

# SAFE-BioPharma Signs ESUBs

## Industry is using SAFE-BioPharma™ digital signatures for FDA and EMEA eSubmissions.

Going fully digital with SAFE-BioPharma signatures improves cost and time efficiencies -- both for sponsors and agencies. The need to create, sign, store, and maintain paper originals and to burn CDs, DVDs or tape is eliminated. The agencies have earlier access to submissions.

Before SAFE-BioPharma digital signatures, signing FDA forms involved multiple steps and handoffs. Using SAFE-BioPharma digital signatures simplifies workflows. It provides more time for quality submissions.

### Each SAFE-BioPharma Digital Signature...

...uniquely links the user's identity to the document being signed

...is valid for the life of the document  
 ...creates a permanent record of the date and time the signature was applied  
 ...is legally enforceable, non-repudiable, and instantly auditable  
 ...is recognized by the FDA and EMEA  
 ...is 21 CFR Part 11 compliant

**SAFE-BioPharma's unique roaming digital ID feature** improves efficiencies by allowing submission documents to be reviewed and signed with complete security anywhere there is Internet access.

**Using the SAFE-BioPharma standard requires becoming a SAFE-BioPharma member and getting SAFE-BioPharma digital certificates.**

- Obtaining certificates can take as little as a few minutes.
- Once issued, they simplify how documents are handled and signed. They also simplify how internal and external identities are managed.

**To learn more about eSubmissions** and how your organization can benefit from the SAFE-BioPharma digital identity and signature standard, contact John Hendrix [john.hendrix@safe-biopharma.org; (973) 272-8621]

## "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.

[www.safe-biopharma.org](http://www.safe-biopharma.org) for specifics.



# SAFE-BioPharma Signs ELNs



As many SAFE-BioPharma members have discovered, SAFE-BioPharma™ digital signatures are a superior way to sign electronic laboratory notebooks (eLN).

## Each SAFE-BioPharma Digital Signature...

- ...uniquely links the user's identity to the document being signed
- ...is valid for the life of the document
- ...creates a permanent record of the date and time the signature was applied
- ...is legally enforceable, non-repudiable, and instantly auditable
- ...is recognized by the FDA and EMEA
- ...is 21 CFR Part 11 compliant

**Electronic laboratory notebooks** are rapidly replacing paper notebooks used by lab scientists to record the day's scientific research. These electronic records help assure the integrity of the entries – indicating the time they were made, their authorship and content – potentially useful evidence in the event of a future patent challenge.

Obtaining a certificate can take as little as a few minutes. Once issued, the SAFE-BioPharma digital certificate simplifies how eLNs and other documents are handled and signed. SAFE-BioPharma digital certificates also simplify the way internal and external identities are managed.

SAFE-BioPharma's unique roaming digital ID feature allows an eLN to be signed with complete security anywhere there is Internet access.

To learn more about electronic laboratory notebook applications and how your organization can benefit from the SAFE-BioPharma

digital identity and signature standard, contact John Hendrix [john.hendrix@safe-biopharma.org; (973) 272-8621]



## Among the numerous advantages eLNs have over their paper predecessors.

- Laboratories become more effective because researchers spend more time on research and less time on record-keeping
- Data is easier to search and access
- Data is more available to collaborators
- eLNs provide better protection of intellectual property
- Researchers can sign from any location
- Entries are time and date stamped

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.

## Member Companies:



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