List of Client Engagements

Pharmaceutical Organisation (UK) Apr 2020-Present

- Advising on TMF governance and quality control
- Drafting policies and procedures in relation to records management e.g. record retention, quality control, data integrity, digital preservation, archiving.
- Oversight of the selection, evaluation, and implementation of paper and digital archive provision

Pharmaceutical Organisation (UK & Japan) May 2023-May 2024

- Process mapping and optimisation recommendations
- Gap analysis in relation to digital record-keeping and digital migration
- Provision of advice in relation to enterprise-wide digital transformation strategies
- Formulation of information governance frameworks for early discovery and pre-clinical research

Pharmaceutical Organisation (UK & Portugal) Feb 2023-May 2024

- Provision of advice, support, and the drafting of documentation in relation to the re-organisation and migration of digital content to best preserve its long-term integrity, accessibility, readability, and (where required) usability in compliance with GxP requirements

Pharmaceutical Organisation (UK) Nov 2020-Oct 2023

- Oversight of the selection, evaluation, and implementation of an electronic trial master file and an electronic Quality Management Systems including change management; risk management; policies and procedures
- Ongoing records management / information governance and data integrity gap analyses for pre-clinical and clinical documents and data
- Recommending future options and technological solutions to resolve the gaps, introduce operational efficiencies, and enhance regulatory compliance
- Advising on information management strategy and governance frameworks e.g. enabling technology system requirements definition, evaluation, selection and implementation.
- Member of the Quality Leadership Team advising on change / risk management and process optimisation

Life Sciences Technology and Services Organisation (UK) Jul 2020-Jan 2023

- Review and revision of operational, technical, and quality management policies and standard operating procedures

Pharmaceutical Organisation (France) Sep 2019-May 2022

- Advising on TMF governance and quality control in preparation for introduction of eTMF
- Development of paper and digital archive strategies and governance frameworks

Pharmaceutical Organisation (UK) Aug 2019-May 2020

- Development of information governance policies in relation to TMF and digital archiving

Cell and Gene Laboratories (UK) Jun 2019-Feb 2020

- Data integrity gap analysis and resolution for early discovery and development laboratories

Cell Gene Therapy Organisation (UK) Apr 2019-Dec 2019

- Establishment of a records management function, policies and procedures

Pharmaceutical Laboratory and Manufacturer (Belgium) Oct 2017-Mar 2019

- Provision of specialist information governance and data integrity services for GLP & GMP
- Data integrity gap analysis and CAPA development in preparation for GLP/GMP/GDP inspections

Pharmaceutical Organisation (France) Apr 2015-Dec 2018

- Part of consultancy team advising on change management and process optimisation for eTMF

Pharmaceutical Organisation (France) Oct 2017-Oct 2018

- Part of a team of consultants advising on change management and process optimisation for the implementation of an electronic Trial Master File

Pharmaceutical Organisation (Switzerland) Jan 2017-Sep 2018

- Development of information governance policies

University (UK) Jan 2018-May 2018

- Part of a team of consultants advising on and information governance change management for the implementation of the General Data Protection Regulations

Pharmaceutical Laboratory (UK) Jan 2018-Feb 2018

- Conduct of data integrity audit for analytical sciences laboratories records
- Resolution of regulatory quality management findings in relation to the conduct of clinical research activities

Biologics and Chemical Research Laboratory (UK) April 2017-June 2017

- Development of data preservation strategy

Pharmaceutical Distributor (UK) Jun 2013-Feb 2017

- Lead respondent in client audit in relation to governance issues related to supply of compassionate use medicines
- Provision of advice and assistance with eTMF and EDC solutions user requirements and functional specifications
- Project manager for implementation of fully validated electronic document and quality management system
- Development of an ISO15489 based records classification scheme and retention schedule
- Conduct of business process and gap analysis to recommend efficiency gains in operations and improved compliance in relation to record keeping for regulated activities
- Project managed implementation and validation of Sage200 financial and stock control software
- Revision of relevant standard operating procedures and work instructions for records management

Pharmaceutical Organisation (UK) Nov 2016-Feb 2017

- Advice and training on Good Laboratory and Manufacturing Practice records management

Government Ombudsman (UK) Jun 2016-Aug 2016

- Part of a team of consultants advising on records management issues for a change management project

Pharmaceutical Organisation (UK) Nov 2015-Apr 2016

- Advice and training on Good Clinical Practice records management

Pharmaceutical Organisation (Denmark) Sep 2015-Dec 2015

- Implementation of electronic Trial Master File and associated process optimisation

Pharmaceutical Organisation (Switzerland) Mar 2014-Sep 2015

- Analysis of the business' functions, activities and records collections to facilitate the development of a compliant combined records classification scheme and retention schedule based on ISO15489
- Provision of advice regarding the long-term retention and archiving of electronic records
- Review of local and international legal and regulatory record keeping requirements

Pharmaceutical Organisation (Switzerland) Feb 2014-Apr 2015

- Creation of ISO 27001 compliant information security classification policies and procedures
- Development of criteria for evaluation of existing and new electronic records management systems
- Mapping of US and EU record classification schemes

District Council (UK) Jan 2015-Feb 2015

- Development of user requirements specifications for- and evaluation of- document management solutions

Borough Council (UK) Jan 2014-Nov 2014

- Analysis of the business' functions, activities and records collections to facilitate the development of a compliant combined records classification scheme and retention schedule based on ISO15489

Pharmaceutical Organisation (UK) Dec 2012-Dec 2014

- Provision of records management services including RM training and advice, review of applicable standard operating procedures and assessment of requirements for the introduction of an electronic trial master file

District Council (UK) Sep 2011-Apr 2013

- Conduct of gap analysis to provide an independent assessment of the current state of records management within the authority (including a proposed transition to commercial records storage arrangements) to recommend strategies required to ensure "fitness for purpose".

NHS Primary Care Trust (UK) Nov 2012-Apr 2013

- Provision of advice in the management of paper and digital records during transition and closure, ensuring that records passed to Clinical Commissioning Groups were transferred, archived or destroyed in compliance with the NHS Code of Practice on Records Management and Information Governance Principles.
- Worked with senior managers and key stakeholders in Clinical Commissioning Groups to develop functional file plans and associated guidance to provide staff with the tools and knowledge to manage records effectively and encourage the adoption of compliant records management practices for the future.

Executive Non-Departmental Public Body (UK) Apr 2012-Aug 2012

- Compilation of a global information asset register and provision of a strategic report recommending approaches to: mitigate physical & security risks; improve information governance through the adoption of records management policies and procedures; support the leveraging of information assets for business use and commercial advantage; and ensure effective planning for the introduction of new IT systems and the migration of content into them.

Pharmaceutical Organisation (UK) Jun 2011-Dec 2011

- Developed records classification scheme & retention schedule based upon business processes in preparation for introduction of a new document management system, including review of associated policies & procedures.
- Developed a business continuity plan and drafted supporting processes & procedures.

Pharmaceutical Distributor (UK) Aug 2011-Dec 2011

- Provided advice on records collection, classification, retention & scanning solutions in relation to pharmaceutical manufacturing and supply records.
- Provided advice on validation requirements for new document management system used for the management of pharmaceutical manufacturing and supply records.

Pharmaceutical Organisation (Germany) Oct 2011-Nov 2011

- Mapped multifarious clinical trial master file plans to a new centralised file plan.

Pharmaceutical Organisation (UK) Aug 2011-Nov 2011

- As part of a consultancy team, provided support in preparation for development and implementation of an electronic document management system and supporting processes based upon insight into and experience of industry trends, applicable regulatory and legal requirements, and best practice for records management.
