10th PRISM FORUM
Subject Matter Expert Group
-p & -eArchive

16 October 2002

Archive Presentation

The Description of the Future Pharmaceutical Archive

The Archive Context
As a Component of Records Management

- **The archive process is a component of records management**
- **Contemporary records management includes both the working repositories and the archive repositories**
- **The future records management regime must encompass previously differentiated processes**
  - Traditional Document/Data management
  - Back up and recovery
  - Archives
- **Records management must govern**
  - Assets from creation through destruction
  - Information stored on back up and recovery media

Archive Principles

- **Archiving is the information preservation component of Records Management**
- **Archives contain information identified for preservation according to internal and external requirements**
  - Documents and data, paper, electronic, specimen, microfilm and other assets
  - Meta data information
- **Archived information should be globally accessible**
  - Under the control of access rights
  - In human readable format
- **Information must be indexed and structured to enable effective search and expedient retrieval**
- **The e-archive is an additional form of information preservation. The principle of archiving is the same; it is a business process enabled by IT solutions**
  - The complexity & cost of IT enabling technologies is dramatically greater and the benefits can be dramatically greater
  - Paper archives still exist and continue to grow

Features of the Archive

- **Archive Features**
  - Preservation
  - Ready accessibility
  - Readability
  - Integrity
  - Reproducibility
  - Protection
  - Self documenting
  - Provenance
  - Disposition
- **What it isn't**
  - Back up and recovery
  - Creation, import, review and approval
  - Editing
  - Proactive distribution
  - A black hole

eArchive Standards

- **Archive "package"**
  - Source information, currently viewable renditions, archive renditions and metadata (including audit trail)
  - Renditions defined by company
- **Archive "package" relationships (bundle)**
  - Source information related in context
- **Metadata standards**
  - Purpose - enable storage, searching and to define relationships between archive "packages"
  - Method – define metadata information that supports the overall organization
    - Controlled Vocabulary, Thesauri, Ontologies, Dictionaries

Archive Renditions

- **Source information**
  - The original created rendition
    - HPLC, MS Word, Excel, TIFF, JPEG, IRIS, RTF etc.…
- **Current viewable renditions**
  - Purpose – to store the renditions that are viewable at the time of archive
  - Method – use non-proprietary formats where possible, industry standards where necessary
  - Current examples include:
    - Documents; PDF, ASCII, XML, TIFF (Citt4)
    - Analytical Data; ANDI, XML (GAML not fully non proprietary)
    - Datasets; SAS Transport
    - Graphics; GIF, JPEG
    - Modeling standards (SMILES, SDFILES, MOLFILES)
- **Archive rendition**
  - Purpose – to enable reproduction of the information in a human readable form over the life of the information
  - Method – use non-proprietary formats where possible, industry standards where necessary
  - Current examples may include:
    - Documents; ASCII, XML, TIFF (Citt4)
    - Analytical Data; ANDI, XML (GAML not fully non proprietary)
    - Datasets; SAS Transport
    - Graphics; GIF, JPEG
    - Modeling standards (SMILES, SDFILES, MOLFILES)

Apply Traditional Archive Processes to eArchive Information

- **Identify information to be archived**
- **Identify and protect vital records**
- **Define archive rules and retrieval processes**
- **Identify ownership and stewardship responsibilities**
- **Define access rights**
- **Processes**
  - Define comprehensive lifecycle
  - Define and implement retention schedules
- **Requires some processes standardization**

eArchive Technical Solution Components

- **Content**
  - Archive repositories
  - Conversion
- **Index**
  - Indexing systems
  - Indexing database
- **Delivery**
  - Search and retrieval systems
  - Display (viewers)
- **Transfer**
  - Information transfer from working repositories to archives
    - Single and batch
  - Data migration
  - Export and/or destruction
- **Administration and operations**
  - Security
  - Redundancies
  - Disaster recovery
  - Performance and capacity planning
- **MUST BE VALIDATED**

Technology Principles

- **Define the overall technology architecture**
  - End to end solution does not currently exist
  - Integrate off the shelf components where available
  - Build custom components where existing components are not available
- **Must move toward technical standardization**
  - Establish internal standards
  - Apply industry pressure to standardize and support pharmaceutical requirements eg. ANDI
- **Ensure development of future information systems integrate with the enterprise archive strategy**
- **Plan strategically and implement tactically**

eArchive Business Drivers

Compliance Drivers

- **Regulatory Requirements**
  - GxP
  - 21 CFR Part 11
  - Predicate rules
- **Regulatory submissions and demands for electronic submissions**
- **Regulatory inspections**
  - Citations from audits – some companies are getting close to receiving 483s for records management
  - Currently numerous examples of warning letters
  - Some companies have received 483s for records management

Legal Drivers

- Must keep information for decades
- Must know if the record exists and must be able to find it if it does
- Patent and property defense
- Product liability

Economic Drivers

- **Eliminate/reduce pockets of information in niche content management systems**
- **Manage intellectual property**
- **Enable good knowledge management across the timeline**
- **Get rid of paper, paper handling costs and paper handling risks**
- **Support in-licensing and cross licensing**
  - Smaller companies sell and larger companies buy:
    - Substance
    - Patent
    - Documentation
- **Support mergers and divestitures**
- **Enable collaboration**
- **Legal risk avoidance**
  - must destroy information

eArchive Constraints 1

- **Regulatory Requirements**
  - 21 CFR Part 11 still interpretive
  - Validating archive systems
- **Not all countries accept eSubmissions**
- **Legal**
  - Different legislation in different countries
  - Different level of acceptance of eSigs and eRecords
  - Some data must remain in country
  - Judges rule over company policies
- **Information security**
  - Protect from unauthorized access
  - Appraisal of records (availability/confidentiality)
  - Trustworthiness and authenticity

eArchive Constraints 2

- **Technology**
  - Most legacy systems are not designed with archive in mind
  - Must design based on long term requirements
  - Few tech neutral standards
  - Obsolescence/technology drift are a challenge
  - Need to consider decommissioning of legacy systems
  - No commercially available solutions
  - Back up/upgrade/obsolescence
  - No standards for eSig
- **Organizational**
  - Archiving retrieval processes
  - Ownership identification (who owns what when)
  - Definition of archive objects
  - Access rights
  - Interfaces and interface ownership
  - Agreement on perspectives/definitions

The eArchive Business Case

Stakeholders

- **Stakeholders**
  - Representatives from across the organization
- **The Archive "Owner"**
  - Same functional area who owns the physical archives
  - Driven by organizational design
- **High level decision makers/sponsors**
  - Highest common denominator

Current Costs Measurements

- **Cost of maintaining all information on line vs. cost of storing information off or near line**
- **Cost of avoidance – migrate into archive system, not to new content working system (estimate 30% of new system)**
- **Cost of back up tapes and associated technology and human resources**
- **Cost of maintaining multiple copies (duplication)**
  - Risk/exposure
  - Maintenance costs
  - Human resource
  - Space
- **Cost of archiving paper (storage and retrieval)**
- **Maintenance cost of old systems**

Future Benefits

- **Reduce total cost of ownership**
  - Decommissioning systems
  - Minimizing data migration across generations of systems
- **Significantly decreased retrieval costs**
- **Base measurements on a time value curve**
- **Improve regulatory/legal compliance**
- **Protect vital information (duplicate copies)**
- **Reduce time for response to regulatory queries**
- **Bring new products to diverse markets fasters**
- **Ease the process of de-commissioning systems**
- **Archive provides a service to the organization**
- **Decreases dependence on vendors**
- **Support product x-licensing**

Challenges

- **Pharma must be prepared to influence regulatory authorities to better define requirements**
- **A successful Archive program must include significant organizational education**
- **The Archive must provide for the long term preservation in a time when the only constant is change**
- **An Archive should be implemented according to a Time/value curve**

Conclusion

- **The Archive is an absolute, non-discretionary business requirement than must be heavily supported by IT**

Questions and Answers