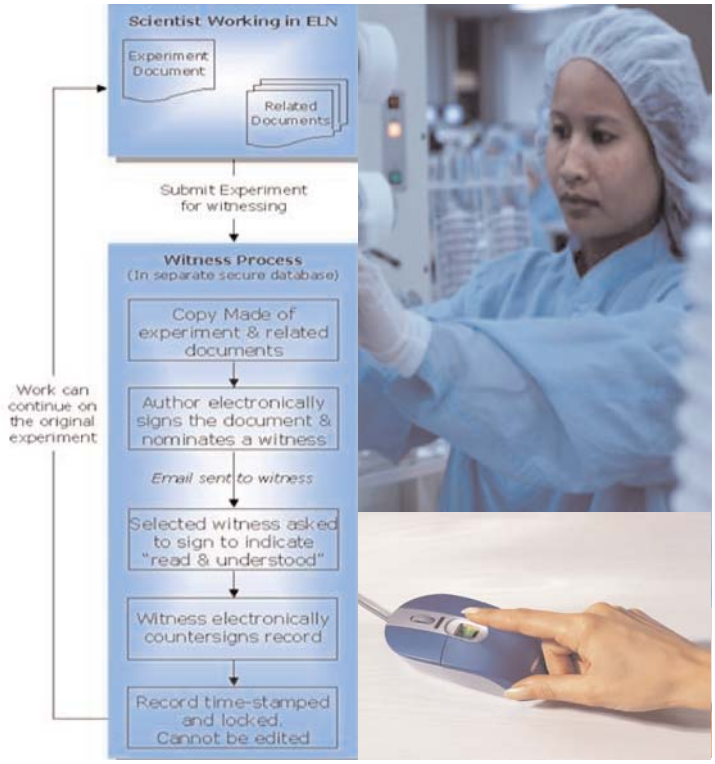
Electronic Signatures Using Biometrics for Pharmaceutical Applications

XYNTEK provides **manufacturing**, **development**, and **enterprise-wide staff user authentication** and/or **electronic signatures** through the use of **biometrics**. Any combination of password, identification card, or biometrics may be used for secure computer access and/or electronic authorization and signing. The **XYNTEK** solution is based upon globally supported **ID Center** Software. **XYNTEK** provides IT integration and support to implement the solution across business-critical data management systems and existing legacy software applications throughout the pharmaceutical enterprise for Electronic Signatures. Applications in Drug Discovery, Drug Development, Clinical Trials, Manufacturing and Release are supported, including popular **Electronic Laboratory Notebooks (ELN)** and **Manufacturing Execution Systems (MES)**.

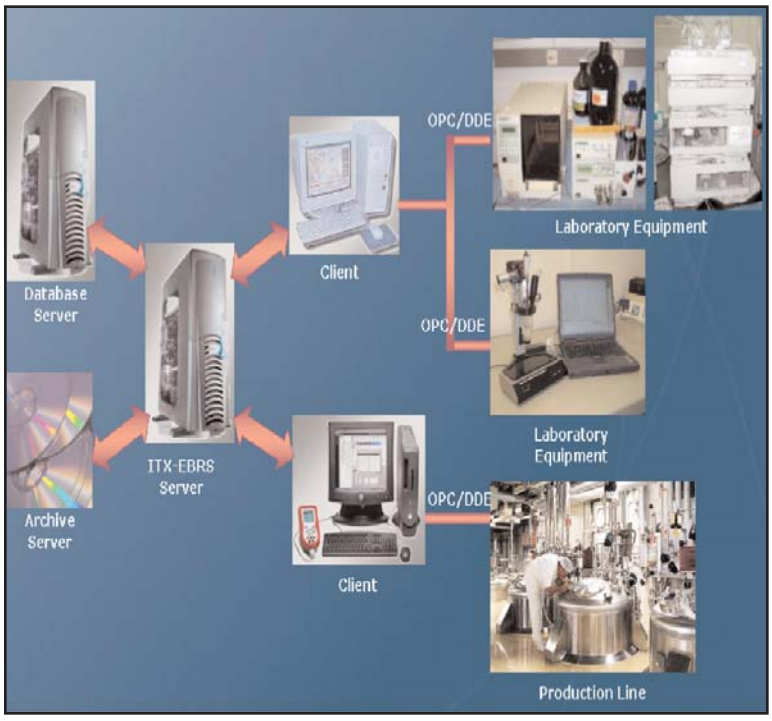
Integration of numerous readily available biometric sensor technologies, including fingerprint, palm vein reader and/or iris scan may be utilized for system access. Biometric sensors from the most popular suppliers (including UPEK and Authentec (commonly found in laptops),



Laboratory Systems Solutions

In the discovery phase for a new drug, chemists perform experiments to identify new compounds. Historically, they recorded their experiments in a paper lab notebook, signed the experiments, and met with another scientist who witnessed the experiment. Eventually, the chemist provided the completed paper notebook to a Records Management organization for archiving. Signing and witnessing is important, since it provides the date-time stamp for when a new compound was discovered. The date time stamp can be vital many years later when the company defends the patent for the drug.

Converting this series of activities to an electronic lab notebook has been a dream for many years. Each step of the process that involves paper takes the chemist away from the lab, and reduces the time actually spent on science. Electronic signatures via biometrics from **XYNTEK** can provide many benefits to the scientist in this process.



Manufacturing Systems Solutions

Electronic Batch Record (EBR) Systems help pharmaceutical companies meet the critical challenges of increasing productivity while maintaining compliance levels required by the FDA in the new "Risk based approach to the GMPs for the 21st century." EBRs free operators, supervisors, managers and quality assurance analysts from devoting large amounts of time consumed by manual activities that are done to ensure that batch records are filled in completely and correctly. By automating these labor intensive activities, savings of 50% or more are realized, primarily in areas of data capture, document preparation, and review.

What many fail to recognize is how the EBR systems affect the human workers who will interact with them. Implementation of Biometrics from **XYNTEK** addresses these issues and facilitates the realization of the financial benefits of Electronic Signatures on any EBR System.

XYNTEK INC.

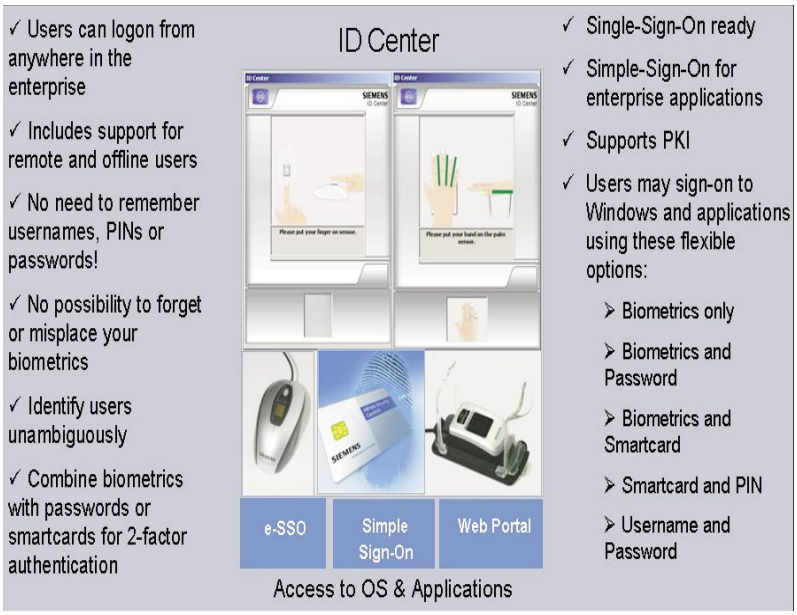
Biometrics

www.xyntekinc.com
sales@xyntekinc.com

Electronic Signatures Using Biometrics for Pharmaceutical Applications

Biometric User Acceptance

- Signatures are non-intrusive and fit with how chemists and operations personnel do their daily work
- Less time is spent managing paper, so more time is spent in the lab and factory floor
- Process of signing and witnessing is speedy, and leads to greater compliance with internal policies
- Completed experiments are available and searchable online, providing cross-site efficiencies that were not possi ble with paper notebooks
- Because experiments and batch reports are signed the same day they are completed, and because the digital signature has a clear identity of who signed and when they signed, long term patent protection and compliance is increased
- Compliance with FDA regulations (such as 21 CFR, part 11)
- Supports dual/multiple signatures
- Simple user-interface
- Supports client-server and stand alone architectures
- Eliminates costly password support



Legal Benefits of Electronic Signatures

Legal enforceability. Digital signatures are the legal equivalent of an ink-based signature. Signatures meet three key legal criteria. With authentication, you are sure of the identity of the person who provided the signature. With integrity, you are sure the document has not been altered since it was signed. With non-repudiation, you are sure that the sender cannot deny signing the document.

Regulatory compliance. Electronic Signatures meet or exceed regulatory guidelines for 21 CFR Part 11 and HIPAA. The standard was designed to meet similar international guidelines, and ensures that new versions comply with emerging regulations.

Strong Security. Electronic Signatures ensure security and data integrity. With two factor authentication, users need both their biometric and their passphrase to digitally sign a document. This is similar to automatic teller machines, which require people to provide both their ATM card and their PIN. The standard uses public key infrastructure (PKI) to apply digital signatures to documents and to assure the integrity of their content

Global. Electronic Signatures implemented with ID Center Software are globally available and supported.

ID Cards and Smartcards can be lost, stolen, shared, etc. – ***can we prevent the unauthorized use of ID Cards/Smartcards?***

High replacement cost and management cost for cards in many situations – ***can these costs be avoided?***

Passwords and Pins can be written down, phished, forgotten, hacked, shared – ***how do we ensure high security without making it unbearable for our authorized users?***

High IT help desk costs for resetting passwords – ***how do we enforce "strong" passwords and frequent expirations without incurring high reset costs?***

When used as a single factor of authentication, neither option is very strong. However, when used in combination, it offers better security but still doesn't guarantee that the "right" person gains access – ***how can we improve security, compliance, efficiency and end-user acceptance in a cost-effective manner?***

Compliance, Audit and Accountability

US Department of Health and Human Services
HIPAA - Health Insurance Portability and Accountability Act, USA 2003
Procedures should clearly identify employees or classes of employees who will have access to protected health information (PHI)
Access to PHI in all forms must be restricted to only those employees who have a need for it to complete their job function

U.S. Food and Drug Administration
FDA CFR21 Part 11
Pharmaceutical industry, electronic books & records
Electronic signatures must not be created until the identity of an individual is verified

www.xyntekinc.com
sales@xyntekinc.com