



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 containers 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



Data used in root cause analysis:

SOP and protocols concerning VVM handling

Information from customers about storage conditions of the batches, was requested

Documentation concerning VVMs receipt and further handling (materials delivery report, receiving report, dispensing lists)

QC records on VVM quality control and approval

Temperature monitoring data of VVM storage conditions

Interviews with personnel

Batch records of VVM packaging line

QC staff of warehouse for packaging materials

Training records



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Investigation results

The investigation determined that the color change of VVMs was caused by mislabeling. The 2 – 8°C vaccine ampoules were labeled with VVM2 (used for -20°C) instead of VVM14. This caused that the VVM 2 label changed color to unacceptable

The untimely change of VVM color indicates unsuitability of the vaccine for immunization, creating possible disruption in the vaccination program. In addition, by using the wrong VVM, there was no assurance that the storage conditions were adequate below 2°C and above 8°C. The non-conformity was considered to be major to critical

Root cause was determined as human error due to lack of training.



Instructions to the group

1. Briefly discuss and comment on the actions taken by the company
2. Briefly, write in bullet-point format in your flipchart
3. Make a brief presentation to the class



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Actions taken:

- Training of the operators involved was done
- Production and shipment of vaccine 1 was stopped, but vaccine 2 continued to be produced and distributed
- All finished batches on site were put into quarantine till the end of the investigation pending further decisions
- Recall of all mislabeled batches was initiated
- The remaining VVM2 labels were located in the warehouse, and segregated accordingly