New Computerized Systems – Support on Implementation

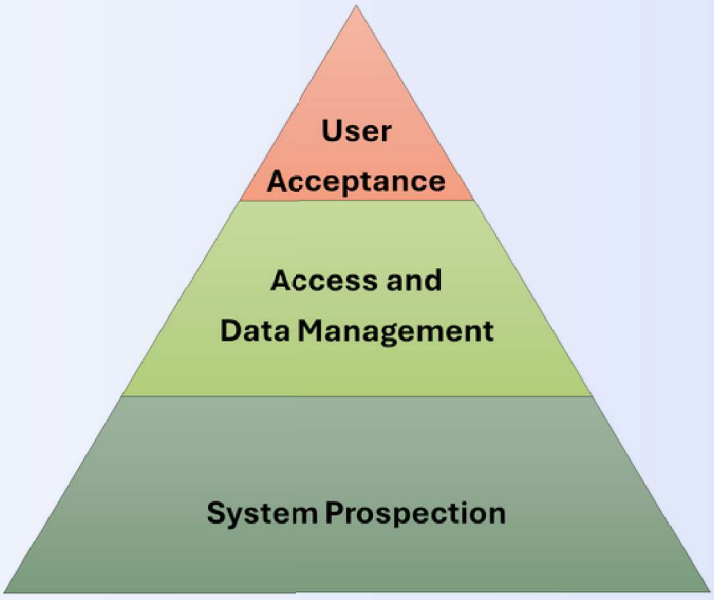
We offer specialized consulting services ensuring compliance with FDA regulations and facilitating seamless integration of new Computerized Systems. Our comprehensive support includes system prospection, FAT/SAT, access management, master data management, document creation, and culture change management to enhance user acceptance

System Prospection and Requirements Gathering

We collaborate with clients to identify their specific system requirements and conduct thorough prospection to select suitable computerized systems. This involves assessing system functionalities, compatibility with existing infrastructure, and regulatory compliance. We gather user requirements, conduct vendor evaluations, and select appropriate systems to meet organizational needs.

Access and Data Management

We develop Access and Master Data Management strategies to ensure controlled access to the new computerized system and protect sensitive data. This includes defining user roles and permissions, implementing authentication mechanisms, and establishing access control policies. We ensure strategies align with FDA regulations and industry best practices to safeguard system integrity and data security.



User Acceptance Strategy Creation

We develop and implement strategies to manage user acceptance of the new computerized system, ensuring that stakeholders are engaged and onboarded effectively. This includes conducting user training, soliciting feedback, addressing concerns, and promoting user adoption. We facilitate communication between users and system developers to ensure that user needs are met and system usability is optimized.

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

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