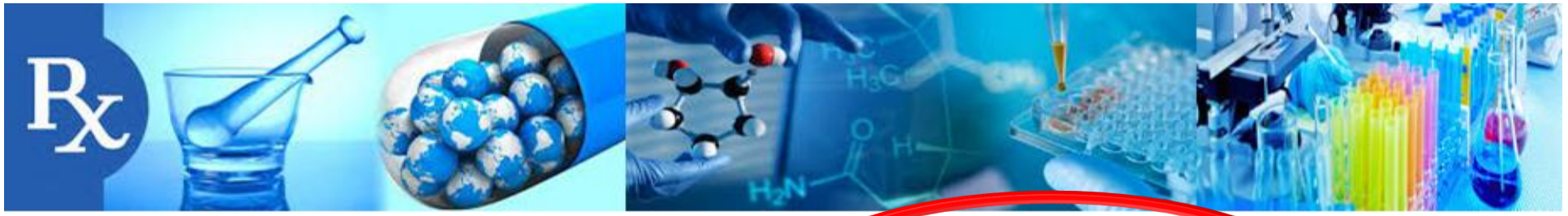


"EXAMPLE"

"CHANGE IN COATING PROCESS FROM SOLVENT COATING TO AQUEOUS COATING "

Description:

Products Dapakan 500mg film coated tablet. Opadry OIC 7000 is afterwards coated with Opadry II.



1: May be colour variation , this should be Monitored.

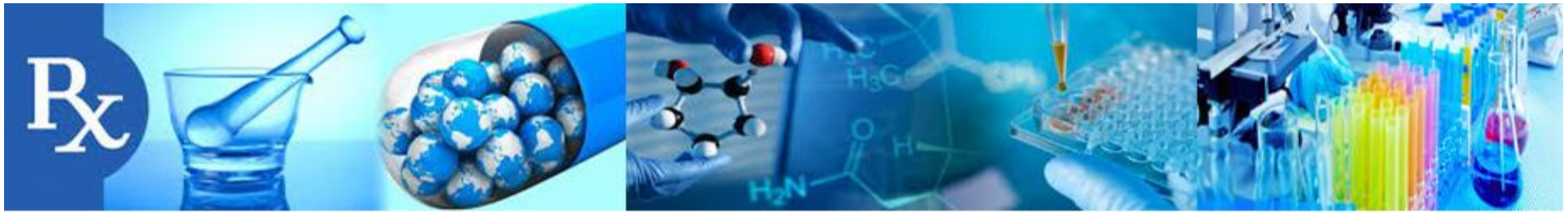
2: And is this change/variation acceptable?

3: How much weight is gained?

4: Is there any change in thickness?

5: Process validation for initial 3 Batches

RISK ASSESSMENT



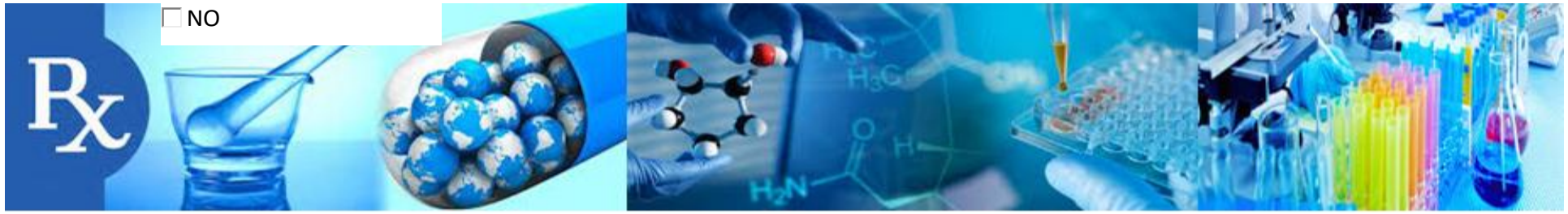
"MATERIAL MANAGEMENT"

Trained Staff?

World Health Organization

ICH

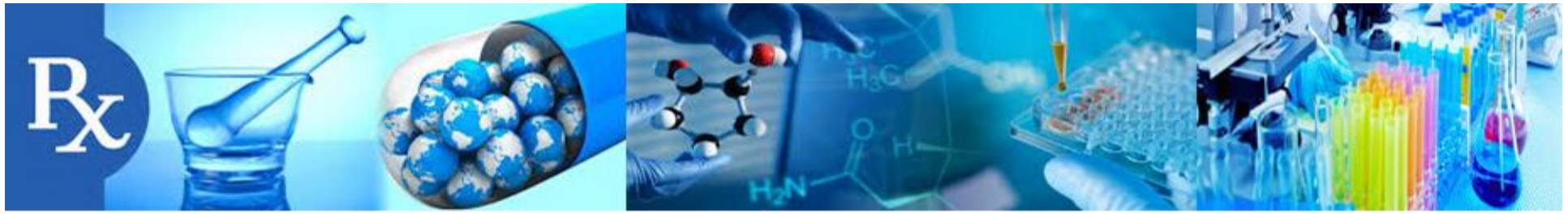
☐ NO



IMPACT EVALUATION:

All those department concerned this change:

Supply Chain:	YES	NO
Quality Control:	YES	NO
Quality Assurance:	YES	NO
Production:	YES	NO
Regulatory:	YES	NO



Supply Chain: Arrangement of material

Q.C : Specs change

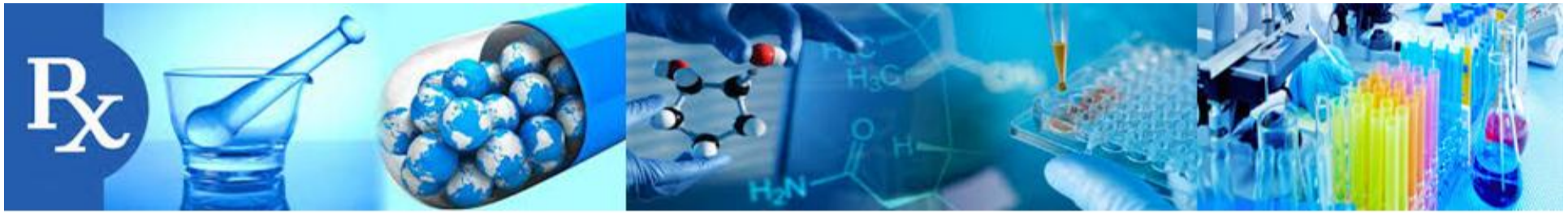
Q.A : Documents changes

Production: facilities/Trained staff

Regulatory : Informed concerned Regulatory Bodies

World Health Organization

ICH



REFERENCES FROM REGULATORY BODIES:

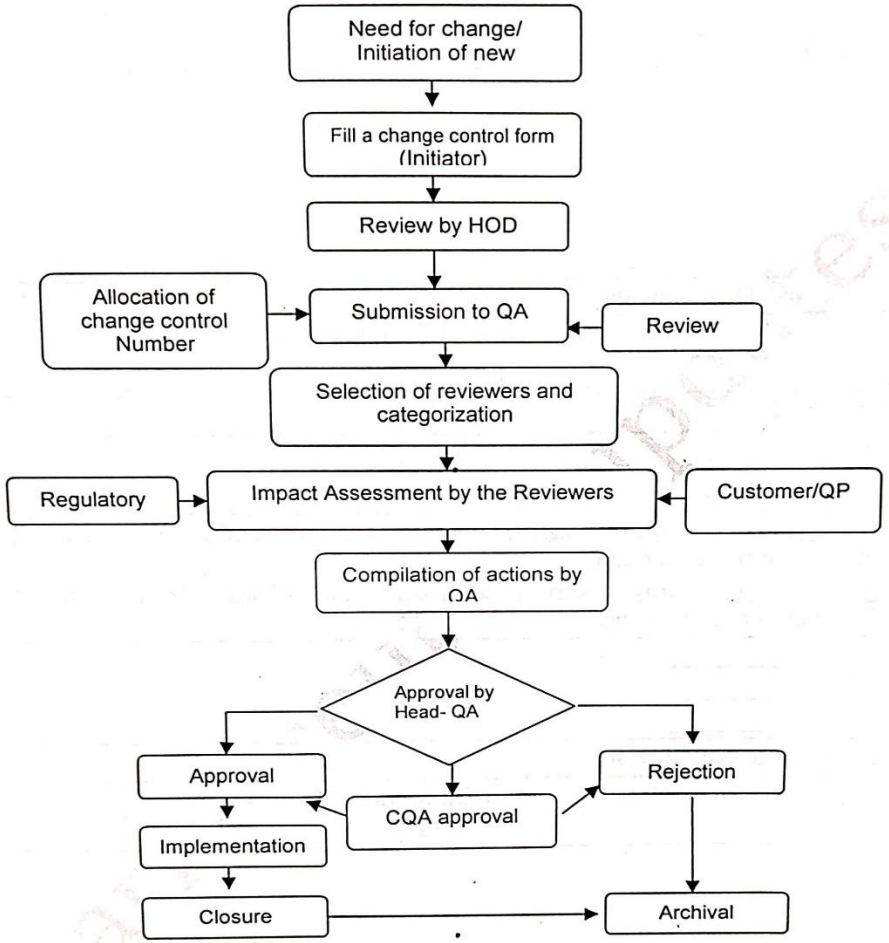
ICH Quality Guide lines.
Q7
http://www.ich.org/products/guidelines/quality/article/quality-guidelines.html

PIC/S
PIC/S Recommendations PI 006-3
http://www.picscheme.org/

WHO
WHO GMP guidelines – Technical Report series n. 937
http://apps.who.int/medicinedocs/en/d/Js20108en

World Health Organization ICH

Flow of Change control



HOD : Head of Department, QP : Qualified Person, CQA : Corporate Quality assurance

- **Define Change Control.** Explain its importance in pharmaceutical quality management systems.
- **List and explain the types of changes** managed under a Change Control system with suitable examples.
- **Describe the steps involved in the Change Control procedure** in a pharmaceutical manufacturing unit.
- **Explain the role of Change Control in compliance with GMP and SUPAC guidelines.**
- **Differentiate between minor, major, and critical changes** in Change Control with examples.

REFERENCES

•Remington: *The Science and Practice of Pharmacy*, 22nd Edition, Pharmaceutical Press.

•Kokate C.K., Purohit A.P., Gokhale S.B. – *Textbook of Pharmacy*.

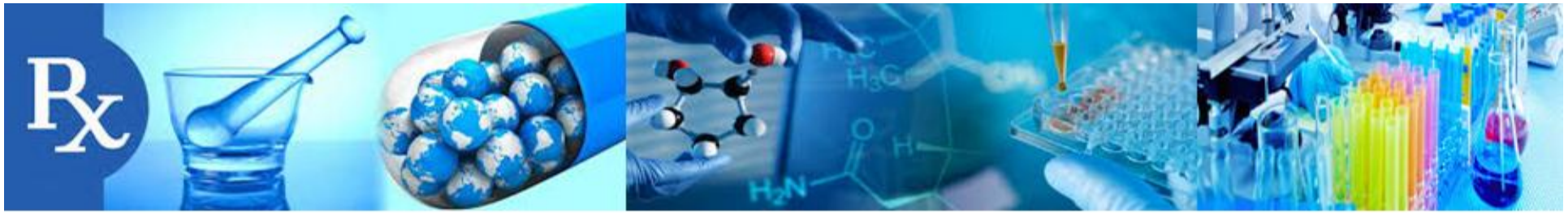
•B. Suresh, S. B. Gokhale – *Pharmacy Education in India*.

•Lachman L., Lieberman H.A., Kanig J.L. – *The Theory and Practice of Industrial Pharmacy*

•Sharma, B.D. *Pharmacy Education in India: Past, Present and Future*. Indian Journal of Pharmaceutical Education and Research (IJPER).

•Rao, N. R. (2025). *Evolution of Pharmacy Profession in India*. International Journal of Pharmaceutical Sciences.

•Indian Journal of History of Science – Special issues on Ayurveda and traditional medicine.



THANK YOU

World Health Organization

ICH