Compliance Case Study #2— Questionable Equipment Qualification

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A compliance case study involving fundamental problems in equipment qualification at a drug product packaging facility is discussed. The event comprised review of documentation associated with qualification of a cartoning machine. This review demonstrated a serious lack of understanding of fundamental validation and qualification practices and requirements including protocol preparation, data handling, approval practices, and so on. Specific good manufacturing practice (GMP) requirements are cited. Suggested corrective action and preventive action (CAPA) for implementation are provided. ...