Impure Injections Used Columbia Unvitersity, NY 2006-2010

A thorough root cause analysis built as a Cause Map can capture all of the causes in a simple, intuitive format that fits on one page.

Research is been suspended at a prominent brain-imaging center associated with Columbia University. Food and Drug Administration investigations found that the Kreitchman PET (positron emission tomography) Center has injected mental patients with drugs that contained potentially harmful impurities repeatedly over the past four years.

suspended

Evidence: University

employee statements

Safety Goal

Impacted

Customer

Impacted

Investigations by the lab determined that no patients were harmed from the impurities, but this is still a significant issue in a nationally renown laboratory.

Schedule

Impacted

How did this happen?

This issue can be investigated by building a root cause analysis as a Cause Map. To start a Cause Map, the impact to the organization goals is determined. In this example, this issue is obviously an impact to safety because there was potential to harm patients. It is also an impact to the production-schedule goal because research has been suspended. Additionally, this problem is an impact to the customer service goal because this issue raises questions about the

disorders make patients more sensitive Evidence: Patients with disorders like schizophrenia Some natients and severe depression may b particularly particularly affected by the injected compounds sensitive to impurities AND Impurities affect same brain receptors as some illnesses AND Lab prepares Compounds degrade quickly compounds FDA regulates AND injections Potential for niections give Compounds Evidence: FDA to patients prepared quidelines incorrectly by lab Injections didn't meet FDA regulations determined no atients had been AND Evidence Findings from FDA nvestigation Potential issues PET scans with validity of AND require injection with a research results

Injections

necessary for

research

Impurities can

change mood

and behavior

Evidence: Radiotractors

that target brain receptors are more likely to be

Certain

To continue building the Cause Map, keep asking "why" guestions for each added cause until the level of detail is sufficient.

Even more detail can be added to this Cause

investigation the level of detail in the analysis is

Map as the analysis continues. As with any

based on the impact of the incident on the

organization's overall goals.

To build a Cause Map, select one goal and start asking "why" guestions to add

causes. In this case, the first goal considered will be the safety goal. There

patients. Why? Because the injections are necessary for research, because

was a potential for injury. Why? Because impure injections were given to

the labs typically prepare the compounds themselves and because the lab

prepared the compounds incorrectly. When there is more than one causes

that contributed, the causes are added vertically with an "and" between them.

Each impacted goal needs to eventually connect to the same Cause Map. If

they do not, the impacted goal may not be caused by the same problem and

the goals should be revisited.

Inadequate

record keeping

Findings from FDA

Poor quality

control

Findings from FDA

Evidence

Evidence:

radiotracer

AND

PET scans

performed

Evidence: Research

documentation

A Cause Map can be as high level or as detailed as needed. The more significant the impact to the goals, the more likely a detailed Cause Map emission tomography will be warranted. Once the Cause Map is completed, it can be used to develop solutions to help prevent the problem from reoccurring.

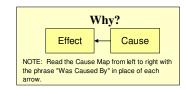
> In this example, the lab is currently changing management and reorganizing procedures to help prevent the similar problems in the future.

Cause Map High Level

validity of research results.



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Impurities in

niections can

affect test

results

injury

vidence:

University

investigation