LABORATORY DATA INTEGRITY AUDIT SITUATIONS & FINDINGS – CASE STUDY

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Developing Countries Vaccine Manufacturers Network

Introduction

Read the newspaper article “DATA INTEGRITY ISSUES CONTINUE TO HAUNT PHARMA SECTOR”.

Case

Warning Letter - April 1, 2016 - SK Pharmaceuticals Ltd. - Unit II - Hyderabad, Andhra Pradesh, India

The U.S. Food and Drug Administration (FDA) inspected your pharmaceutical manufacturing facility. Our investigator identified significant violations of CGMP regulations for finished pharmaceuticals, Title 21, Code of Federal Regulations, Parts 210 and 211.
These violations cause your drug products to be adulterated within the meaning of Section 501 of FD, in that the methods used in, or the facilities or controls used for, their manufacture, processing, packing, or holding do not conform to, or are not operated or administered in conformity with CGMP.

Case - Warning Letter - Objective evidence:

"A QC analyst deleted original test method validation data and admitted plans to fabricate sample preparation data.
According to the HPLC audit trail, on October 7 and 8, the QC analyst injected two sets of similarly named samples of **(X)** (#1:P141007001.lcd and #1:P 141007001.lcd) for an impurity analysis method validation study.
Your analyst deleted data from the first set of injections and submitted only the second set in the validation documentation.

The analyst stated that he planned - to backdate the preparation data within the worksheets once all testing was complete. However, aside from balance scale tickets, your firm was unable to provide sample preparation data for either sample.
Your response states that you abandoned the method validation study, but you continue to use that method for routine testing".

Instructions to the group

1. Prepare an audit checklist including and explain how you would conduct the audit on site

2. Check the two chromatograms provided to the auditor (of the same product).

3. Categorize the findings. Justify

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- Check chromatograms: