Scientific Archivist Group Committee

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SAGACITY

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 hold 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 why not visit our website at www.sagroup.org.uk
A great place to look for some useful links to websites for Archivists and Records Managers.

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 organised by the group. The fund is a fixed amount set aside each year for this purpose. Once the money in any one-year is used up no further requests will be considered until the following financial year. The fund will be used on the basis of a written request from individual members, and will be allocated according to the number of applications received before the bi-annual conferences each year. Requests must be received by the treasurer at least one month prior to the conference date. All applications will be treated in confidence.

Welcome to new Members 2003

Susan Thomas	MARM Student
Sharon Helliwell	Cambridge Antibody Technology
Caroline Dean	Crompton Europe Ltd
Nicola Chadwick	AstraZeneca
Darren Bloore	Clinphone Group Ltd
Cathrine Blake	Covance
Mandy Coles	Elan Pharma Ltd
Amanda Coney	Alizyme
Pierrette Hodnett	QLT Inc
Eric Large	Cheshire Archive Services Ltd
Lorraine Walker	Eli Lilly & Company Ltd
Marie Wayman	AstraZeneca
Charlotte Stanyard	AstraZeneca
Cherry Key	Yamanouchi Pharma Ltd
Kate Baker	Daiichi Pharmaceuticals
Margaret Lloyd	Solbel Research Ltd
Sarah Bathers	Cancer Research UK
Kathy Smith	Medisence Uk Ltd
Verna Bull	Elan Pharma Ltd
Helen Stewart	Bio-Kinetic Europe

Letter from the Chair

As a Group we are indebted to Elaine Stott, our retiring Chairperson, for her dedication, commitment and stewardship during the 17 years that she has been with the Group. However, I am pleased to say that Elaine has accepted the role of Honorary President.

Elaine has steered the SAG through many of the evolutionary chapters of our history (which the Committee now archive!) to become an internationally respected group of Archivists.

Many of the current and out-going Committee members are truly grateful to Elaine for her encouragement and mentorship, and look forward to her continued association with SAG.

As the new Chairperson, I hope that I will continue to develop the Group to meet the growing challenges from the increasing legislation and ever changing commercial environment

We welcome our new SAGACITY editor, Anne Wragg, and we hope that her efforts will not be plagued by computer crashes which hindered our last edition.

In addition we welcome incoming members who have a huge variety of expertise and interests, your Committee looks to all members in the future to produce new ideas for developing the group.

Please do not hesitate to contact me or a fellow colleague on the Committee with your suggestions.

I look forward to meeting many of you at the forthcoming Conference in Edinburgh.

Best wishes for 2004.

Mary Paul

mary.5.paul@gsk.com

Note from the Editor

There are times when you wonder if the weekend will ever come around again, or if a particular project will ever get off the ground. I have to say, I have been wondering if I would ever get this edition of Sagacity out to all of you!

I take my hat off to all the previous editors, and now I understand why, when a willing person comes along, they are so happy to pass the experience on!!! Thanks Guys!

As you all may notice as you read on, I have played around with the layout. If anyone has any helpful suggestions on improvements in design and content, I will be more than happy to receive them.

Thank you to all the people who kindly submitted articles. I don't think I nagged but if I did, my apologies!

Now a plea for help. I need a few willing volunteers to wax lyrically with their pens and fill the next Sagacity. Topics are at the writers choosing.

Down to business—In this issue I have included information on the training and education opportunities supplied by Liverpool & Northumbria Universities, first impressions from the Belfry conference from 2 first time attendees, information on the 3 new committee members, a letter from our new President Elaine Stott and much more so read on!

Anne Wragg

Information on Committee Members Personal expenses

As all the members are aware, every member of the committee gives up a lot of free time to work on SAG issues, some committee members have very supportive managers, who allow them to use time and resources during working hours. However, the cost of attending 2 conferences and at least 2 committee meetings a year can be a little difficult to justify.

Though time is also costly, a few of the committee members are allowed time to attend committee meetings, but not financial backing. Because of this SAG reimburse the personal expenses incurred in attending the committee meetings to those individuals.

Why are we pointing this out? At our last committee meeting, this subject of expenses was discussed and complete transparency of personal expenses payments is important. We also want the SAG members who think they would like to join the committee, but know that their employer will not pay for committee meetings, to be aware that if they have the time there is an option of SAG paying the personal expenses.

If anyone would like further information on this subject please contact myself or SAG Treasurer Liz Tribe

Anne Wragg

News from the president's parlour

I must admit to being overwhelmed at the autumn conference. I knew that it would be difficult standing down as Chairperson after so many years, and it rendered me speechless, even though most of you would not be able to imagine this happening, but it did.

It is sometimes sad when things change and this will be a BIG change for me; I have been a member of SAG for 17 years; serving on the committee in various roles for 14 of them. I am proud of the fact that I have never missed a SAG Conference and thoroughly recommend them as a brilliant training ground and a means of obtaining the most up to date GXP knowledge. SAG has also enabled me to get out and about and see different parts of the country, visit other like-minded companies and have a good look around some of their archives. Over the years I have seen several changes' the biggest one, most of us have experienced, is the mergers and take-overs resulting in some companies no longer existing.

I think that the most memorable occasion has to be the first DIPLOMATS receiving their diplomas, having been with them through their training and then watching them develop, gain in confidence, and go on to fly the SAG flag.

During the early years I was so inexperienced that at my first meeting I was so confused listening to fellow members discussing the issues surrounding wet tissue storage I thought that I had come to the wrong place. As far as my experience went you threw wet Kleenex in the bin, little did I know of the mysteries of samples floating in Formaldehyde and the importance of their environment.

Next came wax blocks …well you can imagine the only time I had come across the danger of wax melting was to have a very painful procedure on the legs etc. carried out in a beauty parlour…I soon learnt!!! In my defence I had only experienced GCP procedures and there were not a lot of GCP members of the group in the beginning. I am pleased that we now have a more balanced GXP group today.

I have now come to the bit where I want to thank you all for the beautiful flowers and the gift vouchers that you gave me to commemorate my stepping down as chairperson. I am afraid that I was unable to voice my thanks, at the time, as I was very emotional but I really did appreciate them…

Thank you.

Last but certainly not least I was so grateful and honoured at SAG bestowing the honour of making me the president. It really means a lot to me as you can imagine SAG has been a large part of my life for the past 17 years and I feel privileged to have been able to share these times with you. I, as all the members that have served on the committee, have given up lots of time and effort in making SAG as successful as it is today and I must say that it has been willingly given, but, I do urge you to support your new chairperson and the committee as they really do work hard on your behalf…it is not easy to try to please the majority most of the time!!

I will close now and send you my good wishes for 2004 and hope that you all have a happy and restful Christmas.

Elaine Stott
SAG President.

SAG Members Session and AGM – Autumn Conference 15-Oct-2003

The Annual General Meeting (AGM) of the Scientific Archivist Group (SAG) was incorporated into the members session which took place at the Autumn conference at the Belfry.

Elaine Stott - Chair, welcomed everyone and opened the session stating that nominations had been invited and received for the Committee positions up for Election. Elaine also informed us that this was to be her last Conference as Chair as she was standing down due to her retirement from AstraZeneca at the end of February 2004.

Those nominated for election/re-election are listed.

Position	Nominated	Proposed	Seconded
Chair	**Mary Paul**	Elaine Stott	Alan McQuitty
Vice Chair	**Alan McQuitty**	Elaine Stott	Mary Paul
Membership Secretary	**Stuart Hatcher**	Elaine Stott	Anne Wragg
Conference Organiser	**Liz Hooper**	Mary Paul	Stuart Hatcher
European Liaison/SAGACITY	**Anne Wragg**	Elaine Stott	Mary Paul
Secretary	**Michelle Asson**	Elaine Stott	Anne Wragg
Ordinary Member	**Laura Logie**	Anne Wragg	Mary Paul
Ordinary Member	**Christine Morris**	Tim Stiles	Mandy Flynn

The three newly elected Committee Members (Christine, Laura and Michelle) introduced themselves to everybody by giving a brief synopsis and said they were looking forward to serving on the Committee and hoped to actively contribute to future meetings.

A request was noted that the **Membership Secretary, Stuart Hatcher** update the membership database with names, addresses and telephone numbers to reflect the appointments to the Committee and changes in SAG Membership.

Apologies were received from **Mary Paul & Liz Hooper** about the quality of the September 2003 issue of SAGACITY along with an explanation of the publishing problems encountered which resulted in it's delay being issued.

Liz Tribe - Treasurer, reported that the Euro Account was now set up and running and that the Groups account balance was healthy and had been audited. The audited end-of-year accounts are available from Liz.

Ideas had previously been invited on how some of the account funds could wisely be utilised to advance and promote SAG. Liz informed us that Microsoft Publisher had already been purchased for the production of SAGACITY.

Additional suggestions received were that the Group research the costs and look into purchasing their own equipment (Laptop, OHP etc.) It was felt that investing in such display equipment would give SAG a more professional approach and also assist presenters and presentations at future Conferences and Committee Meetings. It was put to a vote and with 100% show of hands was agreed.

Richard Pennicard – Website Co-ordinator, informed the session that the presentations from the Dublin Conference were still not publicised on the Web and that his imminent intention was to ensure that it would be available ASAP and that he would also include the presentations from this Conference at the Belfry.

Richard also reiterated the SAG E-Mail address ***saginfo@dial.pipex.com***. Members were asked to contact Richard by E-Mail if they were experiencing any problems with access to the web or needed their passwords. He also invited any future suggestions for improvements.

Jim Gumley – Ordinary Member gave a light-hearted and enjoyable presentation on Conference Trends – 2 vs 1 per year.

Alan McQuitty – Vice Chair (newly elected), gave an update on the SAG records that he is preparing for archiving.

He currently has 7 boxes which cover the period 1981 to date. Archive material includes Minutes, Accounts, Brochures. DIPSAM, Diploma Training etc All of which are included on the retention schedule which has also been produced listing specific document types.

Datacare is the Company that SAG will be using and documentation authorising the transfer and recall of data to and from them will be produced and implemented end of Autumn 2003. (post meeting note – this is now complete).

Elaine Stott – Chair (retiring), asked members if there had been any recent inspections within their companies. The following members gave a brief feedback to the group.

Recent GMP Inspections

MDS Pharma Sophie Cros
Yamanouchi Anne Wragg

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SAG Members Session and AGM – Autumn Conference 15-Oct-2003

Recent GLP Inspections

Vericore	Laura Logie
Eli Lilli	Russ Appleton
Covance	Jim Gumley
AstraZeneca	Michelle Asson
Quintiles	Elizabeth Curran

The members were also informed that there is a new GLP Inspector, Mr Andrew Gray who was present at some of the GLP inspections.

Mary Paul – Chair (newly elected) thanked Elaine for all her hard work, commitment and dedication shown towards the Committee and the support she has given to all past and current SAG Members.

Michelle Asson - Secretary

New Committee Members

SAG SECRETARY – Michelle Asson

Michelle started her career working as a Legal Administration Assistant for BP Petroleum Development Ltd., East Yorkshire.

A couple of years later she moved to Cheshire where she spent a short period working for an Agency

In 1989 she joined ICI as a temporary member of staff and then permanently as a GLP Administration Officer within Safety of Medicines.
Since then she has seen the company demerge and form ZENECA Pharmaceuticals and then merge with the Swedish company ASTRA.

Michelle is currently an Information Associate for Documentation, Records and Archives Group, Safety Assessment at AstraZeneca UK Ltd.

Since 1989 she has been involved with every GLP Inspection conducted within Safety Assessment and Drug Metabolism & Pharmacokinetics apart from one to date.

Michelle became a member of SAG in 1998 and at the Autumn Conference 2003 was elected Committee Secretary

Laura Logie

After many years travelling with her family, attached to the forces, Laura returned to full time education in 1993 to renew her administration skills.

In 1996 Laura joined Grampian Pharmaceuticals (now called Vericore – a subsidiary of Novartis Animal Health, Switzerland), as a part time office assistant. A year later Laura became the full time secretary in the Research & Development laboratories, producing all documentation for 13 scientific staff.

Laura took over the role as Office Administrator/Archivist in 1999 and her first duty as archivist was to overhaul and revamp the archives to become GLP compliant. Laura has an appointed deputy to assist her with the archives and she still produces all documentation for the scientific staff in the R&D laboratories.

Laura is also Health and Safety Officer for her department, and is still continuing her personal development by studying for an Advanced Diploma (open learning) in Administrative Management through the Institute of Administrative Management.

Christine Morris

Christine has over sixteen years experience of working within records management as a Regulatory Archivist in organisations working in compliance with GLP and GCP regulations.

Since joining Qualogy she has established their dedicated regulatory contract archive service. The systems and procedures introduced by her have been designed to meet the current requirements of Good Laboratory and Clinical Practice.

In her current role as Archivist, she has total responsibility for the operation and management of the archive services of Qualogy.

Before joining Qualogy in July 2001, Christine was the Archivist for a large international CRO. In this role she was responsible for the retention of GCP, GLP and GMP documentation and electronic records for many hundreds of studies in addition to the company records.

Working with a staff of nine she managed a very large archive with over four miles of shelving containing paper, slides, samples, microfilm and computer records. All being maintained to the standards required by the regulatory authorities.

In her role as Archivist she has experienced regulatory inspections from the United Kingdom, US FDA, US EPA., Korean and Japanese authorities in addition to many audits from study sponsors from around the world.

In 1996 Christine obtained the Diploma in Scientific Archive Management from Anglia University.

She has been a member of the Scientific Archivists Group (SAG) since 1989 and has served on the groups training committee.
Christine is also a Member of the British Association of Research Quality Assurance.

SAG CONFERENCE AT THE BELFRY: 15 and 16 October 2003

(or 'Flying the Flag for SAG at the 18th Hole')

by Catherine Blake (Covance Clinical Research Unit)

When, upon my arrival at Covance in the Summer of this year, my Managers kindly offered to enrol me in SAG. I was bemused and as a newcomer to Scientific Archiving I wondered "is it time for liposuction?"

Fortunately, they informed me that SAG was the Scientific Archivist Group and was full of like minded people all of whom worked in the field of Archiving and Records Management. It would be an opportunity to learn more from people who had experience in the field and hopefully, make some pals at the same time.

As time went past I began to hear tales from Jim Gumley at Covance Harrogate about the Dublin conference and the next thing I knew I had been offered the chance to go to the Belfry. My first ever conference and the opportunity to make my Dad (a golf enthusiast) incredibly jealous, I jumped at the chance.

After an easy journey I arrived at the Belfry, and more beautiful surroundings would be hard to imagine. So near to motorways, yet completely secluded. I checked into my room straight away aided by friendly and helpful staff (as they all were for the whole stay) and got ready for the main event.

Upon entering our conference room I was met by a friendly face- Jim- and having collected my name badge began my first attempt at networking. Within minutes I had met Betty from Quintiles who put me at my ease and my nerves evaporated. Joined by other friendly delegates we sat (with our free pens and sweeties) ready for the first speaker.

Richard Pennicard, who stepped in at short notice for P.P Joannou, gave us a talk on 'Preparing for a GLPMA Inspection'. His tips on dealing with an audit will be most useful not just for GLP archivists but GCP people such as myself, and I will certainly be prepared for those inspectors when they arrive. I must also add how well Richard did, stepping into the breach. I take my hat off to him.

Tim Stiles next, on behalf of Qualogy, and a look at 'Clinical Investigators – The Paper Nightmare' (or the plans for his next holiday). It was great for me to hear about GCP and responsibilities from the Investigators point of view. The duration of storage issue certainly gave me food for thought, if we have to retain data for up to 40 years where will it go? David Browne (another last minute speaker) led us up to lunch with his talk on 'Electronic Archiving and the New Guidance on 21 CFR Part 11'. Electronic archiving is not something I have had a great deal of experience with so far and David gave a great insight into the issues around 21 CFR Part 11. He was also very entertaining and I'm sure I'm not alone in wondering how he managed to get such an impressive (and amusing) presentation together so quickly.

A marvellous buffet lunch and plenty of time to chat fortified us for the afternoons AGM and a talk from Pamela Charnley Nickols.

At the AGM I put faces to names and learnt a little more about SAG. Jim Gumley gave a presentation about the Group and it's functions, how members benefit and made several mentions of Guinness (which aroused jealousy in those of us who didn't attend Dublin).

Pamela Charnley Nickols raised many important issues. The difference between 'Essential' and 'essential' certainly piqued my interest, GCP guidelines may be clear but we still need to look beyond section 8. Also, the common inspection findings have prompted me to pay particular attention to our audit trails. Plenty of insight into the retention and destruction of data came in very handy, as it is relevant to my work at the moment.

All in all, an informative and interesting day. The speakers kept our attention throughout and there was something for everyone involved in Archiving and Records Management.

In the evening the drinks reception gave us the opportunity to speak to those we may have missed and catch up with those we already knew. There was a light-hearted atmosphere and I was made to feel at ease throughout. Dinner was marvellous, three courses of mouth-watering food, beautifully presented, and plenty of wine.

A moment of sadness as Elaine was presented with a gorgeous bouquet at her last conference as Chairman (it was nice to meet her in her official capacity as Chairperson and I am sure I will meet her again as a fellow SAG member).

Those of us who weren't too tired (and some who were) headed off to the Bel Air nightclub for a bit of a dance and a small sherry. Let's just say, "a great night was had by all".

Day two and, after a much needed cup of tea and enormous breakfast, it was off to the workshop.

I can only comment on the GCP workshop I attended, but Joan Perou passed on to us a great deal of very important information, which was clearly only the tip of the iceberg where her knowledge of GCP was concerned. The new guidelines due on 1 May 2004 will affect us all but anyone working with GCP would benefit enormously from a chat with Joan. After giving us the benefit of her knowledge we were still asking for more and her notes will be invaluable for May next year.

So, what can I say? "Far too much", I hear you cry. My first conference was a great learning experience and utterly enjoyable. I met some great people, learnt a great deal from experts in the field of records management and stayed in a beautiful hotel with marvellous food. I was made to feel welcome from the start and I have all you SAG members to thank for that.

My first conference is only just over, and I'm already looking forward to my second.

Archiving: Preparing for a GLPMA Inspection

Aggi Joannou Battelle AgriFood Ltd

An Archive is a fundamental requirement for a Test Facility in order for it to become GLP compliant. This article will give some ideas on preparing for a GLP Inspection from the GLPMA that are based on my own experiences over eight regulatory inspections – ALL from the same inspector!!! These include regular inspections, facility close down inspections and a new facility start up inspection. I have also conducted sponsor audits of other test facilities and I will include some of these experiences in this article.

Most of this article, particularly the parts concerned with planning and preparation, is concerned with preparing for routine GLPMA inspections. However, the parts on conduct during an inspection are relevant to unannounced visits as well. An inspector's expectations will be higher for visits that have been arranged in advance – he/she will expect to see the facility working at its best, which doesn't mean that he/she will accept low standards at other times; one important principle is to be prepared for an inspection AT ANY TIME.

Many of the principles behind preparing for GLPMA inspections apply to all parts of the facility, and the examples here include incidents that are not directly concerned with archives, but which illustrate points that do apply to them.

For most part, a regulatory inspection will be organised through QA, who might very well cover all the points that are raised in this article. However, you can be proactive even if QA have thought of everything, and you may take pressure off them at a time when they are most likely to be under stress.

Larger organisations within the UK GLP Compliance Programme have been asked to supply a pre-inspection dossier for review before the Inspector arrives. If you have been involved in this process you may have been asked by QA to provide Archive floor plans, list of the relevant procedures for the archives and an organisation chart showing the reporting relationship of the archive to management.

If you have not been asked for these details for a pre-inspection dossier, then get them prepared because the Inspector will want to see them and give them to the Inspector on his arrival. Sometimes QA will prepare a dossier and give it to the Inspector at the Opening Meeting.

It is also worth noting the value to management of the archive being represented at the opening meeting, as it may be possible for them to arrange a time for the Inspector to visit the archives at this meeting. Any advance warning of when the Inspector is due in a specific area is always welcome! The inspection is likely to include the archive early on in his visit as he will normally want to look at archived data during his inspection, either in the archive or, if this is permitted by your procedures, on loan.

I recall one particular inspection where we left the schedule completely open for the Inspector to decide where and when to go which resulted in one department being left on tenterhooks for 3 days waiting and waiting and waiting until the Inspector finally walked in.

It is very important to arrange a meeting with QA to discuss the Inspection, as QA are usually the central focus of the Inspection and are usually involved in the preparation of the Inspection. QA should drive the preparatory work, but as I said, if they don't you can score brownie points by taking the initiative yourselves.

Find out how the inspection will run and tell QA of the staff availability for the archive. Suggest to QA the best possible time for the Inspector to visit the archive based on staff availability – and that doesn't mean when nobody's around! If everybody is around, there will be lots of help to retrieve materials.

Decide who will be involved from the archive area. The archivist and or the deputy(ies). Will the manager of the archive area be present? In any event, it should be the archivist that takes the lead role. In an early inspection during my career, the manager of the archive area decided to join us when the Inspector went to the archive. It soon became clear to the Inspector by what the manager was saying that he had never ever been in the archive and didn't know anything about it. That didn't leave a good impression with the Inspector, who suggested, to the archivist's joy that the manager needed to get more involved with and be more committed to the area he was responsible for.

Finally discuss with QA any outstanding compliance issues and arrange for them to conduct a final facility inspection (official or unofficial) as a dummy run to the inspection.

Look back over the previous inspection report to see if there were any adverse comments regarding the archive area. If there weren't any comments don't get complacent and believe you will ok this time around as well. Past history, especially a good inspection, counts for little. In one inspection, our research farm had "no previous form" and the department thought this inspection would be just as straightforward and so did few preparation checks. When the Inspector arrived he had a "field day". Believe it or not he opened one freezer and found a dead woodpecker in an unlabelled bag. The Inspector said, "What's this" and got the reply "It's a dead bird" "I know it's a bird and it's dead but what is it doing in the freezer with GLP samples". "Oh, we liked the colours and decided to keep it"

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Archiving: Preparing for a GLPMA Inspection

Aggi Joannou Battelle AgriFood Ltd

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the scientist replied. Suffice it to say that he reported back to management that the area had significantly deteriorated since the last inspection. He didn't mention the woodpecker in his report but we did get a critical observation for our freezer procedures.

If there were adverse comments from the last inspection, then there would have been an official reply of corrective actions. Check that the corrective actions have been put in place and you did what you said you were going to do. If you didn't do that and you ended up doing something else, prepare your reasons and some examples to show the Inspector. Check that all of the corrective actions been completed? If not why not – again prepare yourself.

Finally review any compliance issues raised by your QA in their inspections of the archive area. Again go through the QA comments and any corrective actions in the same way as with the official comments from the last inspection.

Check that your documentation is up to date and in particular that your SOPs are current and reflect your working practices. In one inspection, an area was found to be working to a draft SOP as a result of an over-zealous individual who thought that it was better to have something in draft than nothing at all. The Inspector criticised this as a breakdown in the SOP system, but we managed to persuade him this was an isolated incident and that the department normally only worked to authorised documents. As laboratory work had already been conducted under this draft SOP, we had to retrieve the offending draft from back-up tapes and place a copy of it in the study file and in the archive with a covering note! We then issued the SOP in the normal procedure.

Review your archive index and ensure that all your information is up to date. On one occasion I went to visit a sub-contracted laboratory and asked to see some of our data from recently completed studies. The studies were on the master schedule as completed and archived, yet when I requested one study – they couldn't find the data! They looked everywhere. In the end we left the laboratory and they still had not found the data. By the time we drove back our place of work there was a fax waiting for me stating that they had found the data in the archive and copied some pages to prove it. Irrespective of whether or not I believed them that the data was in the archive, I was not impressed with their systems. If they knew we were coming some 2-3 weeks beforehand, why didn't they check to ensure that all our data could be readily retrieved from the archive?

Arrange with QA for a final inspection of the archive as a dummy run for the inspection. Remember to record your entry in the archive entry log, as on one occasion the Inspector visited the archive and carefully watched what the deputy archivist was doing. The deputy archivist, being very nervous, let us into the archive and proceeded to retrieve the material that the Inspector had asked for. Immediately the Inspector said "Ah, I see you are not following your procedures" and the deputy archivist got even more flustered not knowing exactly what she had done wrong. The Inspector gleefully informed her that her SOPs required her to fill in the archive entry log. In this instance the Inspector didn't cite the incident in the report but it did make him question whether the deputy archivist was fully trained.

Check the fabric of the building, particularly if it is in an area which is not visited regularly. Make sure you do this on the day of the inspection as it would be embarrassing to take the Inspector to the archive and suddenly find it had just flooded.

Finally run through your normal practice of archiving and retrieving material, with your SOPs to hand and check that what you actually do is what is written in the SOPs. Too often an SOP is written and the procedure looks good on paper but it is not workable and therefore not adhered to. In one case we had written in an archive SOP that temperature and humidity in the archive would be regularly monitored, and quoted the conditions for temperature and humidity in the SOP. However, it turned out we were only measuring and recording temperature, because we didn't have a hygrometer in the archive to measure humidity. So we weren't compliant with our SOPs. This can be a particular problem in new facilities. The SOPs must reflect what you are doing at the time, not how you plan do things when all your systems are up and running. In the case above, the Inspector did accept a note, authorised by management, to permit the archivist to record just the temperature until we were able to obtain a hygrometer.

As part of regular QA facility inspections, your QA should be testing your procedures to see if they are working and that you are compliant. If they don't do this ask them to do it as part of the dummy run. Or even between the archivist and deputy, select some material from the archive index and see how well the other can find it. Its important to demonstrate that you are organised and efficient and you know exactly how to find material.

This is particularly important if archiving is only a minor part of

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Archiving: Preparing for a GLPMA Inspection

Aggi Joannou Battelle AgriFood Ltd

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somebody's job. Check that every archivist and deputy can do the basic archiving jobs – remember you have one chance, and if you are ill and can't be there, you need to be confident that your staff can do the job instead.

Also it is important to periodically check the quality of the stored material. Once a study director passes over their study material to you for archiving, then you are responsible for the quality of that stored material.

I recall on one occasion we had transferred wax blocks and slides from one part of the archive to another area, but the quality of the specimens wasn't checked. When the Inspector asked to see some histological slides, the archivist opened up the relevant drawer and found half of the slides were cracked and broken! With this in the Inspector's report we had to catalogue the broken slides and document the impact of the lost slides on the validity of the report and the claim of GLP compliance. Fortunately, and in our defence, there were spare wax blocks from which the histologists could prepare more slides if needed and the Inspector accepted this reasoning and upheld the compliance of the study.

Check your back-up procedures for electronic raw data and in particular the routine exercising of magnetic tapes. What provisions have you made for system retirement? Even if you do not have a fully operating system in place, you should be able to demonstrate that you are aware of the situation and are taking steps to address it.

Naturally, everyone is anxious that a regulatory inspection goes well and so people become nervous when the Inspector is around. Try and be honest, positive and confident with the Inspector, don't be afraid, but don't get flippant or antagonise the inspector. In one inspection, the Inspector opened a cupboard in a laboratory and found an unlabelled volumetric flask containing a pale blue solution. "What's this?" said the Inspector. "Copper sulphate solution that we made up for a local school" came the reply. "I can see its probably copper sulphate, but it's not labelled" said the Inspector. "Well if you realised it is copper sulphate, why did you ask" said the scientist. At that point the Inspector got very angry and proceeded to criticise every little thing possible. Needless to say the scientist was later reprimanded by his management.

Remember also that if the Inspector asks you a question, he expects you to answer it, not QA or your manager. Try to give an informative answer; one that doesn't invite further questions from the Inspector. The more information you can give, and the less the QA have to add, the more impressed the inspector will be. However, don't waffle. If you can't answer a question, be honest and say so.

On another occasion the Inspector opened a fridge door and found half a Mars bar along with the samples. "What's this doing here?" asked the Inspector. "Well you see that's an important part of our daily routine" was the reply from the scientist. "I appreciate it might be the highlight of your day" said the Inspector "but you shouldn't keep this in with GLP samples" joked the Inspector. At this point I was able to intercede and explain that it was used for the mouse traps out in the field and not used for human consumption.

Finally my advice is to you is to prepare as much information as possible to have at your fingertips, so demonstrating you know what you are doing, giving the Inspector confidence that the stored material is in safe hands.

It is generally part of QA's remit to prepare and run the GLP Inspection and to escort the Inspector around the facilities. However when they come to the archive, then QA would expect the archivist to lead the Inspector around the facility and to explain your working practices. As I said earlier, prepare and practice with your colleagues how to tour the facility, in which order to take the Inspector around and what you will show the Inspector when you explain your daily practices.

Generally the Inspector would start off by asking "Talk me through what you would do when you receive material from a study director". Remember that the Inspector will have already read through your SOPs before coming to see you, so will be looking to catch you out. That's why it's important that you have checked your SOPs against what you actually do.

Gaining a GLP certificate is part of a team effort, and you as archivists have a very important role to play to persuade the Inspector that regulatory material is stored safely without deterioration, and that it can be readily retrieved. All too often the archives are given very little consideration by management and in particular the importance of a good archive seems to be lost on management. I have seen a number of facilities where the archives comprise of one or more filing cabinet with no consideration to the fabric of the room, nearby water pipes or other activities which could represent a fire hazard.

As archivists it is your duty to ensure that management are aware of these issues and that you can demonstrate to any inspector that material in your possession is safe.

Aggi Joannou

The Eli Lilly Page

SAG Conference at the Belfry, Warwickshire - 15th & 16th October 2003 by Lorraine Walker

I joined the Scientific Archivist Group in July 2003 and was really looking forward to attending my first conference at the Belfry Hotel. I set out in plenty of time with a calculated journey duration of 2 hours, however, 3½ hours later after a terrible journey on the M6, I finally arrived hot bothered and a bit flustered.

I was fortunate that also attending this conference was a couple of my work colleagues who are already established SAG members, Alan McQuitty and Russ Appleton. They both introduced me to some of the other members and I soon felt at ease and relaxed and part of the group. I feel that conferences like these are a great opportunity to share experiences and advice with people with similar professional interests, which can be invaluable in a group like SAG.

Both days went so quickly and all of the topics covered where vast, informative and varied. There were also open discussions relating to suggestions for future conference topics and ideas for SAG improvements. All suggestions and views from the attended delegates where welcomed and acknowledged.

The aim of SAG is to encourage the exchange of knowledge relating to archives within scientific and associated disciplines. This was why I initially became a member of SAG and was what I certainly experienced at the Belfry conference in October.

It is nice to think that I now form part of this experienced and knowledgeable group and I will be looking forward to meeting some more members at the next conference.

MANAGING SAG RECORDS by Alan McQuitty

Why do we need to manage our records? As records management and archiving professionals we need to manage the records produced by the Scientific Archivists Group as professionally as if they were produced by our own organisations. The benefits of doing this are:

1. To provide an historical record of the groups activity

2. To have on record the actions taken and decisions made by and on behalf of the group

3. To show that we practise what we preach.

My role on the SAG committee is to be responsible for managing the records produced by the group. To achieve this goal a records retention schedule has been initiated in which –

Each function within the roles and responsibilities of the group has been identified

Record types within these functions have been classified

A process for indexing each record type has been initiated

A retention period has been agreed for each record type to meet business, regulatory and legal requirements.

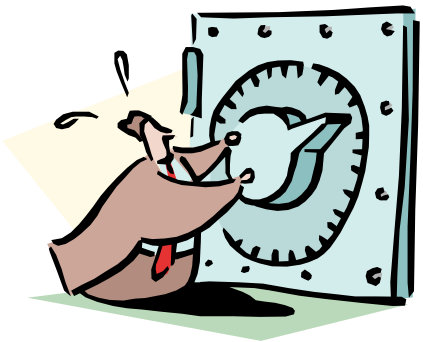
In addition, an MS Access database has been set up which incorporates all of the above criteria and will enable all records archived by the group to be identified.

The last 18 months have been spent reviewing and processing records produced by the group in preparation for their subsequent storage at an approved off-site storage company. Using the criteria detailed above each record has been categorised into business function, record type and retention period.

Several off-site storage companies were asked to submit quotes for the storage and retrieval of the group's records and Datacare, at Upper Heyford in Oxfordshire, were selected as the preferred vendor.

The contract was implemented last autumn and the first SAG records were transferred to Datacare on 19th December 2003. The contract allows for the records to be retrieved from Datacare for use by the Group under strict authorisation by approved committee members, thus ensuring the integrity of the SAG records.

Now that the process is under way, records will be transferred to Datacare on a regular basis and the MS Access database can be revised to incorporate new business functions and record types as and when required. Your committee feel that this is a great step forward in the way SAG is run.



Training Courses

Gaining experience and knowledge through training is important to all professional Archivists/Records Managers.

Members who attended the conference held at Crewe Hall in 2002 and received the February 2003 Sagacity will remember that Margaret Proctor, Assistant Director of Studies at the University of Liverpool gave a very informative overview of education and training programmes available at Liverpool.

The following is taken directly from the University of Liverpool web page and explains what the rm³ partnership is.

"**The rm³ partnership**
The rm³ partnership is a consortium of two of the leading records management educators in the UK: the University of Liverpool and Northumbria University. This partnership offers a uniquely complementary set of records management experience and teaching skills and is the first collaboration of its kind in the UK.

The programme

The programme enables participants to gain or develop knowledge and skills in records and information management through either a set of short courses, or by registering for the Diploma/ Certificate in Professional Studies: Records and Information Management. The programme, which started in 1999 was developed in consultation with the Public Record Office. It is suitable for those working with government records and information at any level who would like to:

? gain an introduction to one or more records or information management topics
? enhance and deepen existing skills or knowledge in the field
? acquire a university accredited qualification

While primarily aimed at government records staff, the programme is suitable for most people working within a public sector records management environment"

More information on all the educational opportunities are available at:
http://www.liv.ac.uk/lucas/index.htm

Courses are being held at both Liverpool and London, the London course were to be held at the Public Records Office in Kew but have been moved to the HM Treasury. The 2004 courses finish at the end of June.

Thought this article has been based on the rm³ partnership, I'm sure that there are other courses and day training sessions out there somewhere.

If any member finds information on Training and education opportunities, don't keep it to yourself, share the information by e-mailing the committee or by putting up a comment on the Member section on the SAG web site.

Anne Wragg
Sagacity Editor.

Training dates and Subjects

14th Jan 2004
Principals of appraisal
London

15th Jan 2004
Archives and permanent preservation
London

9th March 2004
Legal issues
Liverpool

12 March 2004
Records surveys and scheduling
London

16 March 2004
User services and user relations
Liverpool

26 March 2004
Principles and tools for managing records
Liverpool

1 April 2004
Information and communication technologies
Liverpool

29 April 2004
Introduction to records and information management
London

6 May 2004
User services and user relations
London

12 May 2004
Archives and permanent preservation
Liverpool

24 June 2004
Principles and tools for information storage, retrieval and access
Liverpool

30 June 2004
Electronic record keeping
Liverpool

21 CFR Part 11 reinterpreted - the new "Scope and Application" guidance from FDA

- Joe Kennedy, Tempis Software Ltd.

Introduction

Since its effective date of August 20th 1997, 21 CFR Part 11 has surely been the most misunderstood and expensive piece of pharmaceutical industry regulation ever. It has spawned a sub-industry of consultants and solution providers, and yet until recently, consensus on interpretation and implementation was non-existent. FDA has begun to address the problems with the regulation, and has recently issued a guidance document to clarify its attitude to Part 11 compliance while this process is underway.

Joe Kennedy is an independent IT professional specialising in the pharmaceutical manufacturing sector since 1997. Originally a systems analyst on a bespoke ERP system, Joe moved into Regulatory Compliance in 2000 specifically to work as a technical liaison for the 21 CFR Part 11 project, and soon moved into policy formulation and interpretation for Part 11. Joe's work has formed the basis for the corporate strategy for Yamanouchi group companies worldwide. More recent projects include general computer systems validation (CSV) and IT Network Infrastructure qualification.
Joe can be reached at *joe.kennedy@tempis.com*

What is Part 11?

At its most basic, Part 11 is a regulation that applies to pharmaceutical companies operating in, or exporting to, the US market. It describes a minimum expected standard for computerised systems used to maintain records required to demonstrate compliance with US Federal Regulations. The rule deals with two primary areas: Electronic Records and Electronic Signatures. Structurally, the rule is divided into three subparts as follows.

Subpart A (General Provisions)	Includes a scope statement, which has been the subject of a recent clarification by FDA in its final "Scope and Application" guidance.
Subpart B (Electronic Records)	Requires measures such as… l Validation of systems l Audit trails l Limited and controlled system access l Education & training for users and developers l Document control l Encryption where a system is "open" l Provision of data in portable formats to facilitate inspections among others.
Subpart C (Electronic Signatures)	Subpart C contains what was originally requested by industry to FDA, that is, the ability to sign a mandated record electronically. This Subpart is relatively straightforward, although some debate regarding interpretation still occurred. Among the requirements of Subpart C are: l Secure and non refutable electronic signatures l Certification to FDA of intent to treat electronic signatures as equivalent to handwritten scripted signatures l Flexibility in interpreting what constitutes an electronic signature; can be a combination of username, password, tokens/cards, biometrics etc. l Controls for managing passwords associated with electronic signatures such as loss management procedures and password aging l Reporting of attempts at unauthorised usage

Most attention has focused on subpart B, as it has proved the most difficult to interpret and implement. Indeed the recent scope and application guidance has focused on those provisions of Subpart B which were causing the most difficulty.

Part 11 chronology

1990	Pharma industry requested FDA approval to use electronic signatures
1992	Advance notice of proposed rulemaking (ANPRM) published
1994	Proposed rule from FDA published in Federal Register
1994-1997	Industry responses to draft ruling
1997	Final rule, effective date August 20th
1999	Clinical trials guidance published CPG for field inspectors made available under FOI
2000	Focus on Part 11, post-Y2K
2001	Glossary & validation guidance documents published (draft)
2002	Timestamps, maintenance/archiving, e-copies guidance documents published (draft) ISPE Part 11 white paper FDA announce new GMP initiative
2003	Feb 4th: E-copies guidance withdrawn Feb 20th: Scope and Application draft guidance, all other guidance withdrawn Sep 3rd: Final Scope and Application guidance published

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Problems with Part 11

A review of the popular 21cfrpart11.com email discussion list should be enough to convince of the need for a rethink of Part 11. Virtually every line in the regulation has been debated exhaustively (and inconclusively). Some of the problems are outlined below:

- Scope: By far the most common question posed is: *Does (System X) need to comply with Part 11?* This points to a need to restate and clarify the scope of Part 11.
- Interpretation: The delay by FDA is getting guidance out meant that the vacuum was filled by local "interpretations". Most companies documented what they understood Part 11 to mean, and complied with that. Again this points to a flawed, ambiguous regulation.
- Industry and FDA representatives "talked up" Part 11. FDA later acknowledged: "some statements by Agency staff may have been misunderstood as statements of official Agency policy". This is referred to as "podium advice", i.e. advice given by FDA staff under pressure at conferences and workshops.
- There were cases of inconsistent interpretation between FDA and its own field offices.
- Enforcement was low, therefore there was a small base of official opinion on which to base interpretations.
- The rule discouraged the use of electronic technology rather than benefit from technological innovations. Many firms reverted to paper based systems, especially for marginal systems where the benefit from computerisation was less. Also affected were smaller firms lacking the resources to run huge Part 11 compliance programmes.

The "Scope and Application" guidance

This document was published in draft in February 2003, with the final version posted on September 3rd 2003. It marks a major change in direction with regard to Part 11 by FDA. In the document, they state that they are embarking on a re-examination of Part 11. While the re-examination is ongoing:

- Scope will be interpreted narrowly, that is fewer systems will be subject to Part 11
- Enforcement discretion will be exercised for certain nominated Part 11 requirements
- Enforcement discretion will be exercised for legacy systems
- Predicate rule requirements will still be enforced

Narrower scope

Part 11 was initially intended to apply only to systems used to maintain records explicitly required to be maintained, in fact this is stated in 11.1(b) of the published regulation. What happened in the time after publication could be called "scope creep", i.e. industry and FDA seemed to be bringing more and more systems into the Part 11 sphere. Examples of such systems would have included word processors used to type SOPs, and consideration of ladder logic in PLCs as electronic records. In the guidance, FDA has restated the scope of Part 11, and clarified that Part 11 can only apply where there is a predicate rule (a record-keeping requirement codified in a previous regulation), or where systems are used to generate records for submission to FDA.

Enforcement discretion – specific Part 11 requirements

The document states that FDA intends to "exercise enforcement discretion" with regard to specific Part 11 requirements, namely:

- Validation
- Audit trail
- Record retention
- Record copying

21 CFR Part 11 reinterpreted - the new "Scope and Application" guidance from FDA

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A detailed examination of the change in approach to each of these requirements is outside the scope of this article, but the guidance document itself describes clearly the implications for each area, Note that the majority of Part 11 provisions remain in place, and the guidance states unequivocally that FDA expect these requirements to be adhered to.

Enforcement discretion – legacy systems

A major development was the change in attitude to legacy systems. These are systems that were operational before the effective date of Part 11. Contrary to the assertion in section III.I of the preamble to Part 11, FDA now accepts the use of legacy systems, subject to certain conditions.

Where to from here?

The guidance acknowledges that the regulation is fundamentally flawed, and FDA expects to initiate rulemaking to revise Part 11 based on the re-examination process. There is no indication as yet as to a timescale for this revision. The agency are currently re-examining the GMPs under a program entitled "Pharmaceutical cGMPs for the 21st Century: A Risk-Based Approach", and the new approach to Part 11 is part of this initiative.

References

Pharmaceutical cGMPs for the 21st Century: A Risk-Based Approach
(http://www.fda.gov/oc/guidance/gmp.html)
Guidance for Industry Part 11, Electronic Records; Electronic Signatures - Scope and Application
(http://www.fda.gov/cder/guidance/5667fnl.pdf)