



FDA CFR Part 11

September 19th, 2016

Introduction

FDA 21 CFR Part 11 regulation requires that computerized systems include technical controls to assure that electronic records maintain security and integrity and are essentially as inspect-able as paper records, and to assure that electronic signatures meet standards that allow them to have the same legal bearing as traditional handwritten signatures.

Does Authentag / Blulist comply with FDA CFR Part 11?

Authentag / Blulist meets the technical requirements of 21 CFR Part 11 and is well suited for implementation by companies in the life sciences industries.

Controls for Closed Systems	Authentag / Blulist specifically meets the technical requirements	Authentag / Blulist in conjunction with a procedural control by customer needed	Procedural control must be implemented by the customer / manufacturer
11.10 (a) Validation	✓		
11.10 (b) Copies of Records	✓		
11.10 (c) Protection of Records	✓		
11.10 (d) System Access	✓		
11.10 (e) Audit Trails	✓		
11.10 (f) Sequencing of Events	✓		
11.10 (g) Authority Checks	✓		
11.10 (h) Device Checks			✓
11.10 (i) Training			✓

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Inventory



11.10 (j) <i>Electronic Signature Accountability</i>			✓
11.10 (k) <i>Control of System Documentation</i>			✓
11.30 Controls for Open Systems	✓		
<i>Electronic Signatures</i>			
11.50 (a) Content of Signature Manifestation	✓		
11.50 (b) Control and Display of Signature Manifestation	✓		
11.70 Signature/Record Linking	✓		
<i>General Requirements</i>			
11.100 (a) Uniqueness of Signatures	✓		
11.100 (b) Identification of Signers			✓
11.100 (c) Equivalence to Handwritten Signatures			✓

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Electronic Signature Components and Controls			
11.200 (a) Non-Biometric Signatures	✓		
11.200 (a)(1) Series of Non-Biometric Signings	✓		
11.200 (b) Biometric Signatures			✓
<i>Controls for Identification Codes/Passwords</i>			
11.300 (a) Uniqueness of Identification Code/Password	✓		
11.300 (b) Password Management		✓	
11.300 (c) Device Loss Management			✓
11.300 (d) Transaction Safeguards		✓	
11.300 (e) Device Testing	✓		

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