# 27-Point Self-Assessment for FDA Recordkeeping Compliance Checklist

Use Cerulean's self-assessment checklist to help you begin to identify gaps in your organization's FDA records retention and information integrity efforts.

Cerulean provides a formal, two-day information integrity ("Part 11") and records diagnostic service for executives, business owners, quality departments, and due diligence teams. Clients receive a formal analysis, a set of prioritized recommendations, and suggested remediation activities and timelines. Clients can then use Cerulean's report to close these gaps themselves, with or without expert help, or draw upon the report to issue a request for proposal (RFP) for further improvement. For more information on our FDA recordkeeping & document retention expert services, please contact us through our website (www.Ceruleanllc.com).

## Instructions

Answer each question below to the best of your knowledge. If you are not sure, chances are you should mark "No." Do not mark "Yes" unless you have some level of documented proof (*e.g.*, training schedules, policies in hand, etc.). **This is the time to be critically honest**.

The first checklist table covers typical organizational controls and has 13 questions; the second checklist table highlights common technology-related controls and has 14 questions.

| # | Organizational Controls Question | Response |
|---|---|---|
| **1.** | Do you hold annual reviews with your IT, quality, regulatory affairs/legal, HR and records management teams to discuss applicable regulations and rules as they apply to your records and computer systems? (If this is part of preparing for an annual QSMR or APR, choose "yes") | ☐ Yes<br>☐ No |
| **2.** | Do you have a Records Retention Schedule that (at minimum) identifies key regulated record-types (such as training files) and required retention periods? | ☐ Yes<br>☐ No |
| **3.** | Are the records and information management policies (such as retention time) consistent for both physical and digital records? | ☐ Yes<br>☐ No |
| **4.** | Do you provide a records integrity and data quality primer (or training) to all personnel? | ☐ Yes<br>☐ No |
| **5.** | Are recordkeeping and information management policies regularly audited? | ☐ Yes<br>☐ No |
| **6.** | Do you regularly inventory and track all regulated records (such as medical files, product formulations, ingredient or parts lists, etc.)? | ☐ Yes<br>☐ No |
| **7.** | Does your record inventory differentiate between different record categories (*e.g.*, financial, clinical, corporate, HR, etc.)? | ☐ Yes<br>☐ No |
| **8.** | Is the records inventory reviewed at least once every 2 years and updated? | ☐ Yes<br>☐ No |
| **9.** | Is there a policy or guidance on what constitutes a record (including standard naming conventions to facilitate indexing or searching)? | ☐ Yes<br>☐ No |
| **10.** | Do you maintain logbooks of paper records transported to and from offsite archival storage? | ☐ Yes<br>☐ No |
| **11.** | Do you regularly conduct sampling audits of your archived paper records? | ☐ Yes<br>☐ No |
| **12.** | Has your offsite record archive storage vendor been qualified? | ☐ Yes<br>☐ No |
| **13.** | Is there a "clear desk" policy, whereby confidential and privacy-guaranteed records (such as patient files or developing intellectual property) are put away outside of working hours? | ☐ Yes<br>☐ No |

| # | Technology Controls Question | Response |
|---|---|---|
| **1.** | Do you have controls in place to prevent any one individual – such as a computer department employee or contractor – from being able to delete or alter information without being detected? | ☐ Yes ☐ No |
| **2.** | Is there a physical-based access system (keys, badges, etc.) to get into your company offices? | ☐ Yes ☐ No |
| **3.** | Is there a computer-based access system (userID and password, biometrics, etc.) to get into your company's computers and network? | ☐ Yes ☐ No |
| **4.** | Are userIDs (*e.g.*, usernames) unique to each person? *Are you sure?* | ☐ Yes ☐ No |
| **5.** | Are computer hard drives, CDs, DVDs, diskettes, tapes, etc. overwritten multiple times or destroyed before being disposed of? | ☐ Yes ☐ No |
| **6.** | Are logbooks and/or audit trails maintained of electronically archived information transported to and from offsite storage? | ☐ Yes ☐ No |
| **7.** | Does your records inventory track the relative location (i.e., "on the EDMS" or "on Purchasing's shared drive") of electronic files? | ☐ Yes ☐ No |
| **8.** | If compound data files are used (*e.g.*, files that contain other files or that link to one another), are there audit trails and linkage reports? | ☐ Yes ☐ No |
| **9.** | Are records saved electronically saved with an associated data format and time? | ☐ Yes ☐ No |
| **10.** | Are automated backups of electronically-stored information conducted on a regular basis? | ☐ Yes ☐ No |
| **11.** | Are IT personnel (including outsourced providers) aware of their responsibilities regarding confidentiality and privacy rules? | ☐ Yes ☐ No |
| **12.** | Have outsourced IT provider records requirements – including a responsibility for maintaining records integrity – been documented in formal contracts? | ☐ Yes ☐ No |
| **13.** | Do you regularly sample, audit and test restore archived electronic data? | ☐ Yes ☐ No |
| **14.** | Is automated computer virus-protection enabled on all equipment storing electronic records? | ☐ Yes ☐ No |

Cerulean's formal FDA recordkeeping and information management diagnostic services includes a detailed set of questions and checklists that clients can retain and use for further self-improvement in the future. Contact us today for more information on bringing this to your benefit.