



VVM RELATED AUDIT SITUATIONS & FINDINGS – CASE STUDY

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Introduction

VVM is a label containing a heat-sensitive material which is placed on a vaccine vial to register cumulative heat exposure over time. The combined effects of time and temperature cause the inner square of the VVM to darken gradually and irreversibly.

The inner square of the VVM is made of heat-sensitive material that is initially light in color and becomes darker when exposed to heat. The color change is faster at higher temperatures and slower at lower temperatures. At the discard point or end point, the inner square is the same color as or darker than the outer circle.



Case

The company manufactures 2 types of vaccines:

Vaccine X. Shelf life: 24 months at 2 - 8°C. Vaccine Vial Monitor: Type **14**

Vaccine Y. Shelf life: 24 months at -20°C. Vaccine Vial Monitor: Type **2**

- The vaccine manufacturer received a several complaints from 5 different customers about an unexpected color change of VVMs attached to the container of several batches of vaccine X, supplied to the customer months earlier
- Some of the batches had been shipped to the customers and some other remained in the warehouse
- As part of the investigation, retention (control) samples of the vaccine batches involved showed that control samples of vaccine X also had the VVMs with changed color



Instructions to the group

1. Discuss and prepare an audit checklist covering the main aspects to be checked for a root cause analysis.
2. Briefly, write in bullet-point format in your flipchart
3. Make a brief presentation to the class justifying the points to be audited
4. Identify the most probable cause for the situation described