Heparin contamination - 19 lives lost
January 2008

Heparin, which is widely used as an anticoagulant (blood thinner) has been in the news lately and its use is scary. 19 people have died, and 785 have experienced adverse reactions due to contaminated heparin. The heparin in question has been found to contain up to 50% oversulfated chondroitin sulfate, which mimics heparin so closely it can not be distinguished in basic tests but provides no anticoagulant activity. The adverse effects are caused by severe allergic reactions, including low blood pressure which can occasionally lead to fatal shock.

Heparin raw ingredients are widely used, but only a few are available in the U.S. Importing from foreign plants is common to ensure America has the right ingredients. 4 countries have been recalled, including China. The raw ingredients, heparin, are made from pig intestines and are a key component. China leads the world in pig farming and has been hit by a pig disease in China, which has increased the price of heparin ingredients. This has led to some companies looking for cheaper substitutes to keep costs down.

However, the Food & Drug Administration is not sure if the chondroitin sulfate is the reason for the allergic reactions or if there could be even more problems with the heparin, such as an unsanitary manufacturing process or sick pigs that have gotten into the supply chain. The raw heparin is already being used in some foreign plants and is not inspected before entering the market. (It also means that the price for ingredients manufactured from pigs has gone up - more on that later.)

The question that the FDA is trying to answer as they perform their root cause analysis is: How did the chondroitin sulfate get into the raw ingredients for heparin? People who take heparin because they require its anticoagulant properties may have serious difficulties with a dose that is only 50% effective. Because of these concerns, the Heparin in question has been recalled from 4 countries (at last count).

Whether or not the chondroitin sulfate was to blame for the allergic reactions, it also has the potential to cause serious harm by negatively affecting the blood thinning properties of Heparin. People who take heparin because they require its anticoagulant properties may have serious difficulties with a dose that is only 50% effective. Because of these concerns, the Heparin in question has been recalled from 4 countries (at last count).

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.