

Implementation of SAFE Digital Signatures at AstraZeneca

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Topics

- Background
- Regulatory Affairs and SAFE
- First Steps
- Implementation
- Keys to Success
- Benefits
- Status

Background

- AZ's participation in SAFE
 - AZ is one of the founding members of SAFE
 - Safe Team at AstraZeneca

Background

AZ SAFE Governance	Responsibilities	Who
Sponsor	<ul style="list-style-type: none"> • Communicate ongoing plans and strategy to ISLT • Set Strategic direction for SAFE Steering Committee 	Global Drug Development IS
AZ SAFE Board Member	<ul style="list-style-type: none"> • Provide AZ input for BOD decisions • Lead Steering Committee • Keep Sponsor informed of progress and key decisions 	GDD IS US Region
Steering Committee	<ul style="list-style-type: none"> • Set strategic direction for SAFE in AZ • Ensure consistent communication • Promote adoption of SAFE amongst business units and with partners 	AZ SAFE Sponsor Chief Security Officer IT Services AZ Safe Board Member
Core Team	<ul style="list-style-type: none"> • Participate in / interface with working groups – Governance and Business WG, Legal WG, Operations and Technical WG, Vendor WG, Compliance WG, Industry Application Roundtable, FDA/SAFE conference, Pilot projects • Status reports to steering committee • Provide specialized expertise, i.e. security, IT infrastructure, legal, etc. as required to champion the ongoing adoption of SAFE at AZ • Provide Cross functional input to AZ SAFE Board member • Contribute to the creation of business cases where SAFE may be an applicable solution 	Lead: GDD IS BP RA Members: Enterprise Security Enterprise IT Services GDD IS BP Clinical GDD IS Compliance GDD IS Architecture Legal Finance

AZ Regulatory Affairs and SAFE

- AZ Regulatory Affairs - why we got involved in implementing SAFE
 - In conjunction with the implementation of the FDA Electronic Submissions Gateway
 - AZRA involved in the pilot for the FDA ESG

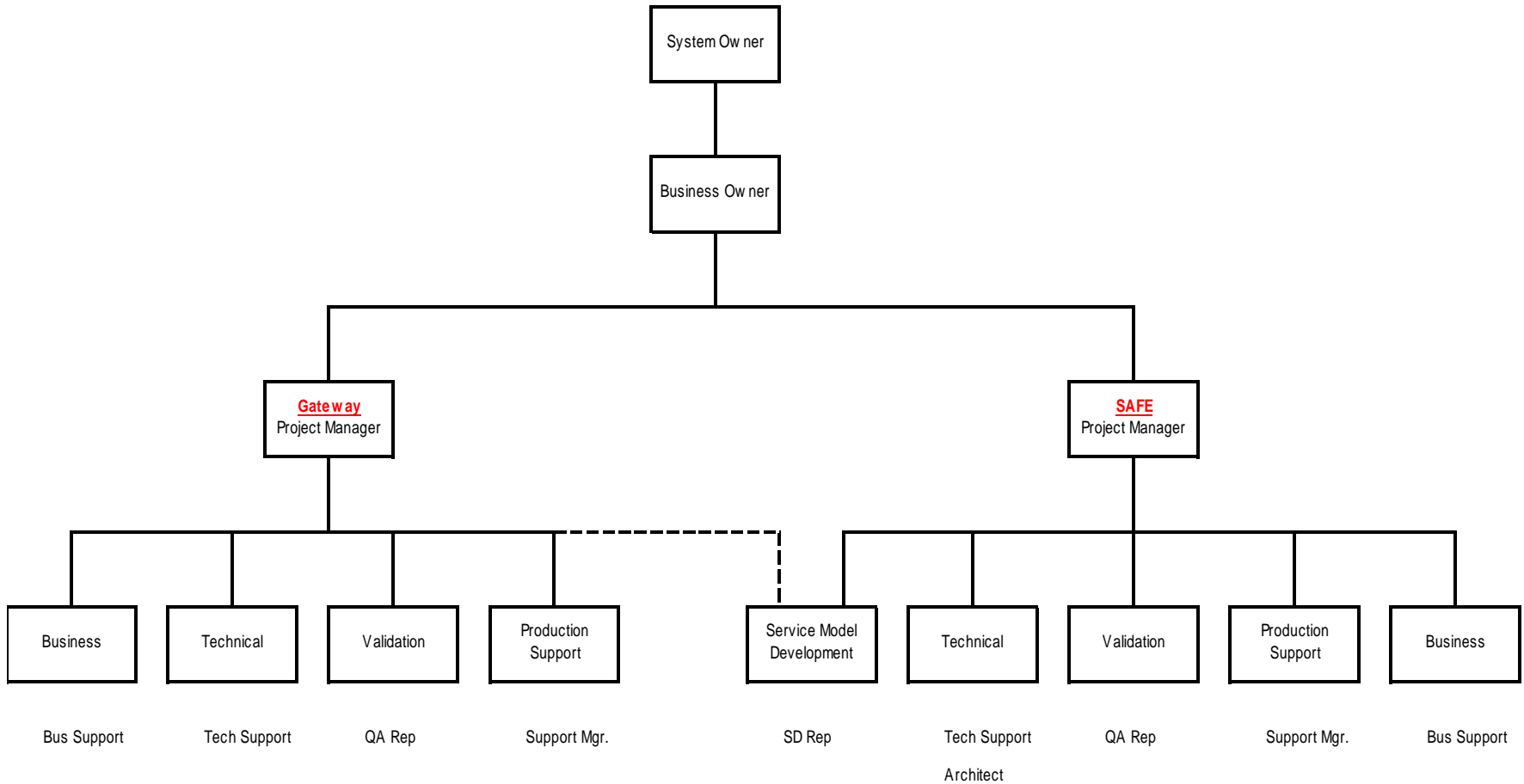
- Implementation FDA ESG
 - Requirement for digital signatures on FDA forms
 - Leverage experience and benefit from AZ membership on SAFE
 - Part 11 compliant
 - Future extension of benefit internally
 - Small group requiring credentials

AZ Regulatory Affairs and SAFE Key Concerns of the Business

- Compliance
- Cost
- Complexity
- Training
- Efficiency gained
- Support
- Timing
- Reputation

First Steps

AstraZeneca Gateway & SAFE Project Organization Chart



First Steps

- Seek expertise
- Determine user requirements
- Investment/“buy-in” by key stakeholders
 - Legal
 - Records Management
 - Architecture
 - Infrastructure
 - Security

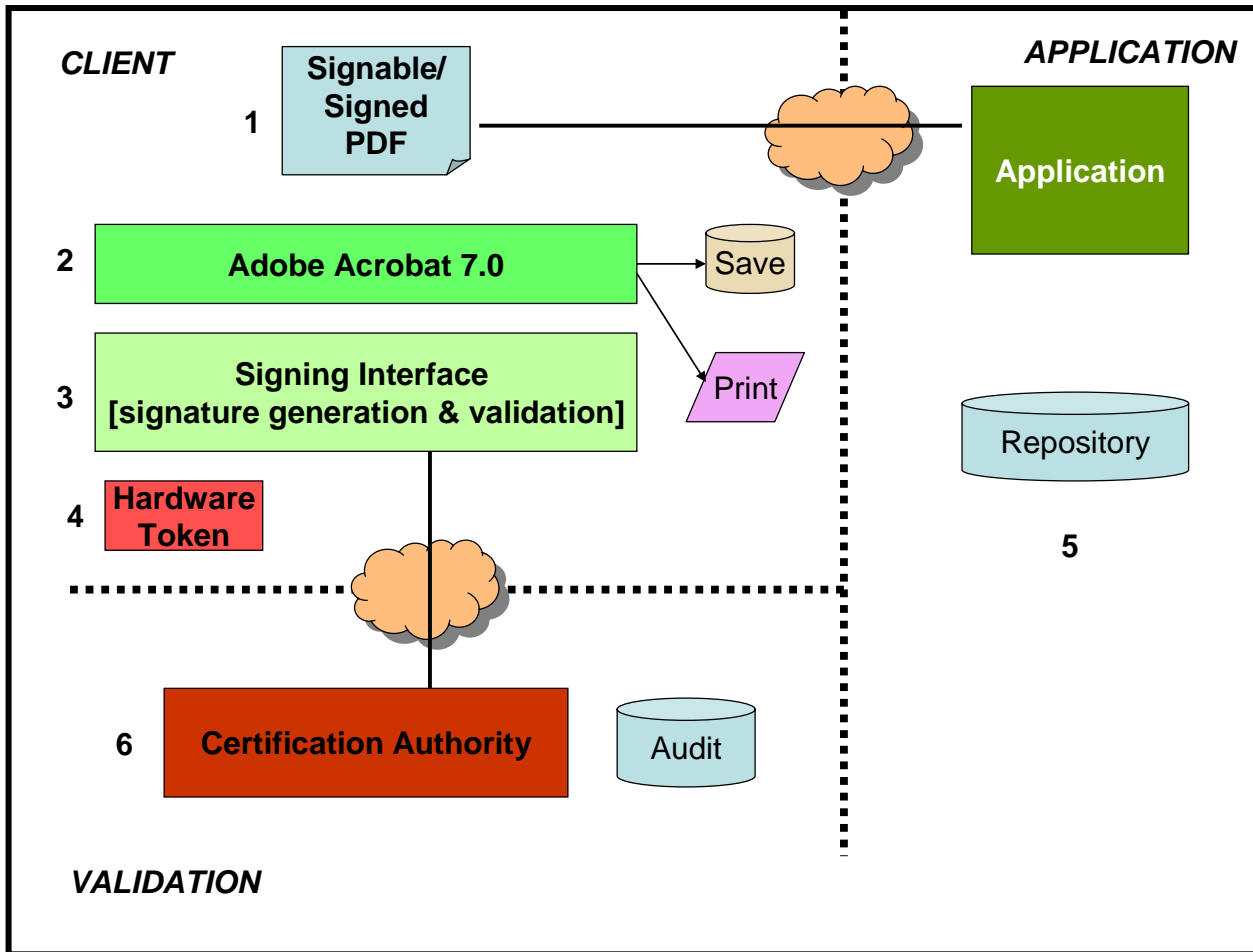
Implementation

- Regulatory Affairs - determine and address process implications
 - “live” digital signature vs. flattened file
- Software – off the shelf, Arcot addressed version SAFE 2.x ruleset
- Validation - (eg, system requirements, user acceptance testing)
- Infrastructure implications – Firewall (open required ports) and Proxy issue
 - Arcot software does not use proxy connection
 - AZ Internet Security Policy does not allow direct access on port 80
- Deployment - Scripting for installation and rollout plan
 - Scripted for automatic rollout to users, complicated by reboot required after driver installation
 - Adobe Acrobat 7 Pro
 - SafeNet token drivers
 - SafeNet Middleware (policy)
 - Arcot Universal Client

Implementation

- Training
- Credentialing - AZ's Trusted Agent – “pain-free registration”
- Communications
- Trouble shooting
 - Java version issues with RACCA registration application
 - Windows SmartCard services are activated by driver install – side effects
 - Apparent interaction with latest Citrix client
 - SafeNet installs four devices by default
 - Scripting difficulties in Arcot installation
 - Server based implementation for SAFE should reduce number of issues encountered
- Security
 - Firewall policy
- Support

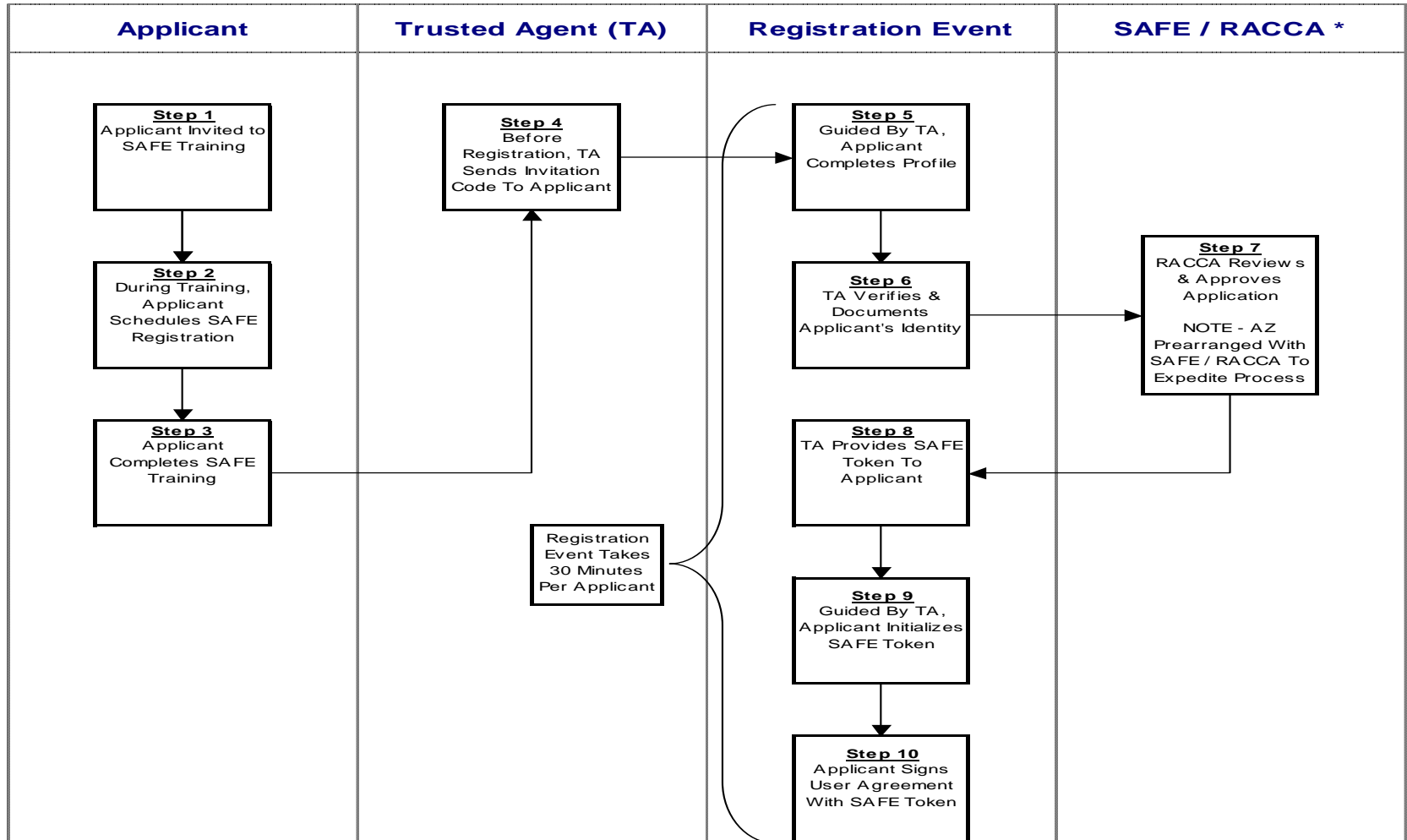
Implementation Architecture



1. Electronic record represented using a PDF document.
2. the client-side document display application
3. SAFE-compliant Signing Interface, which generates and verifies the Digital Signature.
4. User SAFE Credential stored on a SafeNet Hardware Token and appropriate driver and middleware software
5. Regulatory compliant data repository
6. User credential certification authority which validates the digital signature – (via an OCSP request / response over the secure Internet connection)

How it works - Registration

AstraZeneca SAFE Credentialing Process



* Registration & Certificate Configuration Authority (RACCA) - the online, internet-based system that supports the SAFE credentialing process

How it works

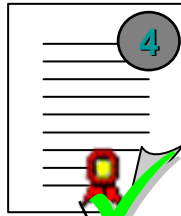
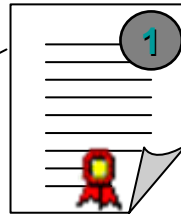
- Software installed
- Process defined
 - PDF of FDA form is placed in an area that allows write access
 - Path to submission form sent the signatory for review and digital signatory approval
 - Signatory (Regulatory Affairs Director or designee, ie, Regulatory Affairs Manager) reviews and applies digital signature to form and alerts the submission manager.
 - Submission Manager replaces the unsigned form with the digitally signed form within the compiled submission.
 - Submission is moved to the electronic archive from which the submission is sent via the FDA ESG.

Application of SAFE Digital Signatures for submissions delivered through FDA ESG

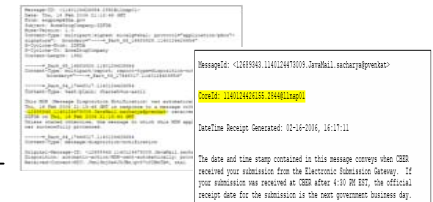
Issuer



AstraZeneca



FDA



- D1 Digital signature applied to the FDA form
- V2 Validation of signature credential requested
- V3 Validation report received
- V4 Validation report and signature bound to document
- D5 Digitally signed FDA form placed within compiled electronic submission. Submission moved to electronic archive
- S6 Submissions sent to FDA via the FDA ESG
- S7 Submission acknowledgments received
- S8 Submission acknowledgment (receipt) placed into electronic archive with submission link page

Keys to success

- Leadership support
- Use of experienced consultants
- Communication, Communication, Communication
- Training
- Support
- Lessons Learned

Benefits: FDA ESG and SAFE

- Improved cost and time efficiencies for both sponsor and agency
 - eg, obviates need to burn CD, DVD, Tape
- More efficient transfer of our electronic submissions
- Facilitates earlier access to the submission by the review division
- Ability to eliminate paper
 - Reduced effort to process and archive
 - Efficiencies related to electronic processing and transfer of forms to signatories
- First movement towards a digital identity
- Industry leadership
- Reputation
- Leveraging investment in SAFE

Status - Where are we right now?

- Efficiencies gained in combination with use of FDA ESG
- Demand for extension of use:
 - SAFE Digital Signatures in Regulatory Affairs beyond the US
 - Potential uses of SAFE technologies beyond current use (ie, Sponsor to Regulatory Agency)
- IT security will own SAFE and sponsor SAFE for the entire corporation