

EudraLex Vol.4 Annex 1 – Strategic Consultancy

Expert guidance and strategic consultancy services for EudraLex Vol.4 Annex 1 compliance, guiding pharmaceutical companies in establishing the framework necessary to adhere to EudraLex Vol.4 Annex 1 requirements. This service focuses on providing expertise to create a robust landscape for compliance, including the development of essential SOPs and the evaluation of existing processes for improvement

GAP Analysis and Assessment

Conduct a thorough review of existing processes and procedures against EudraLex Vol.4 Annex 1 requirements to identify GAPS and areas for improvement. This involves assessing current practices, documentation, and infrastructure to determine compliance readiness.

Document Creation

Collaborate to develop customized documents aligned with EudraLex Vol.4 Annex 1 guidelines, to define the necessary steps and protocols for maintaining compliance with requirements, covering aspects such as cleanroom design, personnel hygiene, and environmental monitoring.

Training and Knowledge Transfer

Provide comprehensive training sessions and workshops to educate the necessary personnel regarding the newest requirements and best practices. This includes training on proper cleanroom behavior, aseptic techniques, contamination control measures, and documentation practices to ensure effective implementation and compliance adherence.



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

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