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Mitigating Compliance Risk in Outsourced Pharmaceutical Manufacturing

Prepare for inspection

Regulatory authorities in Asia Pacific regularly conduct inspections of manufacturing facilities to ensure compliance with GMP standards. These inspections may be scheduled or unannounced, and they evaluate the organization's adherence to quality management systems, production processes and control measures.

Look for evidence of robust Quality Management Systems (QMS).

Manufacturers are required to implement a QMS that ensures consistency in production and control activities. This involves having standard operating procedures in place, conducting regular internal audits and implementing corrective and preventive actions when necessary.

COMPLIANCE RISK

Insist on proper documentation and record keeping

Proper documentation and record keeping is an essential part of GMP enforcement. Contract Development and Manufacturing Organizations (CDMOs) must maintain accurate and detailed records of all manufacturing processes, quality control tests, and any deviations or issues that occur, along with the corrective actions taken.

Know your quality oversight obligations

Companies that use CDMOs for their manufacturing needs are ultimately responsible for the quality, safety, efficacy, and GMP compliance of their products. Conducting your own audits and inspections of CDMOs is important for ensuring adherence to GMPs.

Other Resources

- → Healthcare & Life Sciences Regulatory
- → Supply Chains

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Read the Full Report

* FenXun established a joint operation office with Baker McKenzie in China as Baker McKenzie FenXun, which was approved by the Shanghai Justice Bureau in 2015