GMP Trends

DISTRICT ADDRESS	DATE OF ISSUE
GMP Trends LLC P.O. Box 1111 Firestone, Colorado 80520	Introductory
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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

To: Responsible Person, Director of Quality Assurance

FIRM NAME	STREET ADDRESS
Pharmaceutical and Related Industries	5600 Regulation Lane
CITY, STATE AND COUNTRY United States of America and Worldwide	TYPE OF ESTABLISHMENT INSPECTED Pharmaceutical and Medical Device

DURING A REVIEW OF INSPECTION REPORTS OF U.S. FIRMS (I) (WE) OBSERVED:

MEDICAL DEVICE-MANUFACTURING CONTROLS

1. .....Procedures to ensure that all purchased or otherwise received product and services conform to specified requirements have not been adequately established.

   Specifically, your "Purchasing" procedures have not been adequately established. For example:

   a. Your procedures do not define how sole suppliers or "required" suppliers are to be monitored if they receive a "disqualified" rating. For example, your required supplier of ..... received a quality rating of 50 out of 100, which would cause removal from the Approved Supplier List. There is no documentation of what controls are in place to allow continued use of this supplier.

   b. The "Supplier Rating System" form for ..... supplier does not contain documentation to support the scores received. Additionally, the final supplier status of "Approved," "Conditionally Approved," or "Disqualified" was not documented on the form to indicate whether this supplier was approved for another year.

   c. SOP ..... states that new suppliers will be evaluated, approved and added to the ASL after completion of the "Supplier Risk Analysis and Approval Plan." This plan documents the risk associated with the supplied product or processes used. This form is currently only used for new suppliers.

2. .....Procedures for corrective and preventive action have not been adequately established.

   Specifically, your procedure titled "Corrective & Preventive Action" does not require the analysis of audit reports, service reports, and product returns to detect product or system quality issues.

   a. CAPA ..... does not require verification or validation that corrective and preventive actions do not adversely affect the finished device. In addition, it does not ensure information that relates to quality problems are disseminated to those persons who have direct responsibility for areas affected by the change and to submit relevant quality problems and corrective actions for management review.

3. .....Procedures for corrective and preventive action have not been adequately established.

   Specifically, your written procedure "Corrective and Preventive Action" does not define that appropriate statistical methodology will be employed where necessary to detect recurring quality problems; does not include the requirements for validating the corrective and preventive action to ensure that such action does not adversely affect the finished device; does not include the requirements for implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems.

4. .....Procedures for receiving, reviewing and evaluating complaints by a formally designated unit have not been adequately established.

   Specifically, documentation of the investigation conducted for ..... complaints was incomplete in that the complaints did not include evidence to demonstrate the stated activities were conducted:

   a. Complaint ..... states "the supplier was contacted to investigate the defect and assess the need for correction. However, no evidence was maintained to demonstrate whether the supplier conducted an investigation and implemented corrective actions as needed.

   b. Complaint ..... states "a good faith effort was made during the engineering evaluation to evaluate the ..... process currently being used. However, no evidence was maintained to demonstrate this evaluation of manufacturing processes was conducted (e.g., who conducted the review, when it was conducted, and what was evaluated).

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE **GMP Trends LLC**	EMPLOYEE(S) NAME AND TITLE **Editor**	DATE ISSUED **Introductory**

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