

Secure and Controlled
File Sharing &
Workflow Management for Pharmaceutical Industry

Whitepaper

Valid from 5th of August 2016



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# Introduction

In clinical research, scientific documentation or medical information very often sensitive data such as e. g. scans, diagnoses, patient data etc. must be exchanged between pharmaceutical companies and their partners. Conventional tools as email, ftp services, download links or usb drives do not fulfill the high regulations of pharmaceutics in terms of data protection, security and compliance. Additionally there is a rising demand to increase productivity and reduce costs. This trends cause the need for common mobile content editing in real-time between researchers, healthcare professionals, patients and other business partners.

The Fabasoft Cloud satisfies these needs by a comprehensive set of functions, which are part of the standard editions and validated accordining to EU GMP Annex 11. Furthermore the cloud solution can easily, quickly and individually be modelled according to the needs of the customer. Within the Fabasoft Cloud pharmaceutic companies can securely synchronise, share and edit documents between all users of a project, and can easily design and manage workflows as e. g. the approval of results of a clinical study. All data handling is fully controlled via full audit-proof archiving. The quality management system, the IT service management system and IT security management of the Fabasoft Cloud is capable to provide products and services that are able to satisfy the requirements of customers in the GxP regulated industries, which has been audited in August 2016. This applies equally to the processes during development of the software and to the processes of supplying the software in a private cloud as SaaS.

# Terms and Conditions

In this document the following terms and definitions are used:

| **Term** | **Definition** |
| --- | --- |
| **GxP** | Good (anything) practice quality guidelines and regulationsM = ManufacturingManufacturing of pharmaceutical products or medical devices (but can also be applied to food)C = ClinicalExecution of clinical studies e. g. for pharmaceuticalsL = LaboratoryOperation of laboratories |
| **CFR** | Code of Federal RegulationsCodification of the general and permanent rules and regulations published by executive departments and agencies of the federal government of the USA |
| **EU-GMP** | Defines the GMP rules for the pharmaceutical industry in the European Union |
| **SaaS** | Software as a ServiceSoftware licensing and delivery model in which software is licensed on a subscription basis and is centrally hosted (cloud). |
| **IaaS** | Infrastructure as a ServiceProviders supply resources like physical computing resources, location, data partitioning, scaling, security, backup etc. on-demand from their large pools of equipment installed in data centers. |
| **PaaS** | Platform as a ServiceProviders usually deliver a computing platform, typically including operating system, programming-language execution environment, database and web server. |
| **ITIL** | Office Government Commerce’s IT Infrastructure Library |

# Requirements for Pharmaceutical Industries

Using electronic media for document management as well as workflow management (including digital signatures), the risk for not documented actions by non-authorised persons is higher than working with paper and handwritten signatures. Therefore necessary regulations for electronic tools used in pharmaceutical industry for the above described purposes are defined by the European Commission via EU Annex 11 to the good manufacturing practice guidelines and by the U.S. Food and Drug Administration in the code of federal regulations, title 21, part 11.

The main requirements covered by both guidelines are:

| **Requirement** | **Description** |
| --- | --- |
| **Life cycle and validation of computerized systems** | Computerized systems, which are used for GMP-related activities, must be validated. The validation process has to be defined by means of a risk-based approach. It must cover all relevant steps of the life-cycle and include appropriate documentation. The functionality of the system must be documented fully traceable in terms of specifications or a system description throughout the whole life-cycle. A formal process for change control and a method for the management of incidents have to be defined. Regular evaluation has to confirm that the validated status of the system is maintained. |
| **Suppliers and service provider** | Reliability and competence of suppliers and service providers are crucial. Therefore the evaluation of a vendor shall be done risk-based. Between a regulated company and these third parties a formal agreement has to exist, where responsibilities of the vendor are clearly defined. |
| **Data integrity** | Electronic records as well as electronic signatures have to be as reliable and trustworthy as paper records. The system must have the ability to recognize the changing of records. Manually entered data as well as data, which are interchanged with other electronic systems, have to be automatically audited in terms of proper and secure data handling. The system must be able to generate correct and complete copies for electronic records. The same requirement applies to the accessibility, the readability and integrity of archived data during the retention period. |
| **Audit trail & support for change management** | In addition to the defined change control of the system itself, also changes to GMP relevant data have to be recorded throughout the life-cycle. Such an audit trail must include information about the change (before/after), the identity of the user, a time stamp and the reason for the change. |
| **System access, user authentication and password management** | Only authorised persons may have access to the system. Special attention shall be paid to the password security. Changes to the configuration of user access management must be recorded. The validity of user IDs has to be checked in regular time intervals. In the case of any loss or an exit of a person, there have to exist procedures to repeal access rights. Particular attention shall be paid to equipment, which uses user IDs or password information. |
| **Digital signatures** | Electronic signatures are legally binding and to all respects equivalent to handwritten signatures on paper. Apart from the mentioned requirements concerning user IDs and passwords, the system must be able to clearly assign an electronic signature to one single person. They must be coupled to the electronic records and copying or changing must be prevented. |
| **Open systems** | Using open systems further controls or tools might be necessary in order to secure data integrity and confidentiality. |

# Advantages

The Fabasoft Cloud offers the following advantages for the pharmaceutical industry:

## Security

Customers of the Fabasoft Cloud can decide themselves, if their data shall be stored in one of the Fabasoft data centres in Germany, Austria or Switzerland. Even for single projects, users can select the data location individually. The services are highly available due to redundant servers. Fabasoft has local offices in these countries, such that local contracting partners and agreements following local law ensure that local data protection regulations are met. All data used in the cloud are encrypted end-to-end by Fabasofts’s own encryption standard “Secomo”. Documents can be synchronised and shared between users from different companies easily via so-called “teamrooms”. Therefore it is essential to make sure that shared keys for encryption enable users only to access and read information, for which they have the appropriate rights. The master key is securely stored in the Secomo appliance and never leaves it. For all users the access rights of a teamroom or a document are clearly defined. The administrator of the Fabasoft Cloud can easily manage access rights and e. g. repeal access rights for any exited user. Furthermore data on an external device as a smart phone, tablet or laptop can be remote wiped by the administrator. Thus full data control for shared information remains at the customer. Fabasoft is an independent cloud provider operating its own infrastructure (software, hardware, engineering, support).

## Transparency

Due to the clear front end, any user of the Fabasoft Cloud always knows, where his data is stored. Additionally it is clearly defined with whom one is sharing data with what access rights (read, change, full control). Due to full audit-proof archiving it is recorded at any time, who accesses how what data and when. Using digital signature blocks in workflows results in full transparency about any approvals or other actions on documents.

## Compliance

The Fabasoft Cloud is fully certified as audit-proof archive for data handling. The time travel function gives access to a seamless history of documents and even complete projects. Defined released versions of documents (e. g. terms and conditions) provide a clear and traceable basis for collaboration. This feature is especially valuable in ordert o document who has approved when a document. Defined workflows automate, secure and control important processes.

## Quality

100 percent of the code of the Fabasoft Cloud was created in Europe. The Fabasoft headquarters is located in Linz/Austria. The cloud solution is certified according to the highest European standards and has been awarded so far with most certificates for cloud solutions worldwide – especially related to security and compliance. The Fabasoft Cloud was originally designed and created as native cloud solution. Therefore it is a well established and over several years proven tool for boundless digital records management for pharmaceutical companies.

## Experience

Fabasoft has more than 28 years experience in digitising business processes. Almost all customers are from pharmaceutics, industry, finance or the public sector. So the senior engineers at Fabasoft have specific knowledge about the needs in these markets. Additionally the company has several offices in Germany, Austria and Switzerland as well as docking points for partners in London and Boston. Thus apart from business knowledge, Fabasoft offers its customers know-how about the national market and regulations inside the European Union.

## Agility

Pharmaceutical companies benefit from real-time collaboration of internal team members as well as external partners. Documents can be synchronised, shard and edited via desktop, laptop, tablet or smartphone. Apps for content edition and workflow management even further enhance mobility. Free monthly updates of the Fabasoft Cloud deliver new features and innovations to all customers such that they can permanently work with latest state-of-the-art software. The easy handling of the cloud solution accelerates business processes. The combination of private cloud and public cloud offers scalability when more resources are needed for a single project or other purposes. The experienced Fabasoft Cloud engineers offer their know-how to develop new business models in co-creation with the customer for their specific use cases. An intelligent semantic search makes sure that user quickly find the right information.

## Flexibility

Depending on the requirements of the customer and/or the existing IT infrastructure, the Fabasoft Cloud can be used as public cloud, private cloud or hybrid cloud. Using the public cloud, customers rent their storage packages and a number of user licenses within the Fabasoft Cloud data centres. The private cloud is installed as appliance (combination of hardware and pre-installed software) in the customer’s data centre. Customers interested in a hybrid cloud solution select from a private cloud operated by themselves in their data centre plus the use of the public cloud (for maybe single projects), or their private cloud operated by Fabasoft in one of the Fabasoft Cloud data centres. In the standard edition several interfaces (APIs) are available as e. g. for SAP. Documents can be edited offline and are automatically synchronised once the device is connected to the internet again. Mobile content editing is possible via e. g. Microsoft Office 365. Manifold options for the configuration of the Fabasoft Cloud, platform independence and 22 available languages offer even more flexibility.

## Simplicity

After implementing a cloud solution, the success is totally dependent upon the simplicity how it can be used and the acceptance of the users. Fabasoft has invested a lot of effort to offer highest usability and clarity for users of the Fabasoft Cloud. Additionally it offers full accessibility, which has also been certified by the “Pfennigparade” – a renowned German centre for web accessibility. Using certificates, which are installed on a device, Active Directory or digital IDs users can use single-sign-on to access the Fabasoft Cloud. The adminstrator can simply manage user rights and access rights within the Fabasoft Cloud. New persons can easily and quickly invite external partners to join a project and register to the Fabasoft Cloud. Clients with their own data centre can benefit from using the Fabasoft Private Cloud appliance, which is delivered as hardware unit with pre-installed and pre-configured software, such that the time for installation and commissioning is minimized.

## Support

Local contact persons in local offices ensure a personal, fast and qualified support for customers of the Fabasoft Cloud. 99 percent of 1st level inquiries are answered within 2 hours with specific proposals for the solution. This highly qualitative support is part of signed and guaranteed service level agreements (SLAs). Also users of the Fabasoft Public Cloud can utilize this support. Especially when the requirements for a projects are individual, experienced Fabasoft senior engineers work out a concept with the customer how to optimally utilize the Fabasoft Cloud for the considered use case. Trainings about the Fabasoft Cloud can be booked at the Fabasoft Academy.

## Cost Efficiency

Especially in regulated industries the requirements concerning privacy, security and compliance are very high. Buying, operating, continuously developing and supporting an individual software solution is therefore very costly. This circumstance and the points mentioned at the introduction of this whitepaper drive many pharmaceutical companies towards cloud solutions. The following benefits regarding cost efficiency can usually be achieved:

* Advanced productivity of employees
* Reduction of shadow IT
* Reduction of redundant data
* Multiple functions already included in the standard edition
* Reduction of email volume
* Reduction of costs for internal document management
* Reduction of expenses for IT infrastructure
* Release valueable internal IT resources in ordert o push digital transformation

# Responsibilities of the Pharmaceutical Company

Potential customers of the Fabasoft Cloud in the pharmaceutical industry still have the responsibility to validate the system to verify that it fits for the intended purpose, i. e. a GxP regulated company using Fabasoft’s products and services is still responsible to

* document the supplier evaluation process,
* provide documented evidence that the used products and services fulfill the requirements for the specified intended use consistently,
* have a written contract covering the outsourced activities in compliance with applicable GxP-regulations and
* monitor the performance of the service provider and the fulfillment of the contract.

# Certificates

A cloud solution used for file sharing, common editing and workflow management in pharmaceutics should have the following certificates in order to fulfill the high demands in terms of security and compliance:

| **Certificates** | **Fabasoft Cloud** |
| --- | --- |
| **EuroCloud Star Audit**The EuroCloud Star Audit (ECSA V3.0) certification system is used for the audit and external quality evaluation of Cloud services in Europe. It is based on best practices and is carried out by the renowned organisation EuroCloud Europe. The list of auditing criteria comprises full details of the service provider and the actual location of the data, regulations regarding contracts and compliance, security and data protection, infrastructure operations and their related processes as well as the evaluation of the specific service types IaaS, PaaS and SaaS.  | Fabasoft Cloud received the certification in 2015. |
| **ISO 9001 Quality Management Systems – Requirements**ISO 9001 describes the requirements for a quality management system, which an organisation has to fulfill in order to provide products and services which satisfy customer requirements and applicable requirements of authorities. | Since 2005 the entire Fabasoft company has been certified.  |
| **ISO 20000-1 Service Management System Requirements**ISO 20000 is the international standard for IT service management. It is strongly related to the ITIL framework. | In 2011 Fabasoft received the ISO 20000 certificate for the IT service Folio Cloud (today Fabasoft Cloud) and Folio SaaS. |
| **ISO 27001 – Information Security**ISO 27001 is the international standard for information security. | Since 2008 Fabasoft has been certified by the ISO 27001 standard. In 2015 the audit included also the ISO 27018 – code of practice for protection of personally identifiable information (PII) in public clouds acting as PII processors. |
| **Certified Cloud Services (TÜV Rheinland)*** Secure data hosting
* Secure data transmission
* Secure operation of business-critical applications
* Quality and availability of service provision − high service continuity, high on-demand scalability
* Secure, high-quality data access and data storage − secure login methods and authentication system for data access control on network level
* State-of-the-art protection against attacks
 | The TÜV Rheinland i-sec GmbH certification confirms that the Fabasoft Cloud GmbH services Fabasoft Cloud, Fabasoft Folio SaaS, HeadsUp! User Engagement and Mindbreeze InSite meet the objectives to the left for cloud infrastructure and cloud application. |
| **ISAE 3402 Type 2**The International Standard on Assurance Engagements (ISAE 3402) is the international testing standard that assesses the effectiveness of internal control systems (IKS) of service providing organizations. The standard was created by the International Auditing and Assurance Standards Board (IAASB). | Up until 2011 Fabasoft was tested according to the AICPAs reporting standard SAS 70 Type 2, afterwards according to ISAE. |
| **IDW PS 880**The KPMG Advisory GmbH examined the Fabasoft Cloud regarding auditability by Austrian, German and Swiss commercial and tax law and issued the certificate referred to IDW PS 880. The Fabasoft Cloud corresponds thus in Germany, Austria and Switzerland the required storage rules (GAAP-compliant archiving). | Since April 2016 the Fabasoft Cloud is certified according to IDW PS 880. |

# GxP Compliance

The audit of the Fabasoft Cloud according to the regulations of EU GMP Annex 11 included:

* Overall Processes:
	+ General Aspects
	+ Organisation, Personnel and Qualification
	+ Quality Management System
	+ Documentation Control
	+ Security
	+ Service Provider Assessment
* Managed Operations:
	+ General Service Desk
	+ Operational Change Management
	+ Configuration Management
	+ System Maintenance and Support
	+ Peripherals
* System Development and Project Management:
	+ General Development Aspects
	+ Software Lifecycle and Project Management
	+ Specify and Design
	+ Build and Test
	+ Implement and Use
	+ Project Change and Configuration Management
	+ Infrastructure Management
	+ Quality Planning and Reporting

The audit from August 2016 fully certifies that pharmaceutical companies using the Fabasoft Cloud are capable to fulfill all criteria for the use of computerized systems defined in EU GMP Annex 11.

# Comparison EU GMP Annex 11 & FDA 21 CFR Part 11

A comparison between the European Union’s Annex 11 of GMP rules and FDA’s 21 CFR Part 11 shows, that both guidlines cover the same topics. However, there exist some differences as follows. Only those sections are mentioned, where one of the guidelines has no substantial equivalent.

**Comparison from EU GMP Annex 11 to FDA 21 CFR Part 11:**

| **Annex 11Section No.** | **EU GMP Annex 11:Title** | **FDA 21 CFR Part 11:Substantially equivalent** |
| --- | --- | --- |
| **1** | Risk management | Not covered |
| **3** | Suppliers and service provider | Not covered |
| **4** | Validation | Partially not covered |
| **7** | Data storage | Partially not covered |
| **8** | Printouts | Partially not covered |
| **12** | Security | Partially not covered |
| **13** | Incident Management | Not covered |
| **15** | Batch release | Not covered |
| **16** | Business continuity | Not covered |

**Comparison from FDA 21 CFR Part 11 to EU GMP Annex 11:**

| **Part 11Section No.** | **FDA 21 CFR Part 11:Title** | **EU GMP Annex 11:Substantially equivalent** | **Fabasoft Cloud** |
| --- | --- | --- | --- |
| **11.10(j)** | User accountability for actions initiated under e-signatures | Not covered | Has to be handled by customer – the records as a basis for any decision are available due to audit-proof archiving of all actions. |
| **11.100(a)** | Unique/not reused electronic signatures | Not covered | Workflows can be designed, managed and are documented in the Fabasoft Cloud. A user can e. g. approve a document. His identification is recorded (see 110.00(b) below), when passing the two factor authentification. Therefore no one else can reuse his signature within the Fabasoft Cloud. |
| **11.100(b)** | Verify identity | Not covered | In each user record the Fabasoft Cloud documents how he has identified himself during login. |

This comparion shows that the EU GMP Annex 11 has only single sections, where no equivalent definition exists. But according to the above tabular the Fabasoft Cloud also fulfills these requirements.

# Fabasoft

Fabasoft has been digitising records management and has been realising innovative services for companies, their business partners and for public administration for more than 28 years. More than 200 employees are working for the realisation of the corporate vision: Fabasoft is the standard product for the boundless digital records management in manufacturing, health care, finances and in the public sector in Europe. Fabasoft’s software products ensure the consistent capture, process-oriented handling, secure storage and context-sensitive finding of all digital business documents. These functions are used in both on premise installations in customer data processing centers, as well as SaaS and cloud services.

The Fabasoft Group is represented by subsidiaries in Germany, Austria, Switzerland, Great Britain and the USA. Furthermore, it maintains sales and project partnerships in these and other countries. Fabasoft AG, with its headquarters in Linz, Austria, acts as the Group’s administrative body.

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