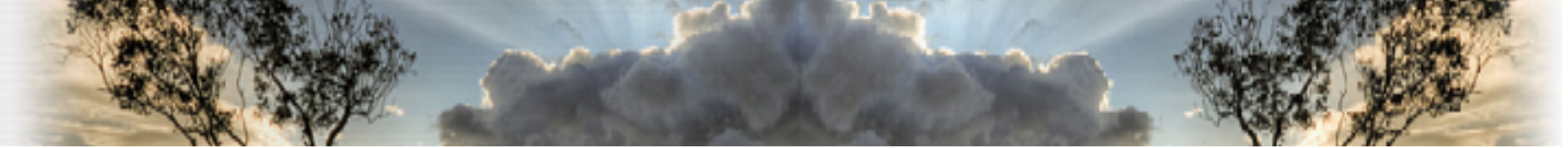


Introduction to E-environment/ Data Integrity workshop

Cecilia Arfvidsson & Mira Doig on behalf of the EBF

12th EBF Open Symposium
Imagine! A New Bioanalytical Earthrise

EBF Data Integrity Workshop Outline

- Introduction to the workshop (~15 min)

  on behalf of the EBF

- Round table discussion (~30 min)
  - *BioA community tables: What are the missing functionalities in today's situation/process to have a reliable and robust data transfer (such as to avoid QC checks)?*
  - *Vendor table: What are we doing/can we do to improve the data integrity of the situation/process described?*

- Wrap-up panel discussion (~45 min)
  - *What are the vendors doing to improve the data integrity of the situation/process described?*
  - *What's stopping the vendors from having a secure data solution in place?*
  - *What do the vendors need from the BioA community to “make it happen”?*
  - *What’s the regulators feedback and view on today's situation and solution vs a more robust interface solution?*

Data integrity workshop at the EBF 11th Open Symposium

The key take home messages from the workshop arranged in 2018 can be summarized as follows:

- Know your software system data and processes
- Map your processes to identify the potential risks and weaknesses
- Reduce the risk by implementing solutions that have been identified as a result of improved software awareness and knowledge
- Open up the dialogue for enhanced interaction between system vendors, pharma/CROs and regulatory authorities to understand current, and define future, system data integrity capabilities.

EBF Data Integrity Survey - Participants

A couple of key questions on Data Integrity were identified by the EBF E-environment team and sent out to our key instrument and/or software vendors;

- Thermo-Fisher
- Waters
- Sciex
- Merck
- Shimadzu
- Gyros

EBF Data Integrity Survey - Questions

Key questions on Data Integrity in the EBF survey;

- **Q1** What would you see as the key aspects to be applied to meet the Data Integrity requirements and what do you see as your main challenges to producing systems that address the Data Integrity requirements?
- **Q2** How do you ensure that your systems meet the Data Integrity requirements?
- **Q3** What can the bioanalytical community do to help and support you in any Data Integrity improvement work?

Q1 What would you see as the key aspects to be applied to meet the Data Integrity requirements and what do you see as your main challenges to producing systems that address the Data Integrity requirements?

- **Intra-application data integrity** - It is assumed that modern analytical software has acceptable levels of Data Integrity measures to ensure a secure dataset. Are database-records actually secured? Once an administrator has access to a database all records can be updated without leaving a trace.

- **Inter-application data integrity** - Systems cannot survive on their own and communication with other systems is key. As such transferring data, in a secure manner, is a challenge for the industry.

- **Data Integrity for autonomous computerized systems** - In the near-future full automated laboratories with autonomous laboratory systems will have software to perform decisions based on pre-defined SOP criteria. Each step must still be recorded in a way that it can be reconstructed or re-created if needed.

Q1 What would you see as the key aspects to be applied to meet the Data Integrity requirements and what do you see as your main challenges to producing systems that address the Data Integrity requirements?

- Data integrity is **more than just a regulatory compliance activity** - value to the business in achieving data integrity.
- **Awareness** is important - make people aware **why** Data Integrity is important to the Bioanalytical process.
- One of the main challenges relates to generating defendable and actionable analytical data with a **near zero need to review, reprocess and make changes.**
- **Artificial Intelligence** can result in self-learning laboratory systems that make all decisions autonomous. When the decision making process is so complex that humans aren't the best qualified to make the decision the Data Integrity becomes a true challenge….

Q2 How do you ensure that your systems meet the Data Integrity requirements?

- We design them with **global/GxP regulations in mind and work with the regulators** around the world to ensure we are creating Data Integrity adherent systems and processes.

- Creating a **landscape and tool set that meets the needs of different audiences**; a simply review platform for analysts, a structured framework for administers to control access and a deliverable that internal and external auditors consider effective.

- Provide **training and do awareness sessions** on Data Integrity with our customers.

Q2 How do you ensure that your systems meet the Data Integrity requirements?

- Our software **has appropriate measures to ensure a secure dataset** - password control, audit trails, configurable roles, secure databases (or files).

- Provide **software that can deal with the common Data Integrity challenges** - unique user profiles, audit trails on data and system, build-in calculations, reporting and a relational database to link all information, apply backups and archive completed studies.

- Exporting and importing data from/to LIMS with several software systems is based on so called '**digital interfaces**'. Solutions are built on joint-effort basis between the LIMS- and the acquisition software vendor.

- For a large set of instrument software no file-less solution is available, ie data is transferred via less secure methods/file formats (TXT, CSV, XML). A **specific middle-ware tool** can facilitate by picking up and securing flat-files once created, followed by transformation into xml and secure transfer into LIMS.

Q4 Finally, would you be interested in taking part in additional future E-environment activities, such as additional surveys as well as in the planning, preparation and execution activities for the workshop at the 12th Open Symposium?

Yes, I would be interested in this, and happy to support.

Yes, I'm happy to join!

Yes, absolutely.

Yes, by all means.

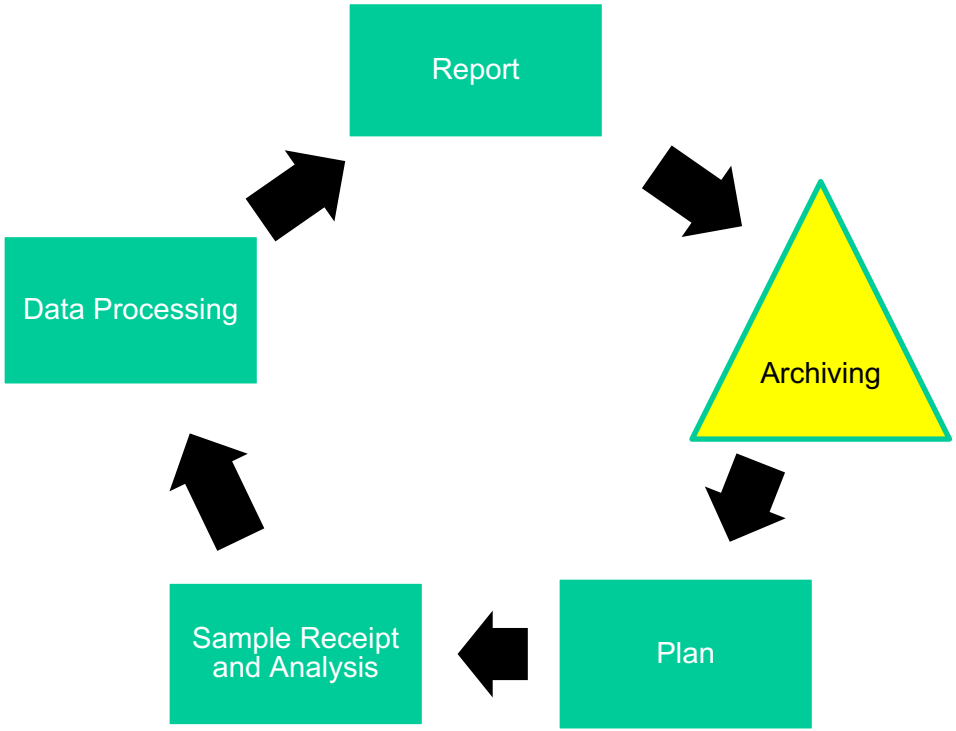
Workshop objectives

- A concrete message to all vendors - this is what the industry needs and where you need to focus your efforts!
- A concrete message to the BioA community – this is what the vendors need from us!
- Identify next steps for a long term solution.
- Share best practices on the current interim data transfer solutions.

TODAY’S SITUATION

Today‘s situation - The Whole Process

- *The life cycle*



Issues with Data Integrity

- Linking samples to the sample manifest
- Creating a run list from a sample manifest
- Recording all instrument settings from sample/96-well plate to detector
- Making sure machine acquired data can’t be manipulated or deleted without a record in an audit trail
- Transferring machine data to tables for reporting

Today's situation – Data transfers

export.txt file is created locally and can be edited without audit trail before saving on the file server

After acquisition and processing of data create export.txt file from final results table copy entire project to folder on departmental server

Folder on departmental server (write-once privileges)

Import export.txt file from folder into LIMS

SYSTEM

Local instrument PC

US Citrix Server / dektop PC

LIMS

import sequence.txt file in instrument Batch editor

Save sequence.txt file from analytical run on departmental server

Personal folder on departmental server

Issues with Data Integrity

- Network area folder could be protected against file modification but this require an ad hoc configuration for each project/study by IT
- Results can be exported from analytical system into any folder and then modified - Manual QC checks (10%) of the data transferred required
- Independent QC process required to verify file name and file path is correct

EBF E-Environment team

- Magnus Knutsson
- Stuart McDougall
- Mark Lewis
- David Van Bedaf
- Natalie Mokrzycki
- Mira Doig
- Susanne Globig
- Marco Michi
- Cecilia Arfvidsson

BACK-UPS

Round table discussion

- *BioA community tables:*
  - *What are the missing functionalities in today's situation/process to have a reliable and robust data transfer (such as to avoid QC checks)?*

- *Vendor table:*
  - *What are we doing/can we do to improve the data integrity of the situation/process described?*

Panel discussion

- *What are the vendors doing to improve the data integrity of the situation/process described?*
- *What's stopping the vendors from having a secure data solution in place?*
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How can vendors help the bioanalytical community to improve Data Integrity?

- Improving the security of data files in a Windows environment
- Transfer of data from one software package to another
- Assist in creating solutions for
  - A common communication protocol to ensure a secure digital data transfer
  - A standard process for secure import and export of files
  - Encrypted databases to ensure all external transactions are recorded and not even a system admin can make an update without leaving a trace
  - Improve capture of instrument parameters especially the ALS and LC parameters when considering LC-MS/MS. For example capturing barcode labels on 96-well plates

Questions related to the challenging aspects

- When a system uses flat files:
- How to ensure proper access to the file to modify integration etc avoiding the possibility to delete or modify the files in windows (no audit trail track in such case)?
- What is the system control to ensure that the exact sample injection order and identity correspond to nominal one defined in the LIMS? If sample injection order/sample position is not maintained can this be identified when data are imported into the LIMS?
- How to ensure and verify that the updated results have been also properly transferred and updated in the LIMS?