HSRAA Conference 25th - 27th April 2018

Agenda[1]

----------25th April 2018----------

13.00hrs-17.00hrs (Workshops)

1. **TMF Essentials**
   Tutors: Jamie Toth & Eldin Rammell

   Suitable for anyone with responsibility for establishing or maintaining trial master files. The workshop covers some of the underlying records management principles (e.g. what is a record? what is the record life cycle?) and then covers the regulatory requirements for the trial master file, including its creation, maintenance and long-term retention. We cover a range of practical issues associated with TMF maintenance. The content is applicable for both paper and electronic trial master files.

2. **Managing Electronic Records**
   Tutors: Sarah Curno & Russell Joyce

   The workshop has been designed to provide practical training and guidance to those responsible for the management of electronic records, including:
   - the management of records in regulated business systems (such as electronic trial master files and SharePoint sites);
   - the management of record life-cycles, including record creation and templates; and
   - the management of electronic archives.

----------26th April 2018----------

09.00hrs-09.30hrs (HSRAA AGM)

An overview of our activities over the last 12 months and a look ahead to the coming year. All are welcome to attend but only paid-up HSRAA members are entitled to vote during the meeting.

09.30hrs-11.00hrs (Regulatory Focus)

1. **Regulatory Aspects of Managing of GxP Records**
   Emma Whale, Medicines and Healthcare products Regulatory Authority (MHRA)

   A Regulatory perspective on the management of GxP records including legislation, regulation, inspection and expectations. The presentation also includes a Regulatory update.

   Speakers Profile
   Emma Whale is a Senior GCP and GLP Inspector for the Medicines and Healthcare products Regulatory Agency (MHRA) in the UK. Prior to joining the Agency in July 2008, Emma worked for eight years as a GLP Auditor and Deputy GLP Quality Manager with experience in both Sponsor Organisations and Contract Research Organisations. Emma has also worked in histopathology for a large agrochemical company and she has an honours degree in Biomedical Sciences.

[1] The agenda may be subject to change due to circumstances beyond our control

In her role at the Agency, Emma conducts GCP inspections of both commercial and non-commercial organisations, phase 1 accreditation inspections, clinical laboratory inspections, GLP compliance monitoring inspections and overseas inspections of organisations conducting bioequivalence studies.

2. **Data and Evidence Requirements for Health Technology Evaluation at NICE**
   Boglarka Mikudina, National Institute for Health and Care Excellence (NICE)

   Boglarka will cover an introduction to the work of NICE and the evidence requirements of health technology evaluation. The presentation will focus on the data and information NICE requires in order to fulfil its remit, to develop timely guidance on new and existing health technologies through the Technology Appraisals programme. It will also explain the relationship of NICE with the life sciences sector and healthcare organisations for generating and collecting evidence.

   Speakers Profile
   Boglarka has worked at NICE as a technical analyst in the Technology Appraisals team for over 3 years. In her current role she is responsible for the development of national guidance on the clinical and cost effectiveness of health technologies (mainly drugs and pharmaceuticals) and supporting the decision making of an independent Appraisal Committee. Boglarka previously worked for health economics consultancies and conducted health technology assessment and budget impact analyses. Boglarka holds degrees in Economics from Corvinus University Budapest, Hungary and Health Economics from Erasmus University of Rotterdam, Netherlands.

3. **Regulatory Q&A Panel Session**

   Your opportunity to question the regulators and subject matter experts on any aspect of GxP records management and regulations.

11.30hrs-13.00hrs (Document Management)

1. **Digitisation of Clinical Research Records**
   Paul Fenton, Montrium

   In this presentation Paul will look at how technology can help life science organisations better manage their clinical trial documentation to centralise and standardise clinical records to enable both sponsors and CROs to contribute and access important clinical documents and information in real-time. The presentation will also consider functionality, advanced collaboration features, and complete scalability all of which is essential to create a comprehensive, dynamic, intuitive and powerful solution to provide unparalleled benefits and value.

2. **The Principles of Doc Management from Opening Act to the Final Curtain**
   Sherman Williams, Daichi Sankyo

   This presentation, based on a recent document management implementation project, will look at the core purposes of document management technologies and provide answers from real-life experiences on how best to create, modify, review, share, and distribute documents. Moreover it will advocate adoption of a rational and consistent means of creating and managing documents to protect the organisation's assets, ideas, day-to-day functions, and long-term goals. Whether your organisation is thinking of implementing a document control policy for the first time or working on ways to improve an existing

document management system, this presentation will be an invaluable resource to achieving success.

3. **Case Study: Implementing a New Records Management Database**
   Jody Salisbury, Takeda

   When a long-awaited new (company-wide) database project is finally approved, what happens?! Two years on: where are we? How were the implementation and migration conducted? What are the successes, pitfalls and learnings? What are our actions now? Has it lived up to its promise, and what direction will we take now?

   Speaker Profile
   Jody has been working in information and records management for over 20 years, mainly on the pharmaceutical R&D side, but also in other sectors. Her areas of special interest and expertise are TMF specifically TMF QC, designing and running records programmes and operations, information auditing, developing communities of interest, MADC projects, and implementing new database programmes.

14.00hrs-15.30hrs (Digital Archiving)

1. **Getting Started with Digital Preservation: an Overview**
   Sara Day Thomson, Research Officer, Digital Preservation Coalition

   Digital data is a defining feature of our age: industry, commerce, government, research, health, education, and the heritage sector depend on digital materials to satisfy diverse information needs and expectations. But digital objects are fragile: at risk of loss, corruption or obsolescence, not to mention unlawful alteration or theft. Digital preservation – the series of managed activities necessary to ensure that digital materials remain accessible - is an issue which all organisations will need to address sooner or later. This session provides an overview of some fundamental principles to equip information practitioners with the knowledge they need to get started with digital preservation.

   Speaker Profile:
   As the DPC's Research Officer, Sara undertakes much of the DPC's project work, becoming involved with some of the latest research in managing, accessing and sharing digital content. She has recently authored two of the DPC's popular Technology Watch Reports on 'Preserving Social Media' and 'Preserving Transactional Data.' She also co-presents DPC's training workshops 'Getting Started…' and 'Making Progress with Digital Preservation.'

2. **Digital Archiving Strategies**
   Daniel Hickmore, Arkivum

   In this presentation Daniel will examine the key strategies required to enable the effective preservation of digital content, recognizing that these need to be flexible to adapt to ongoing changes in scale, technology, and standards. He will explore best methods to reduce risk and achieve best practices to preserve and maintain access to- and the readability of- digital content for as long as it is needed.

3. **Gradual Steps Towards a Paperless Future: Delivering a Small-Scale Proof of Concept to Inspire Broader Change Across a Global Pharma Company**
   Jessica Hogg, Reckitt Benckiser

   By capitalising on upcoming changes at RB, including a re-structure and major acquisition, the archive team are attempting to shift the focus from paper archiving and towards digital, global data-sharing. Collaborating with external digital storage providers Arkivum, we are looking at

long-term data lifecycle options for a currently paper-only R&D archive based in Hull. In a cautious industry where we are surrounded by so many compliance issues, can a measured and exploratory approach to the transition from paper to digital create an impact? The session will look at a method that involves targeting a distinct collection of previously unmanaged electronic data and, with the help of an external partner, protecting it indefinitely.

Speaker Profile
Jessica Hogg joined RB as GxP Archivist in April 2016 having previously worked as an archivist for the BBC for 6 years. She has a master's degree in Information Management and Preservation from the University of Glasgow.

16.00hrs-17.00hrs (Debating Session)

An expert panel will lead debates on a "hot topics" where industry has differing viewpoints. This will also be your opportunity to question, contribute and vote.

Motion 1: That in certain cases, drafts should be considered as records and should be managed and archived in the same way as final documents.

Motion 2: That records cannot be effectively managed as individual record series; they should be managed in "big buckets".

Motion 3: That GDPR is an unnecessary burden on business.

----------27th April 2018----------

09.00hrs-10.30hrs (GxP Data Integrity)

1. **Data Integrity: Research Data, Ethics and the Public Good**
   Brenda Phillips, Research Data Management Advisor, University of Leeds

With a mandate to build clear and consistent research data management advice and guidance to complement the policy landscape, internally and externally, the University of Leeds Research Data Management Service finds itself positioned at the intersect between ethical review and the management of research data. The experience of responding to such a mandate, has given RDMS a valuable insight into the complexities of trying to marry ethical review with research data management, dissemination and data sharing for the public good. This presentation spotlights some of the key 'rub points' exposed through consent, research data classification, retention and dissemination when attempting to validate published research results, and how these 'rub points' have been utilised and repackaged into a training offer guiding researchers in the safeguarding of research data for wider dissemination.

Speaker Profile:
Brenda is currently Research Data Management Advisor, Trainer and Ethics Committee Member at the University of Leeds, where she has been based since 2011. Her previous roles and responsibilities have

included: Archive Officer for a Qualitative Longitudinal Research Programme focusing on informing practice and data sharing in the third sector; Data Resources Officer assisting the core development of the Timescapes Archive for the ESRC funded Timescapes Programme, the first major qualitative longitudinal study to be funded in the UK; Senior Policy Information and Research Officer and Economic Development Funding Officer developing a centralised local information system for quantitative and qualitative economic, social and environmental data; contract management, audit and evaluation.

2. **Data Integrity - Developing the Governance System and "Weaving it into the Fabric of the organisation"**
   David Thompson, Clarity Compliance

   The presentation will explore the challenges with setting up a data integrity governance system and weaving it into the fabric of an organisation. Regulatory authorities are looking for substantial robust governance systems for data integrity: it's not putting sticky plasters on, it's about repeatable robust processes. This presentation will build on real life examples of clients/organisations implementations and the challenges faced and overcome.

   Speaker Profile
   David Thompson is a Computer Systems Validation and Compliance expert. He has worked in the IT/ Computer Systems arena for almost 30 years, the last 18 years he has provided Consultancy, Auditing and Training to the pharmaceutical/biotech and healthcare industry across the UK, Europe, Asia and the U.S.A. He is a Chartered Engineer with both the MIET and the MInstMC and a member of the GAMP MES SIG. In his current role he is Owner and Principal Consultant of Clarity Compliance Solutions Ltd. David was recently proposed by the former Chairman of GAMP European for membership of the GAMP Special Interest Group (SIG) on Data Integrity, and we are proud to say that David's membership of the GAMP Special Interest Group (SIG) on Data Integrity was successful.

3. **Data Integrity in Production -a Case Study**
   David Robinson, DBR QP Services Ltd

   In 2015 in a small pharmaceutical in the UK it was discovered that every batch record dating back to 2007 had been deliberately falsified. The presentation details how this was discovered, immediate actions taken including reporting to the MHRA, expectations, what actually happened, reasons/causes, summary

   Speaker Profile
   David Robinson has over 35 years' experience in the pharmaceutical industry. He has worked in development, production and Quality Assurance with big pharma, small pharma and virtual companies. David has been a Qualified Person since 2000 and QA consultant / contract QP for 4 years.

11.00hrs-12.30hrs (Legal)

1. **Understanding the Disclosure Process in Litigation**
   Lacie Kerner, Brachers LLP

   The disclosure process is a key part of any litigation. All parties to a litigation have strict obligations in respect of disclosure and in accordance with the Civil Procedure Rules. This presentation will help Records Managers understand exactly what the obligations on parties to a litigation are, and how effective management of information, records and documents can help to make the litigation process less time consuming and more cost effective.

   Speaker profile:
   Lacie is a commercial litigation solicitor at Brachers LLP.

2. **Utilising Cyber Security & Cyber Protection to Your Advantage**
   Nick Bridgen, CEO, Harlequin CDIS Ltd

With the increased levels of cyber threats as well as additional levels of compliancy being introduced this year, this presentation will examine cyber security from the perspective of information governance to provide an understanding of what is required in terms of IT when it comes to protecting intellectual property, personal data, commercially sensitive information and trade secrets. With clinical research being conducted in an increasingly collaborative, multi-organisational environment with inherent risks from a security perspective, Records Managers are ideally positioned to raise awareness and to ensure that requisite levels of protection are in place to ensure compliance.

Speaker profile:
Nick Bridgen has worked in Enterprise IT and IT Security since the late '80s working with a broad spectrum of customers from global banks through to small practice law firms. For the last 5 years Nicks focus, and that of his business, has been on IT Security, Reputation/Brand Protection and recently including cyber/data hygiene management. Harlequin CDIS is within the Harlequin Group of companies.

3. **The Role of Records Management in Litigation**
   Neil Gow, UCB

   Neil will present a study of the lessons learned from an actual litigation examining how records managers and archivists can be prepared for- and respond to- investigations. This will be followed by a questions and answer panel session

13.30hrs-15.00hrs (GDPR)

1. **Information Audits -Value, Design, Execution and Maintenance**
   Reynold Leming, Informu Solutions

   Information is a vital and strategic business asset. It is the glue that holds an organisation's structure and processes together. In conducting an information audit an organisation can support initiatives to leverage their information content, mitigate business risks and comply with GDPR; it can validate that their information assets are proportionate, suitably protected, readily accessible and properly governed. This talk looks at the value, design and execution of audits and the subsequent maintenance of the data.

   Speaker Profile
   Reynold Leming is an experienced Information Governance consultant. He also sits in the Executive of the Information and Records Management Society. His company, Informu Solutions Ltd, specialises in the provision of their software for maintaining an Information Asset Register and GDPR Records of Processing Activities.

2. **Case Study: Staging a Data Destruction Strategy**
   Dora Endreffy, ICON plc

   The current global regulatory focus on electronic records retention and a consequent increased interest on record disposition has resulted in the need to develop destruction strategies with a holistic approach. The presentation will offer tools and steps on how to draft a data disposition strategy from roles and responsibilities, to controlled destruction.

   Speaker Profile
   Dora Endreffy is an administration and RM professional with over 10 years of CRO experience.

3. **Preparing for GDPR**
   Juliane Schunselaar, Blue Earth Diagnostics

HEALTH SCIENCES RECORDS & ARCHIVES ASSOCIATION

The new EU data protection regulation (GDPR) will be effective from 25th May 2018. Most of us know this and many are prepared. Although the GDPR is a good change for the data protection landscape, it particularly challenges small to mid-size organisations, who have limited resources. This presentation will summarise how such an organisation, working in the heavily regulated life sciences sector has prepared for the forthcoming changes.

Speaker Profile
Juliane is the Information Manager and Data Protection Officer at Blue Earth Diagnostics Limited, a molecular diagnostic imaging company headquartered in Oxford, UK. She is a records and knowledge management enthusiast. Juliane has over 16 years of work experience, primarily in the life sciences and pharmaceuticals sectors, with significant expertise in project management, records survey and information audits, development and implementation of information management strategies, archive management and data protection. Juliane graduated from the University of Wales, Aberystwyth with a Master's in Information Studies and Records Management.

**** Subject to confirmation***