

Streamline document review and approval with the SAFE-BioPharma Digital Identity and Signature Standard™



SAFE-BioPharma Association is the non-profit biopharmaceutical industry collaboration that developed and manages the SAFE-BioPharma digital identity and signature standard.

We're helping the biopharmaceutical and healthcare communities move to a fully electronic business environment, so they can work faster and with greater efficiency.

SAFE-BioPharma Digital Signatures can be used to sign every conceivable form, contract or other document used anywhere in the biopharmaceutical or healthcare industries with internal employees, external partners, and government agencies.

SAFE-BioPharma Digital Signatures eliminate the time and costs associated with printing, handling, and storing paper documents.

- 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.



With SAFE-BioPharma Digital Signatures, any change to the document invalidates the signature.

SAFE-BioPharma Digital Signatures

- ...uniquely link the user's identity to the document being signed
- ...are valid for the life of the document
- ...create a permanent record of the date and time the signature was applied
- ...are legally enforceable, non-repudiable, and instantly auditable
- ...are recognized by the FDA and EMEA

...are 21 CFR Part 11 compliant

SAFE-BioPharma's unique roaming digital ID feature allows documents to be signed with

complete security anywhere there is Internet access.

"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 entities within the biopharmaceutical and healthcare communities make access to the standard's benefits highly affordable.

Visit www.safe-biopharma.org for specifics.



Digital signatures based on the SAFE-BioPharma™ standard are being used throughout the biopharmaceutical and healthcare industries



They are used to sign

- 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**

Your SAFE-BioPharma Digital Certificate Links to Federal Agencies and Other Companies

SAFE-BioPharma Digital certificates link to the 4 Bridges Forum (www.the4bf.com), an infrastructure that facilitates trusted electronic business with federal agencies, pharmaceutical and healthcare companies, aerospace and defense contractors and colleges and universities.

The 4BF.

...ensures the integrity of online transactions

...provides strong identity assurance

...lowers costs associated with identity management

SAFE-BioPharma Association

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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