



Almost every global biopharma player joined SAFE-BioPharma Association to save money and time

We've simplified our membership, so you can, too



SAFE-BioPharma Association is helping the biopharmaceutical and healthcare communities move to a fully electronic business environment, so they can work faster and more efficiently.

Membership in the association allows them to obtain SAFE-BioPharma™ digital certificates.

We just changed our membership fees so clinical investigators, CROs and other smaller entities within the biopharmaceutical and healthcare communities can enjoy the same benefits with their own SAFE-BioPharma digital certificates.

SAFE-BioPharma digital certificates simplify the way documents are handled and signed. They also simplify how internal and external identities are managed.

The SAFE-BioPharma Standard Improves Document Management

- Documents may be reviewed, approved and signed using electronic workflows.

- Approvals that took days, take minutes. The entire process is accelerated and more easily managed.
- Signatures are valid for the life of the document; any change to the document invalidates the signature and alerts the viewer.
- Each SAFE-BioPharma digital signature creates a permanent record of the date and time the signature was applied.
- SAFE-BioPharma digital signatures are legally enforceable, non-repudiable, and instantly auditable. They are recognized and trusted by the FDA and EMEA. They are 21 CFR Part 11 compliant.

- BioPharma certificates are legally-enforceable and comply with global regulatory requirements.
- Identities validated by SAFE-BioPharma are trusted by US federal agencies and by companies in other industries. Visit www.the4BF.com to learn more.
- SAFE-BioPharma digital certificates can be used to bridge different systems and to provide controlled access to sensitive information.
- SAFE-BioPharma complies with OMB and NIST guidance and with FDA and EMEA regulations.



The SAFE-BioPharma Standard Improves Interoperability, Enables Trust, Mitigates Risk

- SAFE-BioPharma is a secure way to verify identities in electronic transactions.
- Digital signatures based on SAFE-

“Small Entity Membership Fees” now available

SAFE-BioPharma members use SAFE-BioPharma digital certificates in many research, regulatory and business applications. New “Small Entity Membership Fees” for clinical investigators, CROs and other smaller biopharmaceutical and healthcare entities make access to the standard’s benefits highly affordable.

Visit www.safe-biopharma.org for specifics.



Join (SAFE-BioPharma)
Download (digital certificates)
Manage (digital identities)
Sign (anything electronically, anywhere)

Acquiring certificates can take as little as a few minutes

SAFE-BioPharma™ digital signatures are used to sign virtually every type of document:

- **Forms used from discovery through all phases of clinical development** including CMC, preclinical, clinical protocols and reports, Electronic Case Report Forms, etc.
- **Electronic Laboratory Notebooks** used by researchers to document each day's research activities.
- **Electronic Submissions** made through the FDA's eSubmissions Gateway and to EMEA
- **Forms to approve** labels and package inserts, promotional materials, marketing authorization applications, DDMAC forms, etc.
- **GMP and QA forms**
- **Pharmacovigilance reports** and forms: PSURs, ICSRs
- **Contracts** with hospitals, E-purchasing and other forms
- **Advisory board and speaker agreements**
- **Component documents of eCTDs**

SAFE-BioPharma *roaming digital ID*, allows SAFE-BioPharma digital signatures to be used with complete security anywhere there is Internet access. It's one of several ways to store SAFE-BioPharma digital certificates.

20+ companies are making software and hardware that help SAFE-BioPharma members get the most from the standard.

SAFE-BioPharma Association is the non-profit biopharmaceutical industry collaboration that developed and manages the SAFE-BioPharma digital identity and signature standard. The standard is used by virtually every big biopharma for identity management and digital signing.

The vision of SAFE-BioPharma Association

is to be a catalyst in transforming the biopharmaceutical and healthcare communities to a fully electronic business environment by 2012.

Member Companies:



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