Auditing Contract Manufacturers: What Do You Do When Contractors Have Terrible GMP Profiles?

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THE REVEALING AUDIT

Company X has engaged the services of a contract manufacturer to process their pharmaceutical product through manufacture, packaging, and labeling of the final dosage form. Company X has been using this contractor to make this product for seven years. In performing an audit of the contractor, Company X’s auditor finds significant critical deviations from good manufacturing practices (GMPs), sufficient to give cause for alarm.

As the auditor writes the audit report, thoughts of patient risk, contractors shut down by the US Food and Drug Administration, potential blame, and job loss whirl in the auditor’s mind. The auditor sends the audit report to her management and to the contractor. Management decides to wait and see what the contractor’s response is before making any decisions. The contractor’s response states that the corrections requested/required are too expensive to implement, have never been raised by other clients, and the value of Company X’s business cannot justify the expense required for corrective action. The contractor values and wants Company X’s business, but the changes requested are in their opinion unjustified, and they can/will not make the corrections. What should Company X do?

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