

Department	TRG	Project No.	181136_CSLB	Document No.	HBK001	Doc Rev.	01
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CAPA Training Handbook

**Presented By
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1. Tylenol



Watch the news report on Tylenol. Answer the following questions:

- What is the issue?
- Which issues require investigation and may result in CAPAs?

Record your answers in the Table below:

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2. Customer Complaints

The following exercise is aimed to identify possible causes of a customer complaint regarding the visual appearance of purchased McDonalds Hamburgers.

The following is some basic information relating to the issue itself:

A McDonald's customer complained to the parent organisation regarding the significant difference between the Hamburgers portrayed on their store menus and advertising material when compared with examples of purchased burgers. Some key differences were:

Advertised burgers appear:

- Larger
- Have more fillings
- Look more pleasing/healthy

Purchased burgers appear:

- Squashed
- Bun compressed
- Look less inviting/unhealthy



Using the information above:

- What is the issue?

Record your answers in the Table below

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3. Corrections

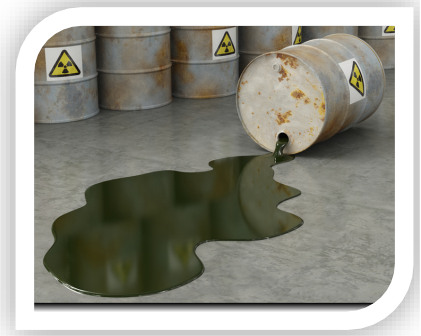
The following exercise is aimed to identify possible corrections.

A drum of concentrated hydrochloric acid has fallen over and spilled at a pharmaceutical facility.



Using the information above, before investigating what caused the leak, what corrections could be taken?

Record your answers in the Table below.



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4. Find the Root Cause



The following exercise is aimed to understand symptoms, casual factors and root causes. From the table below and the information given, fill in the gaps in the white boxes with what you think might be the potential "symptoms", "casual factors" and "root cause".



- **Symptom:**
 - Obvious or detectable manifestation of a causal factor
- **Causal factor:**
 - The condition that directly caused the problem, allowed it to occur, or allowed the consequences to be worse
- **Root causes:**
 - The basic reasons why the causal factors occur or persist

Complete the white boxes in the Table below.

Symptoms	Causal factors	Root cause
	Infected wound	Poor hygiene
Equipment broken	Inadequate maintenance or no maintenance	
Product not homogenous		Procedure in ambiguous and doesn't include sufficient detail
Incorrect information entered into the manufacturing record	Operator did not follow the procedure	
Mathematical calculation mistakes (e.g. rounding errors)		Operator not trained properly on rounding numbers
	Operators failed to detect the incorrect expiration date on label	Excessive load of work

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5. Brainstorming



The following exercise is aimed at using brainstorming techniques to identify possible causes of a train being late.

The Deviation: Expected Train to arrive on time. Train 2 minutes late and no announcement of delay.

Why is the Train late?

Record your answers in the Table below

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6. 5 Why's



The following exercise is aimed at using the '5 why' technique to identify possible causes of an out of specification product.

The Deviation: Final tablet product was found to be dark blue, not light blue as per specifications.

Why is the root cause?

Record your answers in the Table below

Issue:
Why?
Why?
Why?
Why?
Why?
Why?
Possible Root Causes:

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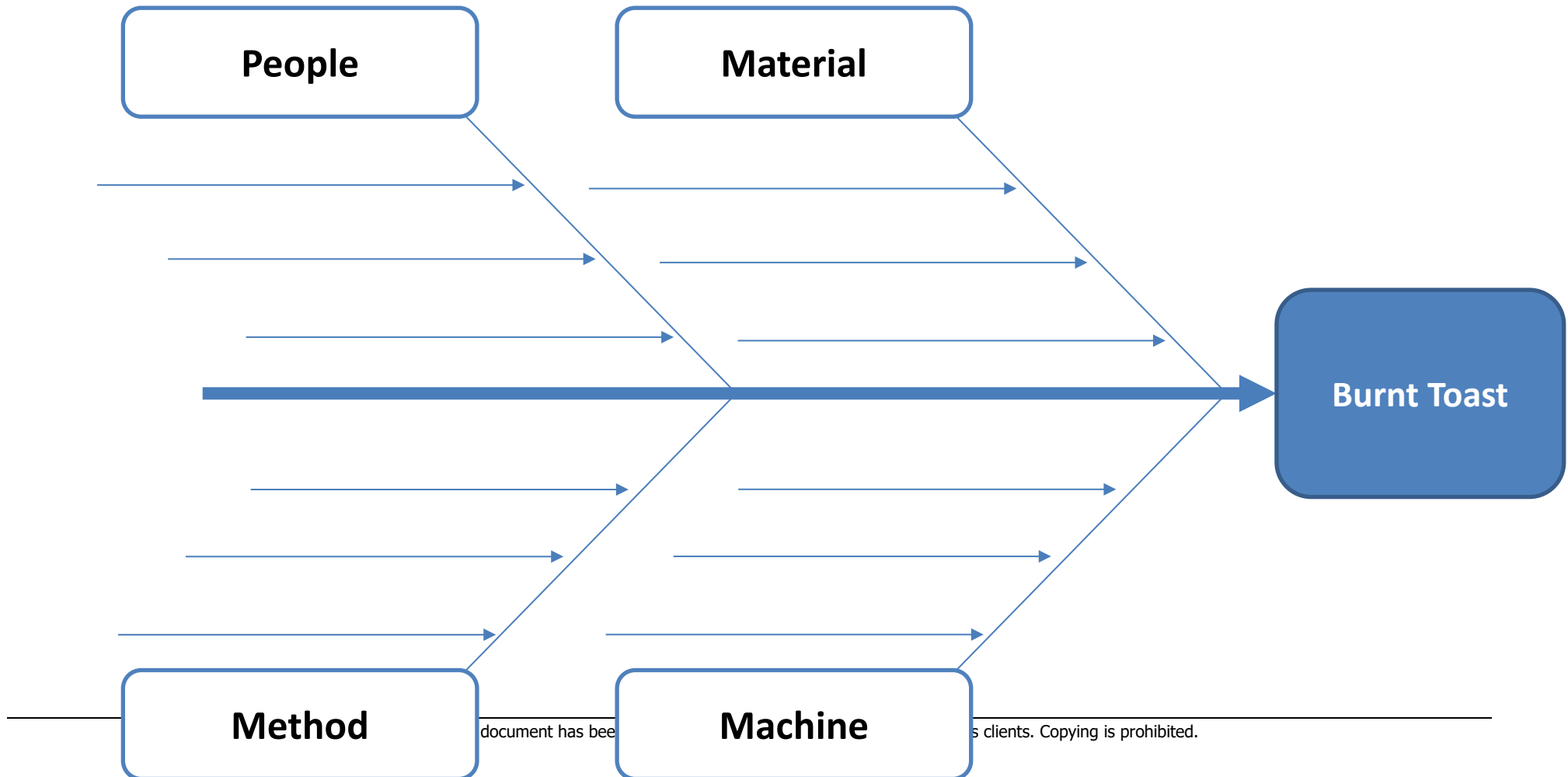
7. Fishbone



The following exercise is aimed at using the fishbone technique to identify possible causes of burnt toast.

The Deviation: Toast came out of the toaster burnt, instead of lightly toasted

Why is the root cause?



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8. Tylenol (continued)



Based on the news report on Tylenol that you watched earlier and your understanding of the issue, use the Root Cause Mapping technique to identify the root cause of the problem.

Then, use a Comparison Matrix to identify the cause of the problem.

Record your answers in the Table below

Root cause mapping

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Comparison Matrix

Did	Did not
Who did it happen to?	Who didn't it happen to?
When did it happen?	When didn't it happen?
Where did it happen?	Where didn't it happen?
Which supplier was involved?	Which supplier wasn't involved?
What happened?	What might you have expected to happen but didn't?

Did the different techniques lead to different root causes?

Record your answers in the table below

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9. Dress Code Violations



During an audit/inspection, repeated dress code violations were observed in a classified manufacturing facility. Identify immediate and planned remedial actions.

Also identify appropriate corrective and preventative actions to address the problem.

Record your answers in the Table below.

Event (Quality System)	Remedial (Immediate)	Remedial (Planned)	Corrective	Preventive
Repeated Dress Code Violations in Classified Manufacturing Area (Audits and Inspections)				

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