"5 Whys" - Example

Problem: Incorrect study drug administered

Why? Wrong vial taken from fridge

Verification step by 2nd person did not reveal any difference (correct drug name/lot #)



- 1) Begin with a specific problem.
- **2)** Ask why the problem happened and write the answer down below the specific problem you listed in step one.
- **3)** Keep asking "why" to each of the successive answers you write down until you reach the root cause of the problem.
- **4)** This may take more or less than five "whys" to get to the root cause(s).

Two vials were identical (same drug name/appearance)

Why?

Two separate studies were using the same investigational product/drug

Why?

N/A

"5 Whys" Problem Solving Tool



