Batch Record Review – GAP Assessment

Specialized consultancy related to GAP Assessment execution, to evaluate the implemented process to Batch Record Review, to identify any discrepancies with applied regulations such as FDA and EMA guidelines. Our services aim to pinpoint GAPs in compliance and provide actionable insights to enhance processes and ensure regulatory alignment, thereby safeguarding product quality and regulatory adherence

Regulatory Compliance Evaluation

We conduct a thorough analysis of necessary regulations pertaining to Batch Record Review processes, identifying specific requirements and expectations.
Our experts assess the existing batch record review process against these regulatory standards to pinpoint areas of non-compliance or potential GAPs.

GAP Analysis and Documentation Review

Zamann team performs a comprehensive GAP analysis to compare the current state of Batch Record Review processes with regulatory requirements.
We review existing documentation, procedures, and quality records related to the activity to identify discrepancies or deficiencies in compliance.

Recommendations and Action Plan Development

Based on the findings from the GAP assessment, we provide actionable recommendations and develop a strategic action plan to address identified GAPs.
We collaborate closely with clients to prioritize corrective actions, implement process improvements, and enhance regulatory compliance in batch record review processes.

Reckitt | BIONTECH | ratiopharm | SANOFI | Boehringer Ingelheim | Biotest | Heraeus | Takeda

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

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