

Global ELN Deployments –
Experience from the frontlines

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Desktop Software
Enterprise Solutions

Research & Discovery
Applied Bioinformatics

Knowledge Management
Chemical Databases

CambridgeSoft
Life Science Enterprise Solutions

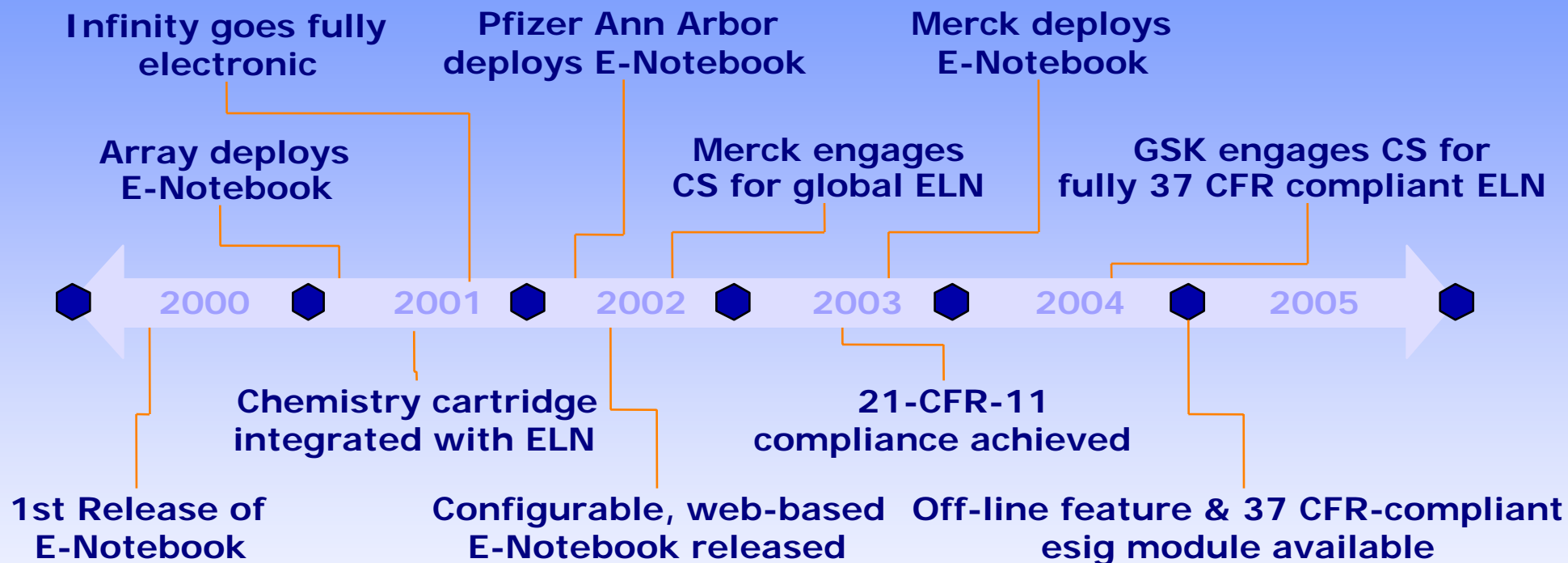
Introduction

- 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



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 Repubblica (513) 1997

- **UK**

 - Civil Evidence Act of 1995 – “Document”

 - Electronic Comm. Act 2000

Go Vertical



To Enable Horizontal



Chemistry

Biology

IT

Development

Legal

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

The Electronic-to-Paper Transition

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

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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!