Over-the-counter (OTC) Medications Recalled
Multiple Countries, 2010

Step 1. Outline
Define the Problem

What	Problem(s)	Recall of over-the-counter products
When	Date	April 30, 2010
	Time	N/A
	Different, unusual, unique	Contaminants in raw material
Where	State, city	Fort Washington, Pennsylvania
	Facility, site	Manufacturing facility
	Unit, area, equipment	Liquid product manufacturing line
	Task being performed	Routine inspection

Impact to the Goals

Safety	Product did not meet required quality standards	
	Remote concern for health risk to consumers	
Environmental	N/A	
Cust. Service	Product recall (1,500 lots)	
Property, Equip, Mtls		?
Production-Schedule	Manufacturing on hold	?
Labor, Time	Investigation	?
	This incident	?
Frequency	5th recall in less than a year	
	Annualized Cost	?

On April 30, 2010, following a 10-day FDA inspection of a U.S. manufacturing facility, 43 name-brand over-the-counter (OTC) children's liquid medications were voluntarily recalled. Although there have not yet been any reported adverse events associated with the recalled medication, the impact of the issue has been far-reaching.

Timeline

Date	Description
January, 2010	After receiving reports of moldy smells emanating from over-the-counter medicines made at a plant in Puerto Rico, the company recalled several hundred lots of adult and children's products
	FDA sent warning letter expressing concerns about the control over the quality of its drugs and the company's failure to aggressively investigate and correct quality problems
February, 2010	FDA met with high level management of the company and expressed the agency's serious concerns about their manufacturing operations
April 19, 2010	FDA inspection of Fort Washington facility began
April 30, 2010	Recall of 43 name brand over-the-counter liquid medications

Once we've completed the first step, we move on to the root cause analysis, or Step 2. We begin the analysis with the impacts to the goals and ask "Why" questions to complete the Cause Map. Because the FDA's investigation report has not yet been released, the Cause Map we have so far is very basic. Essentially, the recalls occurred because unacceptable product was released to consumers. It was released because the finished product met testing requirements. However, it was unacceptable because it did not meet quality standards, because of contamination in the raw materials that were used. At this point in the map, we run into more questions. Even more detail can be added to this Cause Map as the analysis continues and more information is released. As with any investigation the level of detail in the analysis is based on the impact of the incident on the organization's overall goals.

There is the potential (although believed to be remote) for an impact to consumer health, which is an impact to the safety goal. Additionally, the drugs were recalled for not meeting required quality standards, which can also be considered an impact to the safety goal. The product recall, which encompassed 1,500 lots of 43 products, is an impact to both the customer service and property goal. The cost of this recall has not yet been estimated. The manufacturing facility is on hold, which is an impact to the production goal. Lastly, the time and costs associated with the investigation to determine what went wrong is an impact to the labor goal. We can record these impacts to the goals in the outline (Step 1).

Step 2. Cause Map
Root Cause Analysis