PROGRAMME

TUESDAY 3RD OCTOBER - WORKSHOPS 13:00-17:00

Records & Archiving – Keeping up with your vendors. Requirements and Realities of Outsourcing

Presented by: Dora Endreffy, Marken & Marion Mays, Kivo

This workshop will provide an overview of best practices with regulatory requirements in mind for managing records & storage vendors. We will walk through the various steps in the lifecycle of outsourcing your records management needs. The workshop will look at both paper and electronic. From selection to long term relationship building through the evolving regulatory challenges.

The Principles of Managing a GxP Archive

Presented by: Neil Gow, UCB & Sarah Kitching, Hedian Records Management

This workshop is a condensed and up-to-date version of our popular "GxP-Regulated Archives and the GxP Archivist" training course. We will focus on the regulations impacting GxP archives, the role of the Archivist and the requirements for the design, operation and management of an archive, and provide an overview of how the principles apply to the archiving of electronic records.

WEDNESDAY 4TH OCTOBER

SESSION ONE - WELCOME **09:00-10:15**

AGM

The Annual General Meeting of the Health Sciences Records and Archives Association (HSRAA) will take place at the start of HSRAA23.

Transforming patient records into dynamic medical digital twins to unleash the age of precision medicine

Presented by: Oran Rigby, AKKURE Genomics

The next era of medicine is fast approaching with the imminent application and convergence of a range of enabling technologies already transforming medicine from the age of information into the age or precision (or personalised care).

Blockchain, big data, 4th generation genomic sequencing, Ai in all its diverse techniques (including NLP, ML, Neural networks) have accelerated the existing societal trends in privacy, citizen centric ownership and collaborative sharing to unleash an age where products, services and therapeutics will become personalised to individual patients yet driven and standardised by large population level data insights.

Paramount to this is dynamically updated personal health data. Transforming this into a mobile digital asset and the accompanying digital infrastructure to permit sharing of these enriched 'live' assets will fundamentally disrupt how medicine is practiced while creating entirely new medical economic models for value creation. The opportunity exits to create new AI medical digital twins from existing siloed and analogue EMR records, setting the foundations for a new marketplace in personalised information, analytics, insights and novel therapeutics including cures.

BREAK **10:15-10:30**

PROGRAMME

SESSION TWO - STANDARDS — 10:30-12:30

CDISC TMF Reference Model – the benefits of becoming a standard for long term records retention and clinical trial reconstruction

Presented by: Karen Roy, CDISC & Paul Fenton, Montrium Inc.

TMF records need to be stored for long periods of time (up to 25 years), be readily retrievable and still tell an accurate story of what happened in the clinical trial at any point in time. This can be very challenging given the large volume of records and the diversity of records. Prior to the TMF Reference model, each organization organized their records in their own structure, however, as the vast majority of organizations have now implemented the reference model, we are already seeing some of the benefits of standardization. With the TMF Reference model joining CDISC, there are many opportunities moving forward to evolve the TMF Reference model standard and ensure that TMF is at the heart of the clinical trial information landscape. In this session, we will discuss the drivers behind the TMF Reference model becoming part of the CDISC family, we will present the various different standardization initiatives we are working on today including the EMS and system interoperability, development of controlled terminologies with NCI, and alignment with the DDF and ICH M11 initiatives. We will also discuss some of the future directions we may head towards in order to be able to tell a complete and accurate story of what happened in our clinical trials way into the future.

Records Management Think Tank

Lead by: Marion Mays
Panelists: Reynold Leming, Sarah Hitching, Eldin Rammell & Neil Gow

Review of Archival and Records Regulations, Standards and Guidance: Program Kryptonite or Yellow Sun?

Presented by: Angel Ramos, BeiGene

Provide overview of new and existing archives and records management principles, guidances, and standards, for example, ICH E6(R3), EMA Guideline for Computerised Systems and Electronic Data in Clinical Trials, European Regulation 536/2014, CDISC TMF Exchange Mechanism Standard (TMF-EMS), ISO WG16's guidances for records system design and implementation of controls and processes, system GxP validations, and data migration validation. Connect these principles, guidances, and standards to executable steps for practitioners to build and strengthen their archival and records processes and programs. Review data integrity and records management requirements for health sciences archivists and records managers, epscially, TransCelerate Digital Data Flow (DDF) initiative, FAIR Principle, ALCOA++, and ARMA International information governance maturity model. Finally, the session will explore program assessments with audience interaction by group breakouts to explore risk-based approaches to build business cases based on requirements and best practices.

LUNCH — 12:30-13:30

SESSION THREE - MIGRATION — 13:30-14:30

Deciphering & Delivering on Data Transfers

Presented by: Teresa Montes, Daelight Solutions

New system, consolidation, and the opportunity to do something great! The promises are real, and the benefits considerable when you retire GxP redundant systems, streamline processes, and leverage new functionality. As the person tasked to deliver, plans need to be made, resourced, and communicated. The only problem, data and document consolidation is an uncommon event. Whether migrating a workflow system or a repository, this session focuses on key planning considerations and preparation needed to make your data and document migration a success.

PROGRAMME

Moving House? What to think about when establishing a GxP DataArchive

Presented by: John Blunden, NNIT & Jamie Toth, BeiGene

Digital transformation initiatives, Mergers & Acquisitions and IT consolidation strategies all trigger a need to migrate and archive data and documents from one environment to another in a controlled manner. As industry moves to unified platforms, the scale and complexity of such migrations has increased significantly in recent years and most technology vendors only recognize the need to migrate, and not archive. Successful data migration and archiving can accelerate data management best practices, build the trust required for user acceptance and establish the foundations for digital transformation. Using those same technology vendor platforms for active AND inactive data/documents is a change from the past where active and inactive information sit in different repositories.In their talk John Blunden, from NNIT's Migration Services team and Jamie Toth, Global Head, TMF Management and Records at BeiGene, will highlight what to plan for when migrating and establishing an archive, based on lessons learned from past projects.

BREAK **14:30-15:00**

SESSION FOUR - DATA INTEGRITY/REGULATIONS **15:00-16:30**

Changing face of Data Integrity regulatory inspections

Presented by: David Thompson, Clarity Compliance Solutions Limited

Regulatory inspections for data integrity are changing. Previously they have been focussed on making systems ALCOA compliant and that the basic quality attributes are in place, now with Data Integrity almost 10 years old the inspections are changing focus from basic compliance to data integrity maturity, management, and governance. In addition, Annex 11 for Computerised Systems is being updated to reflect changes in technology, changes in compliance risk and clarification in key areas applied to the new technologies. With a changing stance on Data integrity inspections and changes in annex 11, the session will explore what this means for the industry and how we can start to prepare and be ready to confidently host our next inspections.

Managing Data Integrity and Software Integrity in GxP Data Archiving

Presented: Benjamin M. Bader, Zentral Archiv Service
& Natasa Milic-Frayling, Intact Digital Ltd

This presentation considers challenges associated with 1) the regulatory demand for securing data integrity in electronic archiving and 2) the management of digital obsolescence that affects software use for interaction with dynamic electronic data.

DRINKS RECEPTION & CONFERENCE DINNER **19:00-23:00**

sponsored by PHLEXGLOBAL
A ➤ PHARMALEX Company

PROGRAMME

THURSDAY 5TH OCTOBER

SESSION FIVE - INSPECTIONS — 09:00-10:30

Factors Affecting Inspection Readiness – a Comparative Case Study

Presented by: Sarah Hitching, Hedian Records Management

How does your company approach inspection readiness? It could depend on the type of inspection (GCP, PV, GLP etc). Or the type of company (Pharmaceutical, CRO, Biotechnology etc.). Or where the company is on its lifecycle journey (start up, clinical phase, well established etc.). But my recent experiences of GCP MHRA inspection readiness suggests there are other important factors involved which I will show by presenting a comparative case study of two similar biopharmaceutical companies. After my session, you will be armed with ideas that you can use to positively influence your companies inspection readiness approach in the future.

Demystifying Inspections

Presented by: Jamie Toth, BeiGene

Interactive presentation on the updates regarding GxP inspections from FDA, MHRA, EMA. If only we had a crystal ball for how these inspections would go? After all these years, why do findings still emerge and CAPAs get opened? Is it the people? the process? the technology? all of the above? or something else? That's the mystery we will solve together!

BREAK — 10:30-11:00

SESSION SIX - FUTURE OF RM — 11:00-12:30

Trusting the machines: Artificial Intelligence and Machine Learning opportunities and threats

Presented by: Diarmaid O'Reilly, Vice President, IT, Marken

Our biggest fears and also our highest expectations - getting to understand what is real and what is hype. We will build a common understanding of AI capabilities, where it is, where it is going, understand the opportunities that are now available for the first time. How and where to proceed with caution and how to ensure you are successful and manage your responsibilities and obligations with records.

Ask not for whom the bell tolls; is the death of the Records Manager near?

Presented by: Eldin Rammell, Phlexglobal Ltd

Over the last 15-20 years we have seen a paradigm shift in business from us managing documents and records to managing information and data. In the early 1990's and before, we all understood what a record or a document was and could likely hold up a physical copy of record. Identifying - and therefore managing - documents and records was relatively easy. Today, this is often not the case. In many parts of our regulated business we're capturing information as data items and it is almost impossible to conceptualise a "record" or a "document". We have "information assets" rather than documents. So how do we meet the obligations of our retention schedule when it says "destroy 6 years after project closure"? How do we identify and isolate applicable data items? And how exactly do we extricate them from a relational database for destruction? In a digital age when records disposal schedule can be programmatically embedded into systems, is the role of the Records Manager dead? Or should it morph into something different?

LUNCH — 12:30-13:30

PROGRAMME

SESSION SEVEN - DIGITAL/TECHNOLOGY | 13:30-14:30

A Goldilocks approach to risk-based digital preservation of GxP data: not too hot, not too cold, but just right!

Presented by: Matthew Addis, Arkivum

This talk will present how a risk-based approach to data integrity can be combined with Long Term Digital Preservation good practice in order to help organisations identify how to better manage their digital content for long-term regulatory compliance. The talk will show how an risk assessment of data against long term regulatory requirements such as ALCOA can be translated into realistic approaches for ensuring that data remains complete, correct, accurate and readable - and most importantly in a way that doesn't fall short and put data at undue risk, but equally doesn't go over the top and result in disproportionately high costs and effort. The regulatory guidelines talk about the need for quality risk based approaches to data integrity, which includes data archiving, but say little about how to achieve that in practice. This talk aims to help fill that gap.

5 Key Steps to Onboard a Digital Archive

Presented by: Lan Tran, Daiichi Sankyo Inc.

Several challenges are facing our profession today. One critical issue that we need to address is how we preserve and ensure our digital content is accessible for the entirety of the regulatory retention requirements. In order to handle this major task, we need to think through the problem, and create a plan to implement a digital archive. Doing so will position us to be able to maintain data integrity and digitally preserve our unique information for the decades to come. Join me on a journey to visit the 5 steps that will help prepare us in meeting the needs of our organization and those of the regulatory agencies on digital record archiving.We will explore regulatory requirements, digital preservation, data integrity as it relates to archiving, how to survey and analyze your current IT landscape, how to build a business proposal for a digital archive, and stakeholder management.

BREAK | 14:30-14:40

Rewind the clock and take Trial Master File back to basics: The paradigm of maintaining simplicity while embracing technology

Presented by: Jacqueline Petty, Phlexglobal

In 20 years, the Trial Master File (TMF) has moved from paper in dusty lever arch files, to electronic systems with placeholders, workflows, and artificial intelligence. The race for the most advanced eTMF is most certainly underway. However, in a world surrounded by technology it is easy to forget the basic principles of the TMF – the 'what' and the 'who' – as we focus so much on the 'how'. We shouldn't have those moments where we whisper quietly to our colleague, "it was so much easier when it was paper".Before everyone falls too far down the technology rabbit hole, we need to take a step back to recall simply what the TMF is and who its key stakeholders are - identifying what we need from the 'essential' TMF by way of regulations, system, process and oversight. This isn't saying we should ignore the technology in front of us, that would be foolish. It is about finding the balance and identifying the technology that really changes the game for eTMF management.We shouldn't be scared to take a step back in order to open the window to the future!

A case study – The journey towards defining and implementing a global records retention policy

Presented by: Hobson Lopes & Jennifer Grant-Hyman, Regeneron

The journey begins by establishing a global records retention policy and defining the Enterprise Records Retention Schedule. The road to developing and implementing processes and procedures to ensure compliance is intricate and lengthy. From revising SOPs to assessing systems to support compliance. This presentation (discussion) will share our journey and lessons learned along the way.

Chairperson's Closing Remarks

CLOSE | 15:40