ZAMANN PHARMA SUPPORT

Computerized Systems Validation
Audit Readiness – Strategic Consultancy

We provide an strategic guidance on how to be prepared for Computerized Systems Validation audits. This service equips clients with the knowledge and tools necessary to develop effective strategies for audit preparedness, ensuring compliance with regulatory requirements and industry standards

Regulatory Guidance and Interpretation

Provide in-depth analysis of regulatory guidelines such as FDA 21 CFR Part 11 and EU Annex 11 to interpret requirements relevant to computerized systems validation. Offer insights into regulatory expectations and best practices for audit readiness.

Customized Audit Preparedness Plan

We collaborate with clients to develop customized audit preparedness plans based on their specific system configurations, validation needs, and regulatory landscape. Define clear objectives, milestones, and action items to guide the preparation process effectively.

Training and Capacity Building

Conduct training sessions and workshops to educate key stakeholders on audit preparation strategies, validation principles, and regulatory compliance requirements. Empower internal teams with the knowledge and skills necessary to implement audit readiness initiatives and effectively respond to auditor inquiries during validation audits.

1. Analysis of Regulatory Requirements for Computerized System Validation
2. Defining Objectives, Milestones, and Action Items
3. Regulatory Expectations and Best Practices for Audit Readiness
4. Educating Stakeholders on Audit Preparation and Compliance

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

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

Contact:
quality-services@zamann-pharma.com
www.zamann-pharma.com