

# Custom Software Developers



## Business Need

For custom software developers, their success relies on their ability to build solutions to handle tough software and systems engineering challenges; their focus is on providing the best-in-class solution. However, in regulated environments, they need more than creativity and ingenuity to serve their clients. They need a compliant infrastructure, turn-key startup platform and high availability for their custom solutions.

Every company that works with clinical data or validated applications requires a fully qualified environment with a robust Quality system to ensure compliance. For their Life Sciences clients running or getting ready to run clinical trials, having the capability to run the custom solution concurrently with the clinical trial becomes paramount. However, a significant capital and human resources investment is required to build and maintain a compliant platform. In particular, if the company is starting from the ground up to develop a quality system to integrate with its custom solutions, this activity is typically cost-prohibitive.

## Solution

Validated Cloud provides and manages all aspects of compliance requirements and services to ensure ongoing compliance and security. By leveraging Validated Cloud, companies do not have to reinvent the stack of quality documentation or build and maintain the technology stack; they can simply focus on building and deploying their custom applications.

In addition, Validated Cloud offers a turn-key startup platform where the custom application can run concurrently with clinical trials as needed.

## Benefits

Validated Cloud offers a fully qualified and secure hosting platform compliant with 21 CFR 820, 21 CFR 11, HIPAA, Annex 11 and ISO 13485:2003. Utilizing Validated Cloud's SaaS (Software as a Service) offering, the company gets a fully managed compliant platform with high availability:

- Focus on the core business.
- Operate on a secure and compliant platform.
- High availability with fully redundant data centers.
- Scalability from the start and only pay for what is needed.
- Optional disaster recovery: with fully redundant qualified production data centers in California and Massachusetts, Validated Cloud ensures access to validated systems in case of a disaster.

For references for this case study, contact us at [info01@validatedcloud.com](mailto:info01@validatedcloud.com).