

Optimizing Pharmaceutical Operations and Improving Compliance

Unlocking Excellence: Introducing the 4Ps Method

Agenda

- Introduction
- Challenges in Pharmaceutical Industries
- Concept of 4Ps Method and overview
- Key benefits

Introduction

“Resources India” established with objective, to conquer and ameliorate existing challenges of operations and compliance management system of pharmaceutical industries.

We derived a method designated as “4Ps Method” to conquer challenges as:

- Repeated observations cited by Regulatory Authorities.
- Repeated deviations from established procedures.
- Deficient Procedures.
- Inconsistent practices.

Challenges in Pharmaceutical Industries

- Challenges of pharmaceutical industries have been surfaced out based on:
 - Two decades of experience with leading companies.
 - Exposure to many regulatory audits i.e., USFDA, MHRA, WHO, TGA etc and its compliance processes.
 - Working together with Quality Leaders, Subject matter experts and consultants across the globe.
- Also, we performed data analysis for more than 50K observations given by USFDA for last 16 years from fiscal year 2006 to 2022 to surface out challenges.
- Data analysis performed deriving Categories, Sub-categories, Type of observations and Specific Areas, from the long descriptions of observations available at USFDA website. Analysis of observations and insights illustrated in next slides:

Source of data: <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/inspection-observations>

Challenges in Pharmaceutical Industries

Yearly trend of observations (52.2K, In Nos.)

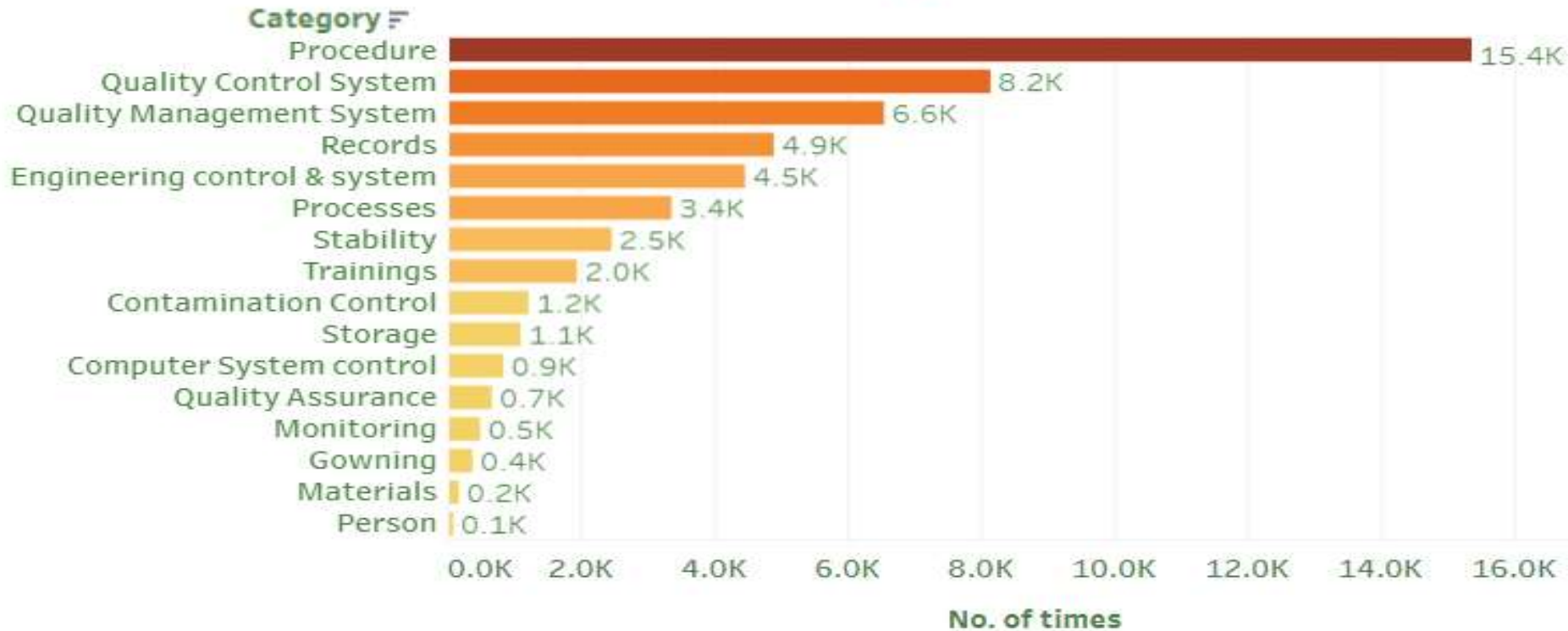


Insights:

- Average 3K observations are cited by the USFDA across the globe per year.
- Less observations in Year 2020- 2022 are due to less inspections conducted during COVID-19 pandemic.
- Trend for last 18 years reflecting challenges are continuing.

Challenges in Pharmaceutical Industries

Observation Categories



Insights:

- 52.2K observations are categorized into 18 types.
- Procedures are identified as highest (15.4K) in all categories.
- Other major categories are Quality control system, QMS, Records, Engineering control system, Processes, Stability, Trainings and so on.

Challenges in Pharmaceutical Industries

Procedure's observations yearly trend

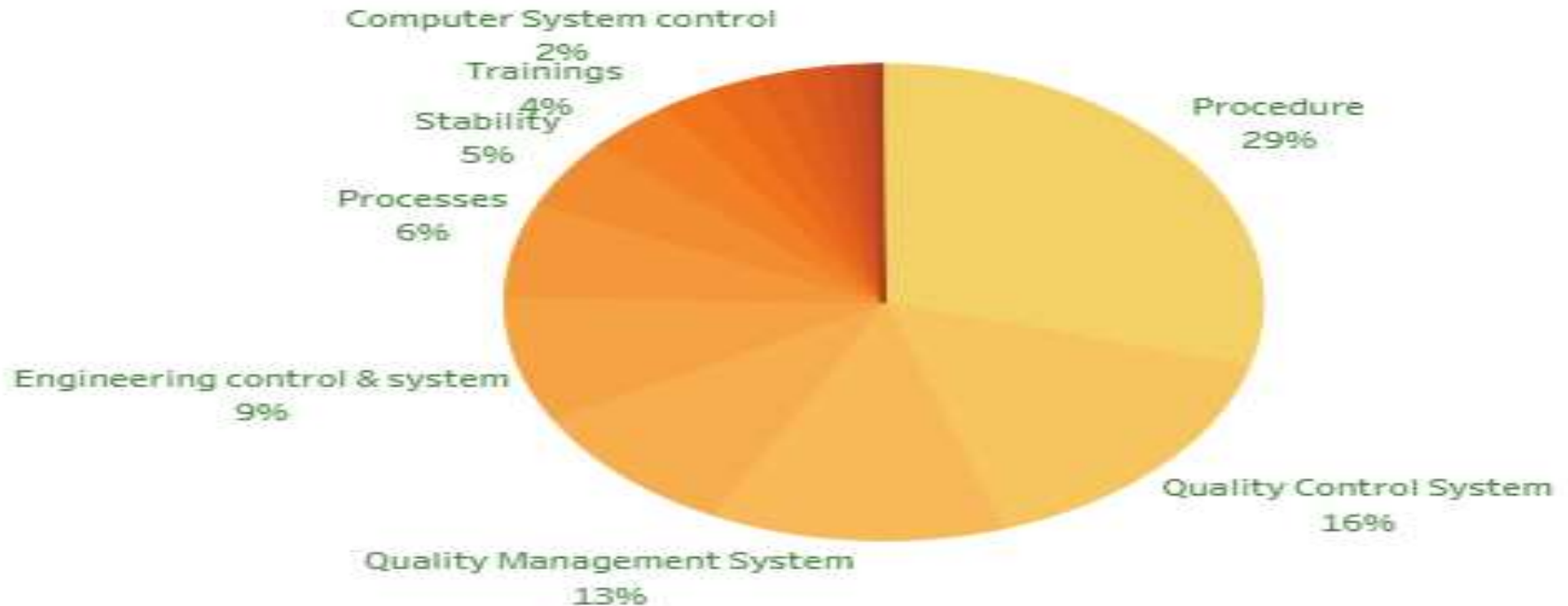


Insights:

- Average 0.9K nos. out of 3K nos. per year observations are related to 'Procedures'.

Challenges in Pharmaceutical Industries

% Categories

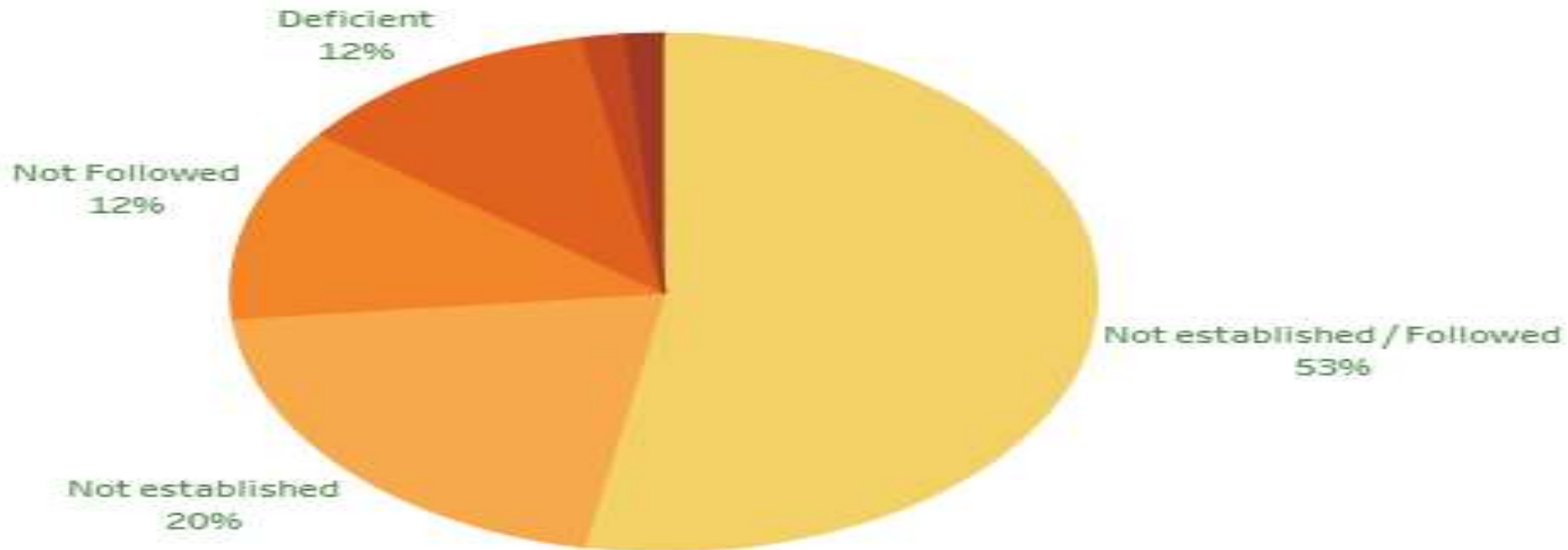


Insights:

- % of observations reflecting as 29% are related to 'Procedures'.
- % of other major categories are Quality control system (16%), Quality management system (13%), Records (9%), Engineering control (9%) and so on.

Challenges in Pharmaceutical Industries

Type of observations



Insights:

- Procedures categories analysed further for 'Type of observations' and identified as 85% observation are either procedure not established or not followed or both.
- **Analysis given insight as 'Procedures: Not established / Not followed' are the biggest challenges of Organization.**

Challenges in Pharmaceutical Industries

Procedures are being established / revised by **People** in organizations and
People are following or practising these procedures.

Then

Why procedures are not being followed adequately?

Why there are challenges to practicing established procedures?

Analysis performed to answer these questions and reasons are identified as:

- Mindset.
- Inadequate understanding of processes.
- Inadequate communication methodologies.
- Inadequate design / structure / contents of procedures.
- Inadequate allocation of resources.

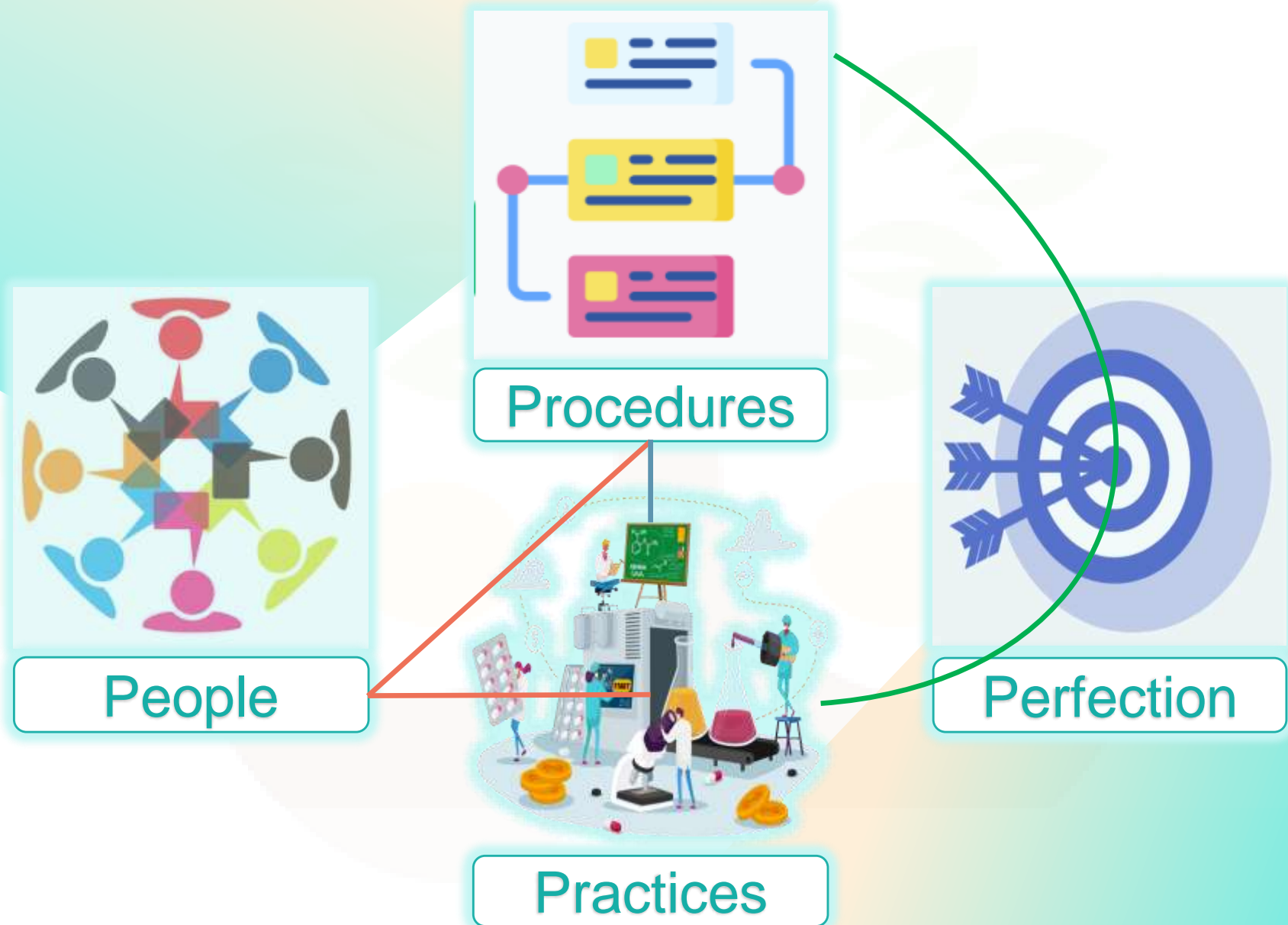
Concept of 4Ps Method and overview

- In 4Ps Method, 4Ps represent **People, Procedures, Practices and Perfection**.
- '4Ps method' developed to conquered challenges after experiencing for two decades with pharmaceutical industries.
- Two key resources i.e. People and Procedures are identified as success factors to conquered and ameliorate these challenges.
- People are the admirable resource of the organization who are governing all other industrial resources. And procedures are leading resources which ensure consistent operations and qualities of processes and products.
- This method comprises management techniques to identify, conquered and ameliorate contributing factors of these challenges.
- This method will improve efficiency of operations and compliance management systems.

The 4Ps Method Overview

So, Resources India derived a method which comprises of management techniques to improve coordination's between People, Procedures and Practices to achieve Perfection. The method designated as '**4Ps Method**' to overcome one of the biggest challenges of compliances and operations.

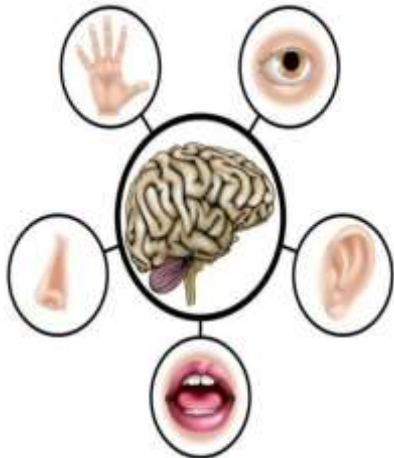
The 4Ps Method Overview



People



People



- People are the admirable resources whose capabilities includes:
 - ❖ Human Intelligence.
 - ❖ Power of communication.
 - ❖ Capacity for knowledge acquisition and sharing.
 - ❖ *Mind* having storage capacity of 2.5 million gigabytes which is equal to storage of three million hours (Approx 343 Years) of TV shows.
- An innovative journey started from ancient era to this scientific era are evidencing the capabilities of people.
- People can do miracles; Mindset is the key.

Procedures



Procedures



- Procedures are leading resources of all other resources.
- Procedures elucidate methods, parameters monitoring and controls, records, frequencies and handling abnormalities of activities to be performed.
- A standardized, simplified and presentable procedures enables people to handling other resources uniformly and efficiently.
- Procedures ensure compliances to regulatory guidelines and relevant scientific laws.
- Procedures guide people to make right decisions.



Practices



- Practices are the key towards involvement and get mastery in activities.
- Practices of procedures will make people master of activities and ensure compliance of procedure consistently.
- Right practices of procedures will ensure consistent performance and qualities of products.
- Mastery in activities, improve efficiency of associated resources.

Perfection

- Techniques will be used to step up the qualities quoted to achieve perfection for People, Procedures and Practices.



Techniques

People

- Cognitive
- Proactive Management
- Trainings & Workshops
- Appreciations

Procedures

- Comparison
- Sequencing
- Punctuations
- Visualization
- Brainstorming
- Communication

Practices

- Demonstrations
- Displaying
- Workshops
- Resources

Comparison Technique

This technique will be used by comparing the existing instructions of procedures with following elements:

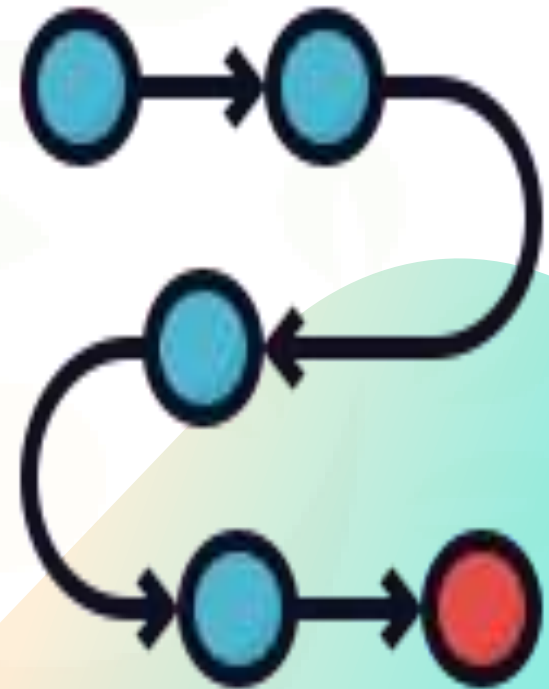
- ❖ Guidelines / Scientific Rationale.
- ❖ Instructions in other procedures.
- ❖ Recording Methods and Formats.
- ❖ Rationale for frequencies and acceptance criteria.



Sequencing Technique

This techniques will be used to review the procedures for writing in a sequential manner as processes flow. Elements to be involved in these techniques are

- ❖ Review and preparation of sequence of processes flow.
- ❖ Verification of sections, subsections and instructions of procedures as per process flow.



Brainstorming Technique

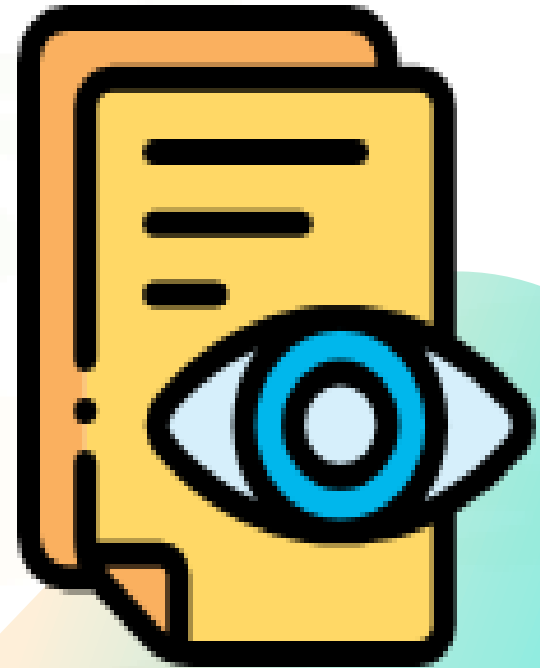
In this technique, draft procedures are being discussed with subject matter experts, team members involved in preparation, execution review and approval of procedures and their valuable inputs will be incorporated.



Visualization Technique

❖ Visualization Technique: In this technique following elements are involved to improve understanding of procedures and its consistent practices:

- ❖ Display of instructions / symbols / indicators,
- ❖ Flow Charts / Checklists,

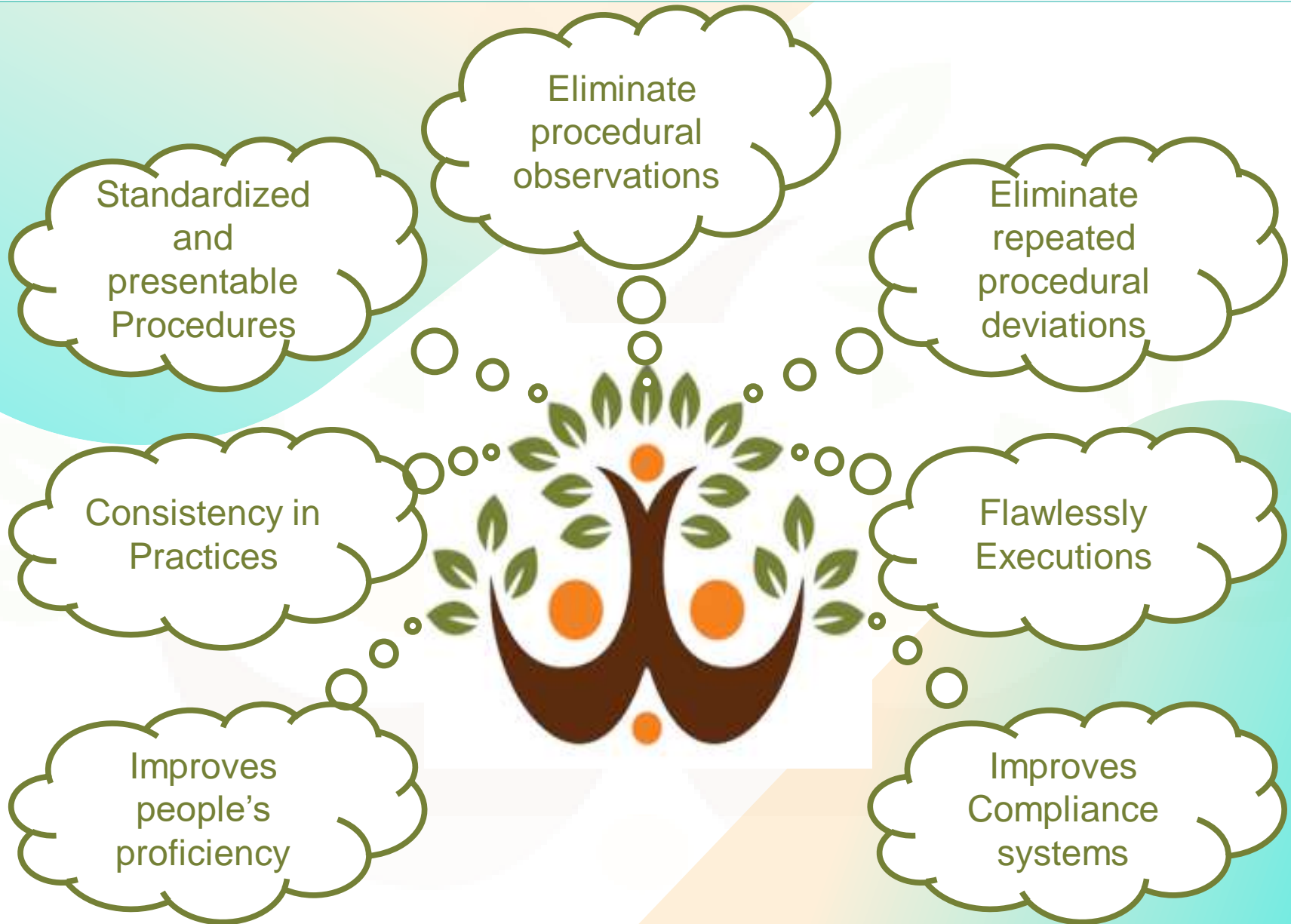


Demonstration Technique

❖ **Demonstration Technique:** In this technique, procedures are demonstrated to the people who are involved in execution of activities.



Key Benefits







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Thank You