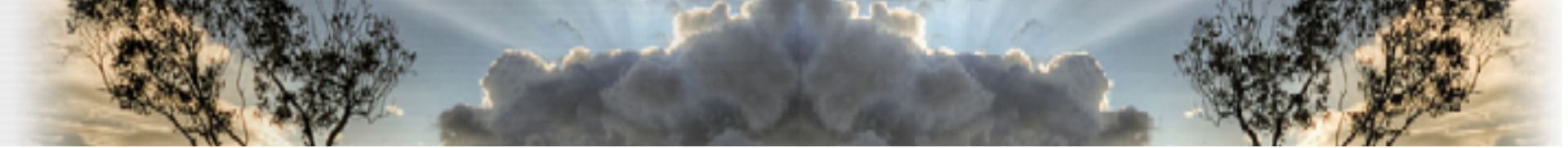


EBF and the e-Environment: The Journey Continues

Cecilia Arfvidsson, on behalf of the EBF

12th EBF Open Symposium
Imagine! A new bioanalytical Earthrise

http://www.e-b-f..eu

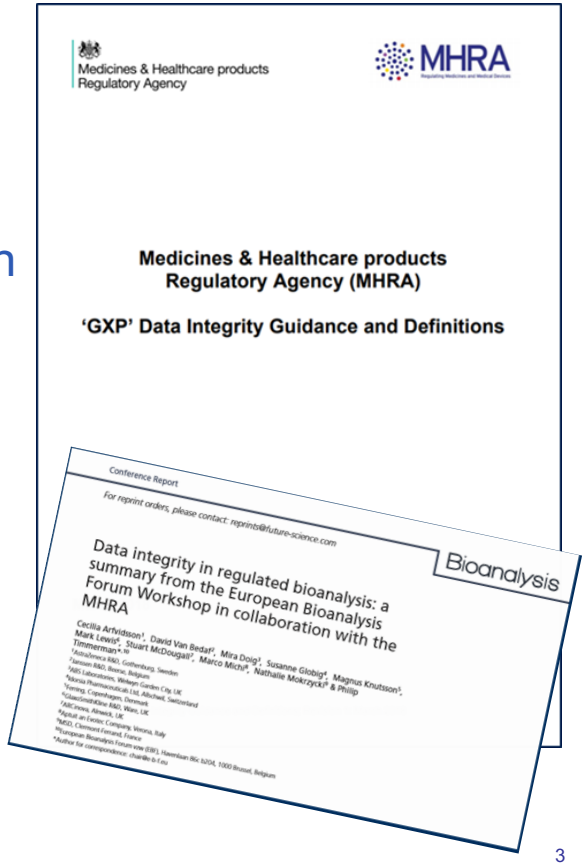
EBF and the e-Environment theme

- e-Environment discussions at previous EBF Open Symposiums:
  - 2012 ELN workshop
  - 2013 Workshop: defining raw data in regulated bioanalysis
  - 2014 Workshop on e-Data: towards a common standard
  - 2015 Workshop: generic data transfer agreement
  - 2015 Session: Going paperless
  - 2016 Discussion forum: Harmonised implementation of OECD17
  - 2016 Session: e-Environment
  - 2017 Workshop: Approaches on implementing OECD17

- 2018 Workshop: e-Environment / Data integrity with contributions from the MHRA

2018 e-Environment workshop

- MHRA Guidance on GxP data integrity issued in March 2018
- A Workshop on Data Integrity arranged at the EBF Open Symposium last year on behalf of the EBF, in collaboration with the MHRA[1]
- Purpose of the workshop was to:
  - Increase the insight and understanding of regulatory expectations in relation to the new MHRA Guidance on GxP data integrity
  - To provide further insight and guidance on how to implement adequate levels of data integrity control dependent on the criticality of the data generated



[1]Bioanalysis, Vol 11, No 13 (2019)

Data Integrity focus at the workshop

The following two themes were discussed:

- Data control
  - How can we transfer data and ensure no modifications and/or deletions occur in the process?
  - What documentation can we store with our study file to ensure that data integrity is maintained at each data transfer step?

- Audit trail
  - How are audit trails used to ensure modifications and/or deletions of data are identified and captured in line with data integrity expectations?
  - Why do we review the audit trail, what are the risks that we would like to mitigate?
  - How do we document the outcome of the review?
  - Is the audit trail review procedure incl in SOP?

Case studies to share recent inspection findings

- A summary of the major findings from recent MHRA inspection findings at UK laboratory facilities highlighted:
  - The data integrity challenges when transferring data from the analytical system to the LIMS system
  - A transfer process that includes the production of a text file can, if not protected from modifications, be edited and opened in the LIMS system with an amended dataset.
  - In isolation, the QA data review, in the format it resides in your LIMS and with flat file representation of the chromatograms, can not be considered to be representative of the raw data.
  - MHRA's acceptance of a step-wise remediation plan and time to implement the necessary changes to obtain the data integrity controls.

Key message I – there's no quick fix

- Understand the basic concepts and the terminology in the guidance
- There are technical, organizational as well as cultural challenges to overcome when implementing data integrity governance – there are no quick fixes!
- Implementation is a multi-disciplinary activity with resource and financial implications – will take time to complete – implementation of controls to be prioritized based on data integrity risk assessment

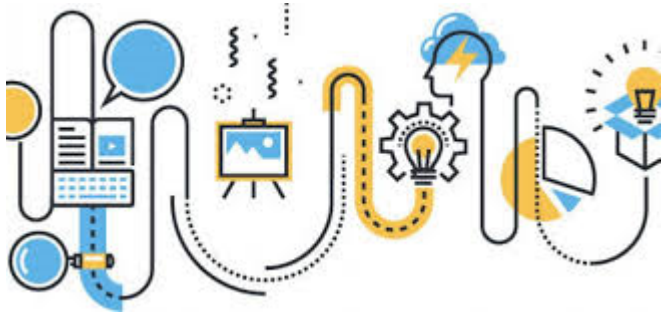
Key message II – map your processes

Two critical data integrity concepts were highlighted:

- Data lifecycle
  - data collection, processing, reporting, review and archiving
- Data governance
  - the processes, systems and ownership

A process map exercise – a valuable tool to define:

- your systems/processes/equipment/people
- your data transfers/touchpoints/imports/exports
- time/process/data criticality



Key message III – understand the use of the data and its criticality

- Understand the use of the data in each step of the process map to identify the critical data and the controls/ oversight measures required for risk mitigation

- Not all data is equal! Data criticality is determined by the intended use of the data and risk management principles should be applied to assess the risks and to identify the necessary mitigation steps

Key message IV – audit trail awarness important

- Know what audit trails are available on your system(s) and what they are recording or not recording
- Understand what ’normal’ looks like - in order to be able to identify any ‘abnormal’ activities within reasonable timeframe
- Understand the system terminology
- Data Integrity - not a forensic approach
  - Review to be targeted and driven by requirements covered in the data integrity policies or SOPs
  - Review by exception based on run and study data
  - Do not only audit the audit trail – if may be too late!

Round table discussions

Lack of data integrity suitable software and interfaces

New software features must facilitate the data transfer process

BioA community – Instrument vendors

Data integrity is now a primary focus when choosing new platforms/software

Improved software awareness and knowledge can help to identify possible solutions

Compliance must be considered when developing new software features

Conclusions from 2018 E-environment WS

The key take home messages from the workshop 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.

E-Environment at the 12th OS

The EBF e-environment team has continued to drive the topic and arrange a new opportunity for dialogue and discussion at the 12th EBF Open Symposium.

- Workshop "**Building Common Understanding for Future System Solutions**"
  - bring instrument vendors, Pharma/CRO labs and regulatory authorities together
  - highlight current key challenges in short "today's situation" descriptions
  - what are the missing functionalities in today's process?
  - what can the vendors do to help improve the current situation?

- Outcome from the workshop: A concrete message to all vendors - this is what the industry needs
  - identify next steps for a long term solution
  - share best practices on the current interim solutions

Acknowledgment

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  - Mira Doig (ABS Laboratories)
  - Susanne Globig (Idorsia)
  - Marco Michi (Menarini)

Thank you for your attention!

- Any questions?

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