



# Trust & Compliance

*We worry about GxP and regulatory compliance so you don't have to.*

## The ZenQMS Difference

- We understand the responsibilities of a GxP/ ISO QA leader
- We provide a simple qualification checklist
- We don't charge for support
- We don't charge for validation materials (UAT templates, etc.)
- We will go on standby for your audits
- We pursue essential 3rd party certifications to mitigate risks
- We provide coverage for data privacy
- We provide thorough, easy-to-understand & accessible documentation

*Does your vendor take your data security and compliance as seriously as YOU do?*

## Message from Panos & Karin



ZenQMS doesn't develop drugs or devices directly, but all of our clients do. So while we may never be directly audited by a regulator, our clients are being audited. We know how critical our software is in those moments and your day-to-day activities, so it's our job to be more thoughtful than our most conservative, at-risk clients. We believe any SaaS services not taking the same proactive approach are selling half a solution and putting a client's quality profile at risk in the process.

## SOC 2 Type II Report & ISO Certifications

ISO 9001:2015, ISO 27001:2013 certifications and a SOC 2 Type II report are the international standard requirements you should expect of any quality vendor. Anything less and you could be putting your data at risk.

In addition to maintaining these certifications, ZenQMS' quality system is audited more than a hundred times each year by experienced client auditors. And with hundreds of clients around the world from preclinical/clinical innovators to fully commercial stage GxP manufacturers, we know just how well ZenQMS holds up to scrutiny.



## 21 CFR Part 11/ Annex 11 & GAMP 5



For regulated companies, maintaining valid electronic signatures and audit trails is a key risk factor when implementing an eQMS. That's why we meet all 21 CFR Part 11/ Annex 11 compliance standards for software validation. Clients can expect a seamless audit trail for all transactions, a quarterly QA validation, and a separate assessment and p. 11 checklist.



ZenQMS subscribes to a GAMP 5 (Category 4)-driven approach to client qualification and validation. We encourage all clients to leverage our validation materials rather than starting from scratch, and the FDA agrees. To that end, we share all validation documents and provide UAT templates to clients at no charge. Our goal is to make sure our customers, even those with small IT teams, can validate our software and navigate UAT in a matter of days.

## GDPR & HIPAA

As data privacy and security provisions emerge and evolve, ZenQMS will continue to adhere to international regulations, ensuring out-of-the-box compliance for all customers. Together with our turnkey implementation services, in-house support, and intuitive platform, we make it easy to get up and running with a secure, user-friendly eQMS that you can trust.



## Amazon Web Services (AWS)

ZenQMS maintains a single, validated, multi-tenant instance in the cloud at all times, hosted by Amazon Web Services (AWS), the only commercial cloud vetted and accepted as secure enough for top-secret workloads. Your data is backed up daily across AWS' multiple server locations with a guaranteed uptime of > 99.99%.