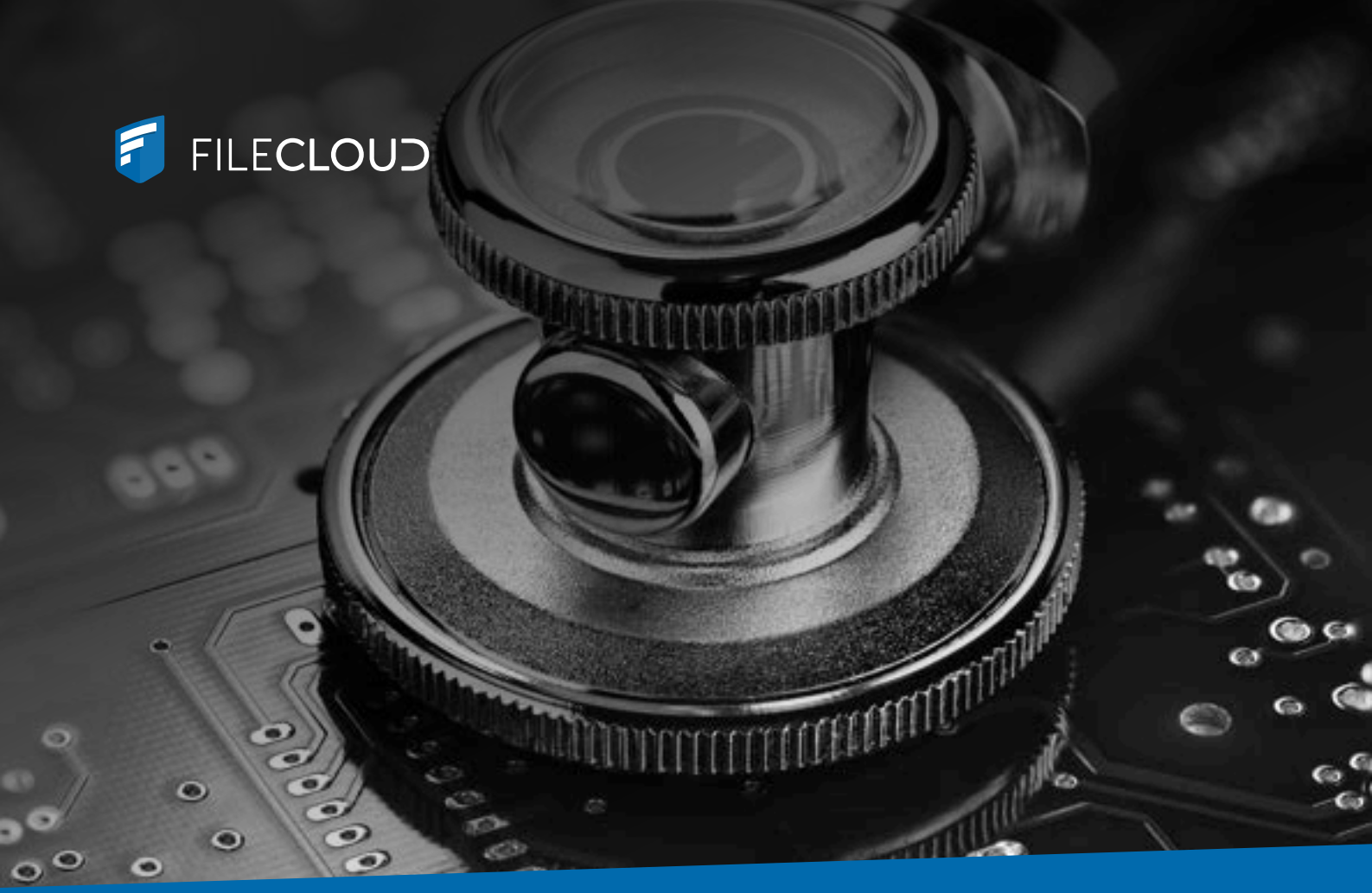

GxP Compliance Healthcare and Life Sciences

whitepaper

GxP compliance is a critical type of regulation for the life sciences industry that sets requirements around the development of drugs, medical devices, and medical software applications.

Regulations and guidelines that fall under the GxP umbrella include Good Clinical Practices (GCP), Good Laboratory Practices (GLP), and Good Manufacturing Practices (GMP). Good Manufacturing Practices may also be further segmented into Current Good Manufacturing Practices (CGMP) or Good Automated Manufacturing Practices (GAMP).

This white paper defines GxP compliance, why it's important, and how it is structured and regulated within the US and EU, focusing on GxP requirements for secure file sharing and data governance within and across computer systems and IT infrastructure. This white paper also describes how FileCloud can support content management and data governance to comply with GxP requirements.

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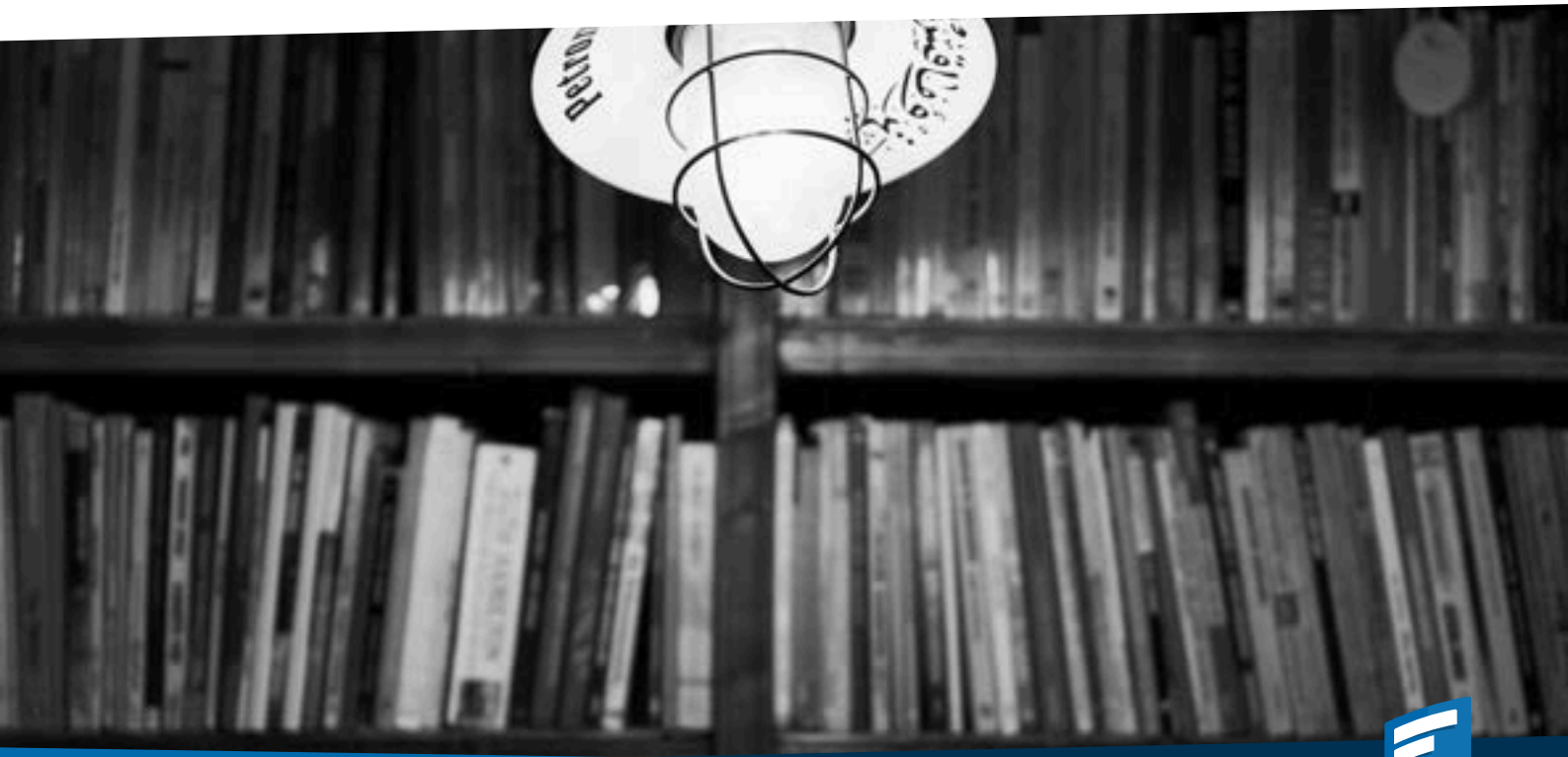


What is GxP Compliance?

GxP compliance is a critical type of regulation that aims to prevent harm or damage, stemming from improper development or testing of medical and food products. The acronym applies to the life sciences industry and sets guidelines pertaining to drugs, medical devices, and medical software applications. "G...P" stands for "Good...Practices," and the "x" is a variable to stand in for relevant sub-industries, e.g., Good Clinical Practices (GCP), Good Laboratory Practices (GLP), or Good Manufacturing Practices (GMP).

GxP is a generalized name to refer to compliance guidelines and requirements; there is no centralized organization that publishes GxP standards. Instead, each country establishes a body for regulatory oversight. These bodies are then responsible for developing and publishing requirements and guidelines. Regulations and oversight may differ from country to country, but since they address the same industry, requirements often overlap or mirror each other across borders.

Life Sciences organizations evaluate their regulatory requirements based on two simple concepts:

Type of products developed

Country of development

In general, GxP regulations aim to ensure the safety of food and medical products for consumers and to safeguard the integrity of data that informs product-related safety decisions. Specific industries are subject to different sets of regulations; for example, a medical device manufacturer would be subject to Good Manufacturing Practices (GMP), whereas a research lab testing vaccines would operate with Good Laboratory Practices (GLP) requirements in mind.

Additionally, life sciences organizations must consider the array of technological tools and systems used to support product development. As more tools have become computerized, GxP requirements have evolved to safeguard the development and distribution process of food and medical products. These requirements ensure technological systems are appropriately deployed, validated, and operated in line with their intended use. Requirements have evolved to address data management and validation solutions developed by IT service providers specifically for the life sciences industry.

In the United States, GxP requirements affecting data and IT systems are regulated by the US Food and Drug Administration (FDA) CFR Title 21 Part 11. In the European Union, regulations are outlined in EudraLex Volume 4—GMP Guidelines, Annex 11.

Why is GxP Compliance Important?

GxP compliance guidelines are essential not just for researchers or developers – they also impact certain operations that are carried out, like product testing, assembly line organization, marketing, distribution, and other information relays. The development of drugs and medical devices involves different kinds of professional expertise and tools.

Each stage requires different kinds of proprietary and precise information; IT and data processing solutions are increasingly necessary to organize, store, and share this information with the necessary parties. As a result, GxP compliance often includes requirements addressing how these solutions handle and protect data.

Businesses and organizations in the pharmaceutical, medical device, healthcare, and life sciences sectors stand to benefit from achieving and maintaining relevant GxP compliance. Organizations can use regulatory compliance to help identify and mitigate risk throughout their development processes. This is especially true when regulations are coherent and accessible for industries, such that regulation becomes a reference for risk management rather than a burden.

Furthermore, any time a major drug or medical device is recalled because of faulty development or lack of quality testing, the entire industry comes under scrutiny. The life sciences industry is entrusted with public health and welfare, and regulations are designed to uphold that trust. Organizations and businesses can leverage regulatory compliance to ensure the safety and efficacy of products, while also protecting their reputation with consumers and their profit margins from costly litigation.

Lastly, complying with regulatory requirements is often cheaper than paying fees and damages for failed compliance in the event of an audit or incident.

GxP-related regulatory penalties are calculated to incentivize the life sciences industry to comply with requirements that safeguard consumer and public health against dangerous or duplicitous products.

How to Comply with GxP Requirements

As discussed above, GxP compliance is a non-specific name referring to best practices for sectors in the life sciences. The most common types regulations are listed below:

Good Laboratory Practices (GLP)

Quality research data relies on foundational tenants like repeatability, uniformity, reliability, and quality. If research is conducted without these tenants, the value of the data is compromised. Regulations help ensure the quality and value of studies and product development as an evolving body of knowledge. Furthermore, lab protocols for non-clinical research are designed to preserve the integrity of health products under research in the lab.

GLP requirements examine risk versus safety measures, as they apply to medicine, cosmetics, food additives, industrial chemicals, and veterinary drugs. The individuals and organizations involved in a study must also be documented, from management and sponsors to Principal Investigators (PIs) and study personnel. The study's development, implementation, tracing, and testing must be conducted using a certified (ISO 9001) quality management system.

ISO 9001 establishes criteria "based on a number of quality management principles including a strong customer focus, the motivation and implication of top management, the process approach and continual improvement."

FileCloud is an ISO 9001 certified Enterprise File Sync and Share (EFSS) solution.

Good Clinical Practices (GCP)

GCP addresses clinical trials and specifies that the ethics of trials and value of human life must be prioritized over corporate interests. This regulation is considered a global standard by the International Conference on Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH). GCP requirements protect the rights, safety, and wellbeing of human subjects and evaluate the potential risks and benefits involved in a study.

Good Documentation Practices (GDP)

Wholesale distributors are subject to GDP to guarantee the quality and integrity of medicines throughout the supply chain. Requirements ensure that:

Medicines are transported in proper conditions (e.g., temperature regulation)

Contamination safeguards are in place (packaging, layering, and labeling)

Shipments are sent only to authorized recipients and within the appropriate timespan

Distributors have mechanisms and policies in place to identify and remove defective products.

Good Manufacturing Practices (GMP)

Manufacturers of medical and food products are subject to GMP compliance requirements, which stipulate standards for cleanliness, sanitation, and hygiene, valid process usage, complaint handling, record keeping, and personnel qualifications. Proactive requirements safeguard the development and distribution of products across safety, purity, and efficacy.

GMP compliance can be further specified into **Good Automated Manufacturing Practices (GAMP)**, which addresses automation efforts. Companies can leverage computerized systems to automate aspects of production; these systems can then be validated to ensure the safety and efficacy of the product on a larger scale.

GMP covers all aspects of production from the starting materials, premises, and equipment to the training and personal hygiene of staff. Detailed written procedures are essential for each process that could affect the quality of the finished product.

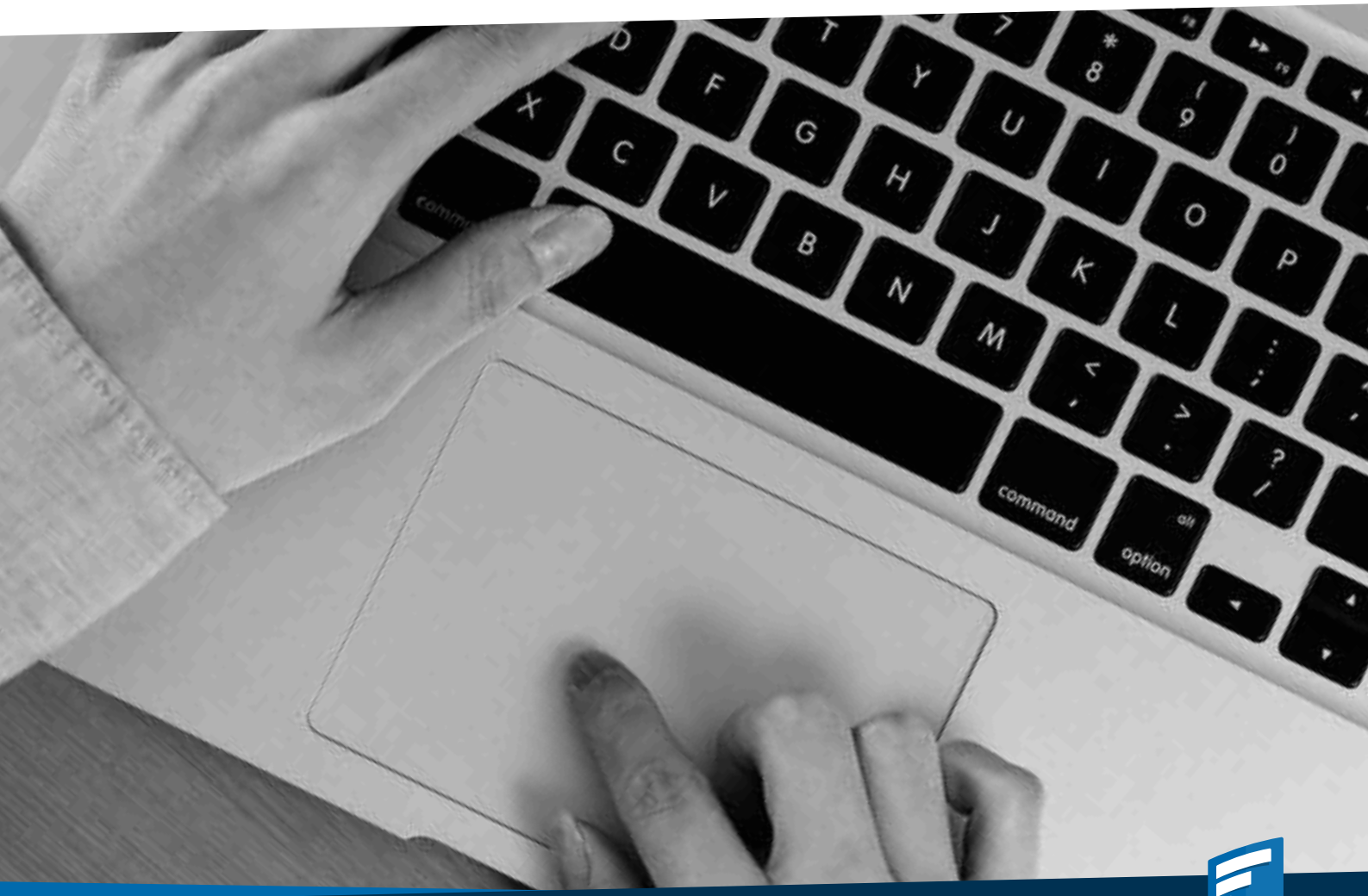
There must be systems to provide documented proof that correct procedures are consistently followed at each step in the manufacturing process - every time a product is made.

Digital Enterprise Solutions Can Help Meet GxP Compliance Requirements

Compliance requirements can be difficult to untangle and even harder to meet. This is particularly true when it comes to expanding application of requirements to digital and electronic data, which must be easy to organize and read, freely accessible to authorized parties in the life sciences industry, and properly secured behind multiple layers of protection.

Responsive solutions have also developed workflows and other automation tools to support process documentation while reducing opportunities for human error. Process documentation is a major element of GxP compliance and is also a primary sources of audit failures. Tools that streamline GxP-required processes and build in validation checkpoints ensure that life sciences organizations meet regulations without compromising their output or overall productivity.

For life science research organizations, pharmaceutical enterprises, and medical device companies operating within the United States, EFSS solutions offer specialized tools and features that can help address elements within the FDA's electronic Code of Federal Regulations (eCFR) Title 21, Parts 11 and Part 80.



FDA GxP Compliance

The FDA's GxP framework is built upon foundational principles of data integrity, traceability, accountability, and risk management. These regulations outline requirements and guidance impacting the development and production of medical devices and pharmaceuticals.

FDA requirements emphasize the importance of process documentation, to ensure consistent execution in accord with approved specifications and full investigation of any deviations. Documentation must demonstrate that quality is built into each stage of the product lifecycle rather than merely tested for at the end.

Increasingly, FDA GxP compliance incorporates risk-based approaches that allow organizations to focus validation and verification efforts on critical aspects most likely to impact product quality and patient safety. This shift toward risk-based compliance strategies is reflected across the FDA's evolving guidance documents, including those addressing electronic systems, manufacturing processes, and software validation.

FDA 21 CFR Part 11

The FDA issued part 11 of CFR Title 21 in March 1997 to regulate “electronic records, electronic signatures, and handwritten signatures executed to electronic records as equivalent to paper records and handwritten signatures executed on paper.” These requirements apply to all program areas regulated by the FDA and are designed for permissive use of electronic technology, even as it strives to safeguard public health.

In 2003, the regulations were amended to limit the types of documentation that could be subject to part 11 requirements. This was designed to curb and prevent inappropriate regulatory burdens on the industry. However, the documentation that remained within the scope of part 11 is subject to increased enforcement.

Summary of Provisions:

- Limit system access.
- Use operational system checks, authority checks, and device checks.
- Ensure persons developing, maintaining, and/or using electronic systems are properly trained.
- Establish and adhere to written policies for individual accountability pertaining to electronic signatures.
- Apply controls over system documentation, including open and closed systems.
- Other requirements related to electronic signatures (e.g., §§ 11.50, 11.70, 11.100, 11.200, and 11.300).

FDA 2011 Process Validation Guidance

In 2011, additional amendments were made in the form of the FDA 2011 Process Validation Guidance: Process Validation Revisited. This peer-reviewed publication provides information on how the FDA evaluates compliance for the life sciences industries and was written to replace the FDA's 1987 Guideline on General Principles of Process Validation.

The 2011 Guidance recommends a lifecycle-based approach that takes into account:

Process design

Process qualification

Continued process verification

Manufacturers are advised to develop protocols that build upon process design knowledge as a means of identifying criteria and process performance indicators. These criteria and indicators allow for science and risk-based decision-making about the manufacturing process as a whole. With a lifecycle-based approach, manufacturers can then answer questions along the lines of "Does the process consistently produce quality products?" and "Is the process in a state of control?

The 2011 Guidance emphasizes documenting and evaluating evidence that answers these questions rather than satisfying a three-batch checklist.

FDA 21 CFR Part 820: Quality Management System Regulation (QMSR)

The aforementioned 2011 Process Validation Guidance provides a methodology and best practices for fulfilling validation requirements which have been legally mandated in FDA 21 CFR Part 820 Quality Management System Regulation (QMSR). Whereas the Process Validation Guidance focuses GxP guidance around a lifecycle-based approach, Part 820 outlines a quality systems approach.

The FDA first established 21 CFR Part 820 in 1997 to ensure that medical devices manufactured for commercial distribution in the United States met certain requirements and specifications, replacing the previous Good Manufacturing Practice (GMP) regulation.

The current iteration of Part 820 aligns with ISO 13485 standards, aligning domestic requirements with international quality management principles. This regulation applies to manufacturers of medical devices intended for human use and establishes minimum requirements addressing methods, facilities, and controls used in manufacturing, packaging, labeling, storage, installation, and servicing of medical devices.

Because of the similarity of drug and device Current Good Manufacturing Practices (CGMP) requirements, FDA considers demonstrating compliance with one of these two sets of regulations (e.g., Part 820, addressing device CGMP) along with specified provisions from the other set (e.g., Part 4: addressing drug CGMP) as demonstrating compliance with all CGMP requirements from both sets.

Summary of General Provisions:

- 820.10: Requirements for a quality management system
- Document a quality management system that complies with applicable requirements of ISO 13485.
- Comply, as appropriate, with other applicable regulatory requirements to fully comply with listed ISO 13485 requirements.
- Manufacturers of class II, III, and specified I devices (defined explicitly in 21 CFR Part 820.10) must comply with requirements in Design and Development, Clause 7.3 and Subclauses in ISO 13485.
- Manufacturers of devices that support or sustain life must comply with the requirements in Traceability for Implantable Devices, Clause 7.5.9.2 in ISO 13485, in addition to all other applicable requirements in this part, as appropriate.
- Failure to comply with any applicable requirement in this part renders a device adulterated; such a device and any involved persons responsible are subject to regulatory action.

Summary of Supplemental Provisions

- 820.35: Control of Records
  Clause 4.2.5 in ISO 13485; additionally, the manufacturer must include specified information in certain records (complaints, servicing activities, unique device identification, and confidentiality).
- 820.45: Device labeling and packaging controls
  Each manufacturer must document and maintain procedures that provide a detailed description of activities to ensure the integrity, inspection, storage, and operations for labeling and packaging, during the customary conditions of processing, storage, handling, distribution, and, as appropriate, use of the device.

FDA Computer Software Assurance for Production and Quality System Software (“CSA Guidance”)

In 2022, the FDA issued draft guidance, "Computer Software Assurance for Production and Quality System Software" ("CSA Guidance"). This guidance was prepared to streamline validation activities while maintaining compliance with 21 CFR Part 820.

Additionally, the CSA Guidance supersedes Section 6 of the "General Principles of Software Validation" guidance, addressing practices and processes for computers and automated data systems involved in production or quality systems.

“Computer Software Assurance” is defined as a risk-based approach to establish confidence that software used in automation as part of production or quality systems is fit for its intended use. The CSA Guidance emphasizes that software which maintains a "validated state" throughout its lifecycle should perform as intended, helping ensure that finished devices will be safe, effective, and compliant with regulatory requirements.

Computer Software Assurance Risk Framework

The framework described in the CSA Guidance outlines testing methods and activities that support appropriate rigor and confidence in validating computer software while clarifying FDA expectations around software validation for computers and automated data processing systems.

In brief, the framework outlines the following objectives:

a) Identify the intended use – is the software intended for use as part of production or a quality system?

b) Determine risk-based approach – what are reasonably foreseeable software failures, do they pose a high process risk, and what are the appropriate assurance activities?

c) Determine appropriate assurance activities – are these assurance activities commensurate with the risk associated with failure of the medical device or the process?

d) Establish the Appropriate Record – how will sufficient objective evidence be captured to demonstrate that the software feature, function, or operation was assessed and performs as intended?

Though this CSA Guidance is not considered a binding regulation, manufacturers can utilize the resource to:

- Focus validation efforts on features and functions that present the highest risk.
- Reduce unnecessary documentation for lower-risk software functions.
- Leverage supplier documentation when appropriate.
- Implement "least burdensome" approaches to software validation.
- Maintain compliance with other FDA regulatory requirements while improving efficiency in validation activities.

EudraLex GxP Compliance

The European Union organizes rules and regulations governing medicinal products within EudraLex. The publication consists of ten volumes covering pharmaceutical legislation, guidelines, and procedures for both human and veterinary medicinal products.

- Volume 1: Pharmaceutical legislation for human medicinal products.
- Volume 2: Notice to Applicants, procedures for marketing authorization, presentation of applications, and regulatory guidelines.
- Volume 3: Scientific guidelines for medicinal products for human use, helping applicants prepare marketing authorization applications.
- **Volume 4: EU Guidelines for Good Manufacturing Practice (GMP) for medicinal products for human and veterinary use.**
- Volume 5: Pharmaceutical legislation for veterinary medicinal products.
- Volume 6: Notice to applicants for veterinary medicinal products.
- Volume 7: Guidelines for veterinary medicinal products.
- Volume 9: Pharmacovigilance guidelines.
- Volume 10: Guidelines for clinical trials.

EudraLex Volume 4 – Good Manufacturing Practice (GMP) Guidelines

EudraLex Volume 4 specifically addresses Good Manufacturing Practice (GMP) guidelines and is organized into three parts:

Part 1: Basic Requirements for Medicinal Products
Part 2: Basic Requirements for Active Substances used as Starting Materials
Part 3: GMP Related Documents

Similar to the FDA requirements and objectives, EudraLex Volume 4, Part 1 establishes that manufacturers must ensure that medicinal products are fit for their intended use, that they comply with Marketing Authorisation or Clinical Trial Authorisation requirements, and that risk to patients is mitigated through adequate safety, quality, and efficacy measures.

EudraLex Volume 4 also defines the application scope of GMP: the lifecycle stages from the manufacture of investigational medicinal products, technology transfer, commercial manufacturing through to product discontinuation.

EudraLex Volume 4, Part 1, Chapter 1: Pharmaceutical Quality System

GMP guidelines are not, on their own, sufficient to provide the full scope of compliance assurance. EudraLex identifies the implementation of a Pharmaceutical Quality System, which incorporates GMP and Quality Risk Management, as an effective method of meeting requirements.

As a result, EudraLex Volume 4, Part 1, Chapter 1 explicitly describes a Pharmaceutical Quality Systems, with GMP requirements outlined in Chapter 1.8.

GMP Basic Requirements, Volume 4, Part 1, Ch 1.8

(i) All manufacturing processes are clearly defined, systematically reviewed in the light of experience and shown to be capable of consistently manufacturing medicinal products of the required quality and complying with their specifications;

(ii) Critical steps of manufacturing processes and significant changes to the process are validated;

(iii) All necessary facilities for GMP are provided including:

- Appropriately qualified and trained personnel;
- Adequate premises and space;
- Suitable equipment and services;
- Correct materials, containers and labels;
- Approved procedures and instructions, in accordance with the Pharmaceutical Quality System;
- Suitable storage and transport;

(iv) Instructions and procedures are written in an instructional form in clear and unambiguous language, specifically applicable to the facilities provided;

(v) Procedures are carried out correctly and operators are trained to do so;

(vi) Records are made, manually and/or by recording instruments, during manufacture which demonstrate that all the steps required by the defined procedures and instructions were in fact taken and that the quantity and quality of the product was as expected.

(vii) Any significant deviations are fully recorded, investigated with the objective of determining the root cause and appropriate corrective and preventive action implemented;

(viii) Records of manufacture including distribution which enable the complete history of a batch to be traced are retained in a comprehensible and accessible form;

(ix) The distribution of the products minimises any risk to their quality and takes account of Good Distribution Practice;

(x) A system is available to recall any batch of product, from sale or supply;

(xi) Complaints about products are examined, the causes of quality defects investigated and appropriate measures taken in respect of the defective products and to prevent reoccurrence.

EudraLex Volume 4, Part 1, Chapter 4: Documentation

This particular section of the EudraLex emphasizes the importance of good documentation, as a key structural component of GMP and quality assurance systems.

Documentation is defined as either physical (paper, photographic) or electronic. Required GMP documentation includes:

- The Site Master File
- Instructions (including specifications, manufacturing formulae, processing, packaging , and testing instructions, procedures, protocols, and technical agreements)
- Records, reports, and certificates of analysis

EudraLex describes how documentation is to be handled and used as a component of GMP: the generation and control of documentation, good documentation practices, and retention (with more specific instructions outlined for each type of GMP documentation). These documentation requirements are described in brief.

Generation and Control of Documentation:
4.1. All types of documents should be defined and adhered to.
4.2. Documents should be designed, prepared, reviewed, and distributed with care.
4.3. Documents containing instructions should be approved, signed and dated by appropriate and authorised persons.
4.4. Documents containing instructions should be laid out in an orderly fashion and be easy to check.
4.5. Documents within the Quality Management System should be regularly reviewed and kept up-to-date.
4.6. Documents should not be hand-written; although, where documents require the entry of data, sufficient space should be provided for such entries.

Good Documentation Practices
4.7 Handwritten entries should be made in clear, legible, indelible way.
4.8. Records should be made or completed at the time each action is taken and in such a way that all significant activities concerning the manufacture of medicinal products are traceable.
4.9 Any alteration made to the entry on a document should be signed and dated; the alteration should permit the reading of the original information.

Retention of Documents
4.10 It should be clearly defined which record is related to each manufacturing activity and where this record is located.
4.11 Specific requirements apply to batch documentation which must be kept for one year after expiry of the batch to which it relates or at least five years after certification of the batch by the Qualified Person, whichever is the longer.
4.12 For other types of documentation, the retention period will depend on the business activity which the documentation supports.

EudraLex Volume 4, Annexes

In addition to the Parts and Chapters described previously, the EudraLex also includes Annexes, which provide specific guidance on various aspects of GMP.

Annex 1: Manufacture of Sterile Medicinal Products

Annex 2: Manufacture of Biological active substances and Medicinal Products for Human Use

Annex 3: Manufacture of Radiopharmaceuticals

Annex 4: Manufacture of Veterinary Medicinal Products other than Immunological Veterinary Medicinal Products

Annex 5: Manufacture of Immunological Veterinary Medicinal Products

Annex 6: Manufacture of Medicinal Gasses

Annex 7: Manufacture of Herbal Medicinal Products

Annex 8: Sampling of Starting and Packaging Materials

Annex 9: Manufacture of Liquids, Creams and Ointments

Annex 10: Manufacture of Pressurized Metered Dose Aerosol Preparations for Inhalation

Annex 11: Computerised Systems

Annex 12: Use of Ionising Radiation in the Manufacture of Medicinal Products

Annex 13: Manufacture of Investigational Medicinal Products

Annex 14: Manufacture of Products derived from Human Blood or Human Plasma

Annex 15: Qualification and validation

Annex 16: Certification by a Qualified Person and Batch Release

Annex 17: Parametric release

Annex 18: removed and incorporated into Part II (Basic Requirements for Active Substances used as Starting Materials)

Annex 19: Reference and Retention Samples

Annex 20: removed and incorporated into Part III (GMP Related Documents) along with guidance on the Pharmaceutical Quality System

Annex 21: Importation of medicinal products

EudraLex Volume 4, Annex 11: Computerised Systems

GMP guidelines established in Annex 11 are particularly relevant within the context of this white paper due to the regulatory implications around file sharing and data governance within and across computer systems and IT infrastructure.

Annex 11 defines a computerized system as “a set of software and hardware components which together fulfill certain functionalities. The application should be validated; IT infrastructure should be qualified.”

There are 17 requirements outlined by Annex 11, organized by phases: General, Project Phase, and Operational Phase.

General

1. Risk Management
2. Personnel
3. Suppliers and Service Providers

Project Phase

4. Validation

Operational Phase

5. Data
6. Accuracy Checks
7. Data Storage
8. Printouts
9. Audit Trails
10. Change and Configuration Management
11. Periodic Evaluation
12. Security
13. Incident Management
14. Electronic Signature
15. Batch Release
16. Business Continuity
17. Archiving

FileCloud Tools and Features to Support GxP Compliance

The following tools and features answer the regulatory requirements described above, either individually or in tandem with each other. FileCloud's hyper-secure platform establishes an interwoven defensive line through multiple layers of security tactics.

Similarly, FileCloud leverages an intricate yet easy to deploy hierarchy of permission and retention policies to preserve administrative control and user access. Analytics, reports, and audit logs record platform activity to ease compliance and governance requirements.

Centralized Admin Console

FileCloud's centralized console provides admins with one space to manage user features, devices, files and file shares, governance settings, audit logs and reports, and endpoint security policies.

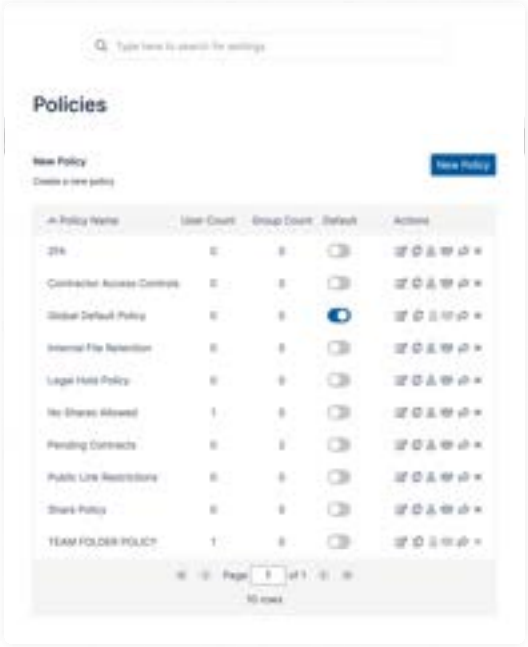
The admin dashboard also shows device access through a Geo-IP map in real time and connects admins with remote device management tools. Admins can block users, wipe data from devices, or send messages and notifications to connected devices. They can also copy or move files from one user to another and revoke share permissions at any time.

Comprehensive Audit Logs

Admins can generate complete audit trails with detailed reporting on all file transfer and sharing activities. Reports and filtering tools can be easily accessed through the centralized admin dashboard and run manually or on a regular basis. FileCloud also offers pre-configured reports for easy deployment or the option to create custom reports. Lastly, reports and audit logs can also be exported as CSV files for ease of internal and external review.

Security Policies

FileCloud offers powerful features to support secure access for authorized users. Admins can implement **two-factor authentication (2FA)** and integrate with **Single Sign-on (SSO)** solutions like SAML. They can also set **password strength requirements** to ensure that user credentials meet a certain threshold. Furthermore, clients can take advantage of **AD/ LDAP integration** to preserve existing login credentials across their network.



With FileCloud's heuristic **antivirus engine**, uploaded files are automatically scanned for viruses. Meanwhile, automated **endpoint backups** provide ransomware protection and peace of mind. FileCloud also deploys **SSL/TLS protocols** for data in transit and **256-bit AES encryption** for data at rest. Additionally, admins can set up file and folder activity notifications to ensure proper attentiveness. With **SIEM integration**, admins can also be notified of suspicious activities and take prompt action.

User & Group Policies, Role-Based Access Controls

FileCloud admins have the ability to create and apply policies across the global array of users, to individual users, or to user groups. This provides extensive and granular control over policy application, which serves to enforce security measures while preserving user access to necessary data.

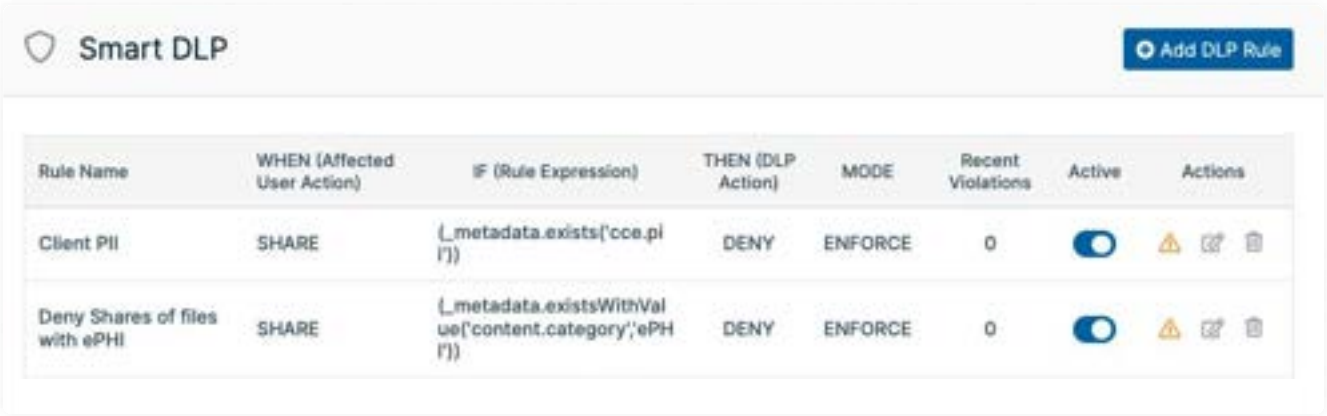
FileCloud also provides Role-Based Access Controls (RBAC) to enable an admin to create Admin roles that restrict access to different admin portal components. These roles can also be used to promote admin-users in a group, which delegates certain powers to team leads, directors, or managers.

Granular Sharing

Admins can set granular permissions over access, file, and folder permissions for each user. Furthermore, features can also be restricted to ensure only the intended users can access, sync, and share data, even within subfolders or specific files in shared folders. Read-only, download limits, and expiry dates on share links provide additional limiting options to protect data.

DLP

FileCloud's Smart DLP system prevents accidental data leaks from end users and can save enterprises from huge compliance fines. Admins can create rules that control user actions (download, share, login) based on IP range, user type, user group, email domain, folder path, document metadata, and user access agents (web browsers, operating systems). The Smart DLP system evaluates rule expressions and variables in real time to "allow" or "deny" selected user actions, logging rule violations for future auditing.



Retention Policies

FileCloud's retention policies allow the automation of record management and disposal according to specific timelines or criteria. Preconfigured policies include:

Legal Hold:
Freezes digital content to aid discovery or legal challenges. Once legal hold is applied, file deletion or modifications are not allowed.

Trash Retention:
Can be configured for automatic and permanent deletion of all files in the trash bin or to expire with no actions.

Retention:
Identifies digital content to be maintained for an unlimited amount of time before deletion or release.

Archival:
Moves and stores old organizational content over the long term. No deletion is allowed until a specified time period is reached. After this time, content is moved to a specific folder.

Admin Hold:
Outranks all other policies and prevents any update or delete of digital content for an indefinite period of time.

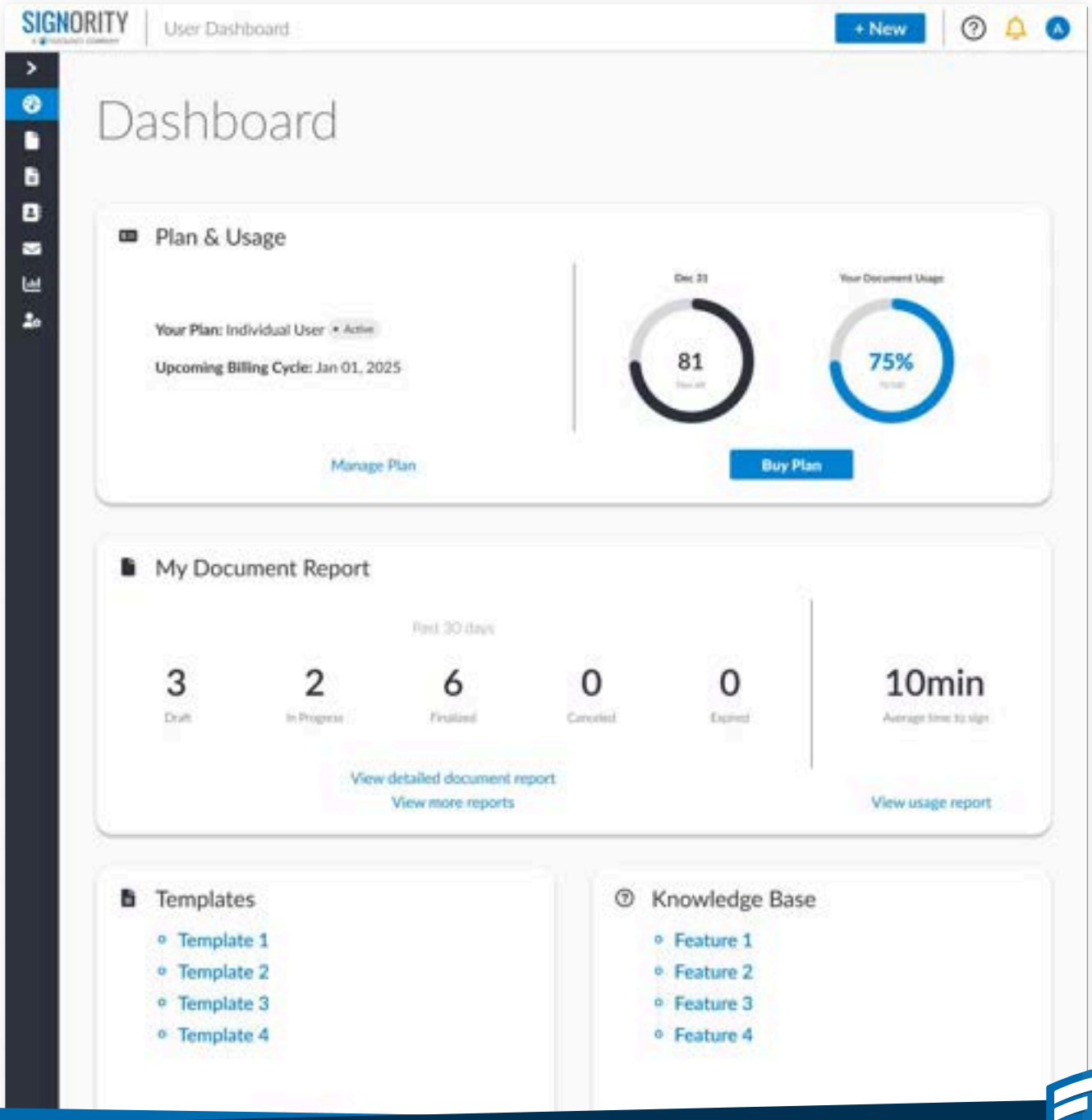
Signority e-signature

e-Signature is easier than ever with FileCloud's Signority integration.

Send diverse file types for e-signing with customizable parameters, choosing between standard and certified signature levels.

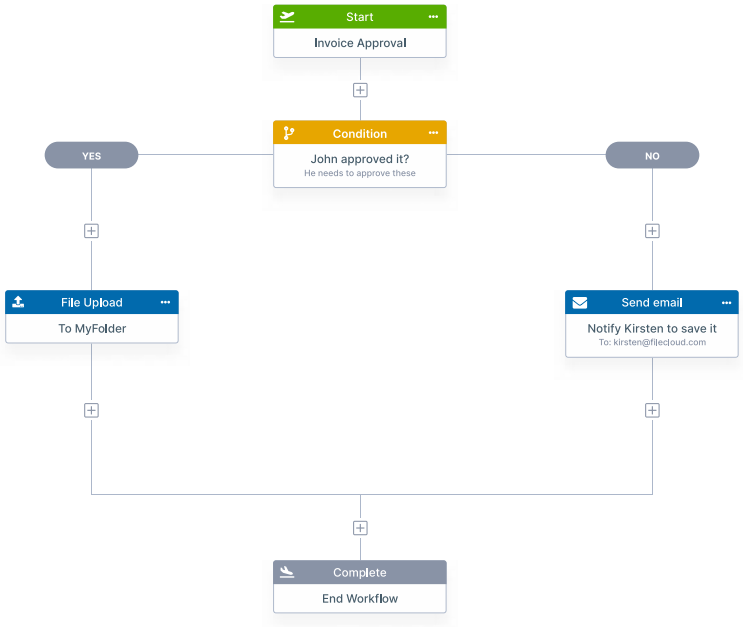
Signature audit logs capture critical data points throughout the document transaction. The PKI encrypted digital signature certificates serve to authenticate the identities of the signing parties and protect the document's integrity against unauthorized access or changes.

Track document status through an intuitive dashboard while maintaining robust security with legally binding signatures, comprehensive audit trails, and digital certificate protection.



Workflow Automation

FileCloud's easy-to-use, drag-and-drop workflow builder empowers users to develop the workflows that suit their unique needs.
Custom workflows can even be shared across teams to improve performance and reduce errors by making high-volume tasks easier to accomplish. Users can respond to workflow notifications through "Actions" available directly from their notifications, and real-time reports provide information on workflow activity.



Digital Rights Management (DRM)

For even greater control over who can access, edit, download, or copy files, FileCloud offers DRM capabilities. These capabilities provide fine-tuned, powerful control over files, even after sharing or distribution. DRM enables users to:

- Restricted viewing mode
- Create access keys for shared documents
- Revoke access even after files have been shared
- Create shares with public/ private/password protections
- Set maximum access counts
- Limit screenshots / printing / copying

Admins can restrict or revoke file access or change view options at any time, placing control over sensitive files back in the hands of the distributor.

About Us

FileCloud is a hyper-secure file sharing, collaboration, and governance solution that provides industry-leading tools for compliance, data leak protection, data retention, and digital rights management. Workflow automation and granular control of content sharing are fully integrated into the complete feature stack.

The FileCloud platform offers powerful file sharing, sync, and mobile access capabilities on public, private, and hybrid clouds. Headquartered in New York, New York, USA, FileCloud is deployed by top Global 1000 enterprises, educational institutions, government organizations, and managed service providers, with over one million users worldwide.

1M+
USERS

3000+
ENTERPRISES

100+
RESELLERS

90+
COUNTRIES

125 Park Avenue FL 25
New York, NY 10017-5550

Fax: +1 (866) 824-9584

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