

Towards excellence in validation

Embedding lean practices to accelerate digitalization & innovation

Drug development requires reliable, secure, and traceable processes and systems. As a result, validation in Pharma R&D is a must to meet regulatory compliance, and it is neither an easy nor fast feat to accomplish.

The key to success is a lean validation approach, risk-based efficiency, and the deliberate use of automation.

Validation can be rigid, time-consuming, and resource-intensive



Complex regulations

Extensive cross-functional coordination, frequent regulatory updates, need for inspection readiness



Comprehensive documentation

Detailed documentation, incl. high-effort creation and lengthy review and signature cycles



Arduous processes

Rigid or outdated internal policies and processes, risk-based approach followed inconsequently

Our best practices enable compliant and efficient validation at speed

Consider validation from the start

Efficient validation begins with selecting the right solution and vendor - consider available quality and validation packages.

Implement consequent risk-based, fit-for-purpose validation

Validate smartly: Know your target use cases and validate only necessary features.

Make Quality Assurance your ally

Quality teams are not only gate keepers but can be allies, too - engage them early and frequently to co-develop your validation strategy.

Minimize efforts via test automation

Leverage automation where possible to reduce human error and standardize and accelerate testing, e.g., to capture test evidence.



Drug development operations must be reliable and validated. However, excessive validation too often leads to burdensome and costly delays in digital transformation initiatives.

Embedding lean validation practices early on prevents these risks and ensures smooth, GxP compliant, and efficient rollouts and operations – saving effort, costs, and accelerating innovation.

Ready to overcome the “validation barrier”?

Let's discuss how we can help you embed lean validation in your digital journey.

Contact us directly on LinkedIn or via email.



Herbert Hensle
Managing Partner
herbert.hensle@vertwo-advisory.com



Markus Heckenmüller
Principal
markus.heckenmueller@vertwo-advisory.com



Oleg Lyashko
Consultant
oleg.lyashko@vertwo-advisory.com