

**DUKE****DOCUMENT NUMBER:** COMM-QA-042 JA3**DOCUMENT TITLE:**

Root Cause Analysis Job Aid JA3

DOCUMENT NOTES:**Document Information****Revision:** 01**Vault:** COMM-QA-rel**Status:** Release**Document Type:** COMM-QA**Date Information****Creation Date:** 28 Jan 2022**Release Date:** 14 Feb 2022**Effective Date:** 14 Feb 2022**Expiration Date:****Control Information****Author:** AKB8**Owner:** AKB8**Previous Number:** None**Change Number:** COMM-CCR-198

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ROOT CAUSE ANALYSIS JOB AID

Purpose:

- A thorough investigation and root cause analysis (RCA) are important to ensure robust GMP documentation around events to identify a root cause. These types of investigations also then allow for appropriate changes, corrective and/or preventive actions (CAPAs), to be implemented to prevent events from happening repeatedly.
- This job aid, COMM-QA-042 JA3, is intended to provide additional guidance on investigative steps to help identify a true root cause and tools for use when conducting a RCA. It should be used in conjunction with the SOP COMM-QA-042 *Deviations and Investigations* and requirements outlined there to best assess how to document and identify the root cause and any contributing factors for an event. The list of RCA tools included below is not intended to be exhaustive or to note an exclusive list of tools that can be used for related investigations.

Investigation Instructions:

- Understand the Event:
 - Work to identify the facts of what happened: Who, What, When, Where, How?
 - Which products and/or batches were impacted?
 - Interview or discuss with staff directly involved in the event.
- Investigate the Event:
 - Develop a chronological timeline of the event, including all important details.
 - Obtain photos, documentation, records, etc. to help support the event and investigation. Focus on data and the facts.
 - Generate any additional data needed to support the investigation.
 - Read relevant SOPs and talk with people, as needed, to clarify any questions.
 - Be concise but thorough to ensure the investigation is easy to read but detailed to describe the event.
 - Work as a team with individuals close to the process and involved with the event.
 - Take a systematic, step-by-step approach to ensure everything is considered and addressed in the write-up.
- Root Cause Analysis (RCA)
 - Engage other people and brainstorm, as needed, to obtain a full picture of the problem and ensure all considerations are evaluated.
 - Determine which RCA technique or tool to use based on the data and the problem.
 - Dig deep to ensure the most basic root cause is identified.
 - Work hard, asking questions, to not stop at “human error” or “failure to follow SOP,” by pressing with further questioning: Focus on HOW and WHY something went wrong, not solely WHO, and consider what enabled the error/event to occur.

Root Cause Analysis Tools:

5 WHYS

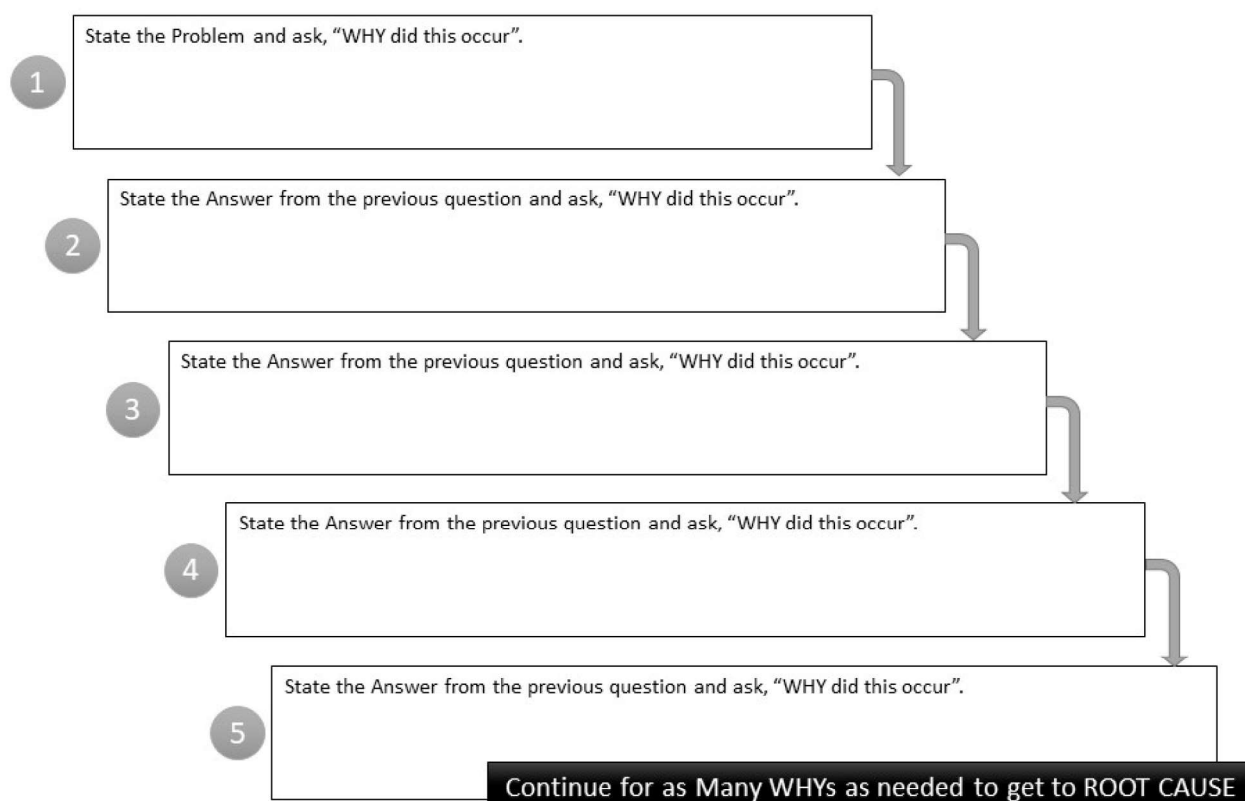
Instructions:

1. The 5 WHYS technique uses a series of “WHY?” questions to drill down into successive layers of the problem, by asking consecutive questions, where each answer becomes the leading information for the next question.
2. Write down the problem statement.
3. Ask why did the problem happen and write down the answer.
4. Ask – looking at the prior answer – again why did that occur and write down the answer.
5. And again, ask– looking at the prior answer – why did that happen.
6. Ask this question as often as necessary until the team agrees that the problem’s real root cause is identified. This may take fewer or more times than 5 WHYS.

Example Template:

This exact template diagram does not need to be used for a 5 WHYS RCA, but the 5 WHYS assessment should be clear and outlined in the associated MasterControl event/documentation.

5 WHYS Diagram



6M

Instructions:

1. The basic idea around 6M is to brainstorm and look at the problem in multiple ways. It includes an assessment of 6 “M” factors, including manpower, method, machine, material, milieu/mother nature (environment), and measurement. Descriptions of each of these factors are below in **Table 1**.
2. In evaluating the root cause, each area is considered, and any potential contributions to the event and as the root cause are documented with a specific focus on cause and effect of relationships. The assessment can be captured as a fishbone diagram and/or in a list format by focusing on and describing any potential root causes in each 6M area.

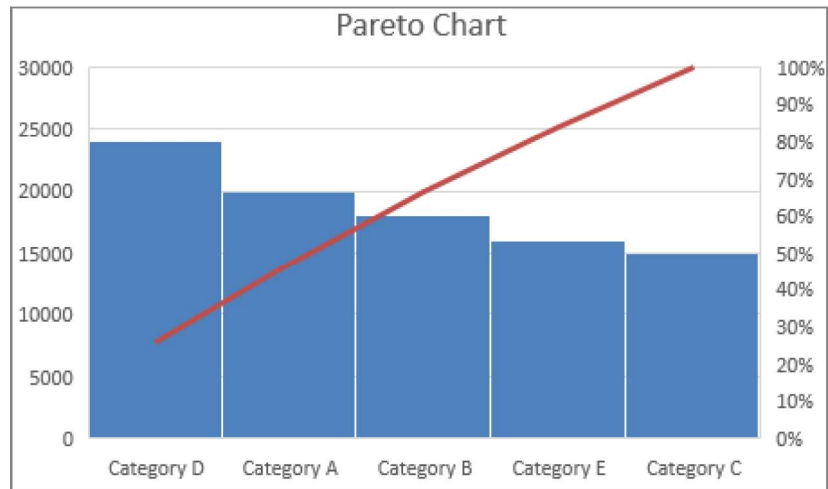
Table 1: 6“M” Factors.

“M” Factor	Description
Manpower	Manpower revolves around the operational and functional labor of people involved in the process. This parameter checks on whether the personnel's technical proficiency, training, and experience are up to standard. Whether the staff has quality consciousness, sense of responsibility and discipline are answered by this 6M method aspect.
Method	Method addresses production and support processes and their application or contribution to product or service delivery. Do any of the methods used in your processes have too many steps and integral activities that don't add value to the whole system?
Machine	Machine seeks to understand equipment, tools, and other facilities together with their underlying support systems. Is the machinery employed for production capable of delivering the intended output? Are machines and tools well-managed to achieve excellence?
Material	Material encompasses raw materials, components, and consumables management to satisfy production and service delivery. This parameter checks on the correct specification of materials, their proper storage, labeling, and subsequent usage.
Mother Nature (Environment)	Mother Nature considers both controllable and unpredictable environmental influences in the operation processes. Weather and other natural events fall into this category. It makes it easy to take note of the many environmental factors that are manageable under ardent considerations and how to handle those that are not.
Measurement	Measurement includes inspection, evaluation, and other physical measures whether manual or automatic. Staying keen about calibration errors and other measurement challenges to avoid inconsistencies becomes important under this parameter.

PARETO CHART

Instructions:

1. A Pareto chart typically contains both bars and a line graph, where individual values are represented in descending order, and a cumulative total is represented by a line. The purpose of the Pareto chart is to identify significant situations/outcomes among a large set of factors. This tool can be utilized when analyzing data about the frequency of problems or causes in a process. It is often used to help identify a problem area that facilitates prioritization of significant problems/trends for corrective measure, when looking across broad operations/processes.



2. Use Pareto charts when analyzing broad causes by looking at their specific components. The left vertical axis commonly represents the frequency of occurrence, and the right vertical axis the cumulative percentage of the total number of occurrences. Each category would represent a situation/outcome/defect/area, etc.
3. To complete a Pareto Chart/Analysis:
 - a. Decide what categories you will use to group items.
 - b. Decide what measurement is appropriate and the timeframe the Pareto Chart will evaluate.
 - c. Collect Data and Subtotal measurements for each category.
 - d. Determine the scale for the measurements collected, the maximum values will be the largest subtotal and mark the scale on the left side of the chart.
 - e. Construct and label bars for each category, with the largest (“tallest”) at the far left, moving left to right in descending order.

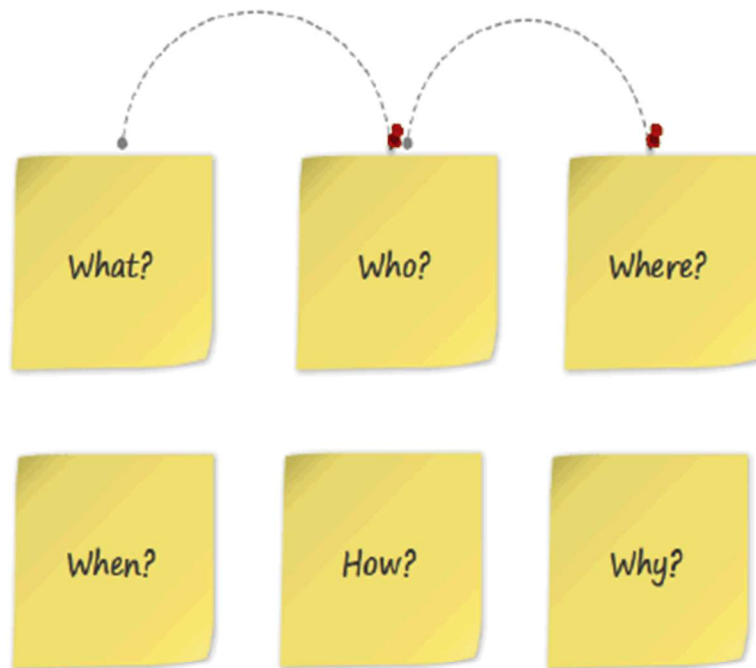
BRAINSTORMING

Instructions:

The brainstorming approach is optimally suited for problem statements that have a relatively small number of possible root causes. For more complicated and challenging problems, other tools and methods may be more efficient. This tool can be utilized for almost any event/deviation and is ideally conducted in a team setting.

1. Review the fact set and data as it is currently understood.
2. Craft a succinct problem statement for this exercise that describes the source of the deviation.
3. Members freely associate possible root causes that would explain the problem statement. There are no bad ideas; write everything down.
 - a. Teams can use sticky notes, erasable board, easel paper, etc.
4. Review the proposed root causes against the fact set and data, eliminating any that don't align with facts and data.
5. For the remaining potential root causes, determine what additional facts and data would be required to test the remaining root causes as a viable hypothesis. Gather the data and repeat the process until one remains.

Example Template:



Signature Manifest**Document Number:** COMM-QA-042 JA3**Revision:** 01**Title:** Root Cause Analysis Job Aid JA3**Effective Date:** 14 Feb 2022

All dates and times are in Eastern Time.

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