



SAFE-BioPharma Association
Secure Access For Everyone

Streamline electronic credentialing and information exchange

Make electronic transactions more efficient and cost-effective with Secure Access For Everyone (SAFE)

Electronic credentialing is costly and complex. Biopharmaceutical companies maintain business relationships with tens of thousands of clinical investigators, teaching hospitals, government regulators and labs — typically this costs more than \$200 per user to issue and then manage the electronic credentials that protect and provide access to their information systems. Further, these credentials aren't able to produce the electronic signatures required to eliminate paper, so companies must continue to maintain hybrid systems that contain duplicative electronic and paper records and files.

SAFE reduces expenses and confusion. SAFE is a standard developed and managed by SAFE-BioPharma Association, a not-for-profit organization consisting of industry-leading biopharmaceutical companies. SAFE compliant infrastructure provides SAFE members — biopharma companies, regulatory agencies and research facilities — with a single, easy-to-use electronic identity credential (or “key”) for all business and regulatory transactions.

SAFE identity keys can be used to create electronic signatures for exchanging data with other SAFE members and regulators. Because they are legally enforceable and regulatory compliant, electronic signatures created with SAFE compliant credentials eliminate the need for paper copies and files and allow companies to rid themselves of the burden of hybrid systems.

Membership Benefits

There are three primary reasons for joining SAFE-BioPharma Association and implementing the SAFE infrastructure.

Reduced Cost and Workflow Efficiencies. The biopharmaceutical industry spends more than a billion dollars per year on stand-alone identity credentialing solutions. And these solutions today cannot be leveraged to lower the nearly 40 percent of all R & D costs attributed to paper-based business processes.

SAFE members reap the benefits of short and long-term infrastructure cost savings. A single credential for all employees and business partners will result in dramatic cost savings per user. SAFE benefits are scalable: as more processes are converted from paper to electronic using SAFE, the more a company eliminates paper, saves time and reduces expenses.

Shared Implementation Lessons and Information Assets. SAFE has created an arsenal of tools and implementation support documentation to help speed and streamline member implementations. Members of the SAFE Community are able to tap into the lessons learned and accumulation of best practices created from prior and current member implementations.

SAFE information assets include legal briefs, reference implementation, working groups, credentials, compliance tools, best practices, implementation checklists and a vendor partner program.

Network of Industry Leaders. SAFE members gain entry to an industry network that includes market leading biopharmaceutical companies, CROs, health systems, clinical investigators, regulators and vendors. SAFE and its members have ongoing dialogues and programs with the FDA, EMEA and the National Cancer Institute.

For example, SAFE is working with a dedicated team of FDA resources to ensure that SAFE meets 21 CFR Part 11 requirements and to address the challenges created by electronic



submissions. And in a pilot program that includes EMEA and EFPIA, SAFE is being applied to EMEA's Eudralink application for access control and document signing.

Who is SAFE-BioPharma Association?

SAFE-BioPharma Association is a not-for-profit organization sponsored by the Pharmaceutical Research and Manufacturers of America (PhRMA) and the European Federation of Pharmaceutical Industries Associations (EFPIA). SAFE-BioPharma is funded and led by leading biopharmaceutical companies with input and collaboration from the U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA).

The mission of SAFE-BioPharma Association is to deliver the standard that enables electronic identity credentials for legally enforceable and regulatory compliant electronic signatures across the global biopharmaceutical environment.

SAFE-BioPharma member companies include Abbott Labs, Amgen, AstraZeneca, Bristol-Myers Squibb, GlaxoSmithKline, Johnson & Johnson, Merck, Pfizer Inc., Procter & Gamble, Sanofi-Aventis, INC Research and Tap Pharmaceuticals.

SAFE Membership Options

SAFE-BioPharma Association has three membership options.

SAFE Full Members:

Any company that participates in the Biopharmaceutical and the extended Healthcare Community can become a Full Member of SAFE. With full membership, companies can use the SAFE infrastructure to enhance their global production operations for both internal as well as external business partner activities. Full Members also have access to SAFE-BioPharma legal briefs, white papers, SAFE best practice compliance and implementation guidelines, and can participate in the SAFE Standard development working groups. Full Members pay annual membership fees based on company size.

SAFE Government Members:

The SAFE Government membership option is reserved for government research sites and regulatory agencies. Similar to Full Members, Government Members can use the SAFE infrastructure for their benefit and have access to SAFE's information assets and participate in the SAFE working groups. Government Members, except regulators, pay annual membership fees based on annual expenditure levels.

Associate Members:

The Associate membership option is reserved for organizations and individuals that have been requested to use the SAFE infrastructure by members or agencies for a limited implementation. At the outset, the SAFE Community has invited any clinical investigator or research organization that works with a SAFE Member to join as an Associate Member. There is no annual membership fee for Associate Members.

Become a Member

For more information, visit the SAFE-BioPharma Association website at www.SAFE-BioPharma.org.



"SAFE provides continuity between Merck and its business partners."

*Pamela Fusco,
Chief Information Security Officer,
Merck*



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