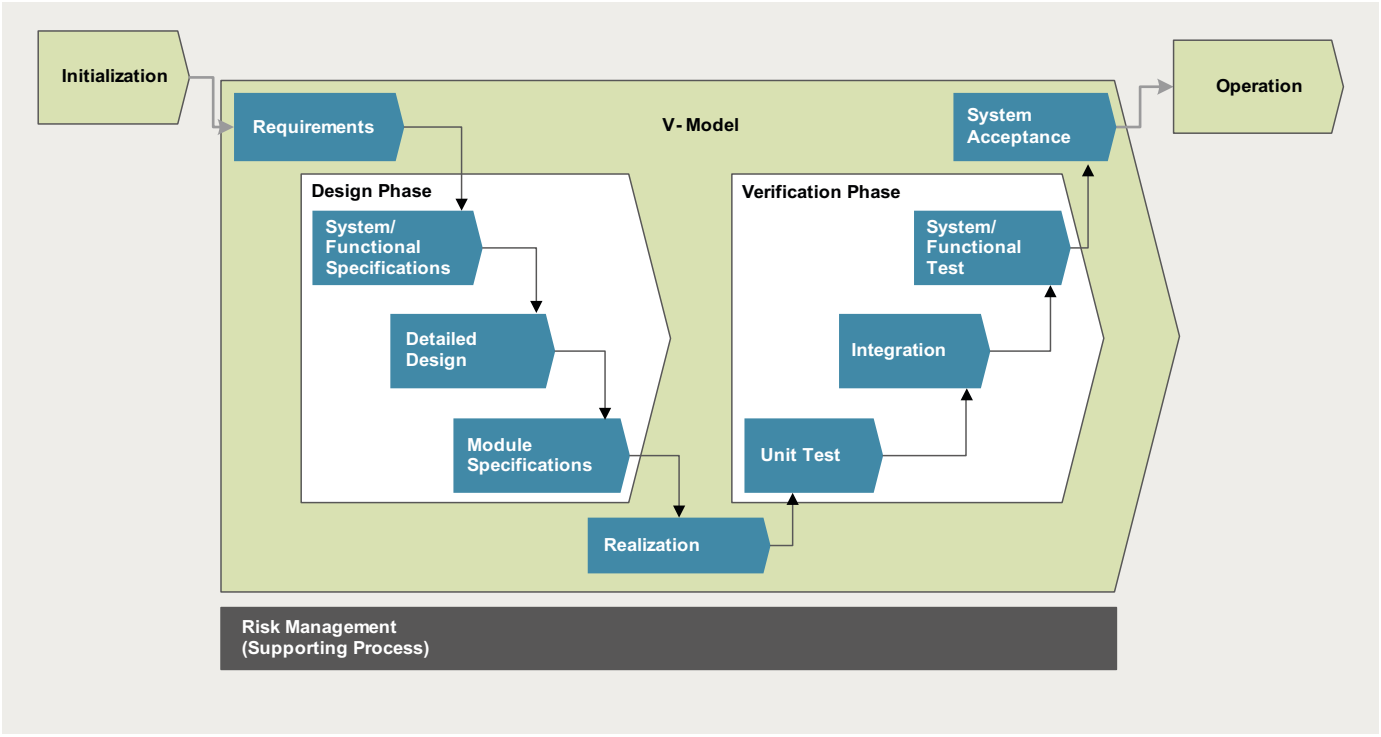
Ensuring quality and reliability

Validation is a Good Manufacturing Practice (GMP) requirement with benefits for both Tecan and its customers.

Validation is a regulatory requirement which enables manufacturers to achieve a high level of quality, even in situations where it is not possible to test each individual component or product. The processes that are most likely to be selected for validation are those whose results cannot be measured without rendering a product unusable. Giuseppe Grignano, Global Compliance Validation Manager at Tecan, explained: "Validation is beneficial to both Tecan and its customers. It is essential that any product, particularly in the medical sector, is faultless, and validation ensures a high standard of product quality, safety and reliability. At Tecan, we identify potential risks at every stage of development and production and, if the product does not perform as expected, we can address the issue in house prior to marketing the instrument. Being proactive in this way has given Tecan a reputation for quality and reliability – guaranteeing that every product we market is of a high quality, is safe and stable, and meets customer expectations – and this is one of the main reasons customers choose Tecan."

"Design validation is just one aspect of the overall validation process. Validation also involves manufacturing processes for which the output cannot be verified. This encompasses the software system used to support quality activities, inspection activities, handling of non-conformance and complaints, and corrective and preventive action (CAPA). To support the management of the validation process, and to achieve full compliance status, Tecan has a Global Master Validation Plan, along with specific Master Validation Plans for individual sites and departments. These are key elements, not only for monitoring ongoing compliance, but also for meeting site business goals in terms of operational performance, quality and efficiency. The results of this monitoring are regularly reviewed by senior management, which gives them an overview of the situation and allows them to ensure validation projects are running according to schedule, taking corrective action if necessary."

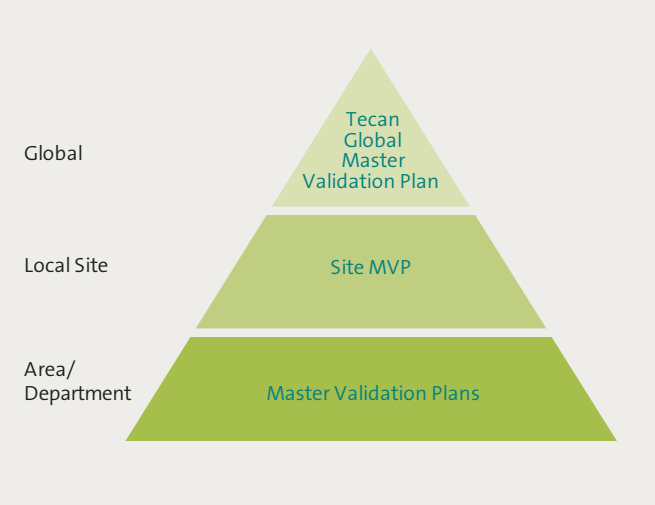
Product development and validation using the V-model standard



"Tecan has developed a validation process following the V-model life cycle industry standard, which outlines all the requirements for correct execution of the validation process. We establish the objectives we want to achieve for each phase of the validation, and formal testing verifies that these defined objectives are met. Our validation protocols include details of how testing should be performed, in what environment, and what acceptance criteria must be met to establish that a product performs as specified. All testing activities are documented and supported by statistical data to demonstrate compliance, such as analysis of variance and/or process capability studies, and records of staff training are also maintained. This ensures that the validation has been performed correctly, and that there is evidence that the required parameters and specifications of the product are met at all times."

Giuseppe continued: "During customer audits, we are frequently asked how a product has been tested and subsequently validated during its development and production. Customers like the way we record our testing activities in detail, and we have received very good feedback about the quality of our validation procedures. If a customer needs to submit validation data to a regulatory authority, for example to prove that the platform they are using for their application has been properly developed and tested, then Tecan can provide them with a copy of this data and the supporting documentation. By relying on our documentation, the customer only has to validate their specific application, saving them time and money while still achieving full compliance for regulatory submission." Giuseppe concluded: "It's a win-win situation, with proper validation building a solid foundation for quality and success."

The Validation Program covers all aspects of the validation within Tecan



Frederic Vanderhaegen, Senior Vice President, Head BU Life Science

Leading the debate

Tecan's greatest strength has always been in staying close to researchers, anticipating their needs and understanding their workflows, and this has fuelled the growth and success of our company for over 30 years.

During this time, the life science world has expanded and subdivided into discrete segments, and these changes have triggered a recent structural reorganization of our company. The term 'life science' now encompasses many demanding niches with distinct technological requirements quite different from one another. By realigning our company structure, we aim to sharpen the focus on each of these niches, making their challenges and opportunities more transparent.

Our new strategy must account for customers demanding more turnkey solutions, deeper expertise and dedicated systems that address smaller processing volumes, bottlenecks in sample preparation, higher detection sensitivity and user-friendly software. Our goal is to identify the most critical priorities for each of these applications, and to mould our strategic focus around their individual challenges. We will develop our product portfolio with this in mind, driving innovation and keeping a look out for new technologies and partnerships that will add value to our offering and benefit our customers.

Thank you for your past support, your encouragement and your future commitment to Tecan.

Email talk@tecan.com to tell us what you think about the significance of the changes to the life science arena, and how technology companies can help to address these changes.