



# ASEPTIC PROCESSING OF WFI / SALINE IN AMPOULES AUDIT PLANNING & STRATEGY

**DCVMN, Hyderabad – INDIA**

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## Introduction

Sterile WFI and sterile Saline solution are used as diluents for freeze dried vaccines, and they are usually done in ampoules by contract manufacturers. Ampoule manufacturing lines use an open flame system to cut and seal the ampoules.

## Case

A one day for-cause audit has been decided after receiving a market complaint caused by the report of one contaminated unit of Saline solution (ampoule) with *Staph. epidermidis*. This contract manufacturer filter sterilizes and aseptically fills saline solution. Then, ampoules are transferred to the labelling and packaging line.



## Instructions to the group

1. Based on the video provided, discuss and prepare checklist listing major aspects, processes, documents, and records.
2. Discuss, identify, justify and categorize any actual / potential non-conformities of this case and on what you see in the video. Identify possible risks and strengths.
3. Briefly, write in bullet-point format in your flipchart
4. Each group to make a brief presentation justifying the points to be audited
5. Identify the most important deficiency of this process.