



43rd
Annual Meeting

Striving for Permanent eRecords: A Pharmaceutical Company Perspective

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Atlanta - 2007

The Procter & Gamble (P&G) logo, consisting of the letters "P&G" in a white, serif font, set against a dark green rectangular background.

Learning Objectives

- At the conclusion of this session, participants should be able to:
 - Understand the difference between electronic and digital signatures
 - Explain the value proposition for legally enforceable digital signatures
 - Understand challenges of implementation



Procter & Gamble Company

- Company of multiple product categories:
 - Personal & Beauty
 - House & Home
 - Health & Wellness
 - Baby & Family
 - Pet Nutrition & Care



Desire for Permanent Electronic Records

- Requires signature solution
- Electronic vs. Digital
- Need for Legal agreement
- Need for implementation ease
 - System vs. individual signing capability
- File format varies



Which Way To Go???



P&G and SAFE Digital Signatures

- SAFE – Signatures and Authentication For Everyone
 - P&G one of eight founding members, 2002
 - Participant in defining the Industry Standard for Dsig
 - SAFE member with pharma as small portion of business
 - Plans to implement within P&G



Digital Signature Value Proposition

- When signature is legally enforceable:
 - Allows permanent electronic record
 - Enhances speed and ease of record retrieval
 - No need for paper storage
 - Allows Records Mgmt organization to take responsibility in new ways
 - No need for redundant paper back-up systems
 - Cost savings in systems and personnel
 - Speed of transactions, internal and external, increased
 - Meets Regulatory requirements for eSubmissions



SAFE implementation @ P&G

- Variety of business units – 2 initial solutions
 - Adobe with SAFE signature plug-in
 - Integration with applications currently in place for .pdf
 - Planned integration for new applications
 - Required format for eCTD documents – simple compliance solution
 - Web based document signing tool
 - Simple web interface for occasional signing needs
 - Solution option when applications do not interface with Adobe
 - Support for external partner signatures



Dsig with Adobe...the education process

- P&G - one customer to request a SAFE specific signature block
 - Rapid decision from Adobe to design and own the plug-in
 - Parallel review of Adobe usage within P&G
 - Analysis showed areas of high use
 - Review of that use: introduction to LiveCycle Products
 - LRES led to review of PDFG and Policy Server



Hairstyle is tangled

- Where to start first
 - Electronic Laboratory Notebook (ELN) project
 - Legal acceptance
 - Adobe LiveCycle products heighten identified need in Product Supply – leads to signature discussion
 - Purchasing – manage eContracts
 - Highly restricted data – added security / enterprise alignment options
 - Clinical / Regulatory / Medical Writing
 - HR SAP



Conditioning the tangles

- Business units evaluating advantage of Dsig with simple implementation solutions
- Opportunity to coordinate some Adobe use – gain efficiency
- Established applications being reviewed for update and advantage of enterprise solution
- P&G SAFE Interest Group formed to raise awareness / share ideas / use solution tools



Early Results

- ELN Project moving into early phase production with SAFE Dsigns
- IP Legal – accept SAFE Dsigns as equivalent of wet signatures
 - General Legal evaluating
- HR SAP – strong desire to move to SAFE signatures
- Identification of security / legal reasons for adding Dsigns work processes
- Cost savings in coordinating software solutions



The Work Continues...

- Awareness / Review / Expansion of use
- Enhanced security of eBusiness Transactions and eRecords
- Paper storage savings
- Information retrieval efficiency / effectiveness
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If I can help...

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