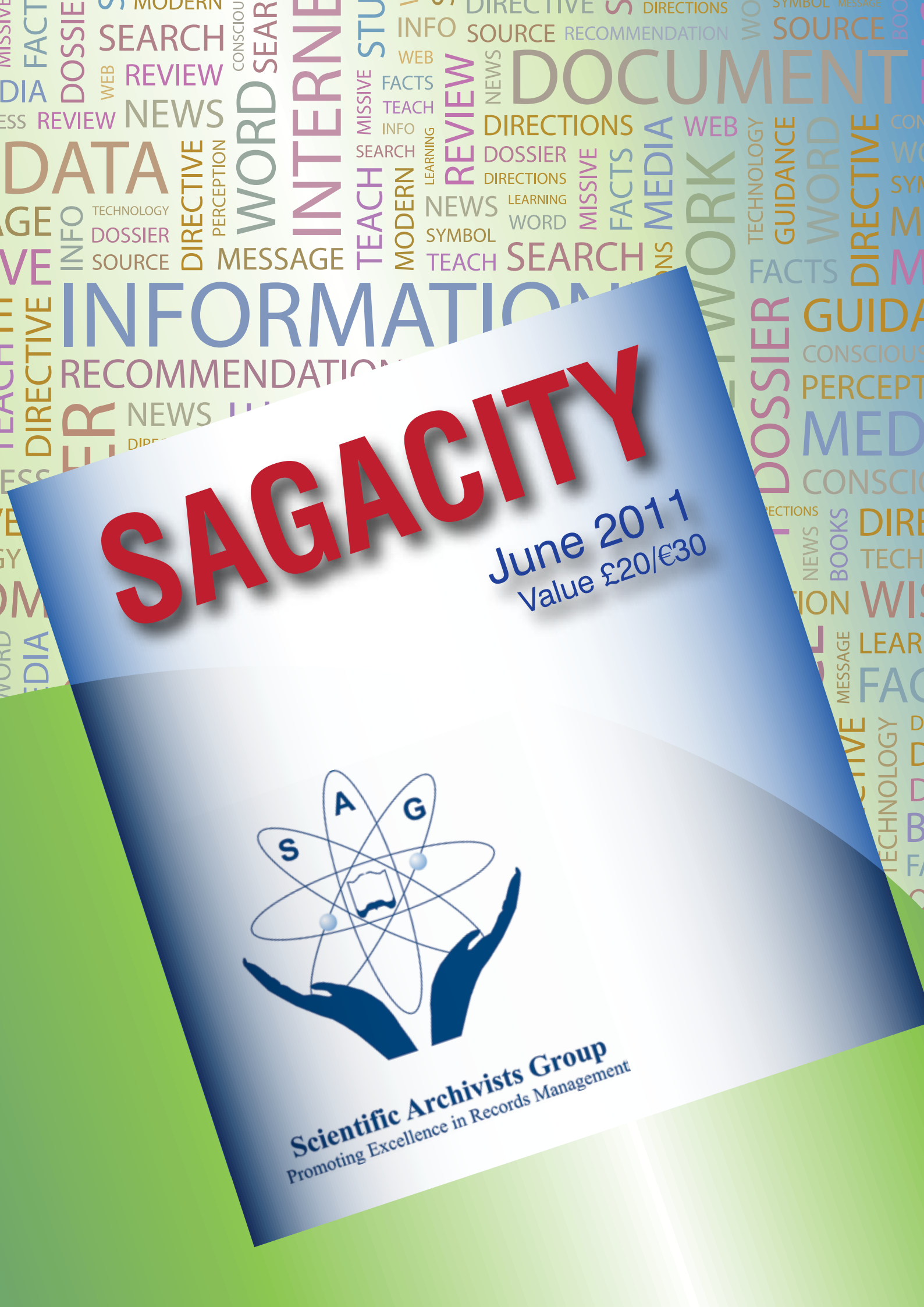
SAGACITY
June 2011
Value £20/€30
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Scientific Archivists Group
Promoting Excellence in Records Management

Scientific Archivist Group Committee

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Entries in Blue are the executive positions

About The Scientific Archivists Group

The aims of SAG are:

- To develop a professional status for members.
- To advance the disciplines of archiving and records management.
- To ensure archives meet business, scientific and regulatory needs.
- To encourage a high profile with regulatory authorities.
- To keep abreast of trends & developments, particularly technological advances and regulatory updates.
- To encourage consistency across borders, particularly within the European Union.

To achieve these objectives the Group will:

- Promote training in the processes associated with archiving and records management, advance the professional competency of its members and promote co-operative relations with allied organisations.
- Promote standards in the profession of scientific archiving and records management.
- Publish relevant information on the activities of the group and subject matter.
- Organise meetings, congresses and symposia which allow exchange of information on the role of the Archivist and Records Manager.

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.

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

For further information visit our website

www.sagroup.org.uk

Inside this issue

Letter from the Editor Gail Dams

*In this edition we have supplied the latest information and progress on how we intend becoming a **Limited Company** and what will be expected from our members to ensure the smooth transition from Scientific Archivists Group to Scientific Archivists Group **Limited**, very exciting times as you will agree. A considerable amount of hard work to enable this transition has been undertaken but will be worth the effort in the long run.*

The articles included this edition range from Health and Safety via Training Files to the Trial Master Reference Model. Sam Alexander very kindly agreed to write an article for us following her very well received Health & Safety presentation at the Autumn conference last year something that we really need be aware of and remain vigilant about at all times. Tim Stiles is passing on his considerable knowledge and advice regarding training files, we all have them and we all need to keep them maintained!

Additionally, we have Karen Roy giving us the progress of the TMF Reference Model group and the background into why the group was formed.

Again we had another successful conference which was held in Bournemouth. Part of the conference was a lively workshop and information on Cloud Computing; these were just a taste of the type of items discussed at the conference. Further, an article from Rob Stiles is interesting, considering it was Rob's first venture into the world of SAG conferences. I get the feeling he'll be back.

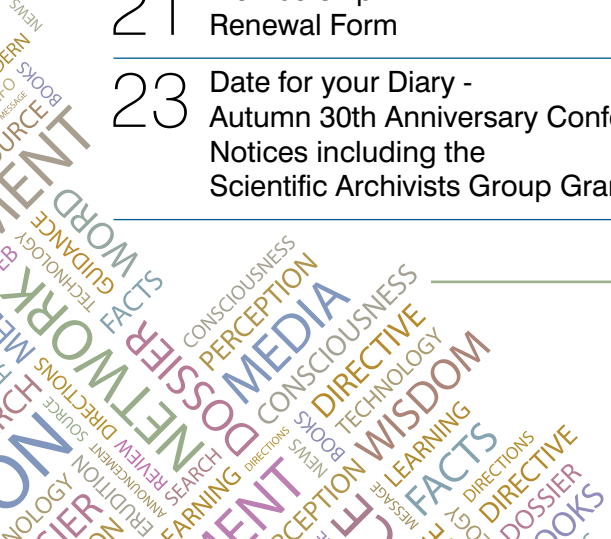
Which brings me nicely to our next conference and just in case you hadn't heard it's the Scientific Archivists Group 30th Anniversary this year. Obviously this will now have to be celebrated at the Autumn conference. More information further into Sagacity refers to details how you may be able to help make this a spectacular event. Additionally, are also hoping to roll out electronic registration and credit card payment system for the event, this will allow us to move into the world of technology which then enables many of us to make easier payments.

Consequently we are putting together a two full day's conference with a variety of workshops that would be of benefit and interest, with this in mind you'll need to book early to ensure you get a place on the workshop which will suit you the most.

Again, as alway, I'm looking forward to seeing as many of you at the celebrations as possible.

So in conclusion whatever your summer favourite is, whether it be Pimms or Sangria – cheers!

Gail



Letter from the Chair
Chris Jones

Welcome to this edition of Sagacity. So far 2011 has proven to be very busy. In May we enjoyed time by the seaside at our Spring Conference in Bournemouth. The presentations were well received, covering a range of subjects from Business continuity to cloud computing, and there was also some healthy discussion in the workshop sessions. As a bonus, the sun shone making the whole experience very pleasant! Thanks to all of you who attended that event and helped to make it a success.

The committee are working currently on a couple of initiatives. We are making good progressing on the transition to the Limited Liability Company, it has been a complex process, and there is still a long way to go, however it will be worth the effort for the protection it will provide for current and future members.

The second initiative is implementing the ability to accept credit card payments. Our "plan A" turned out to be too expensive to implement, so we have identified an alternative, cheaper option that we are optimistic that we can trial for the Autumn Conference fees. If that trial is successful, it will be used for future events. This is a capability that many members have been asking requesting so hopefully this will be a solution that suits all our requirements.

Speaking of the Autumn Conference, I hope that as many of you as possible will be able to attend the event in Manchester, where we will celebrate our 30th anniversary. We are planning some extra activities around that, in addition to the usual conference activities. Many members have been with us for a long time, and we really do want to hear from you around you memories (recent or dim and distant!) of your time with the group. Our anniversary is a great chance for us to reflect on how far we've come, and how much our line of work has evolved through that time. So please share your thoughts with us and I look forward to seeing you in Manchester.

Best Regards
Chris

Election of Board of Directors

As a consequence of the transition of the SAG to a Limited Liability Company, there is a requirement to elect Directors (which are the equivalent of the existing committee positions). .

Anyone wishing to volunteer as a Director must have the support of their Management to:

- attend bi-annual Conferences
- attend quarterly Board meetings
- take on specific tasks relating to the running of the company
- play an active role in Board discussions

There will be two types of Director

- Chairperson (1 position)
- Director (9 positions)

Historically, members of the SAG applied for specific positions on the committee. In the new company, the roles described below will be allocated at the first Board meeting in October. Therefore applications will be for a position as Director (with the exception of Chairperson, which will be subject to a separate nomination/ election process).

An email will be sent out in July, seeking nominations for Directors from members of SAG who have indicated they are happy to join the new company. Should you be interested in a board position, your nomination should be made in email/writing proposed and seconded by a full member of the new company. Specific instructions and deadlines for that process will be described in the email.

Regardless of the number of nominations received, there will be elections for both the Chairperson and Directors. The papers for the vote will be distributed in early September to all company members.

A brief summary of the Roles that need to be covered by the Directors are listed below. Please don't hesitate to contact any of the existing Committee Members if you have any questions or need further information.

Director Role Descriptions

General duties performed by all Directors include:

- Be prepared to attend Board meetings
- Actively partake in discussions during the Board meetings

Election of Board of Directors

(continued)

- 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 fulfil the member's needs.
- Feed to web liaison any useful web sites
- Help promote SAG

Chairperson – additional duties

- Chair the Board meetings.
- Support and encourage the Directors in their roles.
- Host the conference member's session.
- Welcome and introduce the speakers at conferences.
- Chair the SAG member's session.
- 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.

Vice chairperson – additional duties

- Support the Chair in their roles and responsibilities.
- Deputise for the Chair at Board meetings, conferences etc.
- Responsible for co-ordinating project teams, where deemed necessary.

Treasurer – additional duties

- Maintain company bank accounts.
- Receive payments and settle accounts on behalf of the group.
- Responsible for tracking financial position and reporting at Board meetings to company members.
- Liaise with the conference organiser and membership secretary regarding payments.
- Produce formal audited year end accounts.

Secretary and Company Archivist – additional duties

- Organise Board meetings and take minutes. Send out actions.
- Take lead role in Board elections/ballots.
- Responsible for the laptop and projector, set up at conferences.
- Update members at AGM about elections/ballots and take minutes.
- Archive the groups' documents.

Conference Organiser – additional duties

- Agree with the Board the location of the next meeting (usually 12 months ahead)
- Research possible venues and gather as much information as possible e.g. pamphlets.
- Liaise with Board who will decide on an appropriate venue, format, agenda, meals, workshops and or visits.
- Liaise with the agreed company or hotel or combination where the conference will be taking place.
- Contact agreed speakers to confirm their commitment, timings, travel, accommodation, meals etc.
- Produce and post letter confirming booking for conferences.
- Liaise with the appropriate person who is producing the conference handout, supply the relevant information on the speakers and their presentations as soon as available.
- Keep an updated list of members attending the conference and forward monies to the Treasurer
- Update members at the conference

Publications Editor – additional duties

- Commission articles, liaise with authors on timelines, review content for Sagacity to include but not limited to committee biographies, new members and retiring members, letters from the Chairperson and Editor, minutes from the members session following conferences, notification of next conference, any advertisements, copy of the application form
- Agree with committee the date for publications
- Liaise with prospective advertisers

(...continued)

Election of Board of Directors

(continued)

- Act as group point of contact for the designer/printer
- Liaise with designer and provide copy for journal, conference flyer and registration forms together with any relevant publications
- Liaise with Board regarding agenda and content of the delegate flyers for twice yearly conferences
- Design, produce and despatch materials for conferences
- Ensure the Secretary has electronic copies of speaker presentations to be loaded onto the laptop prior to start of the conference
- Ensure copyright is gained if necessary and the distribution has been made to appropriate institutions eg British Library
- Ensure sufficient copies of publications are printed and distributed as required and liaise with Membership Secretary with regard to address labels for sending copies of Sagacity, membership directory, conference flyers and any further publications
- Send and invoice any additional copies of SAG publication requests, ensuring a copy of the invoice is sent to the Treasurer

Membership Secretary – additional duties

- Update SAG membership database
- Send renewals and reminders as appropriate
- Send welcome pack consisting of welcome letter, membership card and copy of most recent journal.
- Check date for extended membership i.e. October
- Send cheque/monies to Treasurer
- Notify the Website co-ordinator to issue a password.
- Canvas reasons for non-renewal e.g. job moves, company moves and mergers.
- Update members at the conferences

Members Pages

General Updates and Information

Welcome to our New Members

Angela Power	Unilever
Aradhana Sharma	UCB Celltech
Clare Adams	Cefas
Aicha Aarab	BTG plc
Steven Johnson	Iron Mountain (UK)
Paul Martin	Kellys Storage Ltd
Stephen Andrews	Butterworth Laboratories Ltd
Karin Richards	Agrochemex
Clare Malshinger	Merck Sharp and Dohme Ltd
Rachel Mahoney	Ipsen Biopharm Ltd
Kevin O'Flynn	Animal Health and Veterinary Laboratories Agency
Jenny Burns	Huntingdon Life Sciences
Helen Turner	Oxford Plant Sciences Ltd
Robert Stiles	Qualogy Ltd
Emma Winney	Medimmune Ltd

SAG at 30 - Call for Your Memories

Gail Dams

As mentioned earlier in this edition, this year the Scientific Archivists Group reaches its 30th Anniversary. To celebrate and reflect on these 30 years we have decided to have a special Autumn Conference in October and an Anniversary edition of Sagacity in December.

To help us make these events special we are asking you to look back over the years that you have been involved with SAG and see if you have any memories or recollections that are interesting, strange, funny - or all of those! We are particularly looking for anecdotes, photographs or other memorabilia that you would like to share with the current membership, to help us tell the story of the group over the past 30 years.

If you could send them to me or to *memories@sagroup.org.uk* that would be very helpful - let's make this event special and celebrate the success of the group over the years!

Members Pages

General Updates and Information (continued)

E-archiving – working party

Tim Stiles Group Leader

Working Group

Practical Guidance on E-archiving of Regulatory Records – "What an Archivist needs to know about archiving electronic records"

Through the ongoing process of research and discussion within the SAG membership, the need for practical guidance for archivists and archiving staff on the process for the archiving of electronic records became apparent.

To that end a work group was established by the SAG Organising Committee and tasked with producing a guidance document that would cover the essential aspects of the subject and offer sound practical advice and support.

The guidance will cover the following aspects.

- What is meant by electronic archiving?
- What is an electronic record that needs to be archived (raw data, source data, electronic records)?
- Documenting what e-records on a study will be produced at the planning stage.
- How should electronic records be archived?
- Description of the archive process.
- Preservation of access to archived e-records including migration
- The responsibility of the Archivist in the management of electronic records
- The e-archive facility and conditions of storage.
- Definition and Management of the process to access electronic records that have been archived.

Limited Company Conversion

Chris Jones

Transition to Limited Liability Company – status update

One of the major efforts SAG is undertaking in 2011 is the transition to a Limited Liability Company. The reason this is effort is that Group members are currently liable for any debts that SAG may incur. The worst case scenario is if the group were found to be negligent and damages were awarded that exceeded our insurance cover, all SAG members would be required to share the cost of the damages awarded.

Transitioning to a Limited Liability Company is important as it limits the amount that members would pay out to what is guaranteed in the Articles of Association of that company. This amount has been set as £1.

The committee are currently busy setting up different aspects of the new company, which will be called Scientific Archivists Group Limited, including the aforementioned Articles of Association, bank accounts and other supporting documentation. Richard Pennicard, our Treasurer, is playing the lead role in this activity.

By the time you read this article, most, if not all of you will (hopefully) have agreed to join the new company. We do need your explicit agreement to join the new company; we cannot transfer you without your consent. If you have not yet responded, I urge you to do so as soon as possible.

The next stage, again which should be underway by the time you read this, is the nomination process for Directors. The new company will have a Board instead of a Committee, and Directors instead of Committee members. In total there will be 1 Chairperson and 9 other Directors to nominate/elect to the Board.

The process for putting yourself forward as a Director/ Chairperson will be very similar to how the process has worked for the old group, namely a nomination supported by two other members. Only those members who have responded to the survey to join the new Company can be nominees or their supporters.

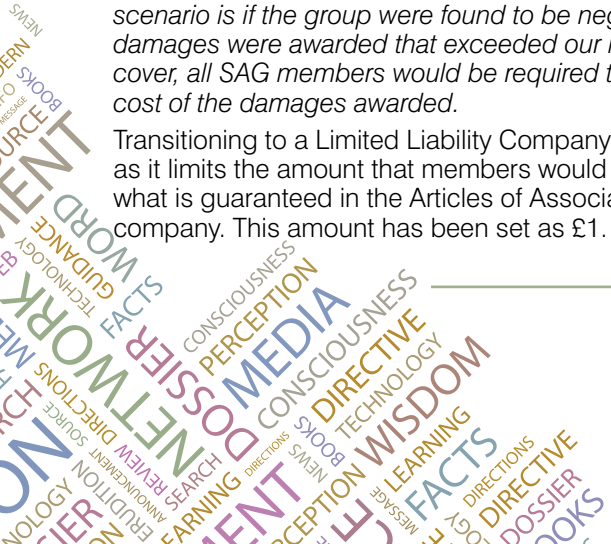
Once the nomination period has closed, there will be an election, in August, to choose the Directors and Chairperson from the nominees. This will happen even if there are fewer, or the same number of, applicants as positions to ensure that the membership of the new company endorse the Directors. Again, only those members of the original SAG who have agreed to join the new company will be able to take part in that vote.

The next step in the transition, scheduled for September will be a resolution to the membership of the existing group to wind it up and transfer the group assets to the new company.

Assuming that the resolution is supported by the group membership, the first Board meeting of the new company will take place just before the Autumn Conference. At that meeting, the roles that are required to organise the group will be assigned by the Directors. That could well be an interesting discussion!

The formal adoption of the resolution to dissolve the group will occur at the AGM during the Autumn Conference. That will be followed immediately by the first meeting of the new company. At that point, the transition is complete!

If you have any questions about this process, please don't hesitate to contact Chris Jones or Richard Pennicard



Health & Safety – Take Another Look

Sam Alexander, A M Health & Safety

As Scientific Archivists for different organisations there is no doubt a fair spread in both the perceptions of risk in your day to day undertaking and practical methods of managing risk within each business. The announcements within Lord Young's Report 'Common Sense, Common Safety'[1] on the day of the Scientific Archivists Group conference in Birmingham that 'employers may be exempt from risk assessment' have since resulted in speculation and confusion about what this may mean for key persons managing risk within organisations.

As the law stands there is a duty of care to ensure that all significant hazards are identified, measured in terms of both the likelihood of harm occurring and the severity of that harm and then, where it would be reasonable to do more to prevent the harm or reduce the extent of harm, apply additional controls[2].

So what reforms might we expect and how could they affect each one of us? Should we delay our plans for investment in health and safety improvements until we know more? Let's look at a scenario that is closer to home for many of you.

When considering the movement of archiving boxes, one of the more significant hazards associated with this activity may be handling the boxes at height. Hazardous outcomes that are foreseeable would be falling from height because of poorly selected access equipment, musculoskeletal injury from overloaded archive boxes, objects falling from height due to incorrect storage and impeding safe escape in the event of a fire or emergency.

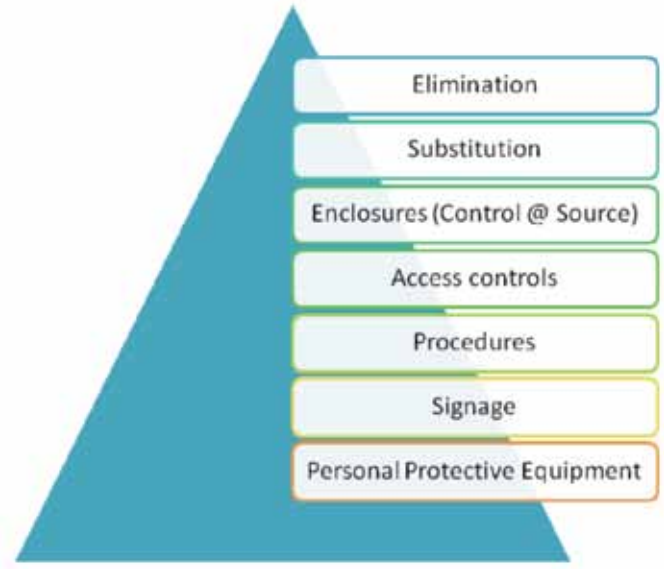
So how might we manage these hazardous outcomes? Firstly there are a range of resources available to check for current best practice. The Health and Safety Executive's website[3] has easy to use guides, case studies and examples that show how real-life organisations have managed their risks down to an acceptable level. Second, discussion can be invaluable, the best persons to involve in any task based risk assessment are those that undertake the task and have an insight into suitability of solutions. Using in-house expertise in the form of engineers and facilities personnel will enable any issues with loading, installation or maintenance to be identified early on, whilst important guidelines can be obtained from occupational health providers as to maximum loads likely to be relevant to the specific demographic of the workforce[4].

Thorough consultation must go into the selection of any substantial control measure. Wherever practicable, trial larger items to avoid any white elephant investments, if trials are not feasible, allow the users clear details on the specifications and time to consider these in relation to the work and working environment.

Since the aim of applying controls is to reduce the risk as low as reasonably practicable, measures which are taken from the top of the hierarchy of controls (see opposite)

tend to be more effective. For example, automated vertical archiving systems would remove the need for working at height at all, as well as possibly resolving issues relating to users overfilling boxes, but introduce additional hazards, e.g. contact or entanglement with the moving carousel, so these should not be forgotten, but evaluated for their relative impact.

The Hierarchy of Controls[5]



But are the rules about to change? The short answer is perhaps, but as the main recommendations from Lord Young's report focus on avoiding unnecessary or burdensome paperwork for smaller businesses or low-risk environments, it is unlikely to precipitate a whole scale repeal of health and safety Regulations.

If you put any political cynicism to one side, the Report's title 'Common Sense, Common Safety' allows rather more than a hint as to the spirit of the exercise from which we may draw some conclusions; if risk management within your organisation is based on a common sense approach, employing a test of reasonableness[6], and ensuring that you consult properly, then it is probable that steps taken to control risk will provide a proportionate benefit to the workplace and reduce accidents.

Whilst Lord Young emphasised a need for consolidation of the current health and safety legislation, this will take time, so until then, it's business as usual. If it then transpires that you have done a little more than required the consequence is that you are likely to be ahead of best practice, whereas the consequences of waiting it out and falling short are that you may be among the first to benefit from one Lord Young's other recommendations; a simplified claims procedure for personal injury claims under £10,000.

References

1 *http://www.number10.gov.uk/wp-content/uploads/402906_CommonSense_acc.pdf*
2 The Management of Health and Safety at Work Regulations 1999.
3 *www.hse.gov.uk*
4 Incidentally, there is already guidance for lifting and handling under the Manual Handling at Work Regulations 1992; which can also be found on the HSE website, a cautionary note; it is only guidance and as such always prudent to consider in the context of your actual workforce.
5 HSG 65 Successful Safety Management Systems
6 The 'reasonable person' is a figure that is often used within the courts to decide if, given available resource, knowledge and forethought, a person could or should have done more in any given situation to prevent harm

Company/ Professional info

Based in Swindon, Wiltshire, AM Health & Safety Ltd is a leading supplier of health and safety training, advisory and consultancy services. The company was established 15 years ago and A M Health and Safety Limited's clients include numerous SME and Public Sector clients.

We have experience in a variety of industries ranging from niche sectors such as pharmaceutical development, electronics and manufacturing through to more main stream industries such as construction, design agencies and accountancy to name a few whilst also working with many household names such as Vodafone, Dolby and Warm Space amongst others.

Sam Alexander, Director, has extensive experience in dealing with valuable and complex projects, as well as the review, development and implementation of Safety Management Systems. Sam holds chartered membership status of the Institution of Occupational Safety and Health (IOSH) and is an IOSH Managing Safely and Working Safely Course Tutor. Sam has specialised in Ergonomics within learning and System Ergonomics, some of her projects include;

- Development of Safety Training Programme for US Based Pharmaceutical and Biotechnology Management Group.
- Development of Safety Management Systems for International container lessor
- Development and overseeing implementation of e-learning, handbook and blended training for Biotechnology organization.

TMF Reference Model – An Opportunity for Industry Alignment

Karen Roy, Phlexglobal

Introduction

There are many activities across the clinical development cycle that are non-negotiable; one of which is the creation, collection, management and storage of the documents that are contained in the Trial Master File (TMF). The TMF contains those essential documents that individually and collectively permit the evaluation of the conduct of a trial and the quality of the data produced. These documents serve to demonstrate the compliance of the investigator, sponsor, and monitor with the standards of good clinical practice (GCP) and with all applicable regulatory requirements.[1]

All sponsors - whether an individual, company, institution or organisation - and investigators conducting clinical trials in the pharmaceutical and biotech industry, as well as those conducting trials in academic research, are required to maintain documentation for each clinical trial. However, regulatory guidance, such as ICH E6 section 8, addresses only a sub-set of documents that companies commonly retain. Documentation requirements for the set-up and maintenance of quality systems, electronic systems, safety monitoring, and proof of an adequate and well-controlled trial, to name a few, are in different parts of different regulations. There has been no comprehensive, common industry model or best practice for a TMF and therefore each company has its own unique TMF structure as defined by its Standard Operating procedures (SOPs).

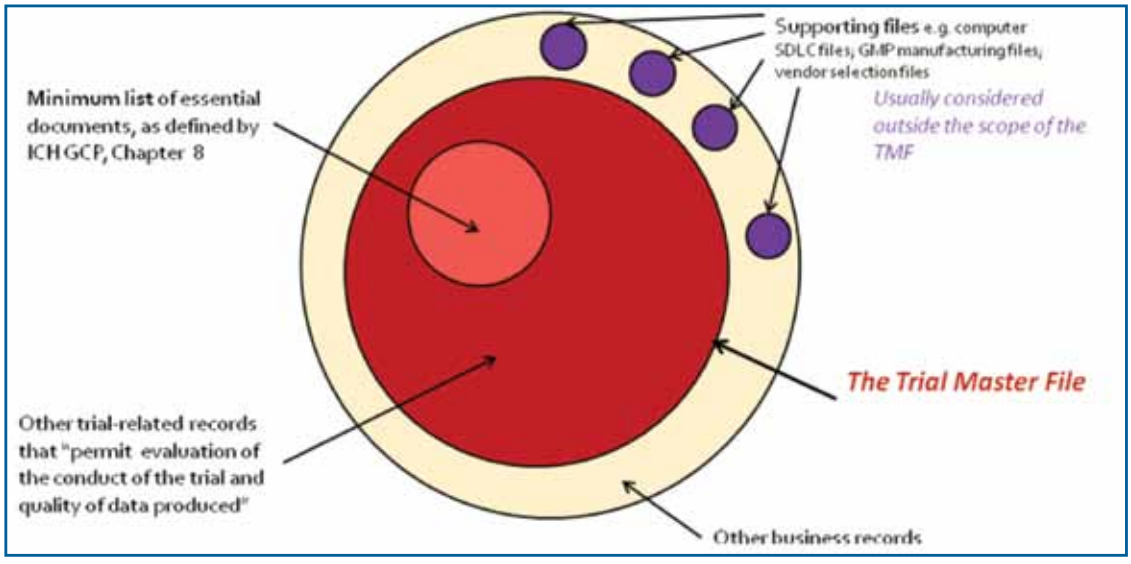


Figure 1: Definition of a Trial Master File

This is a highly inefficient way for our industry to work for many reasons:

- All drug development companies and contract research organizations (CROs) spend considerable amounts in defining and redefining the content of the trial master file for each of their clinical trials.
- The relative burden is very high on smaller companies that usually have limited document management expertise and limited financial resources.
- Records and information exchange between collaborating companies is extremely cumbersome and at times may prevent the transfer of a drug or a joint venture from happening.
- Regulators consistently find different terminology and file structure, sponsor to sponsor – creating inefficiency and a higher degree of variability during sponsor audits

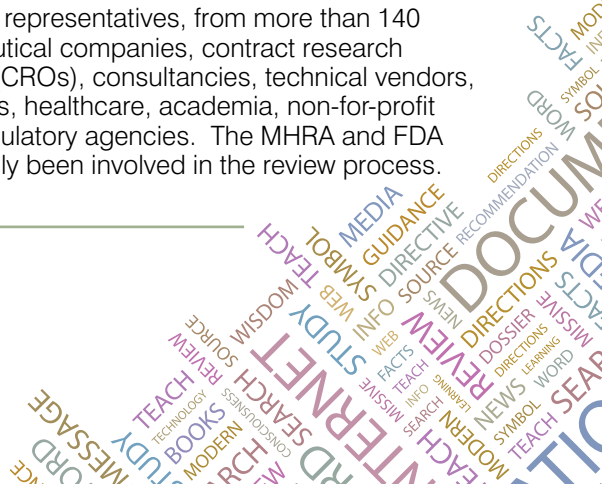
Hence the Trial Master File Reference Model (TMF RM) was created.

History of the Model

The Document and Records Management Special Interest Area Communities (SIAC) of the Drug Information Association, a recognised and highly respected professional association, supported an initiative to create a TMF RM.

Subsequent to the initiation of the TMF RM Team in late 2008, communication of the TMF RM effort involved presentations at DIA events, such as the DIA EDM Conferences in Europe and the US. After recruiting a critical mass, the inaugural meeting of the team was held in March of 2009, and subsequent meetings are held every 3 weeks. By late spring, 2009, the team consisted of 69 members from 51 companies. Early communication efforts were facilitated by word-of-mouth and continued communication efforts through DIA venues.

Creation of the TMF RM now involves more than 200 representatives, from more than 140 bio-pharmaceutical companies, contract research organizations (CROs), consultancies, technical vendors, industry groups, healthcare, academia, non-for-profit / NGO and regulatory agencies. The MHRA and FDA have specifically been involved in the review process.



Structure of the Model

The TMF RM is a single, unified interpretation of the regulations in the form of a list of TMF artifacts which would be accepted by all clinical trial stakeholders and which can be adopted or adapted by any company, institution or organization.

Defined in the model are document types, called artifacts, which one would expect to find in a TMF. The model does not dictate location of the artifacts, just that together they represent the TMF.

The artifacts are labeled as either core, meaning it must be in the TMF as dictated by either the regulations or per the opinion of the TMF RM Team based on good clinical practices (if applicable for the study), or recommended meaning the artifact does not have to be produced but if it is created or collected, it is recommended to be in the TMF. Since the industry often uses unique names, alternate names and descriptions are supplied for each artifact.

The TMF RM is grouped into a series of zones based on the type and source of documents. Artifacts are grouped together under the following Zones:

1. Trial Management
2. Central Trial Documents
3. Regulatory
4. IRB/IEC and Other Approvals
5. Site Management
6. Trial Supplies
7. Safety Reporting
8. Laboratories
9. Third Parties
10. Data Management
11. Statistics

Artifacts are created and exist at three levels; study, country, and site. An artifact, such as "Safety Management Plan" exists at only one of the levels, the study level. In contrast, the artifact "Informed Consent" can exist at all three. These levels define the paper format TMF.

The TMF RM also has basic metadata which can be used as a starting point for building an electronic TMF document management processes. The TMF RM has two groups of metadata – captured and inherited. The captured metadata includes the study number, country and site number. In addition there is a metadata value which indicates whether a record is managed at the trial level or site level. Inherited metadata such as Product/ Compound, Indication, Trial Phase and Route is also attached to each artifact and is intended only to be captured once for all documents.

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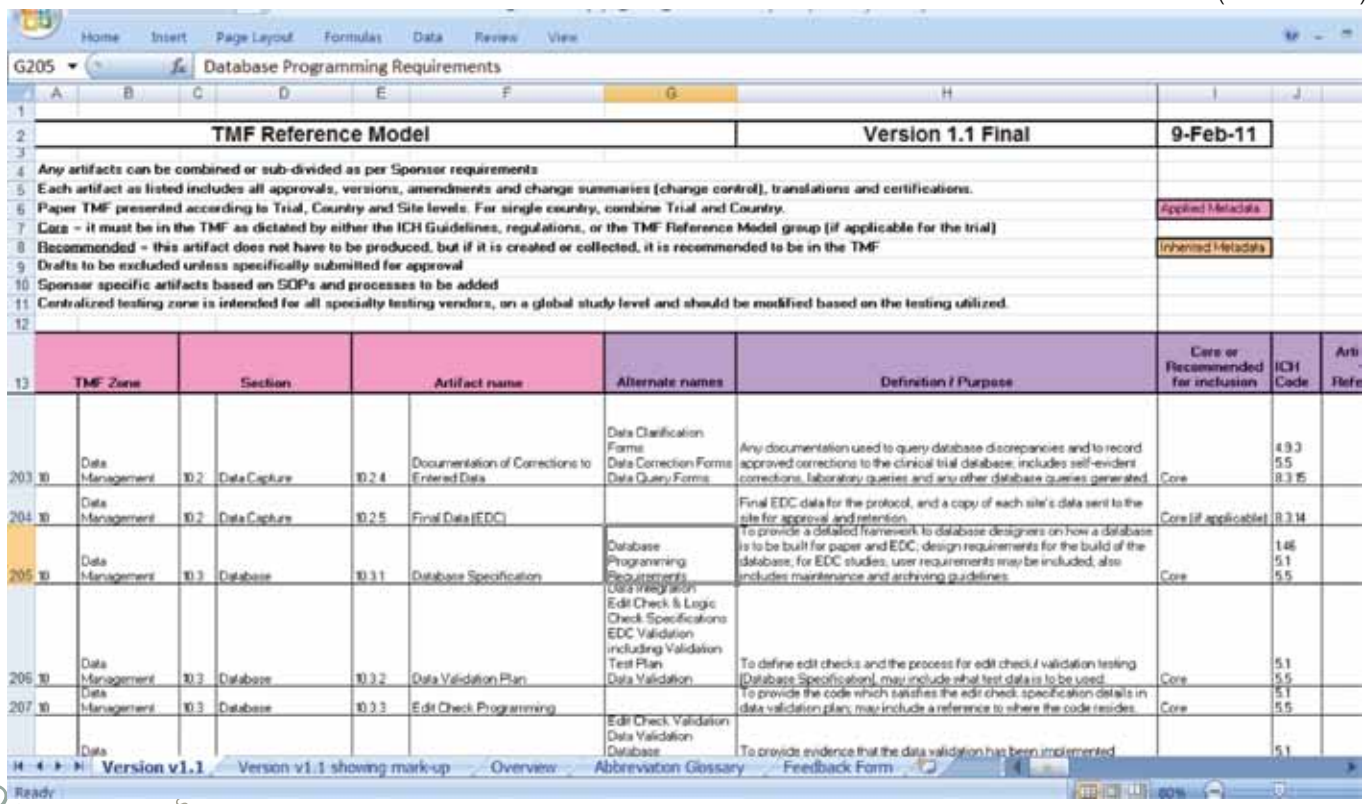

TMF Reference Model | Version 1.1 Final | 9-Feb-11

Any artifacts can be combined or sub-divided as per Sponsor requirements
Each artifact as listed includes all approvals, versions, amendments and change summaries (change control), translations and certifications.
Paper TMF presented according to Trial, Country and Site levels. For single country, combine Trial and Country.
Core – it must be in the TMF as dictated by either the ICH Guidelines, regulations, or the TMF Reference Model group (if applicable for the trial)
Recommended – this artifact does not have to be produced, but if it is created or collected, it is recommended to be in the TMF
Drafts to be excluded unless specifically submitted for approval
Sponsor specific artifacts based on SOPs and processes to be added
Centralized testing zone is intended for all specialty testing vendors, on a global study level and should be modified based on the testing utilized.

Applied Metadata
Inherited Metadata

TMF Zone	Section	Artifact name	Alternate names	Definition / Purpose	Core or Recommended for inclusion	ICH Code	Artifact Ref
10 Data Management	10.2 Data Capture	10.2.4 Documentation of Corrections to Entered Data	Data Clarification Forms; Data Correction Forms; Data Query Forms	Any documentation used to query database discrepancies and to record approved corrections to the clinical trial database; includes self-evident corrections, laboratory queries and any other database queries generated.	Core	4.9.3; 5.5; 8.3.15	
10 Data Management	10.2 Data Capture	10.2.5 Final Data (EDC)		Final EDC data for the protocol, and a copy of each site's data sent to the site for approval and retention.	Core (if applicable)	8.3.14	
10 Data Management	10.3 Database	10.3.1 Database Specification	Database Programming Requirements; Data Integration	To provide a detailed framework to database designers on how a database is to be built for paper and EDC; design requirements for the build of the database; for EDC studies, user requirements may be included; also includes maintenance and archiving guidelines.	Core	1.4.6; 5.1; 5.5	
10 Data Management	10.3 Database	10.3.2 Data Validation Plan	Edit Check & Logic Check Specifications; EDC Validation including Validation Test Plan; Data Validation	To define edit checks and the process for edit check / validation testing. [Database Specification] may include what test data is to be used.	Core	5.1; 5.5	
10 Data Management	10.3 Database	10.3.3 Edit Check Programming		To provide the code which satisfies the edit check specification details in data validation plan; may include a reference to where the code resides.	Core	5.1; 5.5	
10 Data			Edit Check Validation; Data Validation Database	To provide evidence that the data validation has been implemented.		5.1	

Version v1.1 | Version v1.1 showing mark-up | Overview | Abbreviation Glossary | Feedback Form

Ready

TMF Reference Model

(continued)

Typically, companies could expand on metadata to include other key information which can be used to drive processes or for reporting purposes. It is expected that in future versions of the model, other metadata values will be added.

The TMF RM does not provide guidance in terms of the process by which the artifact is created or collected, can be adapted to an electronic or paper based TMF and by design does not endorse, nor require, any specific technology for application.

The Uptake

Version 1.0 of the TMF RM was released in June of 2010. The initial uptake of the model was quick as bio-pharmaceutical sponsors, CRO, and technology vendors used the model as a basis of evaluation or development of their TMF content list. Each of these groups has or will use the revised model to finalize or update work that was started since version 1.0 was released. The model has since been included in the educational offerings of many independent venues.

The perceived benefits for sponsors include more efficient collaboration with CROs and other partners, more rapid and cost effective implementation of technology solutions for document management and improved access to trial documents for audit and inspection. The model has since been included in the educational offerings of many independent venues.

Version 1.1 of the model, released in Feb 2011, reflects updates following feedback received from industry and health authority review, specifically the FDA and the MHRA. Future updates to the TMF Reference Model, if necessary, are planned yearly in line with the US DIA Annual Meeting.

Evolution of the model continues as working groups will begin focusing on country and regional variations of the TMF, documentation required for device trials and investigator initiated trials, process based organization of the TMF, and investigator site documentation.

Taking part

The TMF RM group meets by teleconference every 3 weeks to discuss a variety of issues. Various sub-committees exist such as the Communications, Metrics, Paper Destruction team, and these groups meet separately to discuss the specific aspects assigned to them. In addition, there is a LinkedIn group and a blog. You are invited to follow TMF RM activities on LinkedIn by joining the TMF Reference Model group *http://www.linkedin.com/groups?gid=2663204&trk=anetsrch_name&goback=.gdr_1280345913833_1*. The blog address is *http://tmfrefmodel.blogspot.com*

If you wish to volunteer, please contact one of the co-chairs:

- Karen Redding *kredding@phlexglobal.com*
- Lisa Mulcahy *mulcahy67@comcast.net*

The TMF Reference Model is free and can be retrieved at: *http://www.diahome.org/en/HomePage/EDM+Corner.htm*

Author:

Karen Redding, Global Business Development Director, Phlexglobal, is the co-chair of the TMF Reference Model group and can be reached at *kredding@phlexglobal.com*

Reference

1 ICH Guideline for Good Clinical Practice, E 6, Section 8

Training Records

Tim Stiles, Qualogy

As a way of introducing this presentation, which relates to the recording of training and competency, I believe such records are one of the most complex and difficult requirements of the regulations to successfully implement.

The objectives for training records is the same for all GxP areas and the principles behind the requirement and the recommendations in this article can be justified for all work environments. As part of any good business practice a company should ensure all staff in an organisation are suitably trained and competent to perform the functions required of them. Not only does this ensure an effective and efficient work force but it also ensures the company fulfills it statutory requirements in terms of other regulations such as the Health and Safety at Work Act.

It is for these reasons that training records serve to demonstrate staff have been suitably trained and are competent. So training records should not be seen as a sole requirement of GxP but an essential element of good business practice irrespective of the industry within which you work.

Introduction

The purpose of training records from a GxP perspective is to record the training received and the level of competency attained. Such records can then be provided as evidence to a third party, such as regulatory authorities, Clinical Project Manager or Study Director, that an individual involved in the conduct of a study is suitably trained and experienced to undertake those procedures they have been requested to perform. In addition they can aid management in planning the future training needs of the organisation and its staff.

The way in which such records are maintained is clearly a matter for each organisation but what is defined in this article is a suggestion as to how the regulatory requirement can be fulfilled.

Personnel Training Files

I prefer to give a collective name to such records required for regulatory compliance which is a "Personnel Training File". Such a file may contain, in addition to an individuals record of training and competence, a CV, Job Description, Certificates and records of training record review. By taking such an approach all information relating to the qualifications, training and experience for an individual may be retained in one place. This has a number of benefits which include making it easier for an individual to ensure such records are current and up to date.

Responsibilities

It is my belief that each individual and their immediate supervisor bear equal responsibility for ensuring their training record is maintained up-to-date and is an accurate reflection of the training received and the competence level attained. Management has the responsibility for providing training and to ensure such records are maintained and regularly reviewed. Staff should not be undertaking activities for which they are not trained and competent.

This does require that individuals have direct access to their training file and should ensure that any training received is documented.

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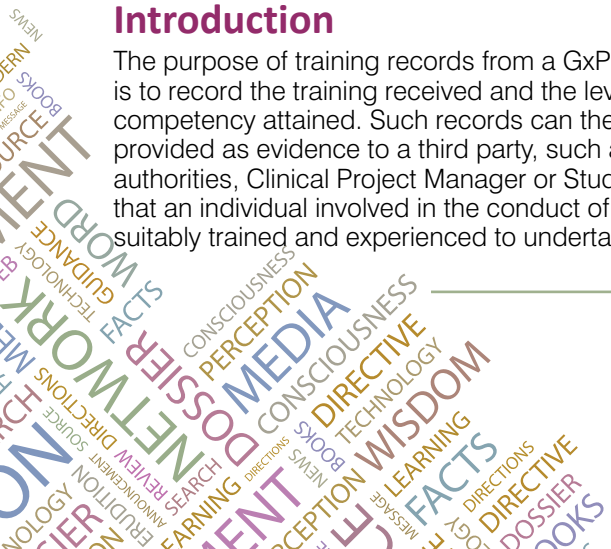


Training Records

(continued)

Who should have a training record?

It is my belief that all staff within and organisation should have a training file. This is irrespective of the function and position within the organisation. Experience tells us that any person working at a site, clinic, GP practice, etc, can influence a study and therefore should be appropriately trained; such training should be documented.

Curriculum Vitae

A CV is documentation of the qualifications and experience of an individual. These records provide information on the career of an individual and are of particular value in detailing their experience prior to them joining the company. The type of information to be included in a CV includes:

- the individuals full name (previous names should also be included)
- academic qualifications
- current and previous positions held
- membership of relevant societies or professional groups
- papers published
- any other information relevant to the position and function in the organisation

The CV should be maintained current and up to date, be signed and dated by the individual to confirm its authenticity. Superseded versions should be retained within the Personnel Training File.

I have spent many an enjoyable moment reviewing individual's hobbies and interests, all of which are probably exaggerated, and none of which have any relevance to the function they perform. Other information such as religion, personnel address and phone number does not have any place on such documents. These items maybe of value when applying for a new job but are not required on a regulatory CV.

It is recommended that companies do have a consistent format for such documents. The provision of a standard format also helps the preparation and consistency of such documents.

Job Descriptions

Job descriptions should define the job, its responsibilities, accountabilities and authorities. Each individual should have their own job description or a Position Description. A Position Description is a standard description of a job which is performed by a number of staff. The individual should sign and date the job description to indicate their acceptance of the responsibilities and limitations of their job. The job description should also be signed by their line manager to confirm the responsibilities defined. The current job description and any previous job descriptions should be retained in the individuals Personnel Training File.

Records of Training

The following is a suggested approach to address the requirements for training records. Many different approaches do exist and there is not a single answer to satisfy the requirements.

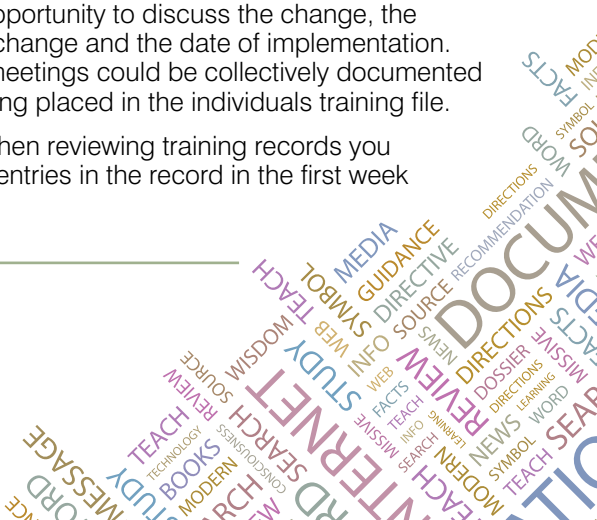
When a new member of staff joins the company a programme for their training should be produced. This programme of training will cover the induction process, that is educating the individual in the operation of the company and cover such areas as safety, company organisation, human resources requirements, pensions etc, and then a programme of training related to the function they are to perform. The training record should commence from day one of the new starter with the company.

Training is not giving an individual a set of the company SOPs and telling them to read them. It is a process of identifying the function of an individual and then providing specific direction and training in how the function/procedure is to be performed. The SOPs should provide support in this process.

Whilst education and training may be linked to SOPs it is strongly advised that the record of training is not directly linked and referenced to an SOP number and version. To do so would mean any up-date to an SOP would then require an up-date to the training record, something many find difficult to achieve, besides we do not train staff in an SOP we train them to perform an activity or procedures which may be defined in an SOP.

Signing "read and understood" lists of SOPs is also not training and in many cases this just provides an opportunity for the individual to commit fraud. When a new SOP is issued, or changes to an SOP are made, the requirement for training or retraining in that procedure should be established. This should also include the identity of the individuals to be trained. If retraining is required then this should be appropriately organised and documented in the training file. If staff need to be made aware of the change and given an explanation for the change, a meeting of those effected should be organised and staff educated in the changes whilst providing an opportunity to discuss the change, the reason for the change and the date of implementation. Such training meetings could be collectively documented with a copy being placed in the individuals training file.

Far too often when reviewing training records you observe many entries in the record in the first week



of employment, a group of entries all on the same day some months later and then a further group of entries all on the same day usually immediately prior to a government inspection. This is not how training is provided and just serves to demonstrate that the companies training record system is not functioning correctly.

Records of training received should be documentation of the procedure or activity in which the individual has been trained and include an indication of the competence level achieved.

When a new employee joins the company who has relevant previous experience, this would be reflected in the CV, then it may be appropriate for a "statement of competence" to be issued. This statement, signed by Management, confirms that the individual is competent to perform the role based on previous experience (This may also apply to organisations which are implementing training records for the first time). Such a statement may negate the need to start training from scratch and documents a level of competence from which specific training will commence.

An example of a possible layout of a page from a training record is given below;

PRIVATE

Activity/ Procedure	**Instruction Given and Supervisory Period Started**		**Work Competence Achieved**	
	*Date	Signatures**	*Date	Signatures**

*** Date = Day/Month/Year**

**** Signature of the trainer and trainee**

The activity in which the individual is being trained should be identified. Avoid grouping too many activities together such as "Laboratory Procedures". Identify tasks or activities in the order in which staff are trained.

Training given; this is the date on which the individual was first given training. Training should only be given by qualified personnel. It is the responsibility of the instructor to sign off and date each procedure for "Training Given" when the instructor is satisfied that the employee has been fully instructed in that procedure.

Competence Achieved; once an individual is judged to be competent in the performance of an activity then they should be signed off as competent to perform that activity unsupervised. The individual should not be permitted to perform unsupervised, activities for which "Competence Achieved" sign off has not been recorded. The "Competence Achieved" sign off decision is the responsibility of an individual's supervisor and where possible "tests" to confirm competence should be performed.

Records of formal training or attendance at courses are relatively easy to maintain as attendance is often accompanied by a Certificate of Attendance. Copies of these certificates should be held in the training file.

Other educational and training activities such as conferences attended and any publications should also be recorded in the training file.

Regular review

The personnel training record should be regularly reviewed to ensure the file accurately reflects current training, competency and academic qualifications of the individual. This review by the individual and line manager should be documented as part of the training record. An example of such a record is given below:

PRIVATE

Date DD/MM/YYYY	**Reviewed By**	**Signature of Reviewer**

In cases where an individual has been signed of as competent but has not performed the activity for some time may require retaining and competency assessment prior to the performance of that activity. This could also be assessed during this review.

General

When an individual leaves the organisation the training record should be archived. However it is strongly recommended that the individual takes a copy of their file, after all it is about them and may be of value in future employment.

When preparing for a government inspection the one thing everybody in an organisation can do is to ensure that their training record is current and up to date.

Finally, remember that the training record is a personal document in that it is about you and nobody else. So make sure your training record truly reflects your expertise, skills and level of competency and take care and pride in the record.

GLP Consultative Committee Minutes

Richard Pennicard, Selcia

GLP Consultative Committee 9 May 2011

The UK GLP consultative committee is a forum for discussion of GLP issues between the GLP inspectors, regulatory authorities such as the HSE, MHRA and FSA, and industry bodies such as APBI, BARQA and SAG. I attended as the representative from SAG. The GLPMA's official minutes, plus a detailed deficiency report and official answers to technical questions will be posted on the MHRA web site.

Welcome

The GLPMA has now moved to 151 Buckingham Palace Road.

Minutes of last meeting and matters arising

Minutes were agreed.

Members' Updates

GLPMA: Mary Baynes has left the MHRA, Steve Monk will be taking earlier retirement in September. One new inspector is being recruited. The risk-based approach to inspections, taken with the decrease in headcount may mean that the interval between inspections could be increased to 30 or even 36 months for companies that have been assessed as being low risk and who have a good compliance history.

BARQA is producing a guidance document on GLP in analytical laboratories.

Both the GLPMA and BARQA expressed interest in SAG's Electronic Archiving Working Group and would like the opportunity to comment on the draft guidance document.

Risk-Based Inspections

The procedure for producing a risk score to prioritise inspections has now been automated using a spreadsheet. This gives a more objective result, but it can be overridden if the result is anomalous. Companies will be told their risk scores following an inspection, but it is unlikely that details of the spreadsheet will be made public.

The MHRA is looking at integration of its information systems. This would enable the GLPMA to use intelligence from throughout the organisation and may result in harmonisation of inspection processes. A decision on this is due next month.

Fees

There will be no change in fee rates for the year 2011-12.

GLPMA Annual review & communication

Summary of Inspection Findings

The full report will eventually be posted on the GLP web site.

There were 62 inspections in 2010. There has not been a significant change from previous years after factoring in numbers of inspections. One critical deficiency was found. A reinspection after 6 months showed that suitable corrective actions had been implemented.

Archiving deficiencies constitute about 9% of the total, with 4 major deficiencies in the area being noted.

Many of the major deficiencies were escalations of deficiencies previously found – i.e. no corrective actions had been implemented.

Conflicts of interest in reporting lines have increased.

Future reports may further subdivide the Facilities category to provide more useful information.

All reports are now peer-reviewed. Where there are disagreements, they are discussed throughout the group.

GLP Mailbox

There have been 219 queries, split between compliance issues and GLP systems. This does not include questions addressed to individual inspectors. There were a significant number of questions about archiving. The GLPMA will send SAG more details.

There were 99 requests to use non-GLP subcontractors. Only 4 were refused. Refusal was on the grounds that the work could be easily subcontracted to a GLP lab, that it was a pivotal part of a study or that it could not be subcontracted to a facility in a different country as this would by-pass that country's GLP laws. Most of the requests came from 3 major UK CROs and were for field trials, formulation analysis and NMR analysis (10 of these).

Web Site

The FAQ page is now live. There has been a new FAQ about report amendments.

The site has been revised to reduce the number of queries to the mailbox that are covered on the site already.

The GLPMA welcome feedback about the site.

Subcontractor notification

A number of issues were clarified:

- The GLPMA will always expect to be informed if a test facility intends to extend compliance for a phase of a study done in a laboratory that is not a members of the GLP compliance program.
- There are ongoing discussions on whether companies need to notify the GLPMA if compliance is not going to be claimed for the work. A critical factor here would be whether the phase was pivotal or incidental to the study. The discussions are currently with other EU countries; if a consensus is reached there, it will be taken to OECD.
- The requirement to notify the GLPMA if there is an intention not to claim compliance for a part of a GLP study is aimed at cases where the work is a full phase of a study done by an organisation that is part of the GLP program, but on premises that are not covered by the GLP certificate. The GLPMA do not need to be notified if the work is a single assay done on premises covered by the company's GLP certificate.

Members of the committee expressed the opinion that consultation before policy announcements could reduce ambiguities in GLPMA guidance. Such consultation may be possible, e.g. by e-mailed discussion with interested members of the committee, but such discussions should not cause delay in issuing guidance.

International Review

India is now a full adherent on the Mutual Acceptance of Data agreement (MAD). This covers all product areas, but at present there are only 16 organisations in India's GLP program.

Brazil is also a full adherent but this only covers pesticides and industrial chemicals.

Canada now has a GLP program for Pharma.

The European Food Safety Authority (EFSA) and European Chemicals Agency (ECHA) are asking the GLPMA to perform study audits during GLP inspections.

There has been no change in China's status. It would take 'a number of years' for this to change.

An electronic OECD discussion group has been set up. At present only the GLPMA are the only UK members, but nominated representative from BARQA and ABPI have been invited to join. The current items under discussion are 1) to identify areas where individual countries' GLP regimes appear to disadvantage organisations in those countries and 2) whether GLP keeping up with technology.

Technical Questions (from SAG members)

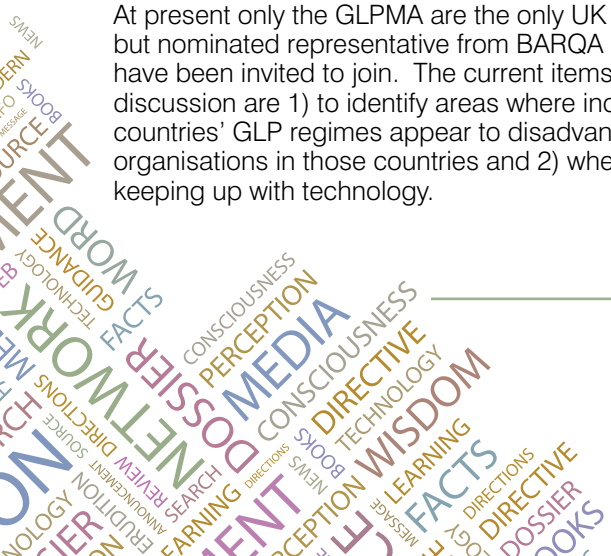
Four questions were submitted. The GLPMA's detailed 'official' answers will be included in their minutes of the meeting, but here is an approximate summary:

1. The GLPMA has recently issued guidance on retention of copies of raw data by a test facility when the original data is sent to the study sponsor. Does this replace or supplement previous advice to test facilities to retain reports and study plans indefinitely?
   It replaces previous advice. They no longer advise facilities to keep study plans and/or reports, but would expect documentary evidence, e.g. from retained copies of master schedules, that the work had been done
2. Is there any updated guidance (since the Guidance Document on GLP Archiving) for closing an archive? In particular can the GLPMA offer any practical advise on what can be done with general facility records, and would passing on training records to previous customers be in breach of the Data Protection Act (DPA)?
   No. Organisations are invited to discuss intentions on a case-by-case basis. Some guidance covering GxPs generally may become available, as this is an issue that also concerns GCP investigator sites. The GLPMA would welcome SAG input into this. The DPA may cover passing on personal information as might be contained in CVs.
3. What are GLPMA expectations of companies contracting out archiving of GLP electronic raw data?
   These are covered in the two relevant sections of the guide to GLP archiving; however 'there may be additional technical requirements'. The Swiss Quality Group has recently discussed electronic archiving.
4. The guidance on retention of copies of raw data states that the interval between inspections does not exceed 27 months. Is this a definite commitment that test facilities can rely on when planning for future inspections?
   There is no commitment on this as the interval between inspections is likely to be increased – see section 2.

Regulatory Authority Liaison Meeting

In future years, the liaison committee (which comprises the GLPMA and regulatory agencies) will meet after the consultative committee to avoid duplication of discussions.

There is still one GLP enforcement case ongoing.



Attendee Experience Spring Conference 2011

Robert Stiles, Qualogy

First Attendee Experience

I work for Qualogy Ltd and I have been with the company for 2 years. We offer a dedicated, regulated archive service for the storage of material from GxP regulated studies while also offering consultancy and training to the regulatory arena.

This year's Spring Conference in Bournemouth was my first Scientific Archivists Group conference. Having heard much about previous SAG conferences from my colleagues and "friends" I attended with a mixture of excitement, curiosity and terror. All the stories couldn't be true?

I travelled down from Cambridge the night before the conference and spent the following morning walking around Bournemouth enjoying the sea air and attempting to spot any fellow attendees amongst the swimmers and penny arcade patrons along the promenade, before decamping to a greasy spoon for some well earned lunch. Little did I know that while enjoying all Bournemouth has to offer, chomping away on my sandwich, a conspiracy was in full swing during the SAG Committee meeting and that at that precise moment I had "volunteered" to write this article about my first conference.

Having checked in and after finding my room in the labyrinthian Royal Bath Hotel, and after negotiating the life size plastic cows, I made my way to the opening of the conference. The member's session ran through all recent SAG business and discussed the imminent conversion to a Limited company. It was interesting to get an idea of what the committee and SAG as a whole is currently doing and what plans there are for the group in the future. It also gave newbies, such as myself, an opportunity to put faces to names of the various SAG Committee members.

This was followed by the first Speakers, Eldin Rammell and Russell Joyce, whose "Records Management Workshop" explored the different challenges within records management and the problems that arise when trying to assign retention periods to ones documents. The workshop element allowed the delegates to interact for the first time while discussing the application of records management The session also worked on exploding common records management myths and examined the received wisdom that, I must confess, was where most of my knowledge on the subject was garnered. I found the whole workshop very informative and at a time when Qualogy is looking to relocate and in the process shed some of our unwanted documentation, extremely relevant to my own role.

With the Thursday programme complete we were given time to freshen up before the drinks reception and conference diner. We all met at one of the hotels private bars for the drinks reception and took the opportunity to become better acquainted with each other. Everyone was very friendly and the conversation was not exclusively restricted to archiving and archives. Following that we made our way to the dining room for what proved to be a very enjoyable evening meal. The dinner provided a great opportunity to meet different delegates from a wide variety of different companies and with an even wider variety of different personal backgrounds. The wine flowed nicely and everyone seemed to enjoy themselves. Having left the dining room briefly to answer a call of nature I subtly and elegantly re-entered the room by tripping up a step and falling flat on my face. I can assure you that this was simply down to my inherent clumsiness and not down to any alcoholic influence.

After this we made our way to the main hotel bar accompanied by a stream of servicemen and women who, I believe, were attending a charity dinner in the hotel and put us all to shame dressed in their very fine mess uniforms.

The next morning, having failed to make breakfast on what was a beautiful sunny day, the conference resumed with a presentation on Training Records by Tim Stiles which examined the problems that can be encountered when trying to keep relevant and appropriate training records.

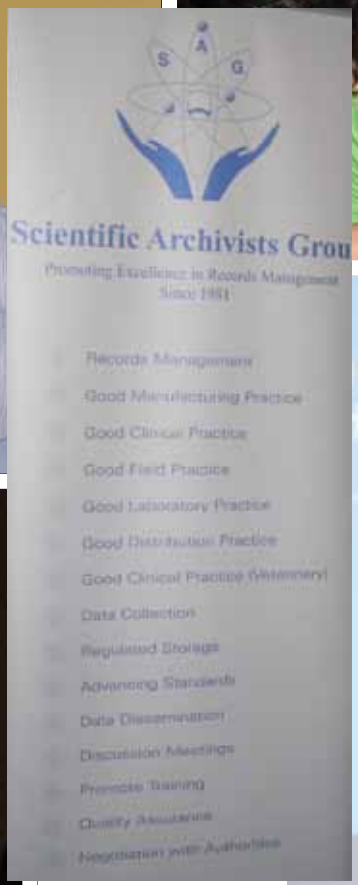
Following this, Nick Berry from Pfizer gave us a presentation on Business Continuity Planning. The presentation gave us an idea of the processes that should be in place to provide as much security as possible in case the worst should happen. The presentation was followed after lunch by a workshop session which divided the delegates into groups and asked us to apply what we had learnt to a fictitious disaster. I found this workshop really interesting, we have a business continuity plan in place at our firm and it's good to have a reminder of procedures that should be in place if the worst should happen.

Next up was a Phil Sawyer's presentation "Implementing Records Retention Policies Across the Company" which served to remind us all of the complexities of Record Retention Programmes, especially when applied across an entire companies operation. Nicole Schulz then gave an enlightening talk on Cloud Computing, which I personally had very little previous knowledge of.

The talk gave an interesting insight into cloud computing and how it works and how it benefits those who utilize it. While using cloud computing directly for archiving primary pharmaceutical data may not ultimately prove viable, I think using it in a wider business context, as access to shared software etc, it provides a very cost effective and exciting option. The conference closed with

(...continued)

Presenters and Delegates Networking Photo Gallery *Spring Conference 2011 – Bournemouth*



Attendee Experience

(continued)

a brief update on the e-Archiving working party and the progress that they hope to make over the coming months in producing a document which outlines the regulatory requirements that should be in place.

All in all, I thoroughly enjoyed my first experience of a SAG conference. As an introduction to the community of Scientific Archivists, it was very useful. The chance to meet new people who work in a similar area to my own was very interesting. Meeting other archivists and discussing different subjects and sharing common experiences and problems gave me an insight into the wider issues within scientific archiving. I feel sure that I will be able to directly apply this new expertise into my work with Qualogy.

The only question I have yet to find the answer to is why the Royal Bath Hotel uses life-size cow statues to compliment their Victorian decor? Answers on a postcard please.

Robert Stiles
Qualogy, Contract Regulatory Archive Services

Members Session Spring Conference 2011

May 2011 - Bournemouth

1. **Conversion to limited company**

   The Chairperson (Chris Jones) explained to the members what had taken place so far as well as the next steps to becoming a limited company.

2. **Change to Constitution**

   The Chairperson explained the change and the reason behind this.

   Previous text
   If the Group is disbanded and there remains a net liability or deficit this will be discharged by equal contribution from all Members of the Group at the time of the winding up. If the Group is disbanded and there remains a net surplus, this will be disbursed by equal contribution to all members of the Group at the time of winding up.

   Updated Text
   If the Group is disbanded and there remains a net liability or deficit this will be discharged by equal contribution from all Members of the Group at the time of the winding up. If the Group is disbanded and there remains a net surplus, this may be disbursed by equal contribution to all members of the Group at the time of winding up or, at the decision of the Membership, may be transferred to another organisation to further the activities supported by the Group.

3. **Treasurer's report**

   The Treasurer went through the provision accounts with the members, details; a more concise report will be available at a later date.

4. **Membership Secretary's report**

   The Membership Secretary informed the group that membership has 123 members which included 13 new members and 19 of which are non-UK members. Certificates will be now sent out by email and the directory available on the website. This was decided as the saving on printing and postage would be worthwhile.

5. **Details of next conference**

   The conference organiser informed the group that the next conference would be in Manchester. This will be a full two day conference.

   Thursday will consist of workshops in the morning and afternoon each attendee will be able to choose one in the morning and one in the afternoon on a first come basis as there will be limited spaces.

Question & Answer session

Q) Will the cost of membership increase with the move to the limited company?

A) No the membership fee will not increase due to this change.

Q) The last increase to the membership fee was about 10 years ago, do you think it's about time the fee was increased?

A) The committee review the membership fee every year and so far it has been agreed that an increase is not need due to the number of members we have had.

Q) Will we be members of the new limited company?

A) Yes as a limited company by guarantee we will have members as opposed to a limited company by shares that have share holders.

SCIENTIFIC ARCHIVISTS GROUP

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

MEMBERSHIP APPLICATION FORM FOR CALENDAR YEAR 2011

The Scientific Archivists Group is in the process of transferring its operations to a new limited company, Scientific Archivists Group Ltd., during 2011. This application will be treated as an application for membership of both The Scientific Archivists Group and of Scientific Archivists Group Ltd.

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

Please return completed registration form, together with payment to:

R Pennicard, SAG Treasurer,
c/o Selcia Ltd,
Fyfield Research and Business Park,
Fyfield Road, Ongar,
Essex, CM5 0GS,
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.

SAG is not registered for VAT.

SAG is approved by HM Revenue and Customs under section 344 of the Income Tax (Earnings and Pensions) Act, for income tax relief in respect of annual membership subscriptions. A copy of the HMRC letter is in the members area of the SAG website.

PERSONAL DETAILS

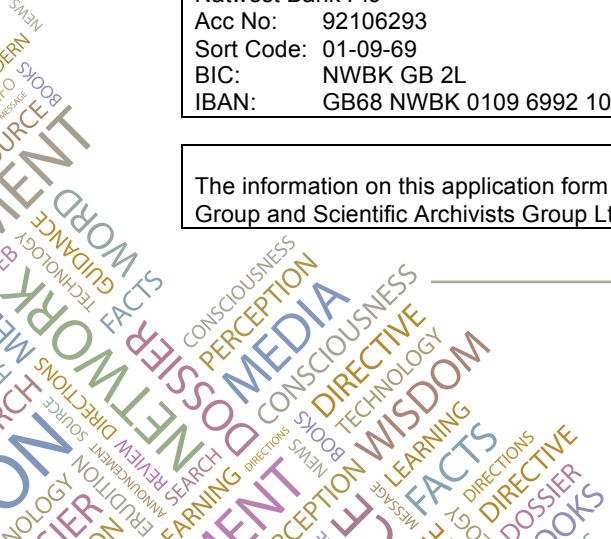
Name	
Job Title	
Company Name	
Address	
Tel No. Fax No.	
E Mail Address	
Discipline (tick those that apply)	GMP ☐ GLP ☐ GCP ☐ GPvP (pharmacovigilance) ☐ Other (please specify) ☐ ……
How did you hear about the group?	

Bank details for BACS payments

Sterling Payments		**EURO Payments**	
Natwest Bank Plc		Natwest Bank Plc	
Acc No:	92106293	Acc No:	550/00/64500632 NXNBBNDK-EUR00
Sort Code:	01-09-69	Sort Code:	01-09-69
BIC:	NWBK GB 2L	BIC:	NWBK GB 2L
IBAN:	GB68 NWBK 0109 6992 1062 93	IBAN:	GB85 NWBK 6072 0264 5006 32

DISCLAIMER

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




DOCUM
INTERNET
REVIEW
DIRECTIONS
MEDIA
GUIDANCE
DIRECTIVE
SOURCE
RECOMMENDATION
TEACH
SYMBOL
WISDOM
STUDY
INFO
NEWS
WEB
DOSSIER
FACTS
MISSIVE
LEARNING
WORD
SEARCH
MODERN
BOOKS
TECHNOLOGY
CONSCIOUSNESS
MESSAGE

Scientific Archivists Group
promoting excellence in records management

AUTUMN 30th ANNIVERSARY CONFERENCE

OCTOBER 2011
MANCHESTER

Topics to include:

- Workshops on
- GLP
- GCP
- Introduction to records management
- Introduction to eTMF's
- SLA's
- Audits

Presentations on:

- Specimen management
- Laboratory notebooks
- GMP
- Data protection
- Member Session
- Conference Dinner

Other topics to be determined

Please note that workshops will be allocated on a first come first served basis and rooms will not be guaranteed until full payment has been received.

Further information visit our website *www.sagroup.org.uk* and for online booking please visit www.sagroup.event.co.uk or for any queries please contact us on *Manchester-2011@sagroup.org.uk*

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 £250 per full page will be charged for all Sagacity adverts. £200 for a mail shot and £150 for email shot

All enquiries regarding advertising must be addressed to the Editor.

Invoices for payment will be sent by the Treasurer.

Please send an original copy to the Editor and a further copy to the Treasurer to enable an invoice to be raised.

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

Call for Articles

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 ***sagacity@sagroup.org.uk*** or telephone **01933 319906** and speak to Gail.

Scientific Archivists Group

promoting excellence in records management

www.sagroup.org.uk