Scientific Archivists Group
Promoting Excellence in Records Management
www.sagroup.org.uk

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ABOUT THE SCIENTIFIC ARCHIVISTS GROUP

The objectives of SAG are:

> To improve the science of archiving.

> To ensure archives meet business, scientific and regulatory needs.

> To encourage a high profile with regulatory authorities.

> To develop a professional status for members.

The group holds bi-annual conferences to promote the exchange of information on the role of the archive and archivist within a changing scientific and regulatory environment. Papers are published in the group's bi-annual journal along with current awareness features and topical articles to enable members to keep abreast of developments within the industry.

To Apply:

Full membership is open to individuals with an interest in archiving scientific records.

For further information visit our website at

www.sagroup.org.uk

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Entries in Blue are the executive positions

Letter from the Chair

Chris Jones

Welcome to another edition of Sagacity. It's been a busy first few months of 2008. We held our Spring conference in Berlin, which was a successful mix of informative presentations, networking and a tour of the city plus a visit to the Schering Museum. This was the first conference since I took over as chairperson, and I was very nervous that something might go wrong, however the whole event went really smoothly, thanks to Liz Hooper and the rest of the committee. I took home some fond memories of Berlin, and I hope the members who attended did so as well. It was good to see so many of you there, and my thanks for your part in making the event such a success.

Our next conference is in Bristol in October, please check our website (www.sagroup.org.uk) for details.

Ah yes, the website! At the time of publishing the last Sagacity, we were about to launch the "public" website. This has been live now for several months, and I think is helping to promote a more professional image for the group to potential new members, as well as acting as an information source about the group and it's activities. Since that launch, I've been working with the web developer on the remainder of the project comprising the content management system, now delivered, and the "members" website, due to complete imminently. I really hope that you like the end result, and will find it a valuable resource.

As well as the conferences and the website, other activities that the latest iteration of the committee have been busy working on in the first part of this year are the membership renewals, budget, publicity/marketing ideas and planning another joint training day with the Institute of Clinical Research (ICR) for later in the year. It can be quite challenging at times fitting in SAG activities with work and home life, however it is enjoyable, rewarding and I'm very fortunate to be working with such a strong, committed group of individuals.

I have also appreciated the feedback and ideas from members that I've received since I became chairperson. If you have ideas or suggestions that you think would benefit the group members, please do get in touch

I hope you enjoy reading this edition of Sagacity, and find it informative. My thanks to Gail for pulling it all together (being persistent and persuasive are key to being a successful Sagacity editor!) and to those of you that have contributed articles.

I look forward to seeing as many of you as possible at the Autumn conference, and I wish you a warm, sunny, successful summer.

Chris Jones
Chairperson, Scientific Archivists Group

Letter from the Editor

Gail Dams

It has been a very busy 6 months for the committee as a whole; in particular with the on-going progress on the Sagacity website. Our Chairperson, Chris Jones has been working tirelessly to get the "public" area up and running and to ensure that this new website promotes a more professional image, which I'm sure you will all agree - so far it does do what it says on the tin!

The Committee also decided that it was time that the membership directory was updated and to that end Neil Gow has put a considerable amount of effort into a new electronic directory. Subsequently Neil has overseen transferring the membership directory into hard copy, to be sent to all our members. Further, as you know we have also re-introduced membership cards – no wallet/purse should be without one.

The Spring Conference in Berlin was a great success as usual, combining informative presentations with the networking that always works so well in these situations. For this conference we were also able to include in the agenda a very fascinating field trip. As always it was good to catch up with old friends as well as make some new ones, that hopefully will be at the next conference.

If you are yet to attend one of the conferences please do take a look at the networking photo gallery and read our Newbie article from Becky Hazell. Becky really does capture the essence of the whole event, even if you were at the conference please read this account, I'm sure you will agree that the conference was definitely worth attending. I always feel full of enthusiasm after a conference as I sit listening to the presenters and talking with other delegates and ultimately realising that we really do play a very important part in the running of our respective companies; without our knowledge things could be very different.

So here's to the next one. This will be our Autumn Conference scheduled for October and to be held in Bristol. We are holding 3 workshops on Thursday plus various presentations for the Friday – which are usually well received, details will be sent out shortly.

In this issue of Sagacity we have the results of the survey which Norman Mortell from Agenda put together for the Spring conference. The survey was designed to assess what the members felt was the biggest security threat to our business to which the results are very interesting.

We are especially fortunate to have another article for our on-going training and education section of Sagacity, this time from Professor Julia McLeod. Julia is from the University of Northumbria and gives her professional opinion and guidance on further education for our specific fields of expertise. Sincere thanks to Julia for taking the time to contribute to Sagacity.

Also included in this edition we have collated the notes from the GLP Consultative Committee plus the Question and Answer Session from the conference which I'm sure you will find informative and useful.

We are always looking to improve on services provided within SAG therefore if you have any ideas regarding topics for articles that may be used in Sagacity or for a conference and would like to, or know someone that would be prepared and willing to, submit an article or present at a conference please let us know.

Have a good summer.

Best wishes and take care
Gail

Committee Positions for Election

The following committee positions are due for nomination and, if necessary, election this year. Details of this process will be sent to all members in July.

Committee Members Job Descriptions

SAG Chairperson

Produce a letter from the chair for SAGACITY.
Respond personally or redirect any questions or requests for information to the relevant SAG expert.
The contact on the SAG website.
Chair the committee meetings.
Support and encourage the committee members in their roles.
Host the conference member's session.
Welcome and introduce the speakers at conferences.
Chair the SAG member's session.
Actively partake in discussions during the committee meetings
Suggest conference speakers – agree conference, workshop themes
Research relevant topics and investigate possible authors.
Help with any housekeeping task at the conference e.g. preparation of the room, circulating handouts etc.
Circulate/Network during the conference to ensure that the members have all the information they need – especially new members
Gather information from the members that would be useful when planning future conferences – to fulfill the member's needs.
Feed to web liaison any useful web sites
Help promote SAG

SAG Ordinary Committee Member.

Be prepared to attend committee meetings
Actively partake in discussions during the committee meetings
Suggest conference speakers – agree conference, workshop themes
Research relevant topics and investigate possible authors.
Help with any housekeeping task at the conference e.g. preparation of the room, circulating handouts etc.
Circulate/Network during the conference to ensure that the members have all the information they need – especially new members
Gather information from the members that would be useful when planning future conferences – to fulfill the member's needs.
Feed to web liaison any useful web sites
Help promote SAG

European Liaison Position

At the most recent committee meetings, the European Liaison position was discussed. This has been an open position for a number of years in the group. Having discussed it at length, the committee agreed that the role is important to help us branch out further into mainland Europe, but that we do not want to burden anyone in the role with all of the additional workload (attending meetings, emails etc) of being a full committee member. However the European Liaison may be invited to specific committee meetings to discuss activities /plans relating to European members.

The description for this role is below

Role Description – SAG European Liaison

Point of contact for Non-UK Members
Help to establish network of SAG members outside the UK
Help non-UK members contribute to SAG activities

Promote the aims of SAG
Research promotional opportunities within the EU
Encourage and promote membership recruitment
Help to develop SAG strategy to meet the European members needs
Suggest conference speakers, research relevant topics and investigate possible speakers
Inform the wider membership of the needs of non-UK members through Sagacity
Feedback to committee information on the Regulatory expectations in mainland Europe which impact upon and of interest to SAG members

Conferences *(if attending)*
Help with any housekeeping tasks at conferences e.g. preparation of the room, circulating handouts etc.
Circulate/Network during conference to ensure that the members have all the information they need – especially non-UK members
Gather information from members that would be useful when planning future conferences – to fulfill the member's needs.

We are pleased to announce that Britta Krusemeyer from Covance in Germany has agreed to serve in the role. Many of you will know Britta from previous conferences, and will be aware that she is a strong supporter of SAG. Members of the committee will be partnering with Britta over the coming months to develop this role and work on specific activities. Please join us in thanking Britta for volunteering to take on this role for the group.

Committee Member Biography - Secretary
Julia Crisp – Unilever

Name: Julia Crisp
Company: Unilever
Position: Archivist/Information Administrator

Q1. Ok tell us about your family?

A1. I have a loving and supportive partner. Together we have raised two children from my previous relationship. A beautiful daughter, 25. She has not long celebrated her first wedding anniversary. A handsome son, 21. He has recently qualified as a heating engineer and has been Corgi accredited. All three have a wicked sense of humour so there is a lot of laughter around. I should not forget the 14 year old cat with an attitude problem and no sense of balance!

Q2. How long have you been involved in archiving/document management?

A2. I have only been working in this area since 2002, so still quite new to it compared to some and learning all the while.

A3. What do you consider to be the best part of your job?

A3. I guess I like the fact that I control my own work flow how and when etc. I'm not sat at a desk 5 days a week. I like the variety of the work, the attention to detail the moving of the boxes in and out and the fact that I come into contact with a lot of people for a short amount of time. Also the peace and quiet of the archive. I'm trusted to do the job by my managers.

Q4. What advice would you give when approaching an inspection?

A4. **Inspection pending** – run around like a headless chicken is always my first reaction, that done, I then check through all the paperwork, (chain of custody in place, signatures, dates etc. Details are important) If I find any mistakes I write a reason, sign and date it. I'll then do checks on my own system (database) call up a report or two, find it physically, check everything is in order (paper trail etc.).

Inspection taking place - It is one of those rare times I say little and listen a lot, the inspectors are looking to see you know your job and you can do it. If you have checked your paperwork and tested your system there is not a lot more you can do. Try not to panic.

Q5. Finish this sentence "being on the SAG committee is like……."

A5. Instantly expanding your knowledge of archiving and records management.

Q6. So what made you join?

A6. Joining the group, it was sheer panic of not knowing enough about the job and looking for some support. Joining the committee I thought would extend my knowledge further and allow me to give something back to the group.

Q7. If you hadn't decided on a career in archiving, what would you be doing?

A7. My previous job was working in a library; I took up my present position as it was to manage a small library and be the deputy archivist, as with everything changes occur. So getting back to the question I would be working in the librarian field.

Q8. What has been your greatest achievement??

A8. This has been a mixed bag of work and personal questions so I will answer in both ways.
Work: Going from deputy archivist to archivist in 12 months, facing an inspection 6 months after that and coming out the other end pretty much unscathed!
Personally: learning to have patience and tolerance, yeah I know this sounds a bit naff but I have gained great rewards and avoided great disasters.

Q9. So far your holidays have been memorable for the wrong reasons – what would be your ideal holiday barring any mishaps?

A9. I guess a short explanation for those who don't know me well.

Holiday mishaps only!

2002/Aug – Centre Parcs – playing badminton – tore ligaments – 4 weeks in plaster

2004/Aug– Hawaii – Sun stroke – snorkeling – 4hr flight followed by 8 hrs flight home!

2006/Feb – Bulgaria – Snowboarding - Fractured wrist and arm – 6 weeks in plaster

2008/Feb – Andorra – Snowboarding – broke bone in foot – 6 weeks in plaster

2008/Oct – New York – keep you posted!

So as you can see I like an activities holiday I don't mind where or when or what, just as long as I'm doing something that gives an adrenalin rush.

Q10. What can't you live without?

A10. My partner and children, they make me laugh, cry, think, they have made me who I am.

Committee Member Biography - Membership Secretary
Neil Gow – UCB Celltech

Name: Neil Gow
Company: UCB Celltech
Position: Head of Records Management

Q1. Of course the first question has to be about your family?

A1. We're a regular 2+2, so we'd fit the standard family archive box. Two teenage sons, whose main interests are watching television, playing computer games and arguing with their parents about unreasonable quotas of time to carry out these activities (actually they are pretty good, because they do play some sport, go to youth club and do their homework). We also have a couple of cats to ensure a good quota of hairs get onto work clothes and school uniforms.

Q2. When and how did you get into archiving/document management?

A2. It's my third career but is a natural evolution of the second, which was Library and Information work. We added laboratory notebook management and GLP archiving to our portfolio, and then as the company focused less on research and more on development, so the management of internal documentation came to dominate over gathering external information. When it was time to move on, this job seemed to fit very nicely.

Q3. If you could wave a magic wand to change one aspect of an archivist document manager's job for the better what would that wish be?

A3. Replace all humans with robots that fill out the forms properly, follow the procedures and don't mix up the valuable regulatory documents with the dross in their filing systems – but still say thank you for a job well done and bring in cakes when it's their birthday.

Q4. Which GxP discipline is your favourite?

A4. None of them! Well, perhaps GPvP.

Q5. Why?

A5. Well GLP wet tissues are a pain, and GCP investigators' files are a right nightmare (we can't have them, they don't want them, but someone has to make sure they are looked after). So it would be GMP because we are generally in control of the documentation and the retention times are well defined – were it not for the sheer number of documents you have to produce during an inspection. We've had no particular issues with GPvP yet, but to be honest I like a bit of a challenge.

Q6. What's the best piece of advice you have ever been given

A6. Well I had a manager once who was a bit of a pig and did my career no favours (I was working in a different discipline then), but one really useful piece of advice he gave me was to carry a book to make notes in rather than use scraps of paper you will inevitably lose.

Q7. What advice would you give in return?

A7. Don't leave the book lying on a bus in Edinburgh.

Q8. Who has been the biggest influence in your life?

A8. I hate these sorts of questions. At the risk of upsetting my parents, grandparents, wife, teachers, past managers and anybody else who wants to take credit for the fine balanced individual that I am, I am going to say John Miles – because he sung/played what I regard as the best rock/pop song ever (it's called simply "Music" and there's a reasonable version of it on YouTube if you're interested).

Q9. What is your long term goal in life?

A9. Blimey, what is this – "In the Psychiatrist's Chair"? Work wise, I like to feel that what I do really makes a difference to people, and that at the end of every day I can go home knowing I've done something useful.

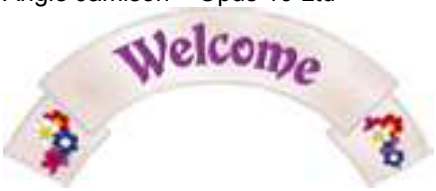
Q10. Describe your ideal day, fantasy or reality you choose

A10. So it is “In the Psychiatrist’s Chair”! Work wise, it would be spending most of the day in a meeting where everyone regards my input as really valuable and take notice of all my suggestions but don’t give me any actions, and then getting back to my desk to find everything is under control and no new sh*t has arrived. Yes, that’s the fantasy. For the reality, just a good fun day out with the family – it can happen sometimes.

New Members

Jane Tierney – Aptuit Limited
Tom Lewis – Phlexglobal
Rachel Webster – TauRx Therapeutics Ltd
Catherine Hutchinson – Roche Products Ltd
Gary Montgomery – Britannia Pharmaceuticals Ltd
Shelagh Payne – Roche Products Ltd
Lynn Seeley – University of Southampton Clinical Trials Unit
Alasdair Haley – Chemtura Europe Ltd
Marie Kitchin – Renovo Ltd

Darshana Desai – Sanofi Aventis
Yaa Adjei – BTG
Lorna Copley – Pharmaceutical Profiles
Angie Jamison – Opus 10 Ltd



General Update on SAG Projects And Upcoming Events

Membership Directory

This has now been completed. Hopefully by the end of June you should all have received it together with your new membership cards.

If by any chance you do not received yours by that time please do not hesitate to contact Neil Gow or other committee member and we will rectify the situation

SAG/ICR Training

Following the success of previous SAG/ICR training courses it has been decided that another will be arranged. This is due to be held on 27 November 2008. Further details will be available shortly this will include costs.

Should you have a particular topic you would like to see presented then please do let us know

BARQA

BARQA Global Conference in Edinburgh 27 to 31 October 2008

The Scientific Archivists Group will be exhibiting at this conference – please do come and visit our stand!!!!!

Website

Since the last edition of Sagacity, there has been a considerable amount of work on the website. Following the launch of the public website in December, the next functionality delivered to the group was the content management system. This allows the designated web support person(s) to make changes to large portions of the website without relying on the web developer or support. This gives the group flexibility to ensure the site is up to date. You may already have seen the updates relating to the Autumn conference - keep checking in for further updates.

The largest part of the project is the final phase, the delivery of the members' area. This is a complicated piece of work, which has involved a considerable amount of effort to address the security needs, ahead of delivering the functionality and content itself. It has along the way required a change to the hosting package being used for the website, which required the whole public site to be migrated. At the current time, the external resources and document library are in progress, with relevant content being identified and added, and the developer is working on the user forum/user account management part. Once this is completed and the area is ready, all current SAG members will be given accounts and notified of their log in details, as well as being provided an overview of the area.

If you have any questions/feedback about the website, please contact Chris Jones.

GLP Consultative Committee Minutes
Richard Pennicard – Battelle UK

31 March 2008

The UK GLP Consultative committee is a body with members from industry and various government bodies such as the MHRA, Food Standards Authority, and of course all the GLP inspectors. It meets once a year to discuss general issues around GLP, and also for the GLPMA to report on its activities. It met on 31 March 2008 when the SAG representative was Richard Pennicard. These are the topics covered that might be of interest to SAG members.

Personnel and Scope
Christine Burwood has joined the group, which is now six strong.

As well as GLP facilities, the group has been inspecting GMP QC labs for a couple of years and is starting to inspect GCP laboratories.

Legal Issues
The GLPMA is advising registration authorities to check QA statements in reports to see if they conform to recent guidance.
A trial date has now been set for a major enforcement case that has been ongoing for a couple of years.

REACH (Registration, Evaluation and Authorisation of Chemicals)
REACH legislation came into force in June 2007. It brings together existing legislation on human and environmental safety of general chemical products and intermediates. Questions should be sent to UKREACH@hse.gsi.gov.uk. It does not cover agrochemical or pharmaceuticals; requirements for these are unchanged.

REACH requires toxicology and ecotoxicology studies to be carried out to GLP. Physical chemical studies don't need to be. However, even these need to be done to a quality standard that assures scientific integrity. GLP studies automatically qualify; any others will need to be evaluated. GLP studies may also still be required by non-EC authorities.

HSE is the UK "competent" authority for REACH. The European Chemical Agency has been set up in Helsinki. It has started issuing advice and guidelines.

Test method regulations are now in place. One piece of guidance that the agency has issued is that soil adsorption studies count as Ecotoxicology and therefore have to be performed to GLP.

Risk-Based Inspections
The GLPMA, along with the rest of the MHRA GxP inspectorate, is moving to a system where the frequency, scope and length of inspection is based on the potential risk that a test facility's activities pose to human or environmental safety. The move is in response to the Government's initiative to make the regulation of industry proportionate to the risk that the industry poses.

The precise details are still to be resolved. It is likely that only very small facilities will see an inspection frequency much greater than two-yearly, because of the GLPMA's duty to comply with EU GLP directives and OECD GLP principles and Mutual Acceptance of Data (MAD) agreements. It will also likely affect scope and length of inspections.

The regime will switch the burden of compliance to the test facility itself. The facility will have to fill out a compliance self-assessment form that will cover aspects such as the responsibility taken by management, the type and amount of studies performed, and the findings of internal QA inspections. The forms will be trialled shortly. The GLPMA will also consider all other available intelligence when assessing the amount of inspection a facility will need.

Detailed proposals will be sent out for public consultation, which will include all bodies represented on the consultative committee. The new regime will be phased in and the process of implementation will be made public. In the meantime, inspections will go on as normal.

Inspection Program
There are 131 members in the GLP program. 9 facilities have left, some of them big, and five have joined: all small.

There have been 56 routine inspections and 2 study audits (covering multiple studies). There was one unannounced inspection, of a company that seemed to advertise on its website that it was performing GLP studies but was not a member of the programme. No further action was taken. The GLPMA will continue to monitor company websites to look for claims to be working to GLP.

There have also been GMP lab inspections led by Mary Baynes, and GCP lab inspections led by Samantha Atkinson. Mostly these have been labs that are also in the GLP program.

The inspection program is within schedule; 90% of facilities were inspected within the 27 months maximum, most of the rest were delayed because the test facility was undergoing reorganisation.

Use of Non-GLP Facilities for Study Work
A guidance document has been issued. The principles are: 1) only do it in exceptional circumstance, 2) the study director is directly responsible for the work, 3) alternative must be fully assessed, 4) the GLPMA should be informed on a standard form (see website), 5) compliance can only be claimed on a study by study basis.

Inspection Findings
Findings were compared with 2005 – when same facilities were inspected. Little difference between the years, when the increased number of inspections, and studies inspected, is considered. Major sources of deficiencies are study performance and QA. Archives account for about 8% of deficiencies.

Inspection of Contract Archives
The inspectors responded to a question put by the SAG representative at the meeting. There is no inspection program for contract archives as such. The GLPMA will expect to be informed of what companies are using contract archives and to what extent. The contract archive will always be included in the inspection if all studies are archived there, but not necessarily if only a small part of studies are. The GLPMA will allow time to inspect contract archives if necessary. The GLPMA expects that there will be adequate SLAs, and that these will include the requirement to comply with GLP principles. They expect that the facility's QA will inspect the contract archive. Details of how inspection of contract archives fits into the risk-based approach have not yet been decided.

Electronic Submissions, the eCTD and Records Management

Geoff Williams – Roche Products

Background

Fully electronic regulatory submissions are now becoming a fairly standard way of working in both the US and Europe. The electronic Common Technical Document (eCTD) has become an increasingly important format for these submissions since its introduction in 2003. This article will explore some background to the topic, explain the key concepts behind the eCTD and then consider what this means to the management of electronic submission records.

Electronic Submissions and the ICH

Electronic submission (e-sub) formats are nothing new as a format for the submission of regulatory dossiers. The FDA started a program for Computer Aided New Drug Applications (CANDAs) in the early 1990's and Europe followed with two initiatives, the German led DAMOS and the French led SEDAMM standards. Alongside these projects, individual companies also started developing their own e-sub standards using proprietary applications and company devised formats for the display of data.

In all cases the main objectives of developing e-sub standards is to provide a more compact way of submitting the large amount of data that makes up a modern regulatory submission. Not only should the e-sub be more portable than the equivalent paper, it should also be easier to use with improved navigation between and within documents, have improved search capabilities to find particular information and copy/paste functionality to assist in the task of preparing assessment reports.

All of these early initiatives achieved these objectives but in different ways. After initially good feedback on the way in which these submissions aided the reviewer, a problem arose. The multitude of formats, including the fact that the applicant often provided the hardware and the software as well as the submission, meant that agencies had to learn the particular company format for each submission they received.

The ICH became involved when a project to create an electronic submission format was accepted. However, it was quickly realised that to enable a global e-sub format there would first need to be a global format for the presentation of the submission. As a result, the Common Technical Document (CTD) was developed.

The CTD provides a single, globally accepted structure for the presentation of submission data. However, the CTD does not provide a common set of data that can be submitted globally and each ICH region has their own individual needs specified in local guidance documents. Within the five modules of the CTD the amount of regionally specified documentation can range from the total amount (in the regionally specified Module 1), through Modules with specific sections dedicated to regional data (such as Module 3, which contains the regionally specified section 3.2.R) to Modules where the main difference is the provision of additional data only (Modules 4 and 5 in the US). As we shall see, this requirement for the CTD to accommodate regional differences has lead to some issues for the eCTD.

The eCTD

The ICH M2 group began work on developing the eCTD specification in 1999. The intent was to develop a specification for an electronic submission format that would meet the objectives of the previous electronic submission formats and, at the same time, accommodate the structure of the CTD at an international level and also the various regional differences.

This last requirement has meant that the work of the ICH has concentrated on the international requirements only. In addition to the work that the ICH has done, each region adopting the eCTD has also had to develop the specification and guidance for the specific use of the eCTD in their own region. This has further complicated the task of implementing the eCTD on a global basis and lengthened the timeline for adoption.

In addition to meeting the objectives of the earlier e-sub standards, the eCTD specification and guidance also meets a further requirement not previously met by the previous formats. The eCTD additionally provides a means to manage and display the

relationships between individual documents and dossiers over the life of the product authorisation, a concept known as lifecycle management.

Document lifecycle management in the eCTD allows the submission of an individual document only once during the products life but for this content to be referenced from locations within the same submission or subsequent ones without the need to resubmit the document. The lifecycle management also allows the tracking of documents as new versions are made available and the specification allows the relationship to previous versions to be established, whether replacing a previous version, adding a additional data or finally withdrawing the document.

At the submission level, lifecycle management allows the relationship between submissions to be shown. For example, following the initial submission of a Marketing Authorisation Application (MAA) there will be responses to authority questions, submission of final labelling and the final approval. While the relationship between these submissions can be displayed, it is also possible to distinguish between separate procedures which may take place simultaneously following the approval, such as parallel variations to include a new manufacturing site or add a new clinical indication.

The Main Components of the eCTD

The eCTD specification covers five main component parts:

1. Leaf Documents: In the eCTD the individual documents that contain the scientific and regulatory data are known as “leaf” elements (the idea being that the eCTD defines a structure, like the branches of a tree, with leaf documents attached to the branch structure). For the most part, the individual documents are PDF files, though some other formats (XML, GIF) are acceptable. The specification describes the minimum standards for the individual files so that they can be navigated and displayed easily, including the fonts that should be used for text, the detail to be included in Tables of Contents and the way in which the navigation aids (bookmarks and hyperlinks) should be added and displayed. The specification does not cover the content of the documents, this is specified in other ICH (such as the E3 guidance on Clinical Study Reports) or regional guidance documents.
2. Folder Structure: At its most basic, the folder structure is a simple container for the leaf documents. However, as there could be several thousand leaf documents in an eCTD, the folder structure provides a logical division of these files to assist the person creating the submission in managing the content. The folder structure is not intended to be the main way to navigate to the content of the submission.

These two components are the common element of any e-sub standard. The use of PDF files for the leaf documents is copied from the FDA’s previous eNDA standard and demonstrates that the ICH were keen to reuse concepts and standards that had already been proven to work. The following components are the items that are unique to the eCTD and separate it from the older e-sub formats. In particular, they are the components that allow the lifecycle management requirements to be met.

3. XML Backbone: The eCTD specification uses an XML (eXtensible Markup Language) file, known as the backbone, to provide the main navigation around the submission, to manage information about the individual documents, the structure of the dossier, information about the dossier and the relationships between individual documents and dossiers over the lifecycle. The backbone file achieves this because alongside the definition of each piece of information (a heading in the eCTD structure or a document) extra information, known as metadata, can be provided. This allows the backbone to contain the information about the relationship to previous documents to be associated with a leaf document, as well as extra information about the submission (such as the applicant, review procedure, agency receiving the file, the trade and generic names) to be submitted as well.
4. The Data Type Definition (DTD): The DTD provides the rules for the XML backbone. It ensures that the structure of the CTD (the correct names and order of the headings) are followed as well as defining the rules for the metadata that allow all of the lifecycle management to take place. As such, it is possible to define what makes a “valid” eCTD by following these rules.
5. A stylesheet: The eCTD stylesheet provides simple way to view a single eCTD submission through an internet browser application.

As the comment against the stylesheet says, the eCTD specification includes only a simple way to view a single eCTD submission. To take full advantage of the metadata in the XML backbone and to display the relationships over a series of submissions, a more sophisticated viewing

application is needed. Indeed, although the eCTD can be built from scratch using standard applications, the creation of an eCTD is helped immeasurably through the use of an eCTD publishing tool. However, the ICH specification leaves the question of "how" to build an eCTD unanswered as this depends so much on the way that the applicant manages the individual documents and submissions within their own systems.

The eCTD – Current Status

The eCTD is designed for use in the wide variety of submission types that support the registration of human pharmaceutical products. The format can be used for innovative submissions as well as generics applications. The format can be used for the original applications as well as the many subsequent submissions that support the final approval of the product. In Europe the eCTD can be used in any one of the four submission procedures used to approve new products.

In Europe the eCTD has been accepted since 2003, when the first draft versions of the regional specification were published to complement the ICH standard. For the Centralised Procedure, the EMEA has recently published guidance and plans to make the eCTD the only acceptable format from 1st July 2009, with a stepwise phasing out of paper and other e-sub formats over the year preceding this. The eCTD is less well established in the other review procedures but a Best Practice Guide was published in April 2008 to support the use of the eCTD in the MRP and DCP procedures. The best estimates suggest that about 3,000 separate eCTD submissions have been received by EU agencies

In the US the eCTD has become well established and is also used for IND submissions as well as NDAs. Over 20,000 individual eCTD submissions have been received and the increasing numbers of eCTDs led to the withdrawal of the older eIND and eNDA formats from use from the beginning of 2008.

Japan has a limited experience with the eCTD, with fewer than 100 eCTDs received. Canada has had an active project to implement the eCTD and has received several hundred submissions. Of other countries worldwide, several have expressed an interest, but Switzerland is the only other country with an active project to implement the standard.

eCTDs and Records Management

Electronic submissions pose some questions in terms of records management. Is the record the item submitted, or the content of that item? Put another way, should we manage the CD that the e-sub is submitted on, or just the set of files that make up the submission? If we retain the submitted item, how useful is this to the potential user?

Therefore, unlike traditional paper records, where we expect to have to visit the records storage location (the library or archive) to use the information, there is an expectation that the more portable and usable electronic content can be made available across a network to a wider group of users. In doing this, we need to decide if we are making the archive record available, or a copy of that record.

The eCTD also introduces a further consideration. Previous paper and electronic submission formats tended to be fairly self contained. If there was a reference to previously submitted data then it was usual to provide a copy of that document within the later submission, rather than assume that the original could be located by the user. The eCTD specifically assumes that content will only be submitted once and that previously submitted data will be available. This means that to fully understand the submission you will almost certainly need access to all of the previously submitted eCTDs and that, on its own, the single submission may be difficult to understand.

From a records management point of view we will need to develop systems and processes that manage what has been submitted to an agency, just as we have done in the past, but that we will need to consider whether an individual record has as much meaning on its own. Therefore, we will need to seek solutions that allow the user easy access to the previously submitted data so that it can be used effectively. This may be in addition to the traditional archive record that retains a copy of the CD or DVD actually submitted.

Archiving Chemicals
Richard Pennicard – Battelle UK

Why Archive Chemicals?
GLP regulations require that "A sample for analytical purposes from each batch of test item should be retained for all studies except short-term studies". The intention here is that throughout a study and as long after as is practical, it should be possible to verify that the correct test item was used and that its purity and composition were fit for purpose. The regulations go on to state "When samples of test and reference items and specimens are disposed of before the expiry of the required retention period for any reason, this should be justified and documented. Samples of test and reference items and specimens should be retained only as long as the quality of the preparation permits evaluation." In other words highly unstable compounds need not be archived at all, and moderately unstable compounds or formulations need only be archived for their useable shelf-life, or until their assigned expiry date. Note, though, that there is an additional implied requirement to archive reference items as well as test items.

It is generally accepted that radiolabelled compounds are inherently unstable due to autoradiolysis, and need not be archived.

GMP and GCP regulations do not require samples of chemicals to be archived.

Archive Conditions
The general requirement for a chemical archive is the same as for any other: that it should be suitable for the material being archived. In practice, this usually means having at least two archives: one at ambient temperature, typically 20ºC, and a freezer at -15ºC or lower. An intermediate temperature archive may also be useful for materials that should be stored at low temperature but that are damaged by freezing. Archive security, access controls, etc. should be equivalent to those of a document archive.

Archive Procedures
Again, these should be the same as for a document archive. The archivist should be independent of study work. Unless he or she has been trained in the handling of chemicals, they should be submitted in sealed containers. There should also be an indication of any known hazard: ideally on the sample container.

Record Keeping
The same records of archiving, access and retrieval are needed as for a document archive. There should also be a record of how much material was archived, the minimum quantity required for a full evaluation, how much has since been taken for further analysis, and how much is still remaining. Any request for removing part of an archived chemical sample such that the remaining quantity would then be less than the minimum quantity required for a full analysis must be questioned closely and "referred upwards" for agreement.

Retention and Retrieval
The major difference between archiving document and archiving chemicals is that you can look at a document and then give it back to the archivist. When you look at – i.e. analyse – chemicals, however, you destroy them, so retrieval is a one way process. You need to have a way of tracking how much material is left (see above) and there should be safeguards to prevent the amount of material accidentally dropping below the minimum needed for an analysis.

Unless the archivist has been trained in handling chemicals, dispensing should be done by the requester in the presence of the archivist.

The other main difference is that there is no assumption that materials will be retained indefinitely. Chemicals are normally unstable to some extent, and generally come with an expiry date. The initial archiving period would normally be up to that expiry date. Some chemicals are so new that their stability cannot be accurately assessed, in which case it is up to the study director submitting the material to define an initial period. The initial period may be extended (or shortened) if more information on its stability becomes available – for example if it is reanalysed. There will, however, come a time when either its composition cannot be assured or it is no longer needed to uphold the compliance of the study. It can then be disposed of; as usual this will require management approval.

Summary
Archiving chemicals in principal is like archiving any other material. The same sort of procedures apply, with the addition of appropriate procedures for handling chemicals which may be of unknown toxicity.

How Not to Archive
Elizabeth Hooper & Russell Joyce

"So why is it always done so badly?"

Having just published its booklet "Guidance on the Archiving of Good Clinical Practice Material" and in doing so informed its membership about what to archive, it seemed fit that SAG should also provide some guidance on how NOT to archive.

Liz Hooper of PhlexGlobal (relieved to have finished a lengthy review of a client's legacy archive) & Russell Joyce of TGRD (Europe), look at some of the common mistakes that pepper the typical archive. It's not just the ubiquitous Christmas trees and pungent trainers that come in for criticism. "Rubbish in, rubbish out" goes the adage; if you don't need it, don't keep it. So, fresh out of the starting blocks has to be the rule "If it's worth keeping it's worth identifying properly". That in mind:

No 1
Don't use vague & meaningless descriptions such as "general", "miscellaneous", "various" or even "TMF Section 7"; fine if you happen to recall to which aspect of the trial "Section 7" refers or if you always have and always will use the same TMF structure - but surely better to describe it "Ethics Committee Approvals" if that's what the documents are about. Don't leave retrieval to chance or memory. Clearly identify and date documentation providing sufficient descriptive information to enable staff to make informed choices so that documents can be readily identified & retrieved.

No 2
Don't "black-hole". Unstructured archiving assists no-one. Use a corporately agreed classification scheme and provide user-friendly guidance to those submitting documents to the archive. Better still, engineer compliance into the archiving process by enforcing the use of pre-populated electronic archive submission forms or providing staff with input access to the archive database. This will avoid staff emptying the contents of desks into an archive box or unceremoniously off-loading day files or working copies into the archive. And make sure that non-English documents are translated; if it can't be read, it's of no value -and contemporaneous translation highlights errors in time for them to be corrected.

No 3
Don't archive non-paper items. Plastic will cause paper to sweat and has a deleterious effect on both paper and print. Left long enough, print will stick to plastic so that documents become unreadable. In the event of water ingress plastic will retain moisture and render the documents worthless. Metals, too, may rust and stain documents, so remove paper clips, bulldog clips and discard expensive & bulky lever arch files, which are invariably either jammed solid or less than full and so wasteful of valuable storage space. Rubber bands, too, disintegrate quickly and stick to paper when rotted. If documents need fastening, use archive quality envelopes or nylon e-clips. ECG records are generally printed on glossy, fax-type paper that fades quickly rendering results unreadable; transfer ECG data to a scanned image or photocopy it to preserve it long-term.

No 4
Don't archive electronic media. If it's important enough to be kept it's important to ensure its future availability. CDs, DVDs, floppy discs & videos have short life spans even in specially controlled environments so are not suitable for long-term retention. Even if these items are stored correctly, they may be damaged accidentally (and documents lost forever) or the hardware/software on which to read them is no longer available e.g. Betamax video and 5¼'' floppy discs (rendering documents time-consuming & costly to retrieve if retrievable at all). Documents retained on networks not only benefit from being backed-up on a regular basis but are also universally available at the desktop on a 24/7 basis - great for information sharing, ideal for speedy retrieval. And harking back to the point made in No 1 above, given that each CD or DVD will contain myriad documents of varying content, it is nigh-on impossible to provide a useable & meaningful index on an archive inventory.

No 5
Don't print documents you hold electronically … unless absolutely necessary. For legal reasons a hand-written, wet-ink signature may be needed and a printed copy will therefore be essential. Also if documents have lengthy retention requirements but the organisation has no digital preservation strategy and is therefore unable to guarantee future access to the document in its electronic format, again a printed copy may also be necessary. Hoever remember that electronic documents contain a wealth of metadata that is lost in printing, metadata that courts may rely upon to prove provenance, integrity & authenticity. This is particularly true of e-mails, which are often printed for archiving but which have questionable if any evidential value in British law[1]. Speak with your IT colleagues to investigate means by which to better preserve electronic data and ensure its continued accessibility.

No 6
Don't mix unrelated documents of differing classifications in the same box. For clinical trials documentation, for example, ensure that records for one compound and/or study only are boxed together and that classifications and retention times applicable to those documents match. Not only does this facilitate registration & retrieval but also streamlines review or destruction as the whole box can be destroyed *en masse* without the need to weed or re-box documents at the time of review or destruction.

No 7
Don't write on boxes sent to an archive storage contractor any information identifying the owner, sponsor, CRO, content of the box etc. A list of the contents pasted to the outside of the box is of no value when the box is stored among a million other boxes in an archive warehouse. For security & confidentiality purposes use only supplier branded boxes and ensure that boxes are otherwise unmarked except for the archive storage contractor's barcode and perhaps your own sequential box number or barcode. Taping boxes will offer protection against accidental spillage (and the possible unintentional & unreported reassignment of contents from one box to another) whilst the use of numbered security seals will achieve the same and additionally guard against unwanted intrusion to provide an auditable access record.

No 8
Don't place all your eggs in one basket by paying for a dedicated storage area in the archive storage contractor's warehouse. The best archive storage contractors will employ real-time barcode or RFID technology to track boxes; so look at storing randomly in their warehouse. Not only does this save on storage costs but again mitigates against unwanted intrusion and any loss or damage in the event of a disaster at the site.

No 9
Don't choose your archive storage contractor on the basis of price alone. Ensure that the warehouse, its environment & its procedures meet minimum standards and that you visit the site to verify the sales speak & literature. Good customer service and a mutually beneficial working relationship are equally as important as the physical attributes of the site itself, providing confidence that those charged with the custody of your organisation's documents will work with you to safeguard the documents & ensure their ready availability when they are needed.

Almost without exception staff regard archiving as a necessary evil, a chore to be undertaken with dogged reluctance because of a relocation; or to create space in cupboards; or as a retrospective, "11th hour 59th minute" activity, an inconvenience because new projects are already begun. Invariably hurried & slapdash, documents are bundled together in an unstructured mess into flimsy, second-hand biscuit boxes thieved from kitchens and presented to "the archives" with the expectation that archive staff will verify content, create order from the chaos & organise the disparate documentation into goldmines of information nuggets. Ever ready to exclaim "It ain't rocket science" we'd counter "Then why is it always done so badly?" We'll fall off the Christmas list for taking a hard line on raising standards …but given we already hold the Christmas tree in the archive –and probably the Christmas lights as well- we cannot help but revel in our self-sufficiency, confident that the festive celebrations are sorted already!

[1] Regina v Rowe & Bhatt: 2003 (quoted in Law Society Journal 100/35 18 Sep 2003) established a precedent regarding the probative value of e-mail as evidence in UK courts. ISO 15489 states that the authenticity of records should be ensured by maintaining traceability on their origin and integrity.

Spring Conference April 2008 - Berlin
Top Ten Security Threats
Norman Mortell – Agenda Security Systems

Scientific Archivist Group Top Ten Security Threats

Agenda Security Services presented the top ten security threats from the perspective of research institutions by focusing on the recommendations of MI5, the ISO27001 Information Security Management Standard, the Secured by Design Standard and the Special Branch Police suggestions at the April Scientific Archivist Group meeting in Berlin. The delegates represented many major research institutions and key suppliers and were particularly interested in data security, management and destruction issues.

Norman Mortell, Director of Operations at Agenda Security Services presented the top ten security threats suggested by the groups above and led a discussion/Q & A session.

Clearly with a diverse group there were differences and the discussion was an excellent opportunity for the delegates to discuss their own concerns and to share best practice. The delegates then completed an anonymous security survey where they ranked the ten suggested security threats and also commented upon any other security issues of concern.

The findings are in the table below with 10 points awarded to the highest threat, 1 point for the lowest threat and the comments listed by type. There were 47 responses in total which provide a good cross section of the scientific archivist community.

Scientific Archivist Group Top Ten Security Threats: April 2008

Security Threat	Score	Ranking
Data/Information Loss	9.0	1st (Highest Threat)
Own Staff/Agencies	6.8	2nd
Physical Security/Access	6.7	3rd
Lack of Training/Competency	6.3	4th
Lack of Security Awareness	6.2	5th
Data/Information Storage and Disposal	5.7	6th
Contingency/Business Continuity Planning	4.4	7th
Regulatory Compliance	4.1	8th
Theft/Fraud	3.9	9th
Extremism/Terrorism	2.3	10th (Lowest Threat)

Comments:

Staff Issues:
Lack of screening of own staff and contractors, staff unwittingly giving information away on e-mail, lack of encryption and sites such as Facebook, loss of key staff "mid job" and the danger of the whole department winning the "Lotto".

Transport of Materials:
Security concerns about the transfer to customers, use of couriers, and movement of hard copy across site and to external storage providers and also the lack of tracking of staff and data movements.

Procedures and Compliance:
Unintentional activities such as accidentally creating randomisation codes, lack of proper procedures, security needs versus day to day activity dilemma, lack of top management priority setting for how records are managed within the organisation and the need to have procedures/risk assessments in place.

Contractual Agreements:
Lack of communication/transparency in contractual agreements with third parties, consistent understanding of who is accountable for service requirements, also concerns over Intellectual Property Rights.

Physical Security:
Concerns over public and shared access, building design, needs more consideration to windows, shutters, fencing and car park barriers, building fit for purpose but not for archiving. Compliance with health and safety and environmental policies and effects can have a knock on effect on the security of a building.

Electronic Data Security:
Concerns over electronic data security and loss, IT issues such as Viruses and Trojans, backup copies of CDs, equipment failure - cannot update records, lack of traceability, lack of validation of the systems, e-archiving system validation and PAT II compliance concerns.

This survey was a valuable tool to enable the consideration of the security threats that archive facilities face today. It should come as no surprise that data/information loss was the primary concern with so many high profile data losses and breaches of the Data Protection Act recently. This is also backed up by some of the comments received where the whole supply chain security is of concern, how materials are transported and stored and compliance with recent regulatory requirements such as the recent BS8470 Destruction of Confidential Materials Standard which was reviewed at the conference.

Screening of staff still remains a concern but this screening also needs to consider third parties with access to your facilities and/or data, contractors, agencies and couriers. Everybody who handles, manages, stores or destroys your data should be screened at least to BS7858 requirements. This should be written into contracts.

Using the principles of “Secured by Design” can assist in the designing in of security processes or assist with the review of current facilities. ISO27001 is an extremely useful standard to review the security and management of information. Externally audited it also shows compliance with regulatory requirements and policies.

The survey provides the scientific archivist community and their suppliers with a useful overview of current security concerns. If you have any questions about this survey please contact norman@agenda-security.co.uk.

Spring Conference April 2008 - Berlin
Members Session Minutes

Chair - Chris Jones welcomed everyone to Berlin and opened the members session

Committee news – Chris Jones

- Chris informed the members that there were two committee positions up for election this year.
- The Chair person, 3 year period.
- Ordinary member, 2 year period.
- A letter will go out to the members in July explaining in more detail the process for standing for a committee position.

Treasurers update – Richard Pennicard

- Went through the accounts for 2007
- The 2008 budget was presented to the group.
- Looking into the possibility for payments to be made by credit card. This could incur an extra fee to cover any extra costs for payment by this means.
- Will look into the possibility of becoming a charity.

Membership update – Neil Gow

- A directory and membership card will be sent out in May this year. Next year it will be April.
- Deadline for payment for membership from next year will be by the end of January.
- The group had 124 members as of end of March.
- Please monitor the website for details.

Autumn Conference – Liz Hooper

- Autumn conference will be held in Bristol, October 9th & 10th. Cost approx £300.00
- 3 workshops will be held, Introduction to Archiving, GLP Archiving and Preparing for Audits.
- Other possible topics, GMP/GCP, Interface, Data Protection act, Divestment of products.

SAG/ICR – Liz Hooper

- The last meeting was attended by 99 people and made the SAG an excess of £1900.00 which will be reinvested in the group.
- The next meeting will be held in November 27th 2008. Cost approx £60.00.
- Members were asked for suggestions for topics to be covered.
- Details will be in the next Sagacity and on the website.

Website update – Chris Jones

- Feedback from the group on the Public area was positive.
- Content management is now up and running and can now be administered by the committee.
- Security has now been dealt with for the Member's area. – There were some issues which resulted in a delay whilst these were addressed. Each member will have their own log in username and password.
- Content for the Members area will start to be populated in the near future. Details will be available as soon as the site is ready.
- Members were asked to give feed back when the area has been populated.
- This will be a good source of information for members who are unable to attend a conference.

Recent Inspections – Open to Members

- GMP Inspection - Concentrated on SOP's.
- GMP Inspection - Systems and processes, QA paperwork.
- GLP Inspection – Archives were not inspected this time round, most facilities said the same of their Archives.
- GLP Inspection – spent a long time looking through Job Descriptions.
- GCP Inspection – last year, still waiting on the report. Others had experiences of long delays between GCP inspections and reports being issued.
- Contract Archives – Who is the nominated Archivist, is this written in the contract Archives documents.
- Contract Archives – looking at security and chain of custody documents.
- Pharmacovigilance – more active than GCP, usually inspect every two years or when they come across any evidence that needs investigating.

Conference Field Trip and Networking
Spring Conference – Berlin 2008

First Time Conference Attendee Experience Berlin 2008
Rebecca Hazell, OmicareCR

Having "volunteered" to take on the role of Archivist within our company, I soon discovered "it will only take one afternoon a month" was a very optimistic under-exaggeration! I was instantly presented with WPG's to rewrite and a system to re-vamp, this coupled with my poor lack of archiving knowledge, I admit left me scratching my head!

I was told about SAG by a colleague and quickly became a member. Armed with the booklet, Guidance on the Archiving of GCP material, I waved the paragraph around stating that "All Archivists and archive staff should undergo a level of training appropriate to their role", and found myself on the way to Berlin for the SAG Spring Conference. I was not sure what to expect really and waiting to board my flight at the fabulous Terminal 5, I kept glancing around wondering if there were fellow attendees and what they would look like. Yes, I was expecting slippers and pipes!

Arriving in Berlin, I had an interesting taxi journey to the hotel, which involved lots of map reading on the driver's side, I later found out that everyone seemed to have been taken different ways and there was a very imaginative fare structure. The hotel was very nice and after a short exploration of Berlin, I went to the bar, as suggested in the itinerary, to meet companions for dinner. After much peering at people I ended up with another "first timer" and the SAG committee (who were very good and didn't talk shop all evening). After introductions were made we headed off for something to eat and to my great relief the first course was German Pilsner and white wine, with definitely no hushed librarian tones or conversations about paperclips. Several hours later we headed back to the hotel bar from where I finally tumbled into bed, after impulsively offering to write this article – why??.

The conference started the next day, after a re-hydrating breakfast of orange juice, with an informal welcome. This was followed by the first speaker, an amusing but thought provoking talk on security threats, data security and destruction. This was followed by Investigator Archiving and an hilarious and very brave presentation called "The Initial Horror" by Nick Brown. Those of you who saw his home movie I'm sure will agree with me and his observations on the acronyms and abbreviations that are used in this industry, interviewing someone recently for a job I kept inadvertently slipping into CRO speak and was rewarded with very strange looks for my PMF and CRF.

We then stopped for lunch and I was beginning to realise that Archivists not only like German Pilsner and white wine, they are also fairly partial to food and socializing. The afternoon was spent with a visit to the Scheringhianum Museum and a tour of Berlin. The Museum trip was very informative and it was touching to hear of the tenacity of the company which struggled back three times from the brink of collapse, through the various hardships suffered in Berlin and Germany. The tour of Berlin was really enjoyable, made highly amusing by our tour guide, I really liked what I saw of Berlin, it's not a beautiful city but it was fascinating and one of the greenest I have visited. Seeing the line of the Berlin wall and how it truly divided the city really brought home the social history of the place.

Back at the hotel we all changed for the drinks reception and conference dinner. Everybody was extremely friendly and welcoming, after explaining my sorry lack of archiving expertise over dinner, I was given lots of practical and useful advice, some of which I have already implemented. The evening and the wine flowed on, I do remember a main topic of conversation being the name of the magazine, sorry Gail but I will always think of it as Saga City! The party seemed to be heading bar wards after dinner, so like any good reporter, I made my excuses and left.

The final day of the conference began with the member's session, the Committee reported to us members on what a good job they were doing and more importantly told us when we would all be getting together again. The next session was with an investigator from the MHRA who told us to expect the unexpected, there were many interesting examples of "horror stories" and made me realise my "one afternoon a month" was probably going to be the time I had left in my other company role after doing the archiving. Next was Electronic Archiving and a look at how this can be achieved using different media. Another impressive lunch was then on offer, which seemed to do a good job at topping up the low blood sugar levels caused by the excesses of the night before. The final session of the conference was a Q&A session, as SAG members do not seem too shy in coming forward there was plenty up for discussion from the previously posted questions.

After another taxi, a different route and a different fare, I find myself back at Berlin airport, which after trying to change my flight to an earlier slot and being told it would cost £550, I came to know quite intimately, in fact I was beginning to feel a bit like Tom Hanks. It did however give me plenty of time to reflect on what I had learnt from the conference. The enormity of my task had not changed, but I now realise there are plenty of people willing and happy to help and advise, so I would say the conference was definitely worthwhile for me.

Question & Answers Session Spring Conference 2008

1. **Q.** QA check of data being migrated between systems: is there any level of checking recommended to confirm the transfer? Should we follow standard sampling procedures like?
   A. The group was not aware of any standards for this type of checking. Inspectors will look for a reasonable process that assesses risk involved. To that end, many QA units use sampling by attributes, rather than the number of records, to ensure checking takes into account the complexity of the records involved in the effort.

2. **Q.** Any thoughts on retrospective validation of system for e-archiving?
   A. The key point to consider is don't try and hide things if you have validating after the system has been implemented. What regulators are looking for in retrospective validation is assessment in operational use. Can you show what evidence you have to prove the system is fit for purpose? How you can document that you have everything? In reality, you probably do not have everything you should have, but be open and honest, and document what you do have.

3. **Q.** Are their any experiences of interruptions of connecting and consequently getting corrupted files, in relation to electronic archiving in a WLAN environment?
   A. Although there is an increased use of wireless networking, this issue is equally applicable to wired networks. You need to plan for the unexpected and build contingency into your system to deal with outages. There was not much experience within the team of document corruption due to network issues.

4. **Q.** Destruction of documents under GCP/GLP/GMP: Has anybody destroyed any documents?
   A. Many companies are very reluctant to do this. The guidance available is sometimes perceived as unhelpful as it tends to leave things open ended. There is an especially strong reluctance to destroy documents that relate to products that have gone into humans. There are also examples of products that have not gone forward in their original indication, but have worked for a different indication (classic example: Thalidomide). This speaks to the key driver for extended retention- potential future business need, and potential business risk.
   Wet tissues are more frequently destroyed, they have a shorter retention period and have issues of viability.
   There is no specific position that the MHRA can provide on this topic, it is an assessment of business risk.

5. **Q.** Investigator Archiving:
   It's their responsibility, but it's in the sponsors interest. Does anybody have recommendations around how to handle the investigator archiving problem?
   A. It is in the sponsor's interest to ensure that investigators manage their records in the appropriate way. Investigators should tell the trial managers that they are not able to archive the records, however the sponsor archivist is not able to help manage or have access to these records.
   A third party provider can be used to do the archiving work, on a regular or an ad-hoc basis, which can include sending out archive boxes, packing the archived records, etc. This work can be paid for by the sponsor, so long as access rights to the records are managed appropriated.
   It is important that monitors get training on how to ensure that the investigators have the proper facilities to manage the study up front. Monitors should also consider if it is appropriate to use an investigator if they do not have the correct facilities for managing the records being produced,
   One of the major challenges in this area is in the past 3 years there has been a dramatic increase in the number of inspections that anticipate that the Sponsor ensures that the archiving is managed properly, bringing this issue into focus.

6. **Q.** Does anyone have experience of 'archiving' GLP data in a source system and how is Archivist control shown. Can it be done through awareness rather than active involvement in managing the system?
   A. The OECD archiving document is clear in terms of the guidance around this. For a record or data to be archived, it has to be under the archivist's control. The archivist must be independent of the data generating group. There are examples of pre- archive systems used in some companies (i.e., Covance). In that instance the data is retained in the pre-archive and written approval is required to move it to and from this area into an archived area. That is one way of showing control.
   Archiving of records electronically vs. paper does not mean that you treat them any differently. It is necessary to show that all archived records do not and cannot get altered in anyway.

7. **Q.** What are the GLPMA's expectations for archiving chemicals (specifically test and reference items)
   A. There is not much that can be said beyond the retention of chemicals is dependent on the characteristics of the specific chemical in question – there is no value in maintaining past the point of viability. The storage needs to be in the appropriate conditions and for as long as it is useful as a test item.

8. **Q.** Divesting and in licensing products, how do companies manage the records transferred to the new sponsor? From a regulatory records perspective, until the new sponsor holds a valid product licence and commences manufacturing the product, should the original sponsor hold on to copies (or original documents) until the new company holds a valid license?
   A. It is unusual to divest a product and not retain any documentation. The contracts and legal people should address all aspects of the transfer, and ensure this is communicated to all the appropriate parties. There are, however, usually grey areas. The key is to aim to be specific as possible and only keep what is stated in the contract.
   It can save a lot of problems further into such an effort if archivists can get involved early in any discussions, to help legal and business development staff plan the extent and nature of the transfer of documentation, in the most effective manner.

9. **Q.** Do SAG members insist that key personnel at any archiving or storage company being used by them are GCP trained?
   A. There is a minimum expectation of training in their own company procedures. The requirement for more extensive training will depend on how the service is provided. When the documents are being stored in sealed, anonomised boxes, then training on regulations affecting the contents of those boxes seems excessive. If there are specific record handling aspects, more training may be pertinent. It is important to define the requirements around the management of the archived records in the contract. Any supporting training requirements should also be agreed and documented.

10. **Q.** Do SAG members insist on archived documents to be held in a gas or non gas suppression environment?
    A. A risk-based analysis should be undertaken to ensure that archived records are adequately protected. Some sponsor companies do insist on gas preventative measures. This is not though a specific regulatory requirement.

11. **Q.** We are seeing more data on memory sticks - Is there any view on that media type?
    A. It is not desirable to store data on memory sticks for an extended period – there should be transfer to a more durable, proven medium. If a CRO is sending out information on such media to a sponsor, then the sponsor should be determine best way for the information to be transferred and stored once received.

12. **Q**. When a clinical trial is over and providing these companies have respective local filing/archiving facilities, do they gather everything at one location (and if yes, according to what criteria?) or do they keep partial TMFs locally?
    A. There is no hard and fast rule, although you must have documented procedures and follow them. It can be acceptable to leave documents locally. Ideally, there should be some tracking of the document locations to aid future retrieval. The risk is that there is no check of the quality of the documents until

such time as they are needed for inspection. It can also be acceptable for data to come back 'in house', however this can be hard to manage effectively.

Where records are held locally, it is usually acceptable for copies to be provided to other locations for inspection purposes, rather than send the original records (which introduces risk through transportation). During GCP inspections, it is possible that copies and originals may be requested for comparison purposes to test the control of your systems.

13. **Q**. What is the Inspectorate's view on interim archiving – or active documentation being held in portacabins?
A. MHRA – certainly have seen portacabins, shipping containers etc amongst other things used for archiving! The sponsor should monitor the conditions, look at where the facility is positioned, ensure that it is not near any dangerous elements, such as at the foot of a cliff with falling rocks. In addition, it is vital to ensure the data is secure.

14. **Q.** When using a third party archiving facility is it usual to avoid transportation of archiving boxes through a hub? If a hub is used, should you they insist on any additional measures?
A. The key is to demonstrate that you are in control of the data at all times. This includes the use of approved couriers, documented changes of custody, and where possible direct delivery between sites. Your QA group can be asked to evaluate the risk. Any hubs or interim storage areas should be part of the audit program. Requirements around chain of custody and what processes are used should be included in the contract with the vendor.

15. **Q.** What can be done with the data when a company has gone into liquidation and you have no contact? Can the data be destroyed and if so how long do you keep it before destroying?
A. The question to ask is "What's in the contract"? In the UK, you can check with Companies House if the ownership has transferred to another entity. National authorities may also have to be asked. All such due diligence activity should be documented. If there is no record of who originally owned the data, and all avenues have been explored there is not much more that can be practically do.

16. **Q.** How long should a company retain a relevant reading list of SOPs, these are the lists that all departments retain and wish to archive?
A. There is no regulatory requirement to keep these lists. It is recommended that details of training received, including on specific SOPs, should be maintained in individual training records. If it is not, then it is more difficult to prove that an individual is competent in a specific procedure. If you are managing reading lists as a means to show training, there could be a good opportunity to simplify your processes.

17. Q. Raw data are defined as paper printouts in addition the electronic data is also kept. Is this procedure acceptable? What is necessary to prove that both data are the same?
A. It all stems from what you define as the raw data to be used to support decisions. If it is the electronic data that is going to be used for decisions in the future, then that needs to be managed in an appropriate fashion.

Training-Education Opportunities

Archive Training Courses

The following one day courses are to be held in September 2008

Tuesday 16th September 2008
Managing and Archiving Preclinical Material (GLP)

Thursday 18th September 2008
Managing and Archiving Clinical Material (GCP)

Courses will include a mix of lectures, discussions and workshops

Each course will address the relevant and specific needs of the current GLP or GCP regulations. The program will provide guidance on the operation of a Regulatory Archive and the practice of data management. It will also clarify regulatory requirements for the structure and operation of an archive and the management of material and records.

Course Location

Qualogy's Training Centre is located in the centre of England, close to air, road and rail links. Full details will be sent when registrations are received.

Course fee - £475 Inc VAT

Included in the course

- Full set of course notes and reference material
- Lunch, morning coffee and afternoon tea
- Certificate of attendance

For further information, or to make a booking e-mail training@qualogy.co.uk

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Education – Training Opportunities
Dr Julie McLeod – University of Northumbria

A Masters qualification in records management from the comfort of your own home

Do you want to improve your future career prospects in records management, undertake some personal professional development, add to your qualifications or gain a first academic qualification but not give up your job? Studying at a distance offers you such an opportunity.

Back in 1996 Northumbria University, Newcastle upon Tyne, launched the first ever MSc in Records Management by Distance Learning, an innovative educational opportunity for records management practitioners. Since then over 100 students from all over the world have graduated from the course and have reaped many benefits from the study. Some have gained promotion within their organisation, others have moved to more senior positions elsewhere, whilst others have become consultants and many have reported significant salary increases – the largest being a five-figure salary increase when moving from one job to another!

The MSc has undergone a number of revisions, based on marketplace demands, technology developments and student feedback. Today students study over two calendar years with materials delivered through the university's e-learning portal and supplemented by selected key textbooks. Beginning in September each year, students are able to attend an optional two-day study school at the university. This introduces them to the philosophy of the course, the learning environment and the different resources available to support them during their study. It also allows them to meet staff and other students studying with them – invariably a student group identity develops as well as strong professional networks. Two modules are normally studied in parallel over periods of approximately 4 months giving students the greatest flexibility in terms of taking holiday, peak periods at work etc. Materials which incorporate a wide variety of activities, some individual, others in groups, and some involving electronic discussions, enable students to exchange ideas, discuss issues and gain a sense of progress in terms of learning. Assignments are often based on the workplace or a case study, which enables theory to be immediately applied in practice.

The first year begins with two modules that together provide firm foundations for today's records professional – Recordkeeping Principles and Managing in the Information Environment. These are followed by modules on Organising Knowledge, vital for all information professionals but often overlooked by records professionals in the past, and Data, Law and Ethics, increasingly important in today's context of doing business openly, transparently and with good governance. Over the first summer period a single module, Recordkeeping Practice, is studied that builds on the earlier principles module. Year 2 begins with modules on Electronic Recordkeeping, which covers the latest and specialist aspects of managing electronic records, and on Research Methods. The latter prepares students for the final module, the dissertation. A second optional study school is scheduled at the start of the 7-month dissertation period to support students in preparing their dissertation proposal and planning their research work which they undertake with individual guidance from an academic supervisor. The dissertation offers a chance to study a topic, either of personal interest or particular relevance to the workplace, in much greater depth. A number of students go on to publish some of the results of this work and the best are entered into a UK wide competition supported by the Society of Archivists for the best archives or records management Masters dissertation.

The programme is part of the School of Computing, Engineering and Information Sciences' portfolio, unusual in comparison with other archives and records management courses located within schools of history, arts and library management. But in the electronic environment close working relationships with information systems and computing colleagues is very beneficial. Their research, and ours in records management, feeds directly into the course content. Our aim has always been to develop quality courses and continuously improve them to meet the changing needs of the target market. Feedback from past and current students is very positive and, when the programme was reaccredited by the Society of Archivists in January 2007, the accreditation panel was extremely complimentary saying:

> "It is clear that all modules are regularly updated to incorporate the latest thinking and terminology and to use the latest texts…We particularly commend the introduction of the new module on Electronic recordkeeping which tackles the management of records born digital using digital means…All materials are produced to a very high standard and are written in a clear and concise manner which makes even the most complicated subjects comprehensible. The material is designed to challenge all students, from those new to a topic to those with more experience. There are regular self-assessment exercises placed throughout the materials, to assure the student that they are understanding what is being taught. These exercises vary, being a mixture of individual and group tasks and are well thought out….The suggested reading and links to websites is fully up to date, which is to be commended given the rate of change."

In addition they commended "the incredibly high standard of teaching materials", our research in the field and the way we make it "accessible to the students, to the benefit of the profession as a whole", our "flexible approach to distance learning, and the desire to constantly improve the student experience."

Past and current students of the course have come with different academic backgrounds and different levels of records management experience from a variety of different organisations and countries, including the public, private and not-for-profit sectors in the Caribbean, Cyprus, Denmark, Greece, Hungary, Iceland, the Lebanon, Malta, Switzerland and the USA as well as the UK and Ireland. Pictured here are some students at a study school and a recent graduation ceremony.

Without doubt studying any course part-time whilst working is challenging but from feedback and evidence of career progression and personal development, it is possible and very rewarding. If you are interested in the Masters further details and an online application form can be found at http://northumbria.ac.uk/?view=CourseDetail&code=DTDRCM6 Applications should be made by 1 July for study starting in September of the same year. To discuss specific queries you can contact:

Programme Leader Prof. Julie McLeod. Tel: + 44 (0) 191 227 3764
Email: julie.mcleod@northumbria.ac.uk

Date for your Diary
Autumn Conference – Bristol 9th & 10th October 2008

Agenda– to be confirmed

Marriott Royal Hotel, Bristol

Thursday 9th October

14.30	**Workshop A** – Introduction to records Management/Archiving - Jim Gumley of Covance Laboratories **Workshop B** – Preparing for Audit or Inspections - Peter Brummitt of Wider Perspectives **Workshop C** – GLP Update & Issues - Tim Stiles of Qualogy
16.30	Workshops finish.
19.00	Drinks Reception
20.00	Conference Dinner

Friday 10th October

08.50	Introduction & Welcome
09.00	A.G.M. and Members Session
10.15	Coffee
10.45	GCP Demonstrating 'Due Diligence' - Eldin Rammell of Rammell Consulting
11.30	An Investigator's view - Dr Daniel Rea (TBC)
12.15	The Human Tissue Act and Clinical Research - Dr Jenny Barnwell of Institute of Clinical research
13.00	Lunch
13.45	Handling Samples, Tissues and Wax Blocks - James Gumley, Covance (TBC)
14.30	Review of SAG GCP Archiving Guideline and the MHRA - OECD Archiving Guidelines Tim Stiles of Qualogy
15.15	Tea
15.30	Divestment of Products - Mary Paul of Roche Products and Chris Jones of GlaxoSmithKline (TBC)
16.15	Conference Close

Notices

SAG Conference Grant

The SAG Conference Grant, was agreed by members at the AGM in October 2000, and is now available as follows. The purpose of the fund is to provide financial assistance to SAG members who, through redundancy or some other circumstance beyond their control, would otherwise be unable to attend conferences organized by the group.

An amount to be set aside will be reviewed and decided upon by the Committee on an annual basis. The fund will be used on the basis of a written request from individual members a minimum of 2 months prior to the conference. The request must be sent to the Group Secretary and the Chairperson. The Committee will discuss each case on its merit and, if justified, will allocate a sum from the fund, based on an amount to cover an individuals conference fees only. Once the monies set aside for any one year are used up no further requests will be considered until the following year.

All applications will be treated in confidence.

POTENTIAL ADVERTISERS – PLEASE NOTE!!

A fee of £150 per Full Page will be charged for all Sagacity adverts.

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The advertisements carried by Sagacity are entirely independent of any endorsement by the SAG Committee.

Should you like to submit an article on a topic you feel would be of interest to our members, please contact the editor by e-mail **gail.dams@quotientbioresearch.com** or telephone 01933 319906

SCIENTIFIC ARCHIVISTS GROUP

Promoting Excellence in Records Management
Web Site: www.sagroup.org.uk
E Mail: saginfo@sagroup.org.uk.

MEMBERSHIP APPLICATION FORM

Full membership is open to individuals with an interest in Archiving, Document and Records Management

Please return completed registration form, together with payment to:

R Penicard, SAG Treasurer,
c/o Battelle UK Ltd,
Fyfield Research and Business Park,
Fyfield Road, Ongar,
Essex, CM5 0GZ,
U.K.

Payment can be made either by:

- Cheque (£50 Sterling) – made out to **Scientific Archivists Group**
- BACS transfer (£50*) to our Sterling bank account
- BACS transfer (**€**80) to our Euro bank account

*£55 for payments from outside of the UK to our Sterling account, to cover bank charges.

Bank details are shown below.

PERSONAL DETAILS

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Job Title	
Company Name	
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Tel No. Fax No.	
E Mail Address	
Discipline (tick those that apply)	GMP ☐ GLP ☐ GCP ☐ GPvP (pharmacovigilance) ☐ Other (please specify) ☐ ……
How did you hear about the group?	

Bank details for BACS payments

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DISCLAIMER

The information on this application form may be put on a computer database for use by The Scientific Archivist Group only. It will not be communicated to a third party.