

#InfoCertReads

Pharma, Life Sciences & Digital Trust-formation

Optimizing business processes with a digital signature platform



Summary contents

01

Life Sciences and digital transformation ↓

02

Compliance and transparency
in the industry: CFR 21 Part 11, FDA ↓

03

GoSign, the signature solution
for the Life Sciences market ↓

04

The impact of GoSign for a major player
in the pharmaceutical sector ↓

05

What's next ↓

06

InfoCert, QTSP leader in Europe ↓

#InfoCertReads

Executive summary

Development of new technologies in the Life Sciences market

The digital transformation currently underway in the Life Sciences market is bringing about major changes at product, process and organizational levels.

However, the adoption of innovative, digital solutions cannot eschew compliance with industry regulations, such as CFR 21 part 11 of the FDA (Food and Drug Administration), which governs how pharmaceutical, biotechnological and scientific companies manage their electronic documents and signatures.

With its GoSign signature solution, InfoCert supports companies in the industry in their journey towards digitization.

GoSign contributes to reducing the hours required for paperwork and administration, so that organizations can use their time to better advantage, on research and the development of new products.

#InfoCertReads



Life Sciences and digital transformation

Towards Digital Health

The digital transformation process currently underway in the Life Sciences market is bringing about major changes at product, process and organizational levels.

Thanks to research, new therapies are available more speedily, production processes are more efficient, and taking on new patients is no longer limited to the 'simple' provision of services but has been transformed into an all-encompassing pathway, integrating drugs, precision diagnostics, devices and care services.

#InfoCertReads

Life Sciences and digital transformation

Digital Health has entered a phase of increasingly competitive challenges that would benefit from a renewed partnership between industry and the institutions. One example of this is the rise in telemedicine services; these greatly facilitate patients who, for various reasons, cannot reach clinical and hospital centres.

Even before being technological, this is a cultural transition, which involves companies in the sector committing to new investments and the development of new skills, in order to:

- ✓ speed up and increase the efficiency of research processes
- ✓ guarantee continuity of business
- ✓ implement collaborative platforms for doctors and patients

Organized and accessible data is needed to do this, in order to improve care, assess the impact of digital technologies and their interactions with drugs, while not forgetting one essential aspect: that of privacy and regulatory compliance.

#InfoCertReads

A close-up photograph showing a hand holding a glass vial, pouring small white pills into a glass bowl. The background is blurred, focusing on the action of pouring. The text is overlaid on the top left of this image.

Compliance and transparency in the industry: CFR 21 Part 11, FDA

In March 1997, the Food and Drug Administration issued the final regulations of Part 11 of the Code of Federal Regulations 21.

This establishes the criteria on the basis of which the FDA considers electronic records and electronic signatures to be trustworthy, reliable and generally equivalent to paper documents and handwritten signatures made on paper.

#InfoCertReads

Compliance and transparency in the industry: CFR 21 Part 11, FDA

These regulations have been designed to allow the widest possible use of electronic technology, consistent with the FDA's responsibility to protect public health. So the regulations apply to the research, production and distribution of medical products, and in the pharmaceutical industry they are among the most important to be complied with.

For companies, the opportunities are many and varied: from the reduction of costs thanks to the use of electronic records that enable the dematerialization of processes, to the improvement of governance within the organization.

In the light of the regulations, the companies in the sector need to adopt solutions that can create, edit, store or transmit electronic data through procedures and controls that guarantee the authenticity, integrity and confidentiality of said data.

#InfoCertReads

**GoSign, the signature solution
for the Life Sciences market**



830 million signature
transactions generated
in 2021

**InfoCert's GoSign is the signature solution
that allows companies to digitally create,
sign and authenticate documents
and contracts, thereby enabling them
to totally dematerialize their processes
and increase their efficiency.**

#InfoCertReads

GoSign, the signature solution for the Life Sciences market



The signature processes are, therefore, managed in a simple and dynamic manner, guaranteeing an intuitive, omnichannel user experience.

The platform supports all types of electronic signature, from simple to advanced, to achieve the required level of trust. In fact, a different level of trust may be required in each signature process, for which a specific signature solution is needed.

#InfoCertReads

GoSign, the signature solution for the Life Sciences market



Electronic Signature

Suitable for low-risk transactions such as internal approvals. The simplest to use.



Advanced Electronic Signature

Based on a digital certificate and the unequivocal identification of the signatory.



Qualified Electronic Signature

Based on an eIDAS-compliant Qualified Digital Certificate issued by InfoCert.

Legal value of a transaction 100% guaranteed.

#InfoCertReads

**On regulatory compliance...
you can count on GoSign!**



GoSign's features make it the ideal signature solution for the Life Sciences market, which is called upon to respond to industry standards.

#InfoCertReads

On regulatory compliance... you can count on GoSign!

Specifically, GoSign meets the requirements of FDA CFR 21 Part 11, guaranteeing the full legal value of transactions:

CFR 21 Part 11 section reference	GoSign functionalities
Sec. 11.10 Controls for closed systems*	✓
Sec. 11.30 Controls for open systems*	✓
Sec. 11.50 Signature manifestations	✓
Sec. 11.70 Signature/record linking	✓
Sec. 11.100 General requirements	✓
Sec. 11.200 Electronic signature components and controls	✓
Sec. 11.300 Controls for identification codes/passwords	✓

*depending on the configuration required

#InfoCertReads

Improve the efficiency of your processes with GoSign



Speed up internal document management

With GoSign you can digitise the management of your HR documents, thereby reducing the time spent on paperwork and administration.



Simplify relations with your suppliers

From the acceptance of offers to the signing of contracts and purchase orders, with GoSign, you can manage your supplier relationships 100% digitally, speeding up and streamlining business processes.



Reduce your impact on the environment through digital transformation

The ESG issue is affecting the decisions of investors and shareholders more and more. With GoSign you will reduce your impact on the environment, save paper, water and ink, and increase your ESG rating.

#InfoCertReads



The impact of GoSign for a major player in the pharmaceutical sector

Challenge

Digitise your processes for better organisational efficiency

A major player in the pharmaceutical sector approached InfoCert to rapidly implement digital signature processes.

The Client had the following requirements:

#InfoCertReads

The impact of GoSign for a major player in the pharmaceutical sector

Requirements

- Guarantee of legal validity of signatures
- Possibility to integrate the solution with already existing business systems
- Possibility to involve external users in the organization of signature workflows
- Possibility to manage processes with different types of electronic signatures such as simple signatures or qualified signatures
- Compliance with industry standards
- Possibility to verify timestamps and digital signatures of different stakeholders, validating the signatory, the integrity of the documents and their legal validity.

The impact of GoSign for a major player in the pharmaceutical sector

Solution



Simple, flexible and compliant signature platform

1 InfoCert supported the Client in choosing services that would meet its organizational needs and the general and specific regulatory constraints of the pharmaceutical sector.

2 The solution proposed was GoSign, to create and manage both internal and external approval flows, fully integrated into the management system already in place.

3 To ensure flexibility and regulatory compliance, GoSign allows the use of different types of signatures, including simple password-enhanced signatures.

#InfoCertReads

4

Additionally, in order to enable the signature of users external to the organization, an identification phase has been provided for the signatory user and the sending of password-protected documents by e-mail.



Thanks to GoSign, the Client has been able to manage its business needs in a simple and intuitive manner and to quickly engage various stakeholders in digital document management.



#InfoCertReads



What's next



Flexibility

Adapting quickly to changes is increasingly important to remain competitive while respecting privacy and security during data exchange.

Relying on Digital Trust is the key to ensuring business continuity even outside the company premises.

#InfoCertReads

What's next



Efficiency

The new challenge is to speed up and simplify business processes while ensuring regulatory compliance particularly in regulated sectors.

Our digital solutions are designed to meet the requirements of business and compliance.



Sustainability

Stakeholders will be increasingly influenced by the ethical conduct of companies in their purchasing and investment choices.

With Digital Trust you can integrate ESG goals into your business strategy.

#InfoCertReads

InfoCert, Qualified Trust Service Provider leader in Europe



Trust

We offer a comprehensive portfolio of Digital Trust services. We certify the identity of the parties involved in the digital transactions and provide solutions to guarantee security and improve operational efficiency.



Compliance

We guarantee regulatory compliance by designing innovative solutions to effectively meet the needs of clients in different sectors and countries.



Cybersecurity

We provide clients with the most comprehensive and secure range of solutions, providing de jure security, with de facto Digital Trust solutions, integrating Cybersecurity.



ESG

We support clients in pursuing Environmental, Sustainability and Governance objectives, analysing the impact of our Digital Trust solutions on the environment.

#InfoCertReads



Find out how
Digital Trust solutions
can help your organization
in the upcoming challenges.



infocert.digital 

#InfoCertReads