

HSRAA Annual Conference

22nd – 24th April 2020

De Vere Beaumont, Windsor, UK



HEALTH SCIENCES
RECORDS & ARCHIVES
ASSOCIATION

The Health Sciences Records & Archives Association hopes that you will be able to attend its 2020 Annual Conference at the distinctive De Vere Beaumont Estate in Old Windsor, UK.

This two-day event, preceded by a choice of two half-day workshops, will take place from Wednesday 22nd April to Friday 24th April, and comprises presentations, discussions, debates and a networking conference dinner.

Programme Coordinator

Russell Joyce

Event Administrator

Jo Rammell Connect Events

HSRAA Operations Committee

Jamie Toth Secretary

Russell Joyce Treasurer

Dora Endreffy Publications

Hobson Lopes Finance

Ben Saxton Marketing

Kristen Bretzius Training

Roxanna Boyd Membership

Enquiries

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Conference Overview

A glance through this agenda will reveal a wide range of topics to provide plenty of interest and relevance to all GxP records managers and archivists.

There are sessions on data integrity, digital archiving, inspection strategies, data protection, information governance, and artificial intelligence and machine learning.

HSRAA is also pleased to welcome the **MHRA** which will present its latest perspectives on the current regulatory environment. The conference will also include the HSRAA AGM and feature updates on progress from the HSRAA's own Special Interest Groups.

Not only is this conference a great opportunity to network with like-minded industry colleagues, but we think you'll agree that this is an agenda not to miss! Places are limited so please book early to avoid disappointment

Wednesday 22nd April 2020

Pre-Conference Workshops

12:30hrs – 13:00hrs Registration and refreshments
Note: Lunch is not provided

13:00hrs – 14.45hrs **Workshop A**
An Introduction to GCP for Records Managers and Archivists

Tutor

Jo Burmester, joburmester.com

This will be an interactive session covering the key requirements of GCP focusing on good document management, TMF and archiving. The session will cover ICH GCP (R2), EU and UK clinical trials legislation and FDA legislation. The interactive sessions will be designed to illustrate how the regulatory requirements impact on the roles of document managers and archivists in practice.

Workshop B

An Introduction to GLPO & GMP for Records Managers and Archivists

Tutor

David Thompson, Principal Consultant, Clarity Compliance Solutions

This will be an interactive session covering the key requirements of GLP & GMP focusing on good document management, TMF and archiving. The session will cover UK, EU and US regulation and legislation. The interactive sessions will be designed to illustrate how the regulatory requirements impact on the roles of document managers and archivists in practice.

14:45hrs-15:15hrs Refreshment break

15:15hrs-17:00hrs Continuation of workshops A and B



Thursday 23rd April 2020

Conference Day 1

- 08:30hrs-09:00hrs Registration and refreshments
- 09:00hrs-09:05hrs **Welcome Introduction**
Dora Endreffy, HSRAA Chairman
- 09:05hrs-09:30hrs **HSRAA Annual Review (inc Scientific Archivists Group Ltd AGM)**
Eldin Rammell, SAG Ltd Chair
- 09:30hrs-10:30hrs **KEYNOTE: Regulatory Update and Discussion**
Martin Reed, Inspector, MHRA
- 10:30hrs-11:00hrs Refreshment Break
- 11:00hrs-11:45hrs **Good Documentation Practice -A Key Indicator of Attention to Detail**
David Thompson, Director, Clarity Compliance Ltd
In the regulated industries attention to detail through Good Documentation Practice is a fundamental requirement. Our documentation sets maybe large, complex, detailed or maybe simple forms but they must be accurate and capture what is required or what has happened. This presentation will explore some of the common pitfalls and how Good Documentation Practice can provide regulators/auditors a very simple and visible indicator (positive or negative) on the organisational quality culture.
- 11:45hrs-12:30hrs **Data Integrity Assessments of Computerised Systems: Short Term Remediation and Long-Term Solutions**
Bob McDowall, RD McDowall Ltd
Data integrity is not just numbers and the scope of the programme of work will be explained by a data integrity model. One of key requirements in a data integrity programme is assessment of computerised systems and their remediation which may include both short term procedural fixes and long term solutions involving technical controls and the elimination of hybrid systems. An example of an assessment of a laboratory system will be presented along with the advantages and disadvantages of procedural and technical controls.
- 12:30hrs-13:30hrs Lunch



13:30hrs-14:15hrs	<p>Implementing a full chain of custody strategy that includes physical archives</p> <p>Chris Giles, Director, iCompli by LegalRM</p> <p>Physical archives are an integral part of a company's information governance strategy. This session talks about why full chain of custody of physical archives is important as well as address a joined-up approach to the adoption of physical and electronic retention and disposition policy.</p>
14:15hrs-15:00hrs	<p>Foundations of an electronic archive: Using the OAIS Reference Model to create a User Requirements Specification</p> <p>Roxanna Boyd, Archivist, TauRx Therapeutics Ltd</p> <p>Having a plan in place for electronic archiving can seem like a huge challenge when we consider the scale and variety of electronic records that we need to preserve in health science organisations. The Reference Model for an Open Archival Information System (OAIS) is a document created by The Consultative Committee for Space Data Systems. This reference model is a great place to start when setting up any records archive, but particularly an electronic archive. This session will focus on how the information in this document can be used to create a detailed User Requirements Specification (URS) for an electronic archive.</p>
15:00hrs-15:30hrs	Refreshment Break
15:30hrs-16:15hrs	<p>Measuring progress in digital preservation using DPC's Rapid Assessment Model</p> <p>Jenny Mitcham, Digital Preservation Coalition</p> <p>The Digital Preservation Coalition has recently developed a new maturity model which is freely available for organisations to use to measure their current position and future goals in digital preservation. The Rapid Assessment Model (DPC RAM) can be used by any organisation, in any sector, who is required to manage digital content for the long term. This presentation will introduce the model and describe how it is being used across the world to help information managers and archivists manage their valuable digital assets into the future.</p>
16:15hrs-17:00hrs	Debating Sessions
17:00hrs	Complimentary Drinks Reception for delegates
18:00hrs	Close of Day 1
19:30hrs	Networking Dinner



Friday 24th April 2020

Conference Day 2

08:30hrs-09:00hrs Registration and refreshments

09:00hrs-09:45hrs **How to talk about Records Management so people will listen**

Jo Burmester, joburmester.com

One of the biggest challenges in records management is getting operational colleagues to do what needs to be done. This session will provide some hints and tips on communicating with How to talk about Records Management so people will listen colleagues and clients so that they will understand the importance of records management and buy in to what you need from them more readily.

09:45hrs-10:30hrs

“For every minute spent in organizing, an hour is earned”

Kath Firth, Head of Quality Operations, GlaxoSmithKline

Tara Isherwood, Senior Director Real World Clinical Consulting, Syneos Health Commercial Solutions

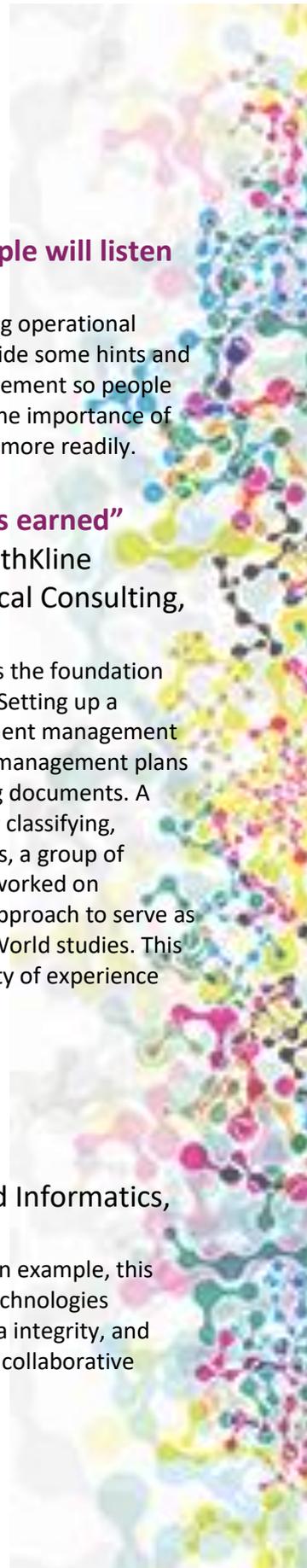
When filing documents, a good document management plan is the foundation that enables efficient and compliant document management. Setting up a document management approach involves setting up a document management plan or reference model to guide users. Successful document management plans establish the rules for creating, storing, retrieving and securing documents. A successful reference model establishes an efficient process for classifying, categorizing and filing documentation. Over the last 18 months, a group of subject matter experts from across industry have collectively worked on establishing a reference model derived from the clinical trial approach to serve as a reference model for managing the documentation for Real-World studies. This presentation explores the power of collective thinking, diversity of experience and our journey from idea to an agreed perspective.

10:30hrs-11:00hrs Refreshments break

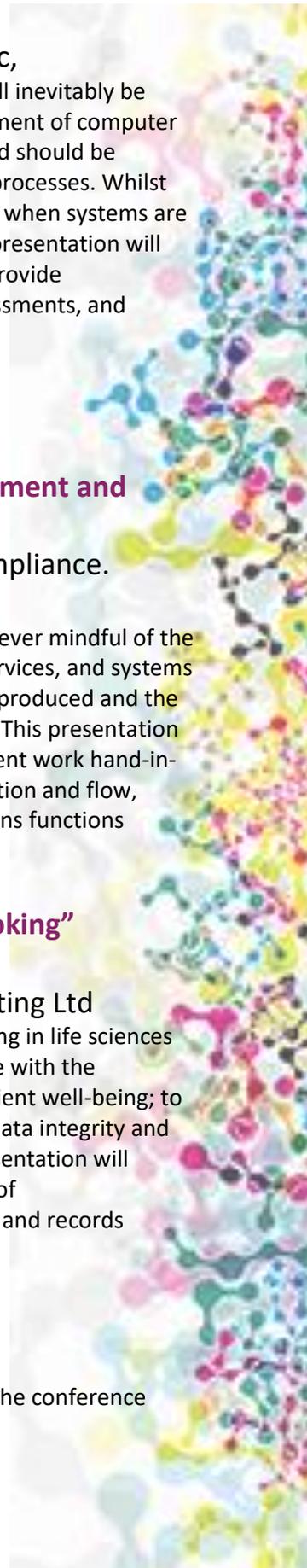
11:00hrs-11:45hrs **Implementing New Technologies (TBC)**

Marc Smith, Head of Operational Technology and Informatics, Lonza

Using the introduction of electronic laboratory notebooks as an example, this presentation will explore best practices for introducing new technologies covering implementation challenges, potential to improve data integrity, and opportunities to enhance information sharing and to facilitate collaborative working etc (TBC)



- 11:45hrs-12:30hrs **Out with the Old, In with the New**
Dora Endreffy, Global Records Manager, ICON plc,
 Throughout their careers, Records Managers and Archivists will inevitably be faced with decisions regarding systems retirement. The retirement of computer systems is an integral component of the validation lifecycle and should be conducted in accordance with well-defined and documented processes. Whilst the adoption and use cycles of validation are well understood, when systems are retired there is less understanding of the consequences. This presentation will examine the challenges associated with systems retirement, provide recommendations and tools for retirement including risk assessments, and lessons learned from experience of retiring LIMS and CDMS.
- 12:30hrs-13:30hrs Lunch
- 13:30hrs-14:15hrs **Quality Management Systems, Records Management and Archiving: Joining the Dots**
Matt Scotney, Director, Quality Systems and Compliance.
 Autolus Ltd
 Total quality management aims to ensure that employees are ever mindful of the need to focus on improvements in work culture, processes, services, and systems etc to ensure the safety, efficacy and quality of the medicines produced and the quality and integrity of the data used to evidence compliance. This presentation will examine how quality management and records management work hand-in-hand to establish and maintain controls over information creation and flow, govern day-to-day operations, and ensure that the organisations functions effectively and compliantly.
- 14:15hrs-15:00hrs **“Quality means doing it right when no one is looking”**
Divya Chotai, TMF Specialist, Autolus Ltd
Russell Joyce, Director, Heath Barrowcliff Consulting Ltd
 Among the most fundamental principles of good record-keeping in life sciences are the ability to provide documentary evidence of compliance with the requirements to protect patient safety, patient rights, and patient well-being; to ensure product quality and product efficacy; to demonstrate data integrity and trial integrity; and to maintain appropriate oversight. This presentation will explore how to use quality controls to deliver optimum levels of comprehensiveness and quality in relation to data, document, and records management.
- 15:00hrs Close of Conference
Dora Endreffy, HSRAA Chair
 Note: Tea/coffee and pastries will be available at the close of the conference before departure.



Conference Fees

- **Full Delegate:** 2-day conference, networking reception and conference dinner on Thursday 23rd April, and all conference session refreshments. **Accommodation is NOT included.**
- **Day Delegate:** Admission to the conference sessions on 23rd April or 24th April, including lunch and refreshment breaks. **This rate does NOT include accommodation or the networking dinner.**
- **Networking Dinner:** For day delegates or delegates wishing to bring a guest (cost is included in Full Delegate rate).
- **Workshop:** One half-day pre-conference workshop on 22nd April, including refreshment break. **Lunch is NOT included.**

HSRAA members whose membership is fully paid at the time of booking are entitled to a discount (13%-16%) on the non-member rates shown below. The member rate for each option is shown on the website.

Non-members wishing to benefit from the discounted member rate may purchase HSRAA membership online for £60. After receipt of payment online, proceed to the conference booking site where member rates can be used.

Non-member conference costs are:

	until Fri 21st Feb 2020	thereafter
Workshops	£100	£115
Day 1 Thu 23rd April	£160	£185
Day 2 Fri 24th April	£160	£185
Full Conference (Both conference days PLUS Drinks Reception and Conference Dinner Conference Dinner	£335	£395
	£55	£55

Save by booking **NOW!**

To provide maximum flexibility, accommodation is not included in our conference ticket options. Please note that YOU will need to contact the De Vere Beaumont Hotel directly to book hotel accommodation (<https://www.devere.co.uk/beaumont-estate>). Quote "HSRAA" when booking accommodation to obtain our reduced rates. Alternative hotels can be found on websites such as Trivago, Expedia, Booking.com etc. Windsor is approximately 5-10 minutes distance by taxi.

Please note: During the booking process you may choose to pay for your conference booking by credit or debit card. To minimise our administrative overheads, we only provide an invoice for payment by BACS or cheque in exceptional circumstances. To guarantee your conference place in the event of high demand, HSRAA recommends that payment is made online using a corporate or personal credit/debit card.

Bookings for this event close on 9th April 2020; no bookings can be taken after this date as numbers for delegates, dinner and other refreshments will have been confirmed with the hotel. To minimise costs and streamline processes, conference reservations are taken only online at <http://the-hsraa.org>

Queries

If you have any queries regarding the conference, please complete the online enquiry form on the HSRAA website or e-mail conf-admin@the-hsraa.org