

Digital Identities and Signatures in the Pharmaceutical Industry:  
A viable approach to better business processing

---

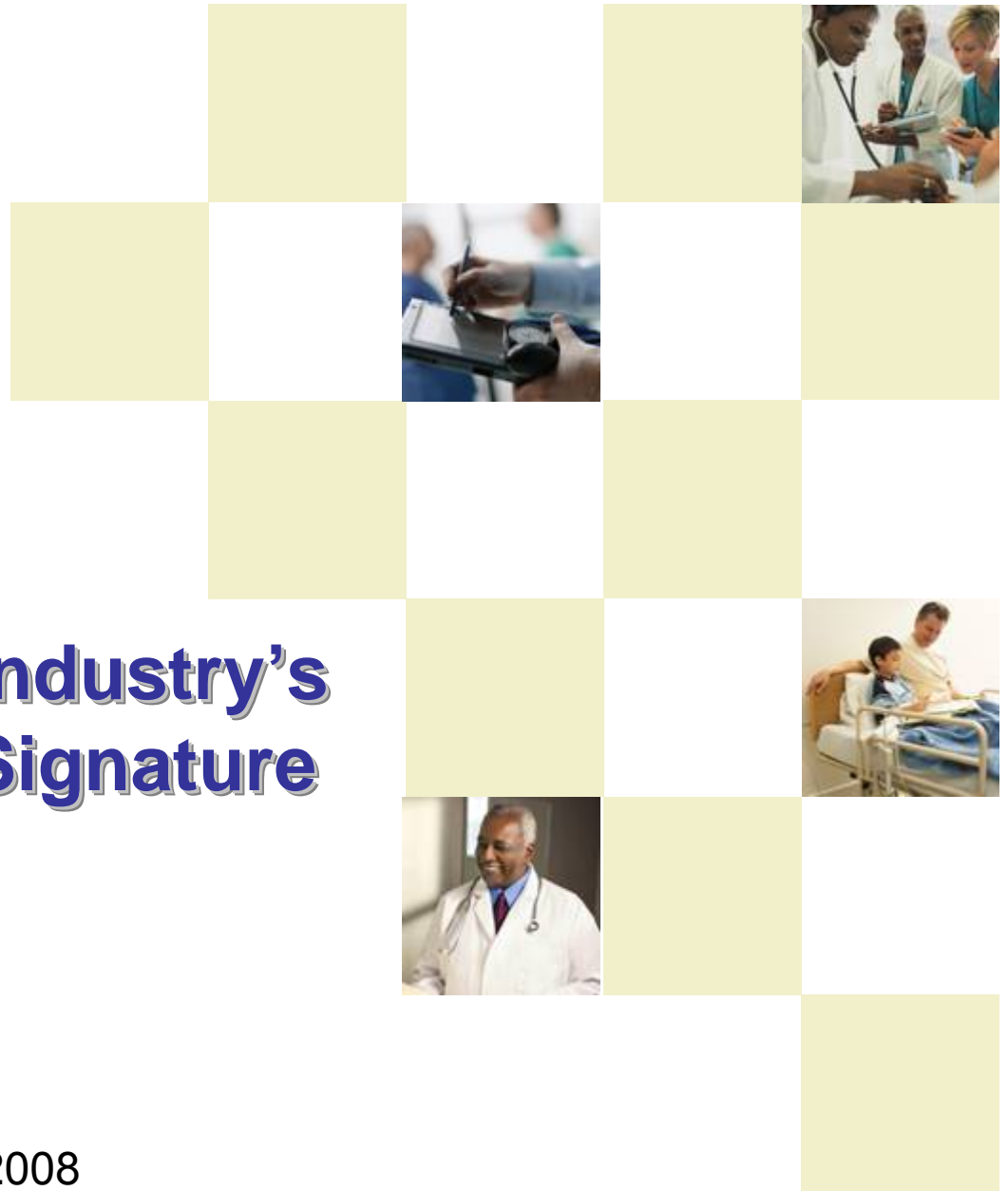
May 8, 2008



# Agenda

---

- Welcome
- SAFE BioPharma and Digital Signatures
  - Mollie Shields Uehling, CEO, SAFE BioPharma
- P&G – Myths and Facts on Digital Signatures in Pharma
  - Kay Bross, Senior PKI Specialist, Procter & Gamble
- Citi Managed Identity Services
  - Frank Villavicencio, Director, Global Transaction Services, Citi
- Q&A



# **SAFE-BioPharma – Industry’s Digital Identity and Signature Standard**

Citi Webinar

Thursday, May 8, 2008

Mollie Shields Uehling



# SAFE Digital Identity and Signature Standard

- **Strategic industry initiative started 11/03 by PhRMA & EFPIA**
  - Transform biopharma and healthcare communities to fully electronic
  - Trusted identity and non-repudiable digital signature
  - Risk Mitigation
  - FDA and EMEA alignment
  - Global
- ▶ **SAFE-BioPharma Association incorporated May 2005**
  - Fall 2005, standard approved.
  - 2006-2007, pilots and early adopters
  - 2007-2008, expansion of standard; increased implementations
- ▶ **Member-governed, non-profit collaborative industry org.:**
  - Amgen, AstraZeneca\*, BMS\*, Genzyme, GSK\*, J&J\*, Merck\*, Organon, Pfizer\*, P&G\*, Roche, Sanofi-Aventis\*

SAFE-BioPharma™

SAFE-BioPharma Association  
Signatures and Authentication for Everyone

# SAFE Mission and Vision Statements

## Mission Statement for

### SAFE-BioPharma Association / SAFE™ Digital Standard

*Our mission is to be the digital identity and signature standard for the global biopharmaceutical and healthcare communities.*

## SAFE Vision Statement

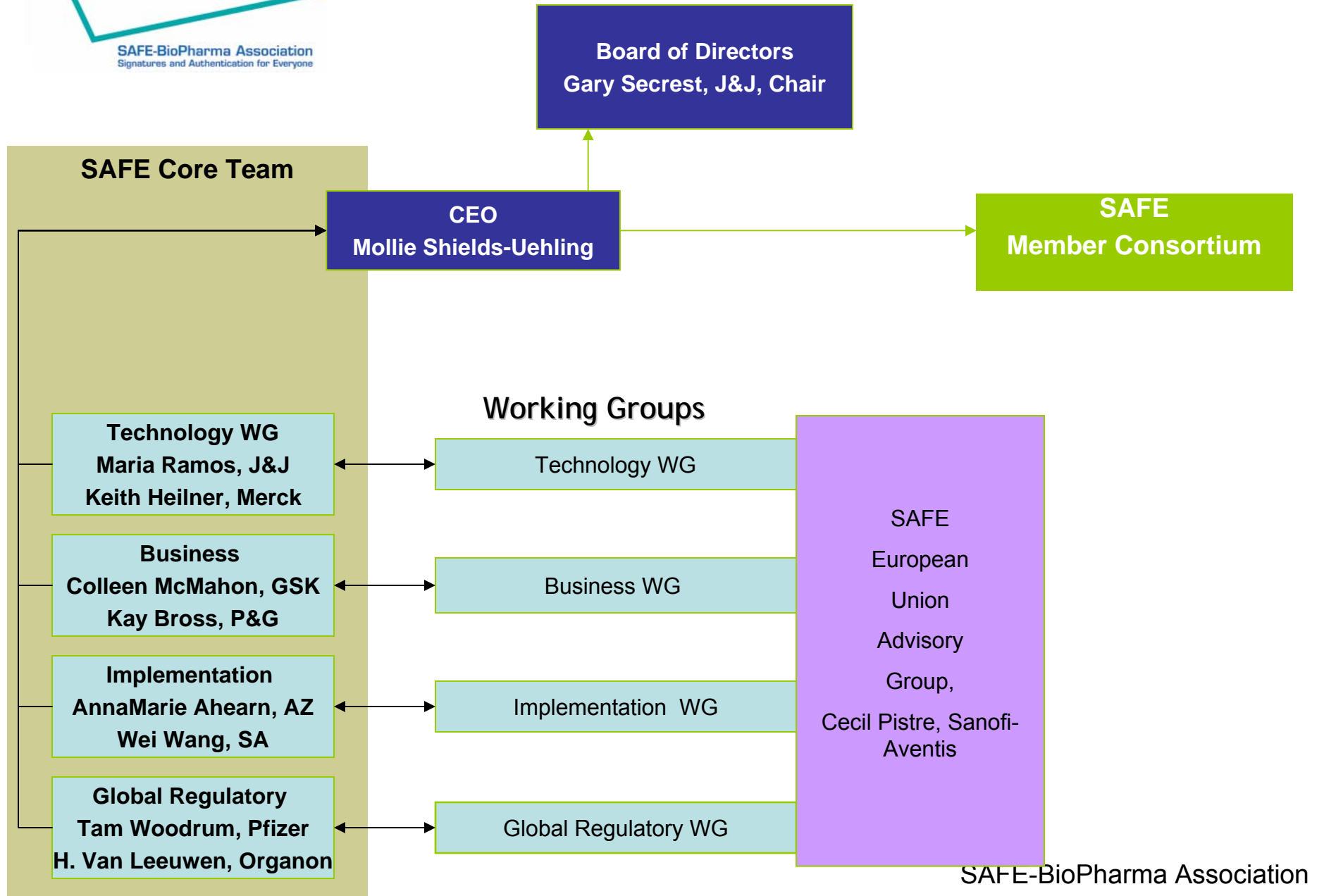
**Our vision is for the SAFE™ standard to be a catalyst in the transformation of the biopharmaceutical and healthcare communities to a fully electronic business environment by 2012.**

Msoffice1

SAFE-BioPharma™

SAFE-BioPharma Association  
Signatures and Authentication for Everyone

## A Non-Profit, Member-Driven Standards Association



**Slide 6**

---

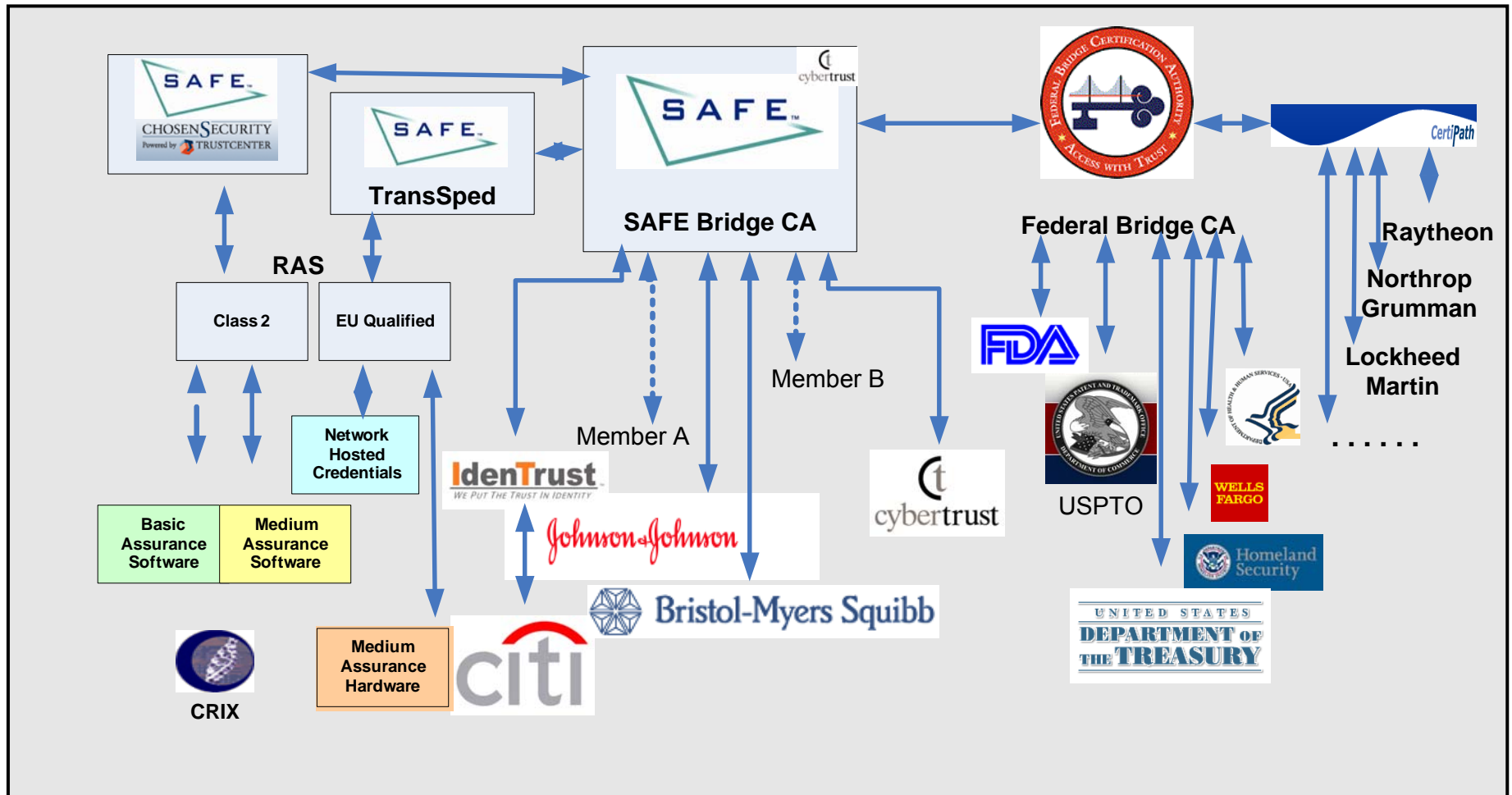
**MSoftware1** Mollie, 3/11/2008



## Tiered Services – Expanded Options

Credential	ID	Process	Risk Profile
Basic Assurance Software	<ul style="list-style-type: none"> <li>•In-person</li> <li>•Remote</li> </ul>	<ul style="list-style-type: none"> <li>•Invite code</li> <li>•RAS</li> <li>•Installs cert</li> </ul>	<ul style="list-style-type: none"> <li>•Ext partner auth</li> <li>•No dig sig</li> <li>•Easy I&amp;A; trust</li> </ul>
Medium Assurance Software	<ul style="list-style-type: none"> <li>•Antecedent</li> <li>•TA</li> <li>•Notary</li> </ul>	<ul style="list-style-type: none"> <li>•Invite code</li> <li>•IT check</li> <li>•RAS – profile;</li> <li>•Installs cert</li> <li>•Signs SAFE agmt</li> </ul>	<ul style="list-style-type: none"> <li>•No hardware</li> <li>•Dig sig (key possession)</li> <li>•US reg, SOX</li> <li>•Not EU qual sig</li> </ul>
Medium Assurance Hardware	<ul style="list-style-type: none"> <li>•Antecedent</li> <li>•TA</li> <li>•Notary</li> </ul>	<ul style="list-style-type: none"> <li>•Invite code/token</li> <li>•IT check</li> <li>•RAS – profile</li> <li>•Downloads cert</li> <li>•Signs SAFE agmt</li> </ul>	<ul style="list-style-type: none"> <li>•HW req'd</li> <li>•Driver download</li> <li>•EU qual sigs</li> </ul>
Medium Assurance Roaming	<ul style="list-style-type: none"> <li>•Antecedent</li> <li>•TA</li> <li>•Notary</li> </ul>	<ul style="list-style-type: none"> <li>•Invite code</li> <li>•IT check</li> <li>•RAS – profile</li> <li>•Downloads cert</li> <li>•Signs SAFE agmt</li> </ul>	<ul style="list-style-type: none"> <li>•Legal dig sig</li> <li>•MSB no config</li> <li>•Portable</li> <li>•Supts multiple auth sys</li> <li>•Not EU qualified</li> </ul>

# High-Level Architecture





# Implementations

- **Now in operation:**
  - ELNs
  - eRegulatory submissions
  - ePromotional approvals/filings
  - Contracts
  - SOWs
  - HR
- **Underway:**
  - ePatent Filings
  - KOL management
  - Alliance management
  - External partner authentication
  - Physician portals
  - CRIX
  - Intra- and inter-state healthcare provider collaborations
  - Pharma-US Govt. Agencies,
  - Pilots to draw upon eHRs for R&D purposes



# SAFE and the FDA

- ▶ **SAFE Member reps with QA/Compliance/Reg backgrounds**
- ▶ **FDA key offices engaged since inception**
- ▶ **Jointly-developed SAFE/FDA Auditor Familiarization Program**
- ▶ **FDA informal statement on SAFE**
- ▶ **In process:**
  - Continued SAFE-FDA Auditor/Compliance Workshops
  - Training audit of SAFE-signed submission
  - SAFE-signed EDC demonstration

**The FDA's goal is to eliminate paper from application receipt and review processes. A completely paperless application process must be supported by implementation of legally binding electronic signatures. SAFE provides that solution.**



# FDA CDER Statement

**“The FDA does not endorse any particular electronic signature solution. The Agency has, however, worked with the biopharmaceutical community over the past two and one-half years to help ensure that the Signatures and Authentication for Everyone (SAFE) Standard: 1) complies with appropriate guidance, especially as related to 21CFR11; and (2) when used as the basis for implementation of a digital signature capability, the SAFE standard facilitates user compliance with 21CFR11.”**



## SAFE and the EU



### ▶ **SAFE-EMA Pilot**

- SAFE Evaluation Team: EMA, GSK, Organon, Pfizer
- Technical pilot

### ▶ **SAFE EU Advisory Council**

### ▶ **EMA proposal to EFPIA to use SAFE as access solution to EudraVigilance data base (~3,000 users)**

### ▶ **SAFE signature is legal equivalent of handwritten signature, simple electronic signature is not -- meets EU “Qualified Electronic Signature” – strongest level of electronic sig**

### ▶ **Next Steps**

- eCTD submission by SAFE member
- EMA and Member State Regulators – SAFE Familiarization
- Pilot within EMA
- Legal/regulatory/technical review of Member State requirements



## EMEA & SAFE: Formal Position

*"The EMEA welcomes the SAFE initiative as a way in which pharmaceutical industry in the US and Europe might create a system to establish and manage digital identities for secure e-business. Like the FDA the EMEA will work with the SAFE initiative and contribute European regulators' requirements to the SAFE specifications. One element of this co-operation will be a pilot to be organised jointly by EFPIA and the EMEA. The EMEA also recommends that the SAFE initiative be discussed at ICH level with a view to making it a de facto standard for e-regulation and e-business for pharmaceuticals."*



## Other SAFE Initiatives

- ▶ **Federal Bridge CA**
  - U.S. agencies (DHHS, CDC, CMS, DOD, VA, DHS, Treasury, Justice, DEA, EPA, USPTO)
  - Other communities – Certipath, Illinois
- ▶ **SAFE-CDISC MOU**
  - Participation in WGs
  - Conduct 2 pilots – using EHRs in R&D; emergency response
- ▶ **SAFE-HL7 MOU and Digital Signature Standard Work Program**
- ▶ **CRIX**
  - SAFE for authentication
  - Digital Signature
- ▶ **eHealth**
  - HIEs



## Strategic Value of SAFE for Industry

- ▶ **SAFE makes end-to-end eRegulatory submissions and eBusiness processes possible for pharma and healthcare**
  - Legal enforceability
  - Regulatory compliant
  - Global standard
  - In EU, digital signature is the only legal equivalent of handwritten
  - Mitigates risk
  - Vendor, technology neutral
  - Secure
  - Only one digital identity per investigator or KOL or other user
  - Provides interoperability
  - Improves productivity
  - Reduces cycle time
  - Facilitates collaboration
  
- ▶ **Enabling technology to transform business and regulatory processes**

**SAFE is the industry's future!**

SAFE-BioPharma Association



- ✓ *Please visit the SAFE website : <http://safe-biopharma.org/>*
- ✓ *Learn more about the SAFE Implementation Toolkit: [http://safe-biopharma.org/index.php?option=com\\_content&task=view&id=254&Itemid=422](http://safe-biopharma.org/index.php?option=com_content&task=view&id=254&Itemid=422)*
- ▶ *Watch the SAFE introductory video: <http://www.phillipsvideopost.com/safe>*
- ▶ *Contact us for more information:*

**Mollie Shields Uehling**

**SAFE CEO**

**[mollie@safe-biopharma.org](mailto:mollie@safe-biopharma.org)**

**(201) 292-1861**

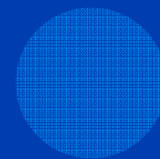
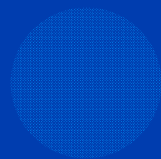
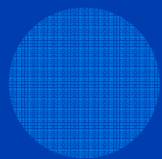
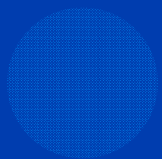
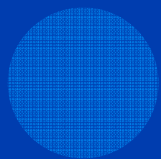
**(201) 925-2173 (cell)**

*SAFE Digital Identity and Signature  
Standard and  
Citi Managed Identity Services:  
Resolving a P&G Need*

May 8, 2008

Kay Bross

Sr. PKI Specialist, P&G

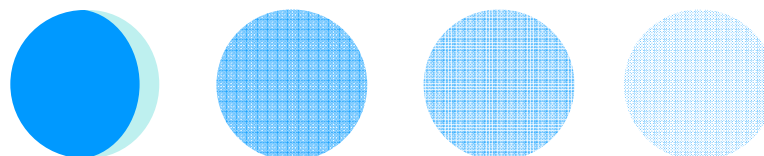


**P&G**

# Business Problem

Two Fold – one specific, one general

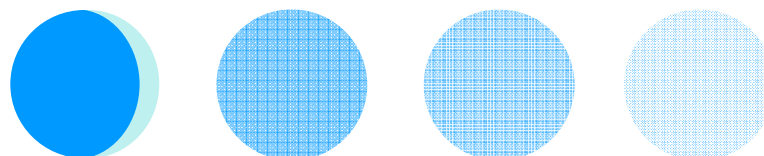
- eLab Notebook (ELN) project needed a final solution piece
  - Legal signature
- Creation of permanent electronic records and need to sign remotely
  - Paperless where possible
  - Move from 'print>sign>scan>send' to electronic signing



# Meeting ELN Need

SAFE Standard initiative came to P&G awareness, Nov. 2003

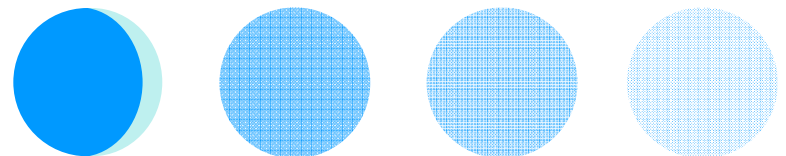
- P&G joined effort to finalize v1, May 2005
- Introduced to ELN team for technical compatibility testing
- Presented to P&G Intellectual Property Legal organization for risk assessment, fall 2006
- Approved for use with ELN, Feb. 2007



# Other Signature Needs

Moving from 'print>sign>scan>send' process to electronically signing

- Variety of business process occurrences – global basis
  - Legal Signature
  - Approval
  - Authorization
- Approval of guidelines for use – General Legal organization
  - Received March, 2008



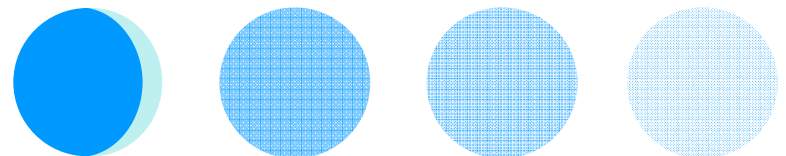
# Signature Options

Could use a SAFE digital signature where legal enforceability is needed and another solution for other signature needs

- Force users to understand the difference
- Force users to decide which to use

Could use a SAFE digital signature for electronic environment signing needs

- One solution
- Quality meets any global transaction need



# Reviewing SAFE Signature Standard Certificate Providers

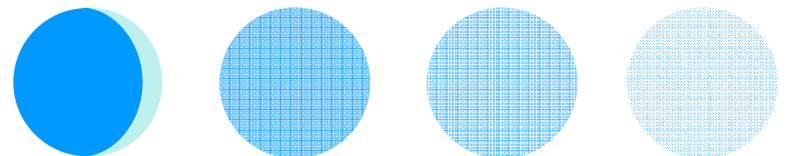
SAFE Standard compliant

EU Qualified compliant

Affordable

Full solution desired – RA / CA / VA

Willingness to be active in continued development  
of digital signature initiative



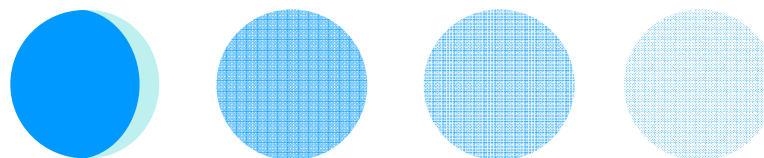
# Progress to Date - certificates

Contract signed, January 2008

ELN using in staged rollout to 4500 users

- Integration of SAFE signature delivery with ELN application
- 200 + certificates issued

Other General uses growing in numbers



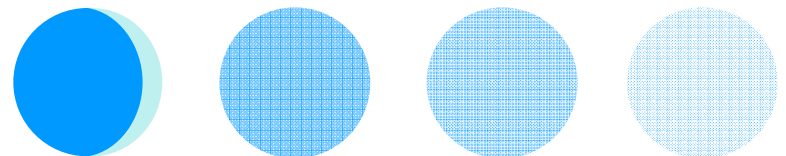
# Progress to Date – Citi / P&G relationship

Citi eager to help work through minor issues

Rollout through P&G – enterprise wide

Joint effort to address needs as they are identified

- New technology / new solutions / new needs
- Together we win!



# Value to be Counted On

## Productivity/Efficiency Gains

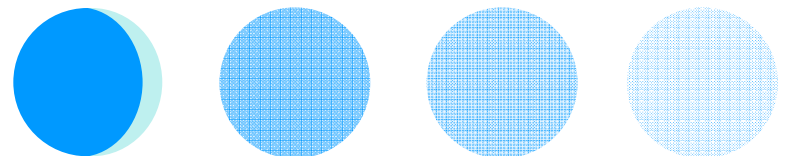
- Time savings (“print>sign>scan>send” process)

## Environmental Sustainability

- Save paper (and printer, ink, toner, and electricity...)

## Innovation for Business Value

- Enable mobile staff
- Permanent eRecords
- Accelerate your cycle time



# Lessons Learned > Wisdom Gained?

User data from business to Security Officers

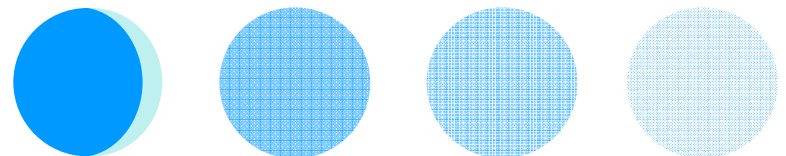
User help files – enabling local Security Officers

Certificate generation process

- Individual user
- Application user

Wisdom? An ongoing process! Continue to:

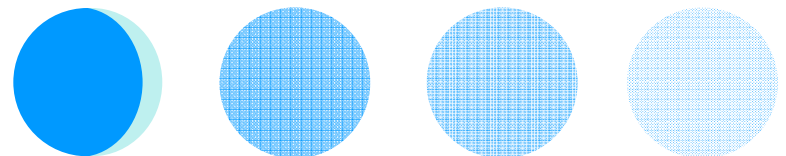
- Define wisdom
- Define the work
- Define the delivery of solutions
- Meet users needs



# Pleased with Decisions to Date?

Yes

Continuation of Relationship – build an increasingly stronger solution to meet business signature needs in an environment of electronic records





## Questions:

Kay Bross

[bross.ak@pg.com](mailto:bross.ak@pg.com)

513-698-6726

Touching lives, improving life. **P&G™**



# Citi Managed Identity Services

## *Introduction and Overview*

---

Frank Villavicencio

*Director, Product Management*

*Citi Managed Identity Services*

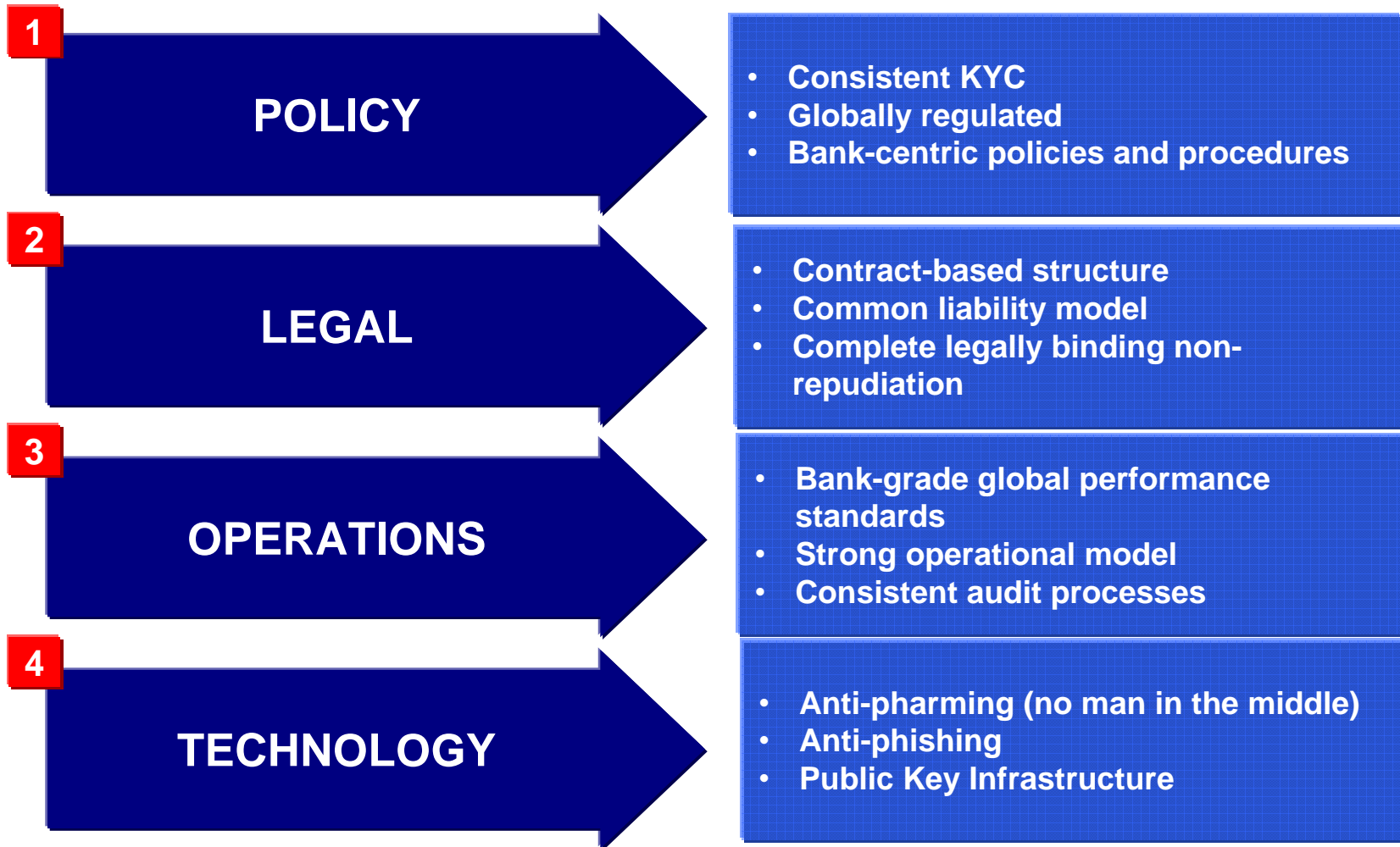
May 8, 2008



# Why Banks? Why Citi?



As a trusted partner to the world's top corporations and governments in more than 100 countries, we are uniquely qualified to address identity management challenges in enabling B2B digital transactions



## Citi Managed Identity Services: *Value Proposition*



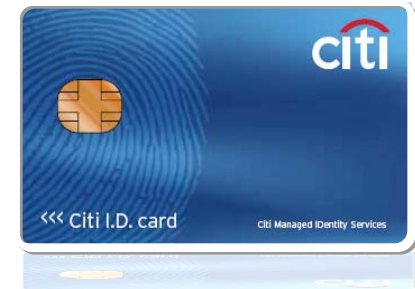
- **Provide visibility, control and risk management**
  - Mitigate risks and reduce liabilities
  - Citi can provide the desired “trust” levels thanks to our KYC process
- **Regulated industries require “known” assurance levels**
- **Outsourced model offers cost effective and scalable model**
  - Citi’s flexible integration models allow plug-and-play solution for Clients infrastructure
  - End user interaction can also be tailored to the organization needs
- **Clients need end-to-end solutions, rather than technologies**



# Product Offering



- **Issuance Services** – Full Registration and Certificate Authority managed services. Flexible delegated administration models. Issuance of high-assurance digital credentials compliant with IdenTrust and SAFE standards



- **Digital Cash Management** – Secure payments via File or CitiDirect (Secure Payment Authorization), electronic signer and account management (Electronic Bank Account Management), and secure and regulatory compliant records management (Electronic Vault)

- **Partner-driven Solutions** – Partnership with software providers and systems integrators to enable solutions that rely on high-assurance digital identities

**Microsoft**



**Curulis**

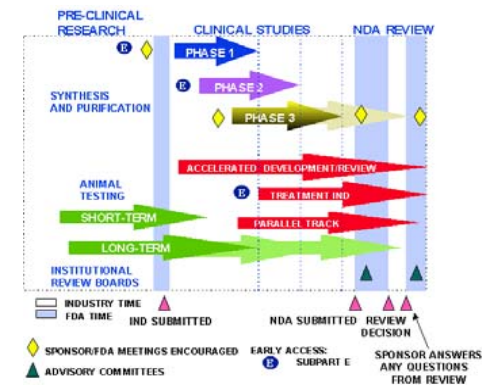


## Cash Management

- Secure Authorization Services
- E-Bank Account Management
- Foreign Exchange Contracts

## Life Sciences

- Electronic submissions to FDA
- Drug patent applications
- Drug R&D process



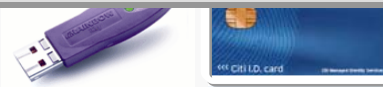
## Electronic Vault (eVault)

- ✓ Secure and regulatory compliant electronic records management
- ✓ Searchable and indexed audit repository
- ✓ Granular access control via entitlements



## Issuance Services

- ✓ Managed RA and CA services.
- ✓ Delegated administration models
- ✓ IdenTrust and SAFE digital credentials
- ✓ Turnkey solution accessible online and via web services



# Our Views on Identity Services

---



- Digital Identities are enablers – real value comes from applications
- Identities should be globally interoperable
  - Hence should adhere to an accepted global standard



- Drive adoption through innovation and broad collaboration



## Thanks - For More Information

---



Contact us at [identityinfo@citi.com](mailto:identityinfo@citi.com) or visit our web site:  
<http://www.citigroup.com/transactionservices/homepage/cash/identity/>

**Note:** This web session is being recorded and will be available for replay on our web site shortly





Digital Identities and Signatures in the Pharmaceutical Industry:  
A viable approach to better business processing

---

May 8, 2008

