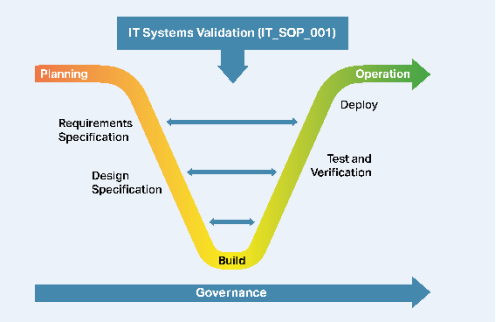
ITQMS

Planning • Build • Operation

Our IT Quality Management System embodies a single, integrated set of procedures, work instructions and templates, which together provide a scalable IT governance "Toolkit" that can be used for any size or type of IT system.



It provides an end-to-end process to support the full system lifecycle from inception through to eventual decommissioning. It is aligned with key industry guidance as outline in GAMP5™ and the associated GAMP™ Good Practice Guidelines to ensure that all aspects of general good IT practice and pharmaceutical specific expectations are embodied within its processes.

The overall approach is presented in a clear, logical and graphical framework, which in, turns support a simple and intuitive navigational and training aid to the constituent procedures, work instructions and their dependencies.

The overall framework is presented in a single overarching "framework" procedure (IT_SOP_001) and each of the associated phases is covered in its own corresponding and linked procedure.

The individual SOP's provide a high-level overview of the various topics and potential activities that may need to be considered for any given situation and high-level dependencies between the phases. Each individual SOP is supported by its own set of focused work instructions which provide detailed instructions which will lead the delivery team through the necessary thought process and support associated decisions making.

Finally, the individual work instruction are provided with outline document templates, where the actual detail can be readily generated; in many cases using detailed text from the work instructions themselves.

A risk-based approach is embedded throughout the QMS, as are security and data integrity compliance considerations.

As a packaged IT QMS, its modular design, integrated within a simple to follow framework, means it can be easily adopted by any organisation who are new to the word of pharmaceutical computer system validation activities, or equally to those organisations wishing to improve their existing IT QMS.

It's structured design allows users of the QMS to quickly understand its principles and supports ease of training to the various IT roles relating to the lifecycle phases.

Integration within an organisation simply requires the key “touch points” to be aligned. Typically, this would be alignment with existing organisation change control, deviation and risk processes. If these are not already in place, we can of course provide procedures to support these areas too.

In addition to supplying the QMS itself, we can also provide any necessary consultancy support required to assist the process of embedding the QMS with your organisation, associated business change, training, and support in its application.

Together the QMS content provides a holistic approach to IT delivery that can be scaled to suit any size or type of IT system delivery and will ensure sufficient and efficient adherence to regulatory requirements and expectations.