Market Complaints – Audit Execution

We offer expert consultancy specialized in both on-site and remote Audits to assess adherence to international regulations such as FDA and EMA guidelines. Their meticulous approach ensures that pharmaceutical processes are compliant and under control, safeguarding product quality and regulatory adherence

Thorough Audit Planning and Preparation

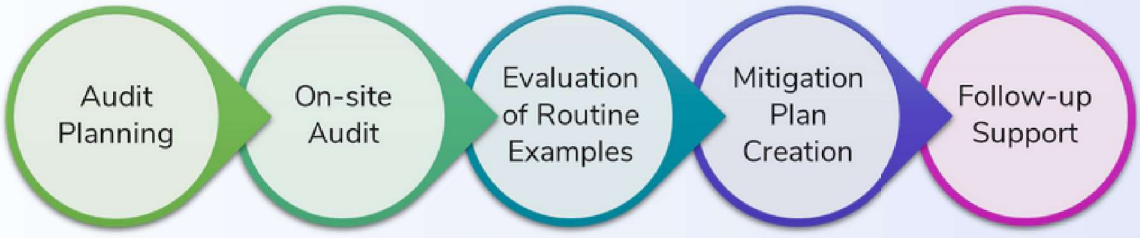
We understand the specific requirements and regulatory landscape, together with reviewing existing documentation, including standard operating procedures (SOPs), complaint handling protocols, and previous audit reports.
Based on this analysis, Zamann develops a customized audit plan that outlines the scope, objectives, methodologies, and timelines for the audit process.

Audit Execution

Zamann's expert auditors meticulously examine the client's market complaints handling processes, starting from the point of complaint reception through resolution and follow-up.
Items like SOPs and evidences of complaint receipt, investigation, and resolution will be checked, in order to ensure compliance with regulatory requirements.

Regulatory Compliance Assessment and Gap Analysis

We perform detailed assessments of the client's market complaints processes against applicable FDA, EMA, and other international regulations, examining each step of the complaints handling process, from initial receipt and evaluation to investigation, resolution, and reporting.
Zamann identifies any GAPs or deviations, and provides the client with a comprehensive GAP analysis report, outlining areas for improvement and recommending corrective actions to enhance compliance and mitigate risks.



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- Quality Consulting and Risk Management
- Qualification and Validation
- Personnel Qualification
- Customer-specific provision of QMS

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