

 **jama connect**® **Customer Validated Cloud**
Package for Medical Device and Life Sciences

Medical device and life sciences companies may need to validate their use of Jama Connect® (depending on their intended use(s) of the system) regardless of whether it is predicated on regulatory guidelines, such as:

- ISO 13485: 2016
- 21 CFR 820.70 Production and Process Controls
- FDA Draft Guidances: General Principles of Software Validation (2002) and Computer Software Assurances (2022)
- Internal organization quality and governance processes

The **Jama Connect Customer Validated Cloud Package** is an Amazon Web Services (AWS) cloud offering specifically designed to help customers meet these requirements. With this package, customers benefit from **Jama Software®'s best-in-class cloud hosting** and **global performance** — scale, response times, usage, and interoperability — while also having ongoing access to the resources needed for critical validation activities, and a release cadence catered to industry-leading validation strategies.

Jama Connect's Customer Validated Cloud Package Includes:

- Hosting in a separate AWS bulkhead reserved only for our Customer Validated Cloud customers
- Jama Connect releases provided bi-annually, approximately six months apart
- **Access to the Jama Connect Validation Kit**
- An additional Jama Connect sandbox environment to perform validation activities
 - 60 days prior to each new production release, customers are provided access in their sandbox environment so they can perform validation activities prior to each release moving to production

Additional Services (included with a subscription to a Jama Software Success Program):

- Jama Connect Validation Kit Training
- Jama Connect Migration to Customer Validated Cloud
- Validation Release Notes Consultation
- Validation Guidance

Jama Connect Adheres to the Following Protocols

Built on Jama Software's Secure and Scalable Cloud Platform



Suitably validated by TÜV SÜD for safety-related development per IEC 62304



Jama Connect is SOC2 Type 2 certified in both the server and application



Ensures strong privacy management practices

TLS

Data transferred is secured and encrypted