CAPA basics and tools you could use.

Presented by Trevor Schoerie

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PharmOut

Regulatory Knowledge, Practically Applied.

Outline

Introduction

- What is CAPA?
- CAPA Tools
- CAPA Workflow

What is CAPA?

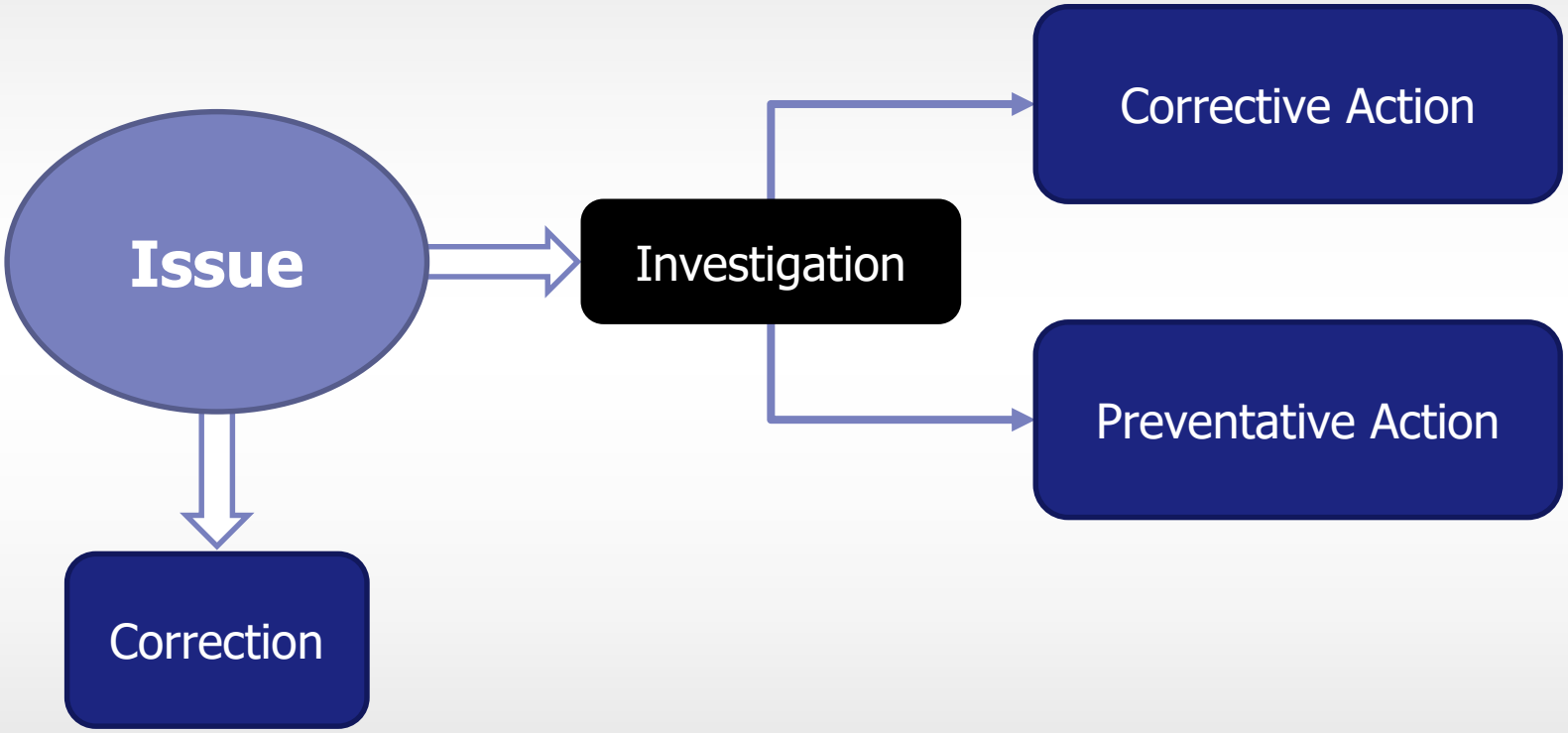
"... CAPA is a quality assurance system, which addresses quality events, which may occur or could be anticipated to occur during healthcare products manufacturing."

An improvement tool used within good manufacturing practice (GMP) principles and various ISO standards

Aims to prevent issue recurrence (corrective action) or to prevent issue occurrence (preventative action)

CAPA is the core of continuous improvement systems

Correction, corrective action and preventative action



Key CAPA definitions

CAPA

Corrective and Preventative Action

A systematic approach that includes actions needed to correct (correction), avoid recurrence (corrective action), and eliminate the cause of potential non-conforming product and other quality problems (preventative action)

Correction

Action to eliminate a detected non-conformity. Corrections typically are one-time fixes. A correction is an immediate solution such as a repair or rework.

- Also known as remedial or containment action.

Key CAPA definitions

Corrective Action

Action to eliminate the causes of a **detected** nonconformity or other undesirable situation. The corrective action should eliminate the recurrence of the issue.

Preventative Action

Action to eliminate the causes of a **potential** nonconformity or other undesirable potential situation. Preventative action should prevent the occurrence of the potential issue.

Corrective or preventative?

Name it **corrective action** only if you already have a product non-conformance or process non-compliance

- Product failing specifications
- Confirmed customer complaint
- Use of obsolete documents
- Audit finding

Name it **preventative action** whenever the product, process or system is still in conformance but you discover root cause with the potential to create non-conformities

- Developing adverse trends from monitoring systems
  - Shifts
  - Trends
  - High Variability, and so on

Name it **preventative action** if it is purely a recommendation to enhance or improve any product, process or system

- Changing to new material or new design
- Implement new (enhanced) processes

The Quality System and CAPA

Quality System

- Defines processes to fulfil product requirements, customer satisfaction and continuous improvement

QMS

- How quality policies are implemented and quality objectives are achieved

Continuous Improvement

- Ongoing activities to evaluate and enhance the Quality System

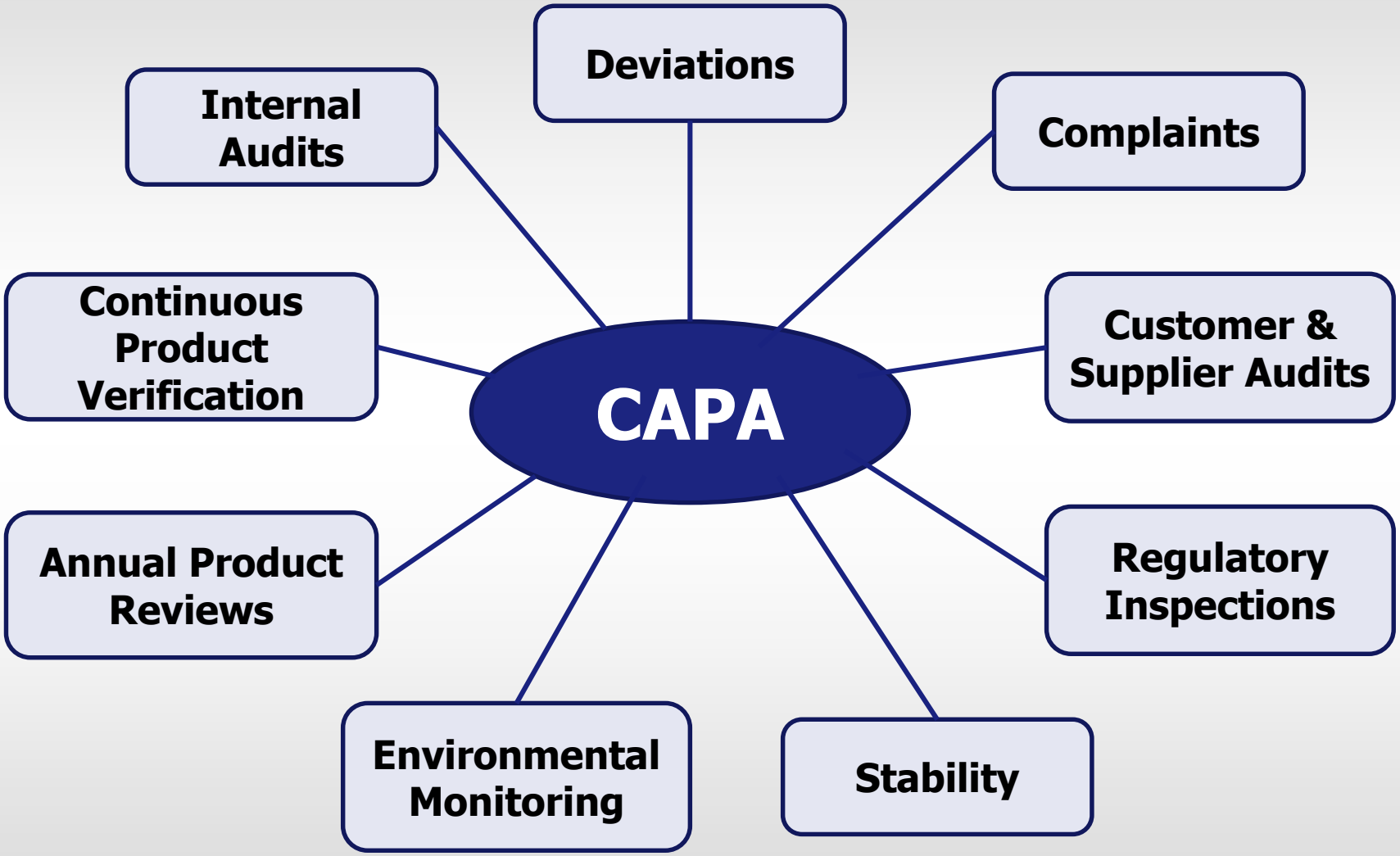
Data Analysis

- Demonstrates the suitability and effectiveness of the QMS

Corrective Actions

- Identifies action needed to correct the causes of identified problems

Quality Systems Centre - CAPA



Tools for identifying causes

Tools

- 5 Whys
  - (Who, What, When, Where, Why, How)
- Cause & Effect
- Problem Description
- Fault Tree Diagram
- Change Analysis
- Factor Analysis
- Brain storming

Tools

- Flow charting
- Root Cause Mapping
- Simple Checklists
- Fishbone diagrams
- Pareto chart
- Failure Mode & Effect Analysis
- Change Analysis

Tool: 5 Why's

- Step 1:

  Establish a problem statement

  E.g. "I was late to CAPA training today"

- Step 2:

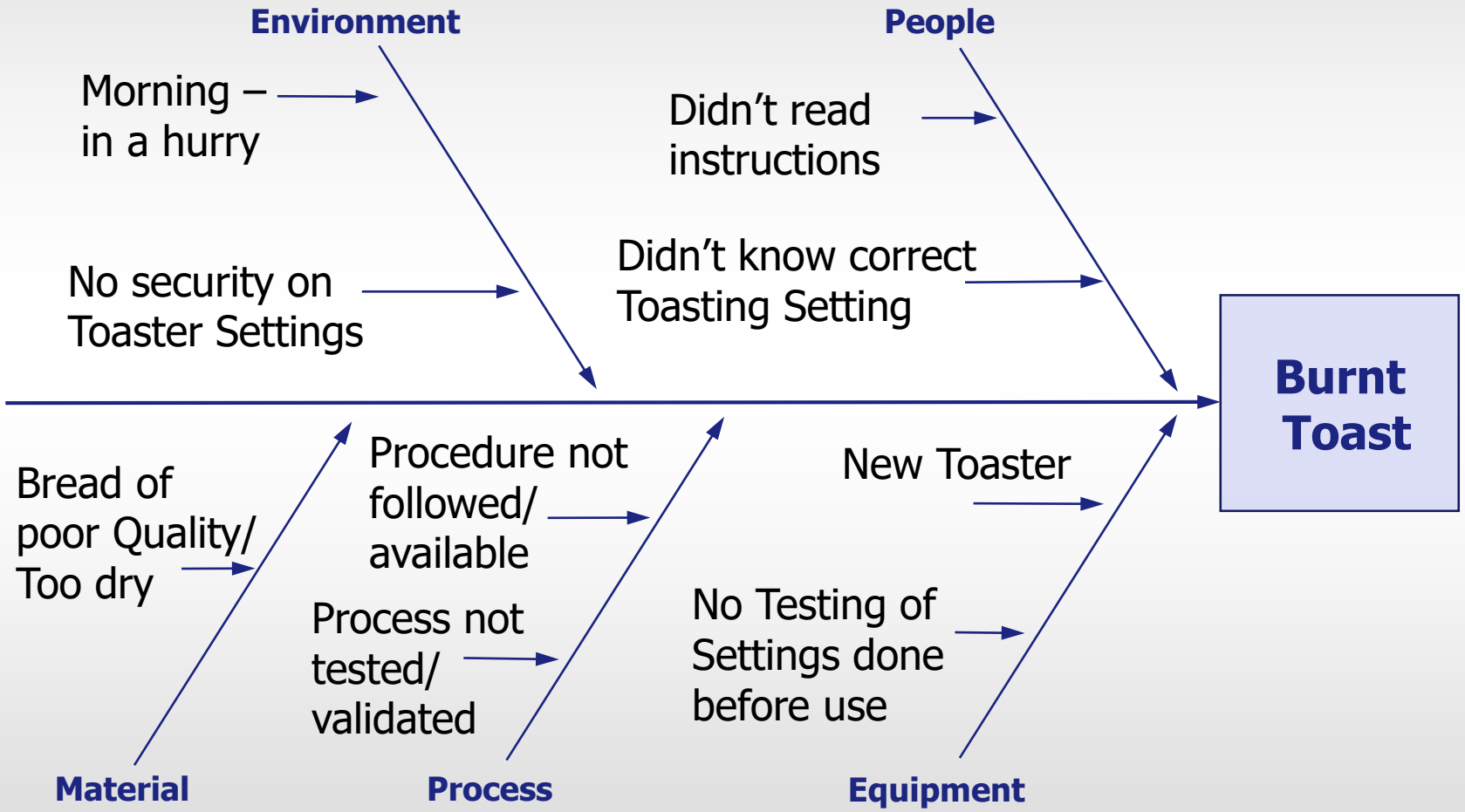
  Ask (and answer) the question "Why" 5 times

- Step 3:

  The root cause becomes apparent by the 5th Why

Tool: Fishbone Diagram

Example: **CAUSES OF BURNT TOAST**



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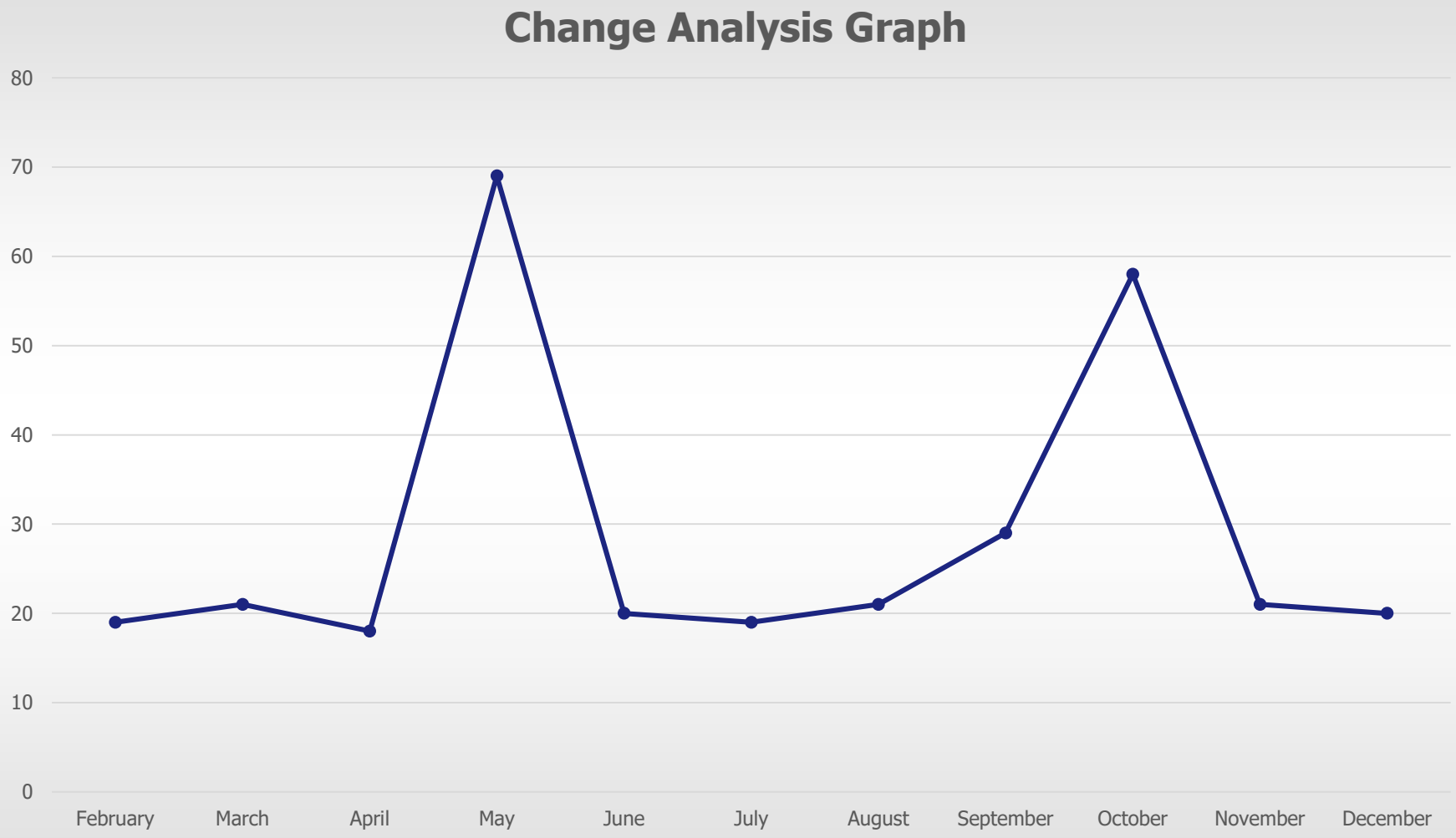
Tool: Problem Description

Date (week of)	Facts
October 12	Results within specifications
October 19	Floor maintenance housekeeping performed during the weekend
October 26	High variability of results. The two balances were found out of tolerance. Balances were calibrated.
November 2	Results within specifications
November 9	Results within specifications
November 16	Results within specifications
November 23	Results within specifications
November 30	Results within specifications
November 7	Floor maintenance housekeeping performed during the weekend
November 14	High variability of results. The two balances were found out of tolerance. Balances were calibrated.
November 21	Results within specifications

Tool: Change Analysis



Tool: Comparison Matrix

	Is	Is not	Possible causes	Further action
Where	Johnstown Plant	Cedarville Plant	Equipment; Inspection procedures	Interview plant management
What	Pit fragments less than 5mm	No fragments larger than 5mm	Improperly maintained pitters; Performance data; Line speeds	Analyse maintenance logs and production records
When	Production after July 30	Production before July 30	Change in fruit characteristics; Pitter performance	Analyse maintenance logs and fruit characteristics
Who	Smith; Abbot farms	All other farms	Soft fruit	Measure fruit softness

Tool: Barrier Analysis

Types of barriers:

Physical barriers

- Separation among manufacturing or packaging lines
- Emergency power supply
- Dedicated equipment
- Barcoding
- Keypad controlling doors
- Software that prevents further input if a field is not completed

Administrative barriers

- Training and certifications
- Clear procedures and policies
- Adequate supervision
- Adequate load of work
- Use of checklist
- Verification of critical task by a second person

Tool: Standard Checklists

Checklists are beneficial in providing a standard, consistent list of potential sources of error.

For example:

- Was the correct procedure followed?
- Was the person trained in the procedure?
- Does the procedure match actual practice?
- Is this a recurring issue?
- Was there an equipment problem?
- Was the equipment calibrated?

Tool: Brainstorming

- Brainstorming can be used in association with other Root Cause Analysis tools
- Brainstorming is a method for generating a large number of creative ideas in a short period of time

Approach:

- Unstructured shout-out ideas
- Thinking "outside the box"
- Structured rotation around the room for ideas

Chronology

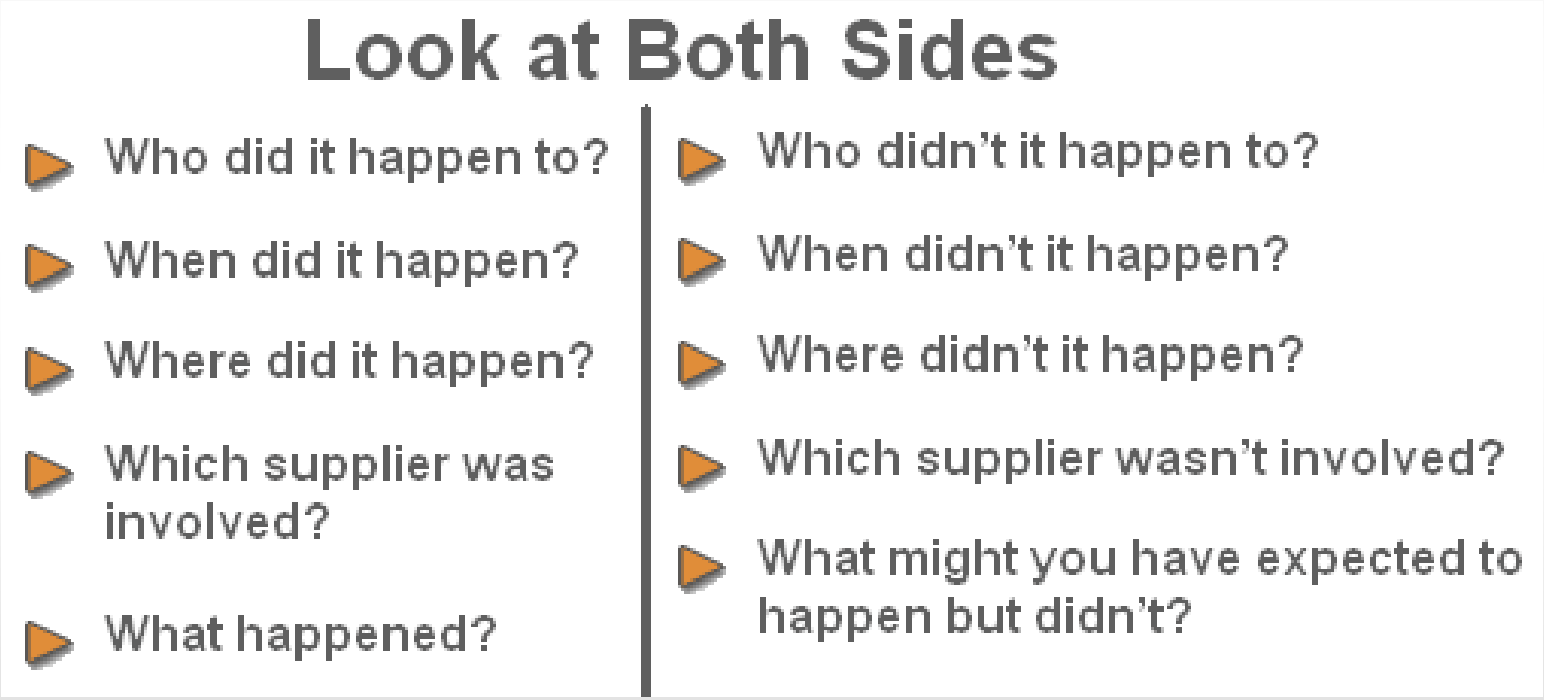
Causes Of Burnt Toast

Time	
Prior to today	Used old Toaster
Last night	Wife introduced New Toaster
8am	Awoke after late night
8.10	Removed bread from Pantry. Noted old bread was dry
8.15	Inserted bread to toaster as per previous day
8.16	Depressed Toasting lever
8.20	Toaster smoking, toast burnt
8.21	Pressed abort and removed burnt toast
8.22	Recognised Toaster was new
8.23	Called wife to locate instructions. Sitting beside toaster
8.24	Went to work with no Breakfast

Tool: Comparison Matrix

Comparison Matrix

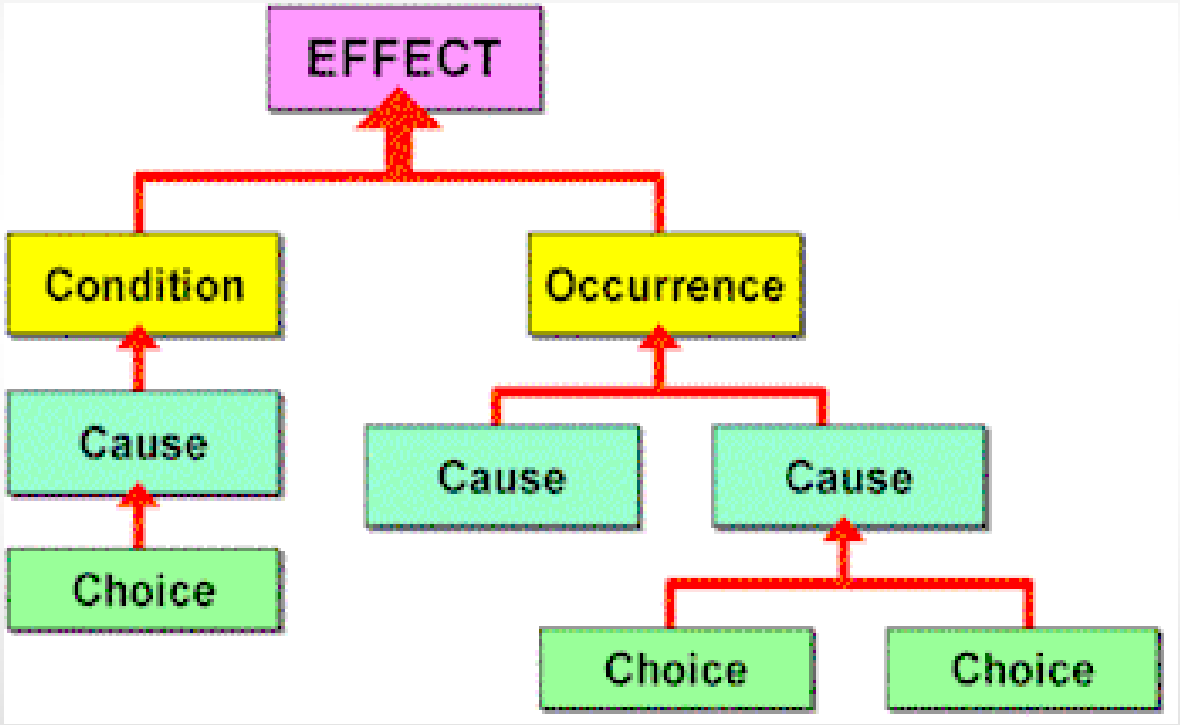
- Tool aimed at focussing on the key areas implicated in the problem and remove areas of investigation not implicated



Tool: Fault Tree Analysis

Fault-Tree Analysis

- Tool used to identify the key activity streams that may have led to the problem being displayed
- Helps identify the true root cause(s)



This method is similar to the Root Cause Mapping

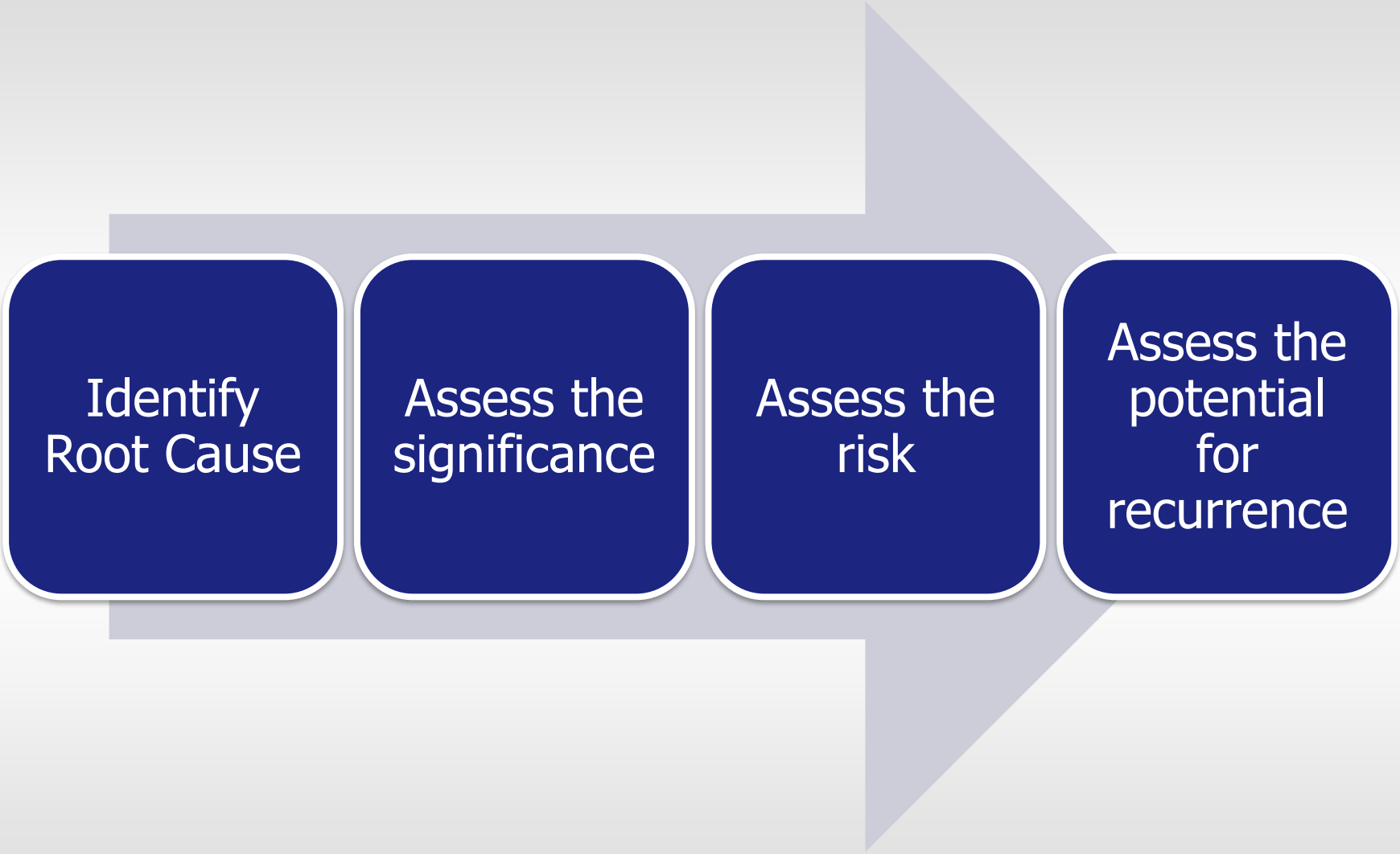
Root Cause Analysis (RCA) tips

Root Cause Analysis (RCA) is a key element to a site's Quality System.

Important considerations include:

- Don't forget the past – has this occurred previously?
- Don't stop at the first plausible explanation – complete the process to eliminate *all* other possible causes
- There may be *more than one* root cause
- If you do not find a confirmed root cause, address the potential root causes and monitor the issue
- Monitor – follow-up on implemented actions

CAPA work flow



CAPA form

Section 1– Issue Details

Section 2 – Immediate actions

Section 3 – Investigation

Section 4 – Root Cause

Section 5 – Corrective actions

Section 6 – Preventative actions

Section 7 – CAPA Implementation Plan

Section 8 – CAPA Effectiveness Check and Summary

Section 9 – Approval

Describe the issue

Part 1 – Issue Management *(Identifying & defining the problem, investigation and identification of the Root Cause(s)*
Issue details *(Define the Issue/Problem)*
What happened:
When (date/time issue occurred):
Where (location issue occurred):
Initial consequence (define any immediate impact from the issue):

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List the immediate actions taken

Immediate actions - *immediate actions required to eliminate/minimise further impact* - *Also known as a correction action (save remaining passengers, quarantine existing product/cease production)*
List any immediate actions:

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Describe investigation undertaken

Investigation
Describe the investigation (identify what was done to identify Root Cause(s)):

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List the root cause(s) of issue

Root Cause
Define the root cause(s) of the issue/problem:

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List proposed corrective actions

Corrective actions to address the issue (short-term actions)
List possible Corrective actions to address the issue:

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List proposed preventative actions

Preventative actions to address deficiencies (longer term actions)			
List possible Preventative actions to address similar issues arising:			
Change control required?	❒ Yes ❒ No ❒ N/A	CC Number:	

CAPA Form

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Detail the CAPA Implementation Plan

Part 2 – CAPA *(Plan implementation of CAPA Actions)*	
Corrective Action *(Refer to Corrective Action listed in Part 1)*	
Provide details on each CA's required:	By who & by when

Detail the CAPA Implementation Plan

Preventative Actions *(Refer to Preventative Actions listed in Part 1)* -	
Provide details on each PA required	By who & by when

CAPA Form

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Describe post-implementation effectiveness checks

CAPA Effectiveness Check	
Define time from Implementation for Effectiveness review:	
Define what should be reviewed/check:	

Describe post-implementation effectiveness checks

CAPA Effectiveness Summary
Was the CAPA Effective?
Are there any further actions required?

CAPA Form

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- **Section 9 – Approval**

Final CAPA Approval

Approval	Signature	Name	Date
Author Reviewed & Approved			
QA Reviewed & Approved			

10 common mistakes

01 Timeliness (lack of)

02 Everything is an isolated event

03 Root cause not identified

04 Correcting the symptom instead of the cause

05 Lack of interim corrective actions

06 Root cause identified by not corrected

07 Lack of true preventative action

08 Lack of effectiveness verification

09 Multiple CAPA systems without correlation

10 Abuse of human error and retraining

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Thank you for your time.
Questions?

Trevor Schoerie

Trevor Schoerie
Managing Director

trevor.schoerie@pharmout.net
www.pharmout.net