Electronic Lab Notebooks (ELN)

PLM World 2006
Product Lifecycle Digital Transformation
UGS Vision for pharma research data management

- Fragmented architecture, data and application silos
- Need for an integration platform
- Need for Generic templates for organizing experimental data
- Need for data structure enabling quick access and navigation
- Need for flexible way of managing data access rights
- Need for new concepts related to Research knowledge management
Business Goals

- Increase researcher productivity by 20%
- Promote knowledge reappplication
- Eliminate paper and paper based microfilming
- Reduce legal response time
- Early identification of patentable ideas
- Streamline records management
Business Processes

- Authoring and witnessing primary lab notebook records.
- Capturing instrument data as adjunct records and relating them to primary records.
- Record life cycle management.
- Identification of patentable ideas and initiation of patenting process.
- Litigation support
Key Roles

- ELN Author
- Witness
- Research Supervisor
- Internal Records Administrator
- Records Manager
- Patenting Office
- Legal
- System Administrator
Typical Environment - Fragmented Architecture

Optimized Functional (vertical) Systems

- Project Management & Planning
  - Planning, Allocation, & Tracking
- Team Space
- Paper Notebooks
- Suppliers
- External DB
- Oracle
- Documentum
- LIMS Servers
- TCE
- Oracle
- Hard Drive
- Formulation Workstation
- Analytical Workstation
- LIMS
- Path/Tox
- TIDVAL
- Clinical Supplies
- Individual Systems

Product Focus?
Key Concepts

- Notebook
- Primary Record
- Adjunct Record
- Microfilm
- RMA Concepts (RMA Folder, File Plan, Audit Record, Disposition Phase, Disposition Schema)
Solution Strategy: Typical Approach
Add Odyssey as a functional bar.

Add as "New" or "Existing Function"?

UGS, 4/17/2006
Records Management Perspective

- **Records** – data/content to be managed (tax information)
  - Record Format (Form 1040)
  - Record Media (paper, electronic)
- **Record Folders** – organizers for records
- **Folder Cutoff** – collect and process annually
- **Disposition Schedule/Phases**
  - Collect annually
  - File by April 15th
  - Retain returns & supporting information for 4 yrs
  - Retain returns for 10 years

**Record Retention**
Electronic Notebook
Disposition Schedule

**Phase 1** (< month)
- New Folders Created
- Monthly Cutoff
- Publicize new knowledge reports and notebook records in central vaults

**Phase 2** (100 years)
- Time
- Destroy knowledge reports and notebook records

- Destroy knowledge reports and notebook records
ELN Simplified Process Flow

- ELN Website
  - Template Chosen or Created
  - Data Entered and/or Linked to Adjunctive Data
    - e-Signature Processed
    - Data Converted and Transported via PLM Platform
      - Data Printed and Signed
      - Data Archived and Indexed
    - Data "Promoted" to ELN
  - Vertical Application Data Screen
  - Project Data Views
Key Custom Features

- Notebook and Record Concepts
- Integration with adjunct data
- Digital signatures
- MS office Integration
- Acrobat Server Extension integration
- UI customization/configuration
- Records Management Configuration
Research and Purpose

ELN/PLM R&D Platform

Notebooking, Records, Management, Process, Search/Index, Reports, Regulatory

IP

Objective Purpose
(See inset Below)

Logical Architecture

Objective Purpose (Context)

Project/Product
IP Mgt
Exploration
Function/Methods
Knowledge Push

Universal Hierarchy

Notebook
Primary Record
Adjunct Record

MS Office
Word
ppt
xl

Chemistry Authoring
e.g., Gensys, ChemPro, etc.

Genetics Application

Instruments
NuGenesis
LabVantage
direct print

Other
ELN 2007 Features

- Record Authoring
  - Primary
  - Adjunctive
- Digital Signature
- Records Management / Retention
- Reports
- NuGenesis Integration
- CyberLabs Integration

* See Speaker Notes for Amplification
In summary

UGS provides:

- A proven integration platform for all research applications
- A system that is referencing and structuring all data
- ELN capabilities integrated in this platform
- An innovative approach validated in an industrial way