

## FACT SHEET

### PROCTER & GAMBLE USES SAFE DIGITAL SIGNATURE STANDARD FOR ELECTRONIC LABORATORY NOTEBOOK PROJECT

To be deployed to up to 4500 P&G scientists and technicians

**WHAT:** Procter & Gamble (P&G) is using the SAFE digital signature standard in its Electronic Laboratory Notebook (ELN) project, reaching potentially 4500 people inside the company. This project is being implemented by P&G Healthcare R&D. Several other P&G business areas currently are evaluating adaptation of the SAFE digital signature. They include Purchasing for management of eContracts, non-pharma clinical studies, and Regulatory, Clinical, and Medical Writing for compilation of submission documents.

**WHY:** P&G's use of SAFE digital signatures is intended to facilitate a total electronic environment that does not need paper backup in support of a wet signature. P&G's IP Legal (intellectual property) department has determined that SAFE digital signatures are the equivalent of wet signatures.

**WHO:** Numerous entities will benefit from the use of SAFE digital signatures in P&G's ELN project.

- **Scientists and technicians** documenting laboratory research, experiments and procedures will be able to digitally sign records and eliminate the need for paper-based "wet" signatures.
- **Records Management** will eliminate the need for paper storage and ease the complexity of information retrieval.
- **IP Legal** will be able to retrieve records easier, faster and more economically than paper when dealing with litigation matters.

**HOW:** Use of SAFE digital signatures within P&G is being implemented via use of the following:

- Adobe Acrobat with SAFE signature plug-in
  - Integration with applications currently in place for .pdf
  - Planned integration for new applications
  - FDA-required format for eCTD (electronic Common Technical Documents) used in electronic submissions – simple compliance solution
- Web Application
  - Simple web interface for occasional signing needs
  - Solution option when applications do not interface directly with Adobe's .pdf format
  - Support for external partner signatures
  - 'Occasional' or 'one-off' needs for signature

**WHEN:** P&G's ELN project utilizing SAFE digital signatures currently is in beta test and is expected to begin operational rollout in June, 2007.

## BACKGROUND INFORMATION:

- An **Electronic Laboratory Notebook** is a software program designed to replace paper laboratory notebooks. Most typically, ELNs are used by scientists and technicians to document research, experiments and procedures formed in the laboratory. ELN's are considered legal documents and may be entered as evidence in a court of law, often in association with intellectual property litigation.
- The **SAFE digital signature standard** provides a secure, enforceable, and regulatory compliant way to verify the identities of parties involved in business-to-business and business-to-regulator electronic transactions. The standard was developed by SAFE-BioPharma Association for use within the pharmaceutical and healthcare industries. Use of the SAFE standard facilitates interoperability and integration among researchers, vendors, regulators, clinicians and other pharmaceutical and healthcare stakeholders.
- **Procter & Gamble** (NYSE: PG): Three billion times a day, P&G brands touch the lives of people around the world. The company has one of the strongest portfolios of trusted, quality, leadership brands, including Actonel(R), Asacol(R), Enablex(R), Prilosec OTC(R), Metamucil(R), Fibersure(R), Align(R), Pepto-Bismol(R), Vicks(R), ThermaCare(R), PUR(R), Crest(R) and Oral-B(R). The P&G community consists of over 135,000 employees working in over 80 countries worldwide. Please visit <http://www.pg.com> for the latest news and in-depth information about P&G and its brands.
- **SAFE-BioPharma Association** is the non-profit association that created and manages the SAFE™ digital identity and signature standard for the pharmaceutical and healthcare industries. SAFE stands for "Signatures and Authentication For Everyone." The Association's founder-members include AstraZeneca, Bristol-Myers Squibb, GlaxoSmithKline, Johnson & Johnson, Merck, Pfizer, Procter & Gamble, and Sanofi-Aventis. For more information visit [www.safe-biopharma.org](http://www.safe-biopharma.org).