
Overcoming Human Errors

Purpose

Learn to overcome human errors as a root cause to deviations, when human errors is wrong diagnosis.

Objectives At the completion of the class, students will be able to:

1. State what the GMPs imply regarding human errors.
2. State the FDA's current thinking about human errors and deviations.
3. Describe the basics of root cause determination.
4. List the possible root causes to human errors.

Prerequisite

Students must have a solid understanding of CGMPs.

Who should attend this class?

This class is intended for anyone from line personnel to senior executives who wants to change their approach to human errors.

About the class

1. Students use in-house deviations and industry case examples to explore overused category of human errors in deviation investigations.
2. Each student receives a student guide containing a representation of the program's slides and graphics with space provided for note taking.
3. This class can accommodate up to 25 people.
4. Duration: 2 hours.

Topics Covered

Introduction

1. Activity: Heard on the street
2. What the FDA says about human errors and deviations
3. How many human errors are too many

Recent 483 observations relating to human error

1. Activity: A simple human error
2. 5-Why's
3. Sequence of events
4. Distinctions
5. Walk through analysis
6. Fishbones and root cause analysis
7. Types of root causes
8. CAPA
9. Control barrier analysis
10. GMP Challenge: Human Errors

Summary

Review the general theme of the 35 dimensions