



# SAFE-BioPharma™ ...the digital identity and signature standard *developed* for the biopharmaceutical and healthcare communities

## FACILITATES INTEROPERABILITY

- SAFE-BioPharma's link to the Federal Bridge Certificate Authority (FBCA) establishes *first network of trust between biopharma and healthcare and Federal agencies*
- Allows secure and trusted information exchange with government agencies such as FDA, Health and Human Services, Department of Defense, Homeland Security, US Patent and Trademark Office, others
- Usable with regional and state Health Information Exchanges

## STREAMLINES PROCESSES

- Eliminates paper-handling and paper-retention; associated time, errors and costs
- Speeds all approval processes with internal and external parties, including contract-signing
- Supports environmentally responsible initiatives

## COMPLIES WITH U.S. AND EUROPEAN REGULATIONS

- Accepted by FDA
- Meets highest legal equivalent of handwritten signatures for mutual recognition across EU and European Economic Area
- Soon to be accepted by EMEA

## MITIGATES RISK

- Secure, enforceable, and regulatory-compliant way to verify identities of parties involved in electronic transactions
- Provides numerous ways to manage internal and external identities
- Identities are verified in strongly trusted manner and comply with OMB and NIST guidance
- Convenient way to apply legally binding digital signatures to electronic documents. Identity of the signer is clearly verified; integrity of document is cryptographically guaranteed
- Enables trust, security, confidence, speed, cost efficiencies and convenience
- Protects intellectual property

### The SAFE-BioPharma Standard

Electronic identities verified by the SAFE-BioPharma standard can be strongly trusted. The integrity of every electronic document signed with a SAFE-BioPharma digital signature is guaranteed. Each signer is clearly identified, and SAFE-BioPharma digital signatures are legally binding.

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# SAFE-BioPharma™ ...the digital identity and signature standard *used* by the biopharmaceutical industry

**AstraZeneca** uses SAFE-BioPharma to sign all E-submissions made through the FDA's E-Submissions Gateway.

**Bristol-Myers Squibb** uses SAFE-BioPharma digital signatures in support of intellectual property protection, regulatory processes, and for promotional and non-promotional approval processes.

**GlaxoSmithKline** uses SAFE-BioPharma credentials to digitally sign FDA forms for E-submissions sent through the FDA's electronic submission gateway.

**Johnson & Johnson Services** is cross-certified with the SAFE-BioPharma Bridge. This assures that J&J is compliant with the SAFE-BioPharma standard and has a known level of interoperability and trust for members of SAFE-BioPharma Association.

**Pfizer** chemists sign CeN (Chemistry electronic Notebook) experiments electronically using a SAFE-BioPharma certificate, with 2200+ users averaging more than 1000 signatures per day.

**Procter & Gamble** scientists around the globe use SAFE-BioPharma digital signatures to sign electronic Laboratory Notebooks. SAFE-BioPharma signatures are also used to sign Statements of Work, to sign/distribute packing standards for new product displays and in non-pharma clinical studies. P&G currently is evaluating replacing pen-to-paper signatures with SAFE-BioPharma digital signatures for a variety of other business processes.



## Digitally sign and manage these and other documents without leaving your desk:

- Internal documents
- E-purchasing forms
- Preclinical, CMC, clinical protocols and reports
- Contracts and other legal documents
- Information exchange and emails
- Packaging inserts and labels
- Advisory Board and speaker agreements
- E-sampling
- E-patent filings
- Electronic Case Report Forms
- GMP and QA/QU forms
- New Drug Applications
- Electronic Common Technical Documents
- Marketing Authorization Applications

**Bold** indicates emerging uses (and those under evaluation) by member companies.

## SAFE-BioPharma Association

The non-profit SAFE-BioPharma Association created and manages the SAFE-BioPharma™ digital identity and signature standard. Its vision is to be a catalyst in transforming the biopharmaceutical and healthcare communities to a fully electronic business environment by 2012. SAFE-BioPharma collaborates closely with other organizations including HL7, CDISC, and eHealth Initiative.

Learn about SAFE-BioPharma's growing Vendor-Partner community at [www.safe-biopharma.org](http://www.safe-biopharma.org)

Member companies:

