

Advantages and Challenges of Electronic Records for Scientific Data at the U.S. EPA

Thomas J. Hughes
QA and Records Manager
Experimental Toxicology Division (ETD)
U.S. EPA, ORD, NHEERL, RTP, NC
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Research and Development at EPA




- 1,700 employees
- \$700 million budget
- \$100 million extramural research grant program
- 13 lab or research facilities across the U.S.
- Credible, relevant and timely research results and technical support that inform EPA policy decisions


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High Priority Research Areas in ETD




- Human Health
Asthma/Food/Mold
- Particulate Matter
(Asbestos/UCAPS/Diesel)
- Drinking Water (OW)
- Risk Assessment
(OPP – Pyrethroids)
- RARE Projects (PIN, WV)
- Homeland Security


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PURPOSE

1. Discuss the paper and electronic record keeping systems in ETD
2. Which system is better for saving data?
3. Current recordkeeping systems in ETD, NHEERL, ORD, U.S EPA
4. Future directions, challenges and success stories for records



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Scientific Recordkeeping Systems in ETD


Notebooks

Advantages:

1. Relatively inexpensive (\$50)
2. Uniform (Standard books/ORD 13.2 PPM)
3. Long-lasting (Franklin - 1776)

Disadvantages:

1. Can be lost/hard to find specific data
2. Sometimes hard to read
3. Bulky (storage and GC data)
4. Compliance time consuming (ORD 13.2)
5. Data are not readily available



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Scientific Recordkeeping Systems in ETD


ELECTRONIC RECORDS

Advantages:

1. Formatted/signed/labeled easily
2. Long-lasting if version control is current
3. Easy to save, share, search, read, audit
4. Can save very large data sets (Genomics, GC data)
5. Data can be on a secure central file server

Disadvantages:

1. Expensive (purchase and maintenance)
2. Data can be lost if not backed-up properly
3. Many versions and software systems do exist; many are not back nor laterally compatible




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Which System is Better for Saving Data ?

1. Electronic records are **almost always better** for scientific record keeping at the US EPA
2. **Reasons:**
 - Communication during study
 - Consistent Format (Access- 4 Lab Study)
 - Auditing
 - FOIA – very quick response
 - Central Database that can be searched and available to shareholders (WTC)
 - The U.S. EPA is a **REGULATORY** Agency; data needs to be easily readable and transferable




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Current Recordkeeping Systems in ETD

1. Fifty percent of the data are in paper form (mostly NHEERL hard bound notebooks but **some three ring binders**)
2. Fifty percent of the data are electronic (e.g., Lotus Notes, Chem Station, NuGenesis, EXCEL, Word)
3. ETD Management is encouraging scientists to have as much of their data electronic as possible.




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Future Directions for Records in ETD

1. Inventory of e-records on laboratory systems this summer
2. An e-records workshop will replace the ETD annual seminar in June. This workshop will start the discussion about a guidance document for scientific e-records
3. A high speed scanner has recently been purchased. Hard bound notebooks are now becoming electronic records




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Future Directions for Records in ORD

1. NHEERL has developed a data management policy for genomic/proteomics data, which must be stored electronically.
2. A central database system is being developed for these large scale databases.
3. ORD E-Records Committee – Lynne Petterson (176 tasks).




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Challenges for Records in ORD

1. Policies and OPs – Lynne Petterson
2. Cost – Servers must be backed-up with redundant servers and not tape systems
3. Agreement of the scientists to comply with e-systems through Management directives
4. Training for software systems (e.g., NuGenesis)




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Success Stories for Records in ORD

1. ORD e-Records Committee – survey of lab scientists on how they manage their data, and a proposal for 5 year action plan
2. NuGenesis and *Documentum* – lessons learned
3. Presidential directives to convert U.S. EPA records to electronic format (People Plus, Web Forms, Lotus Notes e-mail, *Documentum* for e-mail records).




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SUMMARY

1. This QA group must be the movers and shakers for e-records in EPA.
2. The U.S. EPA must lead the e-records conversion. The pharmaceutical industry has already implemented electronic records.
3. The only alternative is for the Agency to buy one million pencils and pencil sharpeners. But then we would have an increase in lead poisoning in EPA's Staff.



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SUMMARY (continued)

4. Notebooks will never go entirely away. However, electronic recordkeeping is the cutting-edge method to manage and retrieve research data from large multidisciplinary studies.
5. The U.S. EPA is a regulatory Agency. EPA must be able to retrieve its research data for reanalysis, defense, reproduction, enforcement, or FOIA requests.



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That's All, Folks!

If you would like to share ideas on QA or Records Management, we would love to hear from you.

hughes.thomas@epa.gov

(919) 541-7644

culpepper.brenda@epa.gov

(919) 606-8073