

Using the 5-Whys technique empowers teams to delve beneath surface-level responses and explore less apparent causes or explanations.

## Step-by-Step Guide:

- ✓ Identify the **strategic problem** you intend to address.
- ✓ Begin by asking “**why**” **questions** related to the issue, continuously probing deeper with each subsequent query.
- ✓ Keep asking “why” until reaching a level of insight that can be **actionable**, typically around the fifth iteration. Cease when further questioning becomes illogical.

It's often suggested that by repetitively asking “Why?” five times, one can uncover the fundamental root cause of a problem. By the fourth or fifth inquiry, attention frequently shifts towards management practices, though more iterations might be necessary for complex issues.

This method aligns closely with Cause & Effect (Fishbone) diagrams, providing a complementary approach to the analysis required for such diagrams.

## ☆ Tips

Aim for depth rather than breadth; focus on thoroughly exploring one reason.

If the final cause identified is beyond your control, revisit the preceding responses to hone in on a controllable factor.

The final answer should not attribute blame to individuals.

## Example

**Problem: The shelf life of a medicinal is not as long as expected.**

**Why (1)?** The medicinal product is failing Assay specification. One year after manufacture, the active substance is 94.2% of the drug product. The acceptance criterion limits are 95.0-105.0%.

**Why (2)?** The active substance is degrading. Laboratory testing shows a proportional increase in organic impurities.

**Why (3)?** The active substance is degrading due to UV exposure. Organic impurities formed are photodegradation substances.

**Why (4)?** The product is being exposed to light.

**Why (5)?** The packaging is not appropriate for the product. The packaging is clear PVC. It should be changed to opaque packaging, such as aluminum.

Define the observed problem:

What is happening?

1.

Why is that?

2.

Why is that?

3.

Why is that?

4.

Why is that?

5.

Why is that?

Identified Root Cause:

### Action Plan to address the problem:

### Review of Action Plan:



1. Does your action plan clearly assign responsibility for each action item?
2. Does your plan include a strategy for communicating with relevant stakeholders?

3. Is there a defined timeline for each component of your action plan? Have deadlines been established?
4. How will you evaluate the effectiveness of the implemented changes? How will you determine if the problem has been successfully addressed?