

Dimension Data's Security Certifications and how they relate to FDA regulations under CFR Title 21 Part 11

The Code of Federal Regulations (CFR) categorizes the general and permanent rules and regulations for executive departments and agencies of the Federal government of the United States. The CFR comprises 50 titles, each of which addresses a different regulated area.

Title 21 of the CFR regulates the food and drugs manufactured or consumed in the United States, under the jurisdiction of the Food and Drug Administration (FDA), the Drug Enforcement Administration (DEA), and the Office of National Drug Control Policy. CFR Title 21 Part 11 sets the requirements with regards to the technology systems that all FDA-regulated organizations use to store and manage information.

CFR Title 21 Part 11 sets forth the criteria under which the FDA considers electronic records, electronic signatures, and handwritten signatures executed to electronic records to be trustworthy, reliable, and generally equivalent to paper records and handwritten signatures executed on paper. This regulation, which applies to all FDA program areas, is intended to permit the widest possible use of electronic technology, compatible with FDA's responsibility to protect the public health.

Subject technology (hardware, software and IT services) companies must prove that their products and processes work as they are designed to and, if there are changes, they must revalidate that proof. Some key principles to be considered when validating electronic recordkeeping computer systems include:

- Evidence that the computer system meets the end user needs and intended uses, implements those needs correctly and that they are traceable to system design requirements and specifications – especially in relation to ensuring record authenticity, integrity, signer non-repudiation, and, when appropriate, confidentiality.
- System features and controls to support electronic records and signatures such as data backup, security, and computer system validation.
- Standard operating processes and controls to ensure that users of the computer system can detect when it is not working as designed.

There are currently no government-mandated or industry certifications in effect for suppliers to comply with CFR Title 21 Part 11. The onus is on each regulated entity, such as pharmaceutical and life science companies, to validate that their suppliers adhere to the FDA regulations. Responsibility for adhering to FDA standards cannot be delegated to the supplier¹.

Dimension Data's Public Infrastructure-as-a-Service (Public Cloud), Private IaaS (Private Cloud), Managed Hosting, Enterprise Mobility-as-a-Service (EMaaS), Cloud Private Network Connection (CPNC), Security Operations Centre (SOC) and Cloud Services for Microsoft (CSfM) have all been certified by independent, third-party auditors according to international information security standards ISO 27001:2013 (with specific inclusion of the privacy controls of ISO 27018), CSA-STAR, and SOC 1 SSAE 16 Type 2.

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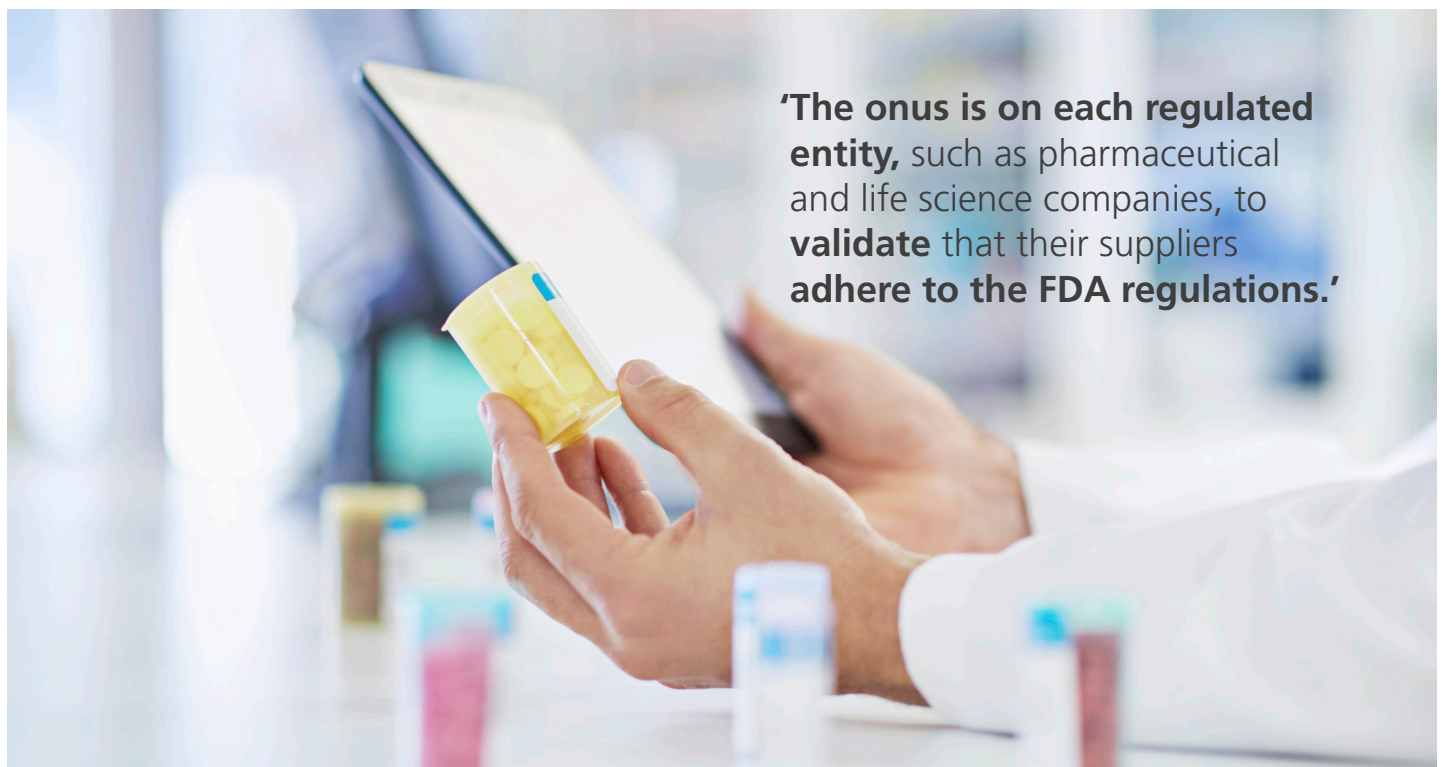
¹ "Compliance oversight and approvals cannot be delegated to the outsource partner" *GAMP® Good Practice Guide: IT Infrastructure, Control and Compliance*, ISPE, September 2005

A full table of Dimension Data's current security certifications for its cloud products is contained below (current as at February 2016). While these standards do not specifically focus on FDA regulatory compliance, their objectives are very similar to the CFR Title 21 Part 11 requirements and serve to ensure the confidentiality, integrity, and availability of data stored on the Dimension Data cloud platform.

	SOC 1	ISO 27001	ISO 27018 ²	CSA STAR	PCI DSS	ASIO T4	ISO 9001	EU Model Clauses
IaaS								
Public Cloud	✓	✓	✓	✓				✓
Private Cloud	✓	✓	✓	✓				✓
Provider Cloud		✓	✓	✓				✓
Managed Hosting	✓	✓	✓	✓				✓
Networking								
Cloud Private Network Connection (CPNC)		✓	✓	✓				
Security Operations Centre								
Managed Security Services		✓			✓	✓	✓	
Real-time Threat Management		✓			✓	✓	✓	
Security Consulting Services		✓			✓	✓	✓	
End User Computing								
Cloud Services for Microsoft (CSfM)		✓	✓	✓				
Enterprise Mobility-as-a-Service (EMaaS)		✓	✓	✓				

Dimension Data clients can request access to the compliance reports or an update on certifications, subject to a non-disclosure agreement, by contacting iss-team@itaas.dimensiondata.com. More information on Dimension Data's global and regional industry certifications can be found at <http://www.dimensiondata.com/en-US/AboutUs/Company-Highlights/Pages/Certifications.aspx>.

² Included in ISO 27001 control set and assessed by an independent auditor



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Middle East & Africa

Algeria • Angola
Botswana • Congo • Burundi
Democratic Republic of the Congo
Gabon • Ghana • Kenya
Malawi • Mauritius • Morocco
Mozambique • Namibia • Nigeria
Oman • Rwanda • Saudi Arabia
South Africa
Tanzania • Uganda
United Arab Emirates • Zambia

Asia

China • Hong Kong
India • Indonesia • Japan
Korea • Malaysia
New Zealand • Philippines
Singapore • Taiwan
Thailand • Vietnam

Australia

Australian Capital Territory
New South Wales • Queensland
South Australia • Victoria
Western Australia

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Austria • Belgium
Czech Republic • France
Germany • Hungary
Ireland • Italy
Luxembourg • Netherlands
Poland • Portugal
Slovakia • Spain • Switzerland
United Kingdom

Americas

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