Global ELN Deployments – Experience from the frontlines

C.J. Ruggles
CambridgeSoft Corporation

230th National ACS Meeting
Washington, DC
September, 31 2005
Introduction

- CambridgeSoft
- E-Notebook History @ CambridgeSoft
- Lessons Learned In Global Deployments
About CambridgeSoft

- Developers of ChemDraw
- Headquartered in Cambridge, Massachusetts
- 100 employees in US, Europe & Asia
- Over 250,000 users of our products
- 20 years of profitability
CambridgeSoft E-Notebook History

- **1st Release of E-Notebook**
- **Infinity goes fully electronic**
- **2000**
- **Array deploys E-Notebook**
- **2001**
- **Pfizer Ann Arbor deploys E-Notebook**
- **2002**
- **Merck engages CS for global ELN**
- **2003**
- **Merck deploys E-Notebook**
- **2004**
- **GSK engages CS for fully 37 CFR compliant ELN**
- **2005**
- **Off-line feature & 37 CFR-compliant esig module available**
- **21-CFR-11 compliance achieved**
- **Chemistry cartridge integrated with ELN**
- **Configurable, web-based E-Notebook released**
Five Lessons Learned

1. Plan for Success
2. Expect Objections
3. Vertical Enables Horizontal
4. Horizontal is Required
5. Cultural Change is Necessary
Plan for Success

- Be Positive
- Encourage Everybody
- Know Your Organization
- Empower All
- Have a Vision
- Be Honest
- Be Persistent
Objections

- Financial
- Technical
- Scientific
- Legal
Financial Objections

- High cost of licenses
- Costly to Maintain
- Risk to IP

How To Address?

Prepare an ROI Pilot Study
The ROI Pilot – Measure the time cost benefits

- Identify Willing & Representative Participants
- Measure Current Notebook Operations
- Optimize E-Notebook Configuration
- Train Pilot Users
- Remeasure Notebook Operations
- Prepare and Present Study Results
The ROI Pilot – Determine the tangible cost reductions

- Scanning Documents
- Handling & Storage
- Report Generation Times
- Meeting Length Reductions
- Travel Expenses
The ROI Pilot – Identify the intangible benefits

- Facilitated Collaboration
- Availability of “Institutional Knowledge”
- Improved Data Organization
- Consistent Data Display
- Error Reduction
- Accurate & Presentable data
An ROI Example - Merck

- 5 Pilot Areas -
  - Metabolic Disorders
  - Bioinformatics
  - Pharmaceutical R&D
  - Automated Biotechnology
  - Analytical Research

- 19 qualified (1 month ELN use) participants
- 30 min. to 2.5 hrs. per user per week saved
Infrastructure Objections

- Bandwidth Utilization
- Computer Accessibility
- Operating System Compatibility
- Current Application Compatibility

How To Address?

Identify Good ELN IT Practices
Good ELN IT Practices

- Utilize “off-line” Capabilities
- Provide in-lab Computer Option
- Utilize Wireless LAN
- Upgrade Pilot Computers
- Identify Current Application Functions
- Have IT Support at the Ready
Scientific Objections

- Not Designed for My Discipline
- Cannot Accommodate My Data
- Limits My Creativity

How To Address?

Develop Workflow Analysis Protocol
Workflow Analysis Protocol

- Perform 1-on-1 Interviews
- Observe Routine Operations
- Create Workflow Focus Groups
- Implement Configured Notebook
- Provide Comprehensive Training
- Perform Configuration Utility Follow-up
- Implement Updated Configuration
- Expose Configuration Functionality
Legal Objections

- Electronic Records are Not Admissible
- What about Global Interferences?
- Is it 21 CFR 11 Compliant?

How To Address?

Prepare a Corporate Legal Brief
Corporate Legal Brief

- USPTO

  In interferences: “… [T]o the same extent that electronic records are admissible under the Federal Rules of Evidence.”

  37 CFR § 41.152(a) “Generally. Except as otherwise provided in this subpart, the Federal Rules of Evidence shall apply to contested cases. * * * ”

- Federal Rules of Evidence

  Business Record exception to Hearsay Rule – 803(6)
  Residual Exception – 807
  Authentication of Evidence – Rule 901
  Records – Rule 1001
Corporate Legal Brief

- **EU**
  - Directive 1999/93/EC
  - Widely adapted in some form or another
  - EU Review: International Journal of Law and IT, March 2005

- **Italy**
  - Art 269702733 of Civil Code 1940
  - Decreto Del Presidente Della Repubbica (513) 1997

- **UK**
  - Electronic Comm. Act 2000
Go Vertical

- Vice President
- Department Head
- Group Leader
- Scientist
- Technician
To Enable Horizontal

Cross Departmental Working Groups

Where The Action Occurs!

Communication of

- Shared Concerns
- Common Frustrations
- Different Business Perspectives
- Misconceptions

Results in

- Shared Goals
- Improved Process
- Esprit de corps
- Conflict Resolution

Paradigm Shift
You are in the lab running the reaction in less time than it would take just to figure out in which continent the notebook resides. Better yet, you discover that someone down the hall made this compound last year and has 3 grams in his [lab]. … This shortcoming is amplified in a global research organization with multiple research sites. If you find a compound of interest in the corporate database, it can take days just to track down the location of the original notebook. Then someone has to copy the page and send it to you. With an ELN, you search-find-copy-paste. It takes 60 seconds and nobody has to be bothered but the refrigerator.”
Thanks to

You! – for your attention and patience
Dave Martinsen, ACS – for organizing this session
Rudy Potenzone, CambridgeSoft – Advice & Guidance
Tony Romano, Merck – ROI Study
James Kanagy, GlaxoSmithKline – Legal Issues
Organizations – Merck, GSK, Infinity Pharmaceuticals, Array BioPharma, Eastman Chemical, Organon, Pfizer, Lubrizol.
Unnamed Others

Thanks Again!