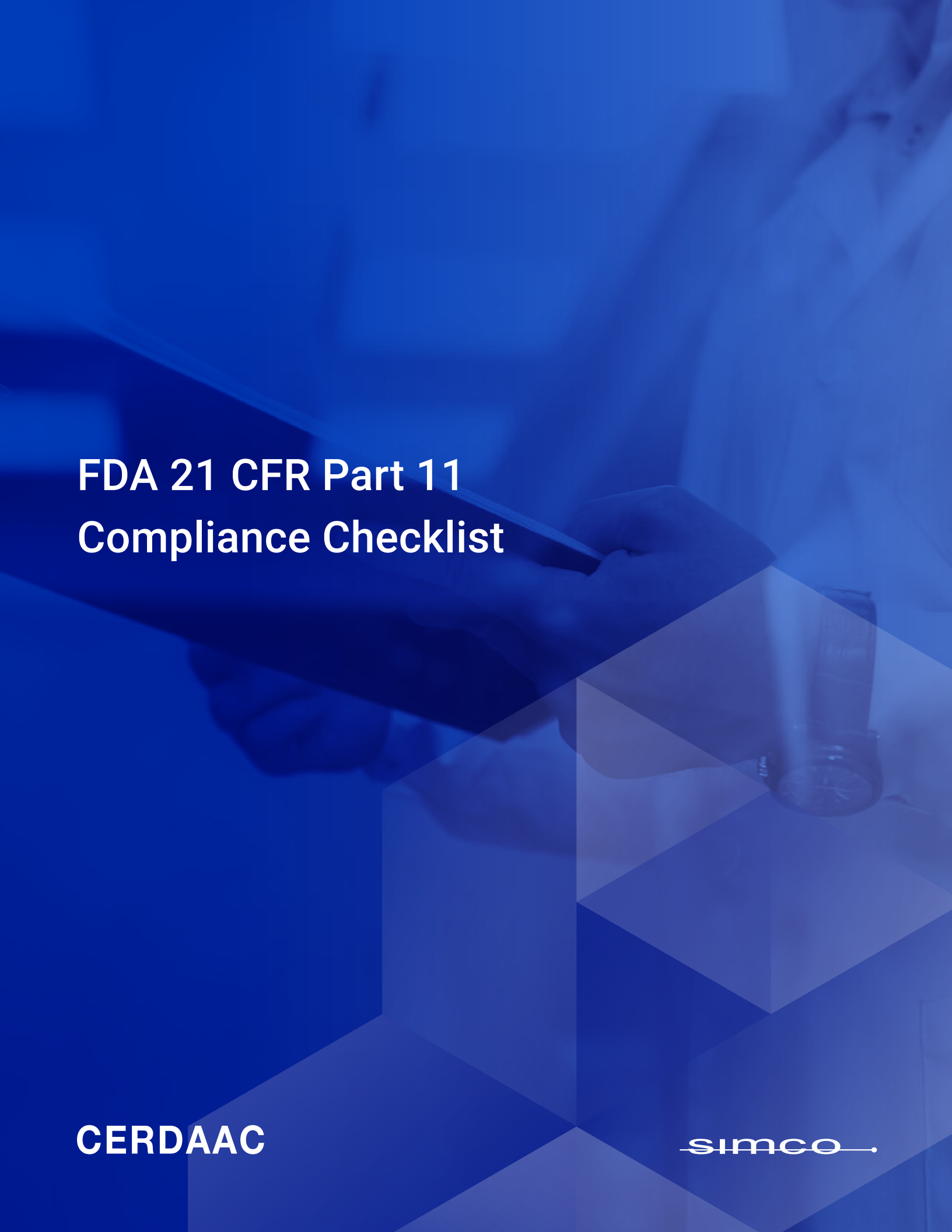

FDA 21 CFR Part 11 Compliance Checklist

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FDA 21 CFR Part 11 Compliance Checklist

Systems	
Has the system been validated to demonstrate accuracy, reliability, consistent intended performance?	✔
Is it possible to discern invalid or altered results?	✔
Are records protected and readily retrievable throughout their retention period?	✔
Is the system capable of producing accurate and complete copies of records in electronic form for inspection, review and copying by the FDA?	✔
Does the system ensure that only authorized individuals can use it, electronically sign records, alter a record, or perform other operations?	✔
Is the sequencing of system steps or events enforced by the system?	✔
Is there documented training, including on the job training, for all users, developers, support staff?	✔
Is there a formal change control procedure for system documentation that maintains a time sequenced audit trail of changes?	✔
Is the distribution of, and access to, systems operation and maintenance documentation controlled?	✔
Is the data encrypted?	✔
Audit Trails	
Is there a secure, computer generated, time stamped audit trail that records the date and time of operator entries and actions that create, modify or delete records?	✔
Upon making changes to a record, is the previous record still available and not obscured by change?	✔
Is an electronic audit trail retrievable throughout the record retention period?	✔
Is the audit trail available for review and copying by the FDA?	✔
Are device checks used to determine, as appropriate, the validity of source of data input or operational instruction?	✔
Is there evidence to show that the system checks the validity of the source of any data or instructions received?	✔
Are there written policies that hold individuals accountable and responsible for actions initiated under their electronic signatures, in order to deter record and signature falsification?	✔
Digital / Electronic Signatures	
Do signed electronic records contain the following information? • Printed name of signer • Date and time of signing • Meaning of signature (approval, review, etc.)	✔
Is the above information shown on displayed and printed copies of the electronic record?	✔
Are electronic signatures linked to their respective electronic records to ensure they cannot be cut, copied or transferred for falsification purposes?	✔
Are electronic signatures unique to an individual?	✔

FDA 21 CFR Part 11 Compliance Checklist

Digital / Electronic Signatures	
Are electronic signatures ever reused or reassigned to anyone else?	✔
Is the identity of an individual verified before an electronic signature is allowed?	✔
Is the electronic signature made up of at least two components, such as an identification code and password?	✔
When several signings are made during a continuous session, is the password executed at each signing?	✔
If signing is not done in a continuous session, are both components of the electronic signature executed with each signing?	✔
Are electronic signatures only used by their genuine owners?	✔
Would an attempt to falsify an electronic signature require the collaboration of at least two individuals?	✔
Access and Control	
Are controls in place to maintain the uniqueness of each combined identification code and password, such that no individual can have the same combination of code and password?	✔
Are procedures in place to ensure that the validity of identification codes are periodically checked?	✔
Do passwords periodically expire and need revising?	✔
Is there a procedure for recalling identification codes and passwords if a person leaves or is transferred?	✔
Is there a procedure for detecting attempts at unauthorized use and for informing Management?	✔
Is there a procedure for reporting repeated or serious attempts at unauthorized use to Management?	✔
Is there a loss management procedure to be followed if a device is lost or stolen?	✔
Is there a procedure for electronically disabling a device if it is lost, stolen or potentially compromised?	✔
Are there controls over the issuance of temporary and permanent replacements?	✔
Is there initial and periodic testing of devices?	✔
Does this testing check that there have been no unauthorized alterations?	✔