JOURNAL OF THE SCIENTIFIC ARCHIVISTS GROUP

SAGACITY

In This Issue:

JULY 1997

EDITORIAL NOTE:

July 1997

"It's Archiving Jim, but not as we know it!"

The Spring SAG conference, held in the beautiful city of Cambridge, was once again a pleasure to attend. The theme of the Conference was 'Computers and their Impact on the Modern Scientific Archive'. The papers presented offered us all food for thought. As I hope the resulting articles in this issue will, for our readers who were unable to attend.

Before the Conference I had not given much thought to electronic data management, but I am now convinced that it will be the greatest challenge facing Scientific Archivists in the new millennium.

The concept of "Fuzzydrives" and "Hypertext" etc may seem futuristic to many Archivists but in reality it is probably closer than we think. We only have to observe the impact of new technologies in other industries to realise the potential for advancement in our own paper dominated environment.

The biggest challenge for the Scientific Archivist will be to keep pace with the technological changes while complying with our strict industry regulations.

So, be kind to your mouse, and don't work your drives too hard!

Regards,

Karen Box

The Scientific Archivist Group would like to thank SafePharm Laboratories Ltd for producing this Journal and Elaine Stott of Zeneca Pharmaceuticals for copying and distribution.

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LETTER FROM THE CHAIRMAN

It is with regret that Alan McQuitty has decided to stand down as Chairperson of SAG due to excessive work commitments. Alan will continue to be a member of SAG. We thank Alan for all his hard work on behalf of SAG and hope that sometime in the future he may feel able once again, to assume a more active role in the Group.

As elected Vice-Chairperson I have now assumed the role of Acting-Chair until the election of a new Chairperson and several new Ordinary Committee Members can take place. These elections will be held at the AGM at the Autumn Conference. This occurrence has left the Committee "a little thin on the ground" so anyone who feels they have the time/commitment/dedication to serve the Group in a committee capacity, please contact Michelle Dorn, SAG Secretary, as soon as possible.

The Short Courses are progressing well and, as a result interest in DipSAM is also on the increase. Our thanks go to Margaret McCabe, Short Course Organiser, for all her hard work.

The Spring Conference, sponsored byAmgen, was held at the University Arms Hotel, Cambridge on 17 April and was well attended. Our thanks go to Pam Young, Michelle Dorn and Amgen, for making the conference a great success.

The Autumn Conference will be held on 9 October 1997 at the Hopcrofts Holt Hotel, Steeple Aston, Oxfordshire and will be sponsored by Datacare Ltd. Datacare is a company specialising in the construction of Archives and provision of offsite Archiving services. One of their archiving facilities is in the Hotel vicinity, a visit to which is scheduled to take place on 8 October. Transport is being provided by Datacare and will leave the Hotel at approximately 3 pm on that day. Any members who's Archive is close to capacity may find this visit interesting and may consider this as a solution to storage problems.

I hope you all enjoy your summer holidays and I look forward to seeing as many of you as possible on 9 October 1997. ■

Lesley Almond, Acting Chair

1997 SPRING SAG CONFERENCE

HOST COMPANY PROFILE : AMGEN

Amgen was formed in 1980 in California and the main focus of the company is cellular and biogenetic technology, genome[1] research and small molecular chemistry as well as an extensive protein-based research program in haematopoiesis, neurobiology and inflammation.

Amgen's main area of research is in the field of DNA cloning. Very simply this is a process in which scientists identify specific DNA gene usage, "snip" out the relevant section of the DNA string and transplant the section to a growth product, such as yeast, and then promote the growth of DNA through the brewing process, so essentially "cloning" the DNA.

Fermentation is a core process in the manufacture of recombinant biologic therapeutics at Amgen. Process development engineers are innovators in the fundamental technologies supporting the industry, striving to continuously improve efficiency, purity and reliability.

The company headquarters are in Thousand Oaks, California, north of Los Angeles. Compared with many companies in the pharmaceutical field it is relatively small with only 4500 employees worldwide. The company is however very successful, it is listed in Fortune 500 in the USA and has a global turnover of 2.2 billion dollars.

In 1989 the company launched its first product EPOGEN® which is aimed at patients on dialysis. By stimulating the production of red blood cells EPOGEN helps to raise patients haematocrits[2], virtually eliminating their anaemia and reducing the need for blood transfusions.

In 1991 Amgen launched its second product NEUPOGEN®. This product helps to restore white blood cell counts to normal in a variety of treatment settings and is beneficial to cancer patients. With the availability of NEUPOGEN patients are less likely to suffer infections, resulting in fewer hospitalisations and less antibiotic usage. As a result, they may be able to tolerate high doses of chemotherapy over longer time frames, expanding treatment options and potentially enhancing patient survival.

Amgen scientists use the most advanced technologies available to ensure that drug delivery methods and product formulations are safe and effective for clinical use.

This year Amgen hopes to launch its third product INFERGEN®. Results of clinical trials indicate that it is safe and effective in the treatment of patients with chronic hepatitis C and may lead to higher response rates in patients than currently available treatments.

A further twelve products are still in the development and trial stages and Amgen have increased capacity in clinical manufacturing; commercial manufacturing and distribution; expanded research and development capabilities; as well as the management and sales force, to make the transition from a two-product company to a multi-product company.

Amgen is committed to investment in research and development and hopes that the important therapeutic products they are marketing will continue to be both a measure and vehicle of their continued success. ■

(1) genome : a single, complete set of the chromosomes present in a normal human cell.

(2) haematocrit : The percentage of the human body's blood that is made up of red cells.

NOTES AND QUERIES

Question : Clear plastic wallets are widely used in offices to separate and file data, why are they not suitable for use in the Archive?

Answer : To be printed in December 1997 issue.

If you can provide an answer to the above question or have any other questions please contact :

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Why has
Spectrum so
many blue chip
clients in government,
banks, commerce, and
industry?

Spectrum, established in 1986, is the parent of an international group. Spectrum UK provides a broad range of DM services including document scanning and microfilm bureau services, consultancy and facilities management. Part of the successful Spectrum Difference is our commitment to Quality and Service, backed by real technical and commercial stengths.

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• On-site data conversion • Facilities management

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• System Specification • IT Strategy

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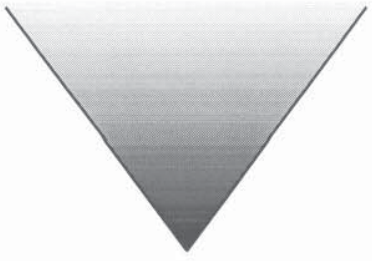


QA Aspects of Computer Systems

A paper presented by Mr Paul Greenstock of Lilly Research Centre Ltd., at the SAG Spring Conference, 17th April 1997, Cambridge.

When considering the QA aspects of computer systems you firstly need to consider your agenda:

- **What Archive controls need to be in place?**
- **What needs to be Archived?**
- **Retention of Archived Records?**
- **What system retirement policy should be considered?**

The basic principle is that the same rules and regulations that are applicable to paper need to be applied to computer data.

GXP Regulations

The regulations governing computer systems will differ depending on which discipline your archive complies with *ie* GLP - Good Laboratory Practice, GCP - Good Clinical Practice or GMP - Good Manufacturing Practice.

* GCP - The Rules Governing Medicinal Products in the European Community. Directive 91/507/EEC.
  - ICH Harmonised Tripartite Guideline for Good Clinical Practice.
* GMP - MCA - Rules and Guidance for Pharmaceutical Manufacturers 1993 (Annex II Computerised Systems)
* GLP - DoH Advisory Leaflet Number 1 (1995). The Application of GLP Principles to Computer Systems.
  - OECD GLP Concencus Document. The Application of the Principles of GLP to Computerised Systems.

Archive Controls

The GLP regulations offer the most information on what controls need to be in place in the Archive. DoH and OECD GLP guidelines state that specific controls for indexing, environment, readability, retention and destruction, (including management approval before destruction), all need to be in place.

All measures undertaken need to ensure that - "long term integrity.....is not compromised", as with comparable paper records.

The EC GMP regulations require that data is checked for accessibility, durability and accuracy. That all data is protected by back-up copies and that the back-up copies are stored as long as necessary at a separate location. Data needs to be readily available throughout the period of retention.

The GCP regulations are probably the most adaptable and accommodating for computer records at present. It states in the EC GCP regulations that data may be held on microfiche or stored as electronic records as long as a back-up copy exists and that a hard copy could be obtained if necessary. The ICH GCP regulations specify only, that companies should retain and maintain adequate back-up of the data.

What to Archive?

The regulations for each GXP will affect what type of data is presented for archiving, not only as electronic data, but in support of the electronic systems in place.

Again the DoH and OECD GLP authorities offer the most comprehensive guide. The regulations specify that the GLP principles for archving data must be applied consistently to all data types. In support of any electronic system in a GLP compliant area QA would expect the source code, development validation and testing documentation, operation and maintenance records, audit trails and change control documentation, to all be archived in support of any system.

The GCP regulations are harder for QA to interpret. The ICH GCP regulations specify that the 'master randomisation list' should be archived. The EC GCP regulations go further and state "....all other documentation pertaining to the trail.....", should be archived.

The EC GMP regulations expect all batch records to be archived and it should be noted that the FDA consider software documentation equivalent to batch records.

Retention

The retention of all records, not only computer generated data, is a key consideration for all companies in todays pharmaceutical industry. The regulations at least are specific about how long the

data should be retained but individual companies are sometimes never able to agree on a retention policy for their archived data. Which leaves the Archivist to facilitate the practicalities of retaining the data.

EC GMP - "for at least one year after the expiry of the finished product".

DoH and OECD GLP - " for at least as long as study records associated with these systems".

GCP - "....not less that 15 years".

- ".....at least 2 years after the last approval".

These strict parameters for record retention are hard enough for the Archivist to enforce with paper records. With electronic data there are the added problems of actually reading the data after a period of time.

System Retirement Considerations

The life span of the average computer system is frighteningly short with updates often being available very quickly after the initial product is marketed. So, to be able to read the archived electronic records, necessary in all the basic principles of GXPs, one of the primary concerns is how you are going to plan for the retirement of your computer system.

There are a variety of options for consideration:

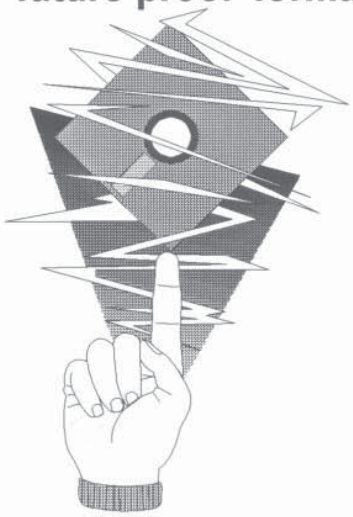
Keep Everything !!!

This is perhaps the most drastic option, but it is an option. Your company may consider archiving the terminal, keyboard, hard drives, tapes etc to be able to reconstruct their archived data in the future. All this equipment will need to be maintained, serviced and regularly checked to ensure that it is still operational.

Migrate to a new system

This option means that as each system is superseded all previously held archive data is transferred onto the new format for future storage. This will entail intensive checks to ensure that data has not been corrupted or in any way altered during transfer from one system to another. If the Archive collection is extensive this option is certainly going to be a labour intensive and daunting task to undertake.

Convert data to a 'future-proof' format



This option involves transferring the electronic data onto a system which is future-proof such as microfiche, ASCI text or.....paper! A consideration at this stage is that perhaps it would have been more efficient to transpose the electronic records into a future-proof format prior to archiving.

It is essential to plan for the future. Prepare in advance an SOP to ensure the Archive can comply with the regulations. As an aid, the following table should help illustrate the regulations and the guidance they offer for the aspects of electronic records retention we should all be considering. ■

This table shows the key requirements that are common to all three 'practices'. A section reference to each document is also shown.

	EC GCP	ICH GCP	DoH GLP	OECD GLP	GMP
Systems documentation	3.3	5.5.3	1a	8	4
Validation	3.3, 3.10	5.5.3	2	7	2
Audit trail	3.4	4.9.3 5.5.3	3	5	10
Change control	Note 2	5.5.3	2	7c	11
Checks on data validity / integrity	3.11	5.5.3	3	6c	6, 9
Standard Operating Procedures	3.12	5.5.3	2	8d	8, 16, 17
Controlled and authorised access	3.4	5.5.3	2	6	8, 10
Data printout capability (for qa/qc)	3.13	-	5 Note 3	1d Note 3	12
Training	2.3 Note 1	5.5.1	6	2	1
Disaster recovery / business continuity	-	-	2	4b	16
Data backup	3.3	5.5.3	3	6d	14
Archiving	3.17	4.9.5	4	9	14
Quality Assurance	5	5.1.1	5	1d	5

Notes:

1. Applies to computer systems and staff by implication
2. Does not mention software change control explicitly but does invoke GMP controls in section 3.2
3. Both DoH and OECD GLP require on-line access for QA purposes

AMGEN'S IMAGING SYSTEM
CARS (Clinical Retrieval System)
by Michelle Dorn and Rachel Simerly of Amgen Ltd, Cambridge

Background

CARS was developed in the US at Amgen's Head Office in Thousand Oaks , California, in collaboration with an external commercial vendor (Microdynamics) in 1992. The system was implemented in the Cambridge office in September 1995 and in the Boulder, Colorado office in December 1995.

Why an Imaging System?

The purpose of CRIC (Clinical Records Information Centre) is to serve as the central repository for all documents pertaining to the conduct of Amgen clinical trials, relevant to clinical data and in support of submissions to regulatory authorities.

Whilst original paper documentation needs to be archived, imaging of the essential clinical documents provides a secure electronic back up and quick access to documents for all.

Rationale/Requirements for Imaging System

Amgen had some specific expectations of the new system:

- Electronic back up of all paper documents.
- Global access to all documents imaged at each location.
- Implementation of the system would avoid duplication across offices, inherent in the previous system
- CARS Retrieve software enables users to view images, giving 24-hour access to electronic documents (an important factor when you consider that Amgen's HQ is in California and eight hours behind).
- Increased security of original documents, as users access images rather than paper.
- The new system would allow the use of images in electronic submissions, ie CALA

Implementation

The implementation of the system began with a series of talks between Head Office and IT and User sponsors in the Cambridge office in May 1995. From these meetings a plan and timelines for implementation were agreed. Areas such as equipment needs and expenses, set up of the system and subsequent validation, user training and technical support, were discussed and parameters established.

By June of 1995 the Cambridge office were ready for training and technical support from Thousand Oaks and by September 1995 the office had started to process documents onto the CARS system.

Added Functionality for Cambridge

The new system provided two important additional functions:

- A link was built into Amgen's CRF (Case Report Form) system to enable checking of receipt, data entry, data check, cleaning etc.
- Amgen's electronic query system was adapted to build in a function called Quergen (Query Generation System) which enables any queries on CRFs to automatically be sent back for checking.

The computerised system also enables the department to measure and display the amount of data processed. An important aspect when assessing work flow and any future resource allocation requirements.

CARS Retrieve

All users within Amgen are trained by CRIC staff, who also provide ongoing assistance. CRIC staff are fully trained in CARS Retrieve and can assist with customising the system to meet user requirements, ie Hot Folders/Saved Searches.

The new system enhances availability of information in the CRIC by providing continuous around-the-clock desktop access to imaged documents and associated document inventory information.

Costs Involved

SOFTWARE - No substantial software costs associated with rollout of CARS in Cambridge, as site licences were negotiated as part of the original CARS project in the US.

Optical server software however needed to be licensed from Microdynamics at a cost of $20k.

Contract Programmer costs to implement enhancements specified by the UK site cost approximately $10k.

HARDWARE - Costs for CARS in the UK implementation were estimated at approximately $100k ($30k for Macs, $30 for optical drives, $20k for high-speed printer, $20k for scanner).

Additional costs for memory upgrades and larger monitor screens - ongoing!

Key Issues

The key issues for anyone to consider when thinking about installing an imaging system are:

- *Will there be adequate technical support at all times? (time differences need to be taken into account!)*
- *Detailed documentation on all aspects of the system is essential.*
- *Network needs to be evaluated.*
- *This will be a large investment in equipment ie software, hardware, storage media etc.*
- *The impact of process change on individuals and departments should never be underestimated. It is essential to involve people from the start as they are less likely to be resistant to the changes.*

The Future

The future for Amgen may well be moving from the existing imaging system, to an integrated document management system that allows for the indexing and retrieval of different document types, ie images, text documents.

Future enhancements could include auto-indexing, OCR/ICR recognition, work flow.. ■

VOLUNTEERS PLEASE !!

The SAG is looking for SAG members to join the Committee.

We are looking to increase the current 7 members to 10. This measure would help the existing committee to spread the workload. Most importantly we have to elect a new Chair Person.

The SAG has over 100 members from the UK, Europe and the US. We hold 2 conferences a year, produce 2 quality newsletters annually, support the DipSAM qualification and provide a network for mutual help and advice about the subject of Archiving.

Please contact Michelle Dorn at:

Amgen Limited
240 Cambridge Science Park
Milton Road
CAMBRIDGE CB4 4WD
Tel : 01223 436224

So if you feel you can further contribute to the Group we would gratefully welcome your support.

NEW VENTURE AT STAMFORD LODGE

In the December issue of Sagacity last year we informed readers of the closure of the Stamford Lodge site of Ciba Pharmaceuticals, at Wilmslow, following their amalgamation with Sandoz to form the new company of Novartis.

The forecast is now more optimistic as the whole site, including laboratories, offices, archive and the grounds have been purchased by Huntingdon Life Sciences. HLS intend to retain the existing staff, facilities and services.

The Stamford Lodge site will be the third UK base for HLS Ltd who came into existence last year with the amalgamation of Huntingdon Research Centre (HRC) and Life Sciences Research (LSR).

CLINICAL TRIALS AUDITS

The fourth Annual Henry Stewart Conference on Clinical Trial Audits was held on Monday 16 June 1997, Café Royal, London

Chaired by Nicki Blackburn, the Head of Clinical Compliance for Glaxo Wellcome Research and Development the programme included:

Planning and Implementing Investigator Audits by Clive Jenkins, GCP Consultant, Ashdown Clinical Research

- Why audit investigators?
  - EC and ICH GCP requirements
  - Supporting the clinical project team
- When should audits be conducted?
  - close liaison with the clinical project team
- Planning the audit
  - Familiarisation with the protocol, amendments and CRF
  - Familiarisation with relevant SOPs
  - What factors determine time spent on site?
  - What about geography/language?
  - Finalising the audit plan
  - Making appointments
- Auditing the Trial Master File
  - Where is it?
  - What is checked and why?
- The Investigational site audit
  - Who should attend?
  - Other departments to be involved
  - Opening and closing the audit
  - A typical procedure
- The Audit Report
  - Who needs it and when?

Auditors : Requirements for the Function by Dr Beatrice Spang, GCP Quality Assurance,

Novartis (Basel HQ)

- Education
- Experience
- Personal attributes
- Language skills
- On the job training

Problem Areas in Audits by Dr Beatrice Spang, Novartis

- Execution of an audit
- Communication with auditees
- Communication with management
- How can audits help to identify problem areas?
- Contribution of audits to help improve quality in clinical trials.

Regulatory Inspections - An Industry Perspective by Sunil Kotecha, Clinical QA Manager, Pfizer Central Research

- What is happening outside the USA
- Recent experience with FDA inspections

Company approaches to regulatory inspections

Regulatory Inspections of Clinical Studies in the UK by Pamela Charnley Nickols. Head of GLP Compliance, Inspectorate and Enforcement Division, UK Medicines Control Agency

- The UK MCA GCP Inspectorate
- Legislative framework for Good Clinical Practice
- The voluntary inspection programme
- GCP Inspectorates outside the UK
- Towards harmonisation of inspections in the EU

Practical Implementation of the ICH GCP Guideline by Denise Marvel, Training Manager Europe of Bristol-Myers Squibb

- Putting the GCP Guidelines into perspective
- What is new?
- Ensuring adherence of SOPs with GCP regulatory requirements
- Ensuring training of company staff
- Ensuring training of investigator

Defining the Balance Between Quality Control and Quality Assurance: Can you separate them out? by Neil Kenopta, Senior Advisor Worldwide Regulatory Compliance, SmithKline Beecham Pharmaceuticals

- Quality Control/Quality Assurance
  - What is the difference?
  - Who is responsible?
- Protocol to clinical report - a quality road map
  - Training
  - Clinical audits
  - Company systems
  - CRO involvement
  - Clinical reports
- The benefits of pro-activity

Clinical Quality Assurance Sourcing - The Logistics by Brendan McDermott, Clinical Quality Assurance Manager, Pfizer Central Research

- Balancing resources - when and what to outsource
  - Pre-contract assessment of CRO
  - CQA contract
  - Training
- Management of CRO CQA
  - Ongoing assessment of CRO CQA
  - Communication and feedback
  - Contract amendment
- CRO performance metrics
  - Key deliverables
  - Quality of service
  - Return investment
- Future development of sourcing strategy

Computer Audit/Validation by Bryan Doherty, Senior International Compliance Executive, International Compliance Group, of Zeneca Pharmaceuticals

- Understanding the key principles and terminology
- Why audit or validate?
  - Responsibilities
- The system life cycle and associated documentation
- Regulatory requirements
- A basic auditing approach

For a copy of the Conference Proceedings, or any further enquiries please contact:

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" COUNTRYSIDE UNDERCOVER - IT'S A DOG'S LIFE"

As many of you will be aware, a Channel 4 television programme was broadcast in early April which involved "undercover" filming inside Huntingdon Life Sciences in Cambridgeshire; which is one of the largest contract toxicology laboratories in the UK. The behaviour of the technicians in the film can only be regarded as disgraceful, both in the manner in which they treated the animals in their care, and in their apparent disregard for basic GLP principles.

The Institute of Animal Technology (IAT) has issued a strongly worded statement condemning the actions of the individuals, stating that : " The unprofessional, aggressive and brutal handling of animals shown in this film, has no place in United Kingdom laboratories".

The IAT go on to confirm that animal technicians have "a moral and legal obligation to promote and safeguard the welfare of the animals in their care, and that any member found to be failing in this duty would be suspended and their professional qualifications revoked".

As well as the television exposé, the infiltrator also sent a package of information to the GLP Monitoring Authorities, which contained further allegations of non-compliance to basic GLP principles.

The day after the film was broadcast the GLP Monitoring Authority made an unannounced inspection of the laboratory concerned. The inspection was conducted behind closed doors, although many data records were called for and key staff were interviewed. At present there has been no formal statement from the GLP Monitoring Authority but a "warning notice" was issued to the laboratory. Failure to comply with the terms of such a notice constitutes an offence which may result in fines or imprisonment.

In recent weeks the GLP Monitoring Authority has made visits to the major contract toxicology laboratories in the UK to ensure that similar problems were not in evidence.

Early signs indicate that this programmed could alter the way that all future GLP inspections are conducted. However, it is unclear at present what effect these recent events will have of the GLP Monitoring Authorities routine inspection programme, which is already behind schedule.

Action to deal with the problem has been swift. The Home Office immediately suspended, pending revocation, the personal licences of the two technicians involved in the cruelty incidents. The matter was referred to the police for possible prosecutions. There has since been one arrest. HLS set up a "free ranging" investigation on the day after the broadcast, suspended four technicians and commenced disciplinary proceedings. An Investigation Panel was set up reporting directly to the Chief Executive and its investigations resulted in several dismissals and significant changes in line management.

Christopher Cliffe, Chief Executive of Huntingdon Life Sciences Group plc, has commented in a recent article:

"Although only about one third of the 1500 scientists, technicians and administration staff employed in the UK have an involvement with animals, there has been a universal outpouring of distress across the company. The company employs over 300 technicians of whom 200 are personal licence holders and they feel even stronger; they believe their profession has been betrayed by a small number".

Everyone in the industry is aware of the necessity for animal experimentation to comply with government regulations, which are in place to safeguard the general public. This awareness is often outweighed by the public's perception of animal experimentation and the general abhorrence of the practices it entails.

Programmes such as this can only promote the cause for banning animal experimentation, which would be to the detriment of human and animal health and safety, as well as scientific research and development. The industry needs to be seen to be responding to the difficult problems this programmed has highlighted in a positive and pro-active way. Otherwise public perceptions will never be changed, and this important area of research will be lost to other countries with less legislative control than our own.

We must remember that the events shown in this programme were apparently a direct outcome of poor management, that resulted in cruel and bad practices being allowed to prevail. The majority of installations performing animal experiments in the UK will be truly appalled by the problems exposed during this programme, and will want to ensure that checks are in place to allow no possibility of similar occurrences happening again.■

K. Box

GLP MONITORING AUTHORITY ANSWER QUESTIONS

Mandy Flynn, of the GLP Monitoring Authority, was invited to answer questions from BARQA members at a meeting held at Astra Charnwood on September 23rd 1996.

While the majority of the question and answer session concentrated on the wider issues of GLP regulations and the pharmaceutical industry, some did concern the GLP Archive.

A selection of questions relevant to the Archive have been reproduced, but if any readers have further enquiries they should contact their own QA Manager (who will undoubtedly be a BARQA member and may have been present), or the GLP Monitoring Authority for further clarification.

Q Internal Guidelines/Company Policy. Do the DoH feel there is a place for them and, if so, when and how should they be used? Do they require any sort of control in the same way SOPs do?

A Policies are useful and are necessary as stated in the guidelines. They should be controlled documents in a similar manner to SOPs.

Q By use of words such as 'adequate' and 'suitable' the UK GLP Principles often make it necessary to be aware of current, often unwritten interpretation of the Principles in order to comply. This is true of the section dealing with archives, where the Principles could apply to a controlled filing cabinet. Most organisations go much further than this. What standards are expected with respect to archives? Can any allowances be made for having back-up copies of data in safe storage?

A Generally as long as data is secure and access is restricted, the size is irrelevant. It is useful to provide backups, although there are no specific requirements.

Q What special measures (if any) are necessary when the QA Unit is given responsibility for the GLP archive?

A If QA administer the archives, then an independent person must be appointed to audit the archive. However, this independent person must have direct access to Management.

Q What do the DoH feel are the GLP requirements for an electronic SOP system?

A The requirements should be no different to a paper system. There must be the same controls and a secure master hard-copy (wet signature) must be retained in the archive.

Q When will the next revision of the 'Blue Book' be issued?

A There is no intention for a revision until the new OECD principles have been issued, which is at least a year away.

[**Post meeting note**: When the Statutory Instrument goes through Parliament (April 1st 1997), the 'Blue Book' will be defunct as the new law comes into operation. Advisory leaflets will remain as advisories.]

Q What measures (in GLP terms) should a company take when it merges with, or is taken over by, another company? Does the Monitoring Authority have a consistent policy with respect to these measures, eg. re-issue of SOPs?

A The main concern is the re-issuing of documentation containing the company identity. SOPs in use by the new company must be authorised for use by the new Management as an interim measure. This can be done as a blanket statement containing a list of the documents affected. Generally, all documentation should be changed within six months. The Monitoring Authority will also need to be assured that the new Management does not affect compliance.

Q What is the current position regarding the merger of the GLP Monitoring Authority with the MCA (should this be a take-over?)

A The move of the GLP Monitoring Authority to the MCA was scheduled to take place this Autumn. However no firm date has as yet been confirmed. It is certain though that the GLP Monitoring Authority will still remain independent

from the receiving authority and will report independently into the Secretary of State. This move is not considered by the DoH as a take-over.

Q Given the importance of data retention as part of any GLP compliance programme, should an Organisation choose to sub-contract the long term storage of Raw Data to an independent archive, why can not that archive be part of the compliance programmed?

A The DoH policy is that a contract archive cannot claim GLP Compliance and be part of the Compliance Programmed as it does not generate raw data.

Q What impact do you see that changes to the OECD GLP Principles having on the way in which we currently interpret the 'Blue Book'?

A The main areas of difference will be concerned with multi-site studies and the Principal Investigator concept. There are no other fundamental changes.

Q Do all computer systems used in a GLP facility have to validated to GLP standards?

A All computer systems used to generate, collect and process pre-clinical raw data must be validated to GLP standards, so that they comply with the requirements set out in Advisory Leaflet No. 1.

Q Why don't the GLPs state clearly what is required? eg. CVs, supplier audits, labelling of broken equipment are expected by Inspectors and accepted by QA personnel but a difficult laboratory manager can appeal to the silence of the GLPs.

A The GLPs are deliberately vague to allow flexibility within an organisation. They encourage individual interpretation which is acceptable to the DoH as long as justification for the decisions can be proved.

Q Can the DoH confirm that copies of equipment manuals can be used to replace elements of SOPs providing they are controlled documents?

A Yes they may be used, but must be archived (once they are no longer used) and be controlled in the same way as SOPs.

Q Many companies are working towards or may have introduced electronic copies of Standard Operating Procedures (SOPs) for used by staff, instead of paper copies. This raises the following points for discussion: the computer system(s) used to process and display the SOPs would need to be validated but may be a word processing application which is used extensively in the company. Therefore, the extent of validation needs careful consideration. Is there a current regulatory view on the extent of the validation which should be conducted during the System Development Life Cycle of a system(s) which process(es) and maintain(s) electronic copies of SOPs?

A The system must be controlled and be secure in the same manner as a paper system. it is considered that only those procedures where security is needed require validation.

Q Approval of the electronic SOPs could be either on hard copy or by electronic signature. Under what conditions would the use of electronic signatures on SOPs be acceptable?

A At present a master (wet ink) copy is preferred. In future electronic signature may be accepted if it can be demonstrated that the system is validated.

Q Since it is possible for some raw data to be grossly contaminated (eg by pathogens) during a study, it may not be practical to retain the original raw data. What approach would the Monitoring Authority find acceptable in such a situation?

A Authenticated/verified copies of the data should be made and a justification as to why the other was destroyed provided.

Q Within a company with production and research facilities in various parts of the world a (pilot) product is prepared abroad but sent for *in vivo* safety testing in the UK. The facilities responsible for manufacture and final lot testing (to pharmacopoeia) are GMP and GLP compliant. Substantial data therefore exists ('in-house') on the characterisation of the test substance. Would it be adequate in the study protocol to state what raw data is held? If not, what would

be the minimum acceptable documentation to be transferred with the product?

A Yes, it is adequate to state this in the protocol. However, the Study Director should assure themselves that there is adequate test substance data for this study (eg. a Certificate of Analysis).

Q Do the UK GLP Inspectors still advise the pharmaceutical industry to retain records of studies carried out under GLP and GCP regulations for the life of the product, and is there any information of the FDA view on this matter?

A The DoH consider it advisable to keep data for the life time of a product. However, this is a decision of the regulatory agencies. The FDA regulations state a period of five years following submission.

Q Now that the code of practice (PD 0008) has been established for the legal admissibility of information stored on electronic and microfilm records has been accepted in litigation, is the DoH prepared to accept study records in these forms and is there any information on the FDA view in this matter?

A Electronic data forms are generally acceptable during study reviews, providing that the data has been collected and is stored on a fully validated system. There is no infor-mation regarding the FDA perspective on this issue.

Q Do the DoH foresee the occasion where the GLPs will become a quality system as opposed to a set of principles/guidelines?

A Probably, in the longer term. The EU are looking to amalgamate accreditation with compliance. However, this may be dependent on the acceptability of this to the FDA and Japanese authorities. If this goes ahead GLP would become a quality standard.

Q Do answers to sessions such as this represent the official position of the Monitoring Authority, and can companies proceed with the formulation of policies in line with these answers in confidence that other members of the inspection team will not have a different view?

A Yes, but only after review by the Monitoring Authority.

NAME CHANGES

In the last issue we asked SAG members to note that the Corning Hazleton company had changed to Covance Laboratories Ltd.

Members should also note that Pharmaco International based in Cambridge is now call PPD-Pharmaco International; and that Pharmakon is now known as Chrysalis, both company addresses are unchanged. ■

If your company is changing its *name or address* please keep the SAG informed either by contacting the membership secretary or the journal editor.

Obituary:

It is with great sadness that we inform you that Mrs Rona Lawrence of Novartis Pharmaceuticals UK Ltd, died suddenly in February.

Rona, who was the Medical Archive Administrator for Ciba Pharmaceuticals (now Novartis), had been a member of the Scientific Archivist Group for many years and will be sadly missed. ■

Professional Development - The Diploma in Scientific Archive Management

The DipSAM is an accredited, professional qualification for Scientific Archivists and Records Managers working in a regulatory controlled environment.

The course is a programme of study accredited by Anglia Polytechnic University (APU) in collaboration with the Scientific Archivists Group (SAG). The course features open, student managed, work-based learning.

The benefits for all concerned with the course are substantial and have been proven in the three years the course has been successfully run. For the student, the benefits are enhanced experience and expertise and a recognised qualification. The employer has the benefit of the experience and expertise for a key member of staff. The SAG benefits from having a higher profile and the prestige of having a recognised, professional qualification and programme of learning.

The SAG and APU are offering students the opportunity in 1997 and 1998 to enrol for the course as a "distance learning" programme.

The programme will be run on a similar, structured format to previous years consisting of:

Module 1 - Reflection of Previous Experience of Scientific Archiving

Module 2 - Principles and Practice of Scientific Archive Management

Module 3 - Project

The new format offers the opportunities for overseas members of the SAG to benefit, as well as being more flexible, allowing students to take a study break if necessary.

Module 1 -

Students will be required to provide evidence of learning acquired during their employment prior to the course. This could be in the form of company training records, operating procedures or a statement from a line manager of applied knowledge and competency.

Module 2 -

This section includes technical and professional support from the SAG in the form of resource publications for distance learning students, and optional one day workshops and residential courses. The learning outcomes achieved would include:

1. An understanding of the principles of Scientific Archiving and its application in the work place.
2. An understanding of the purpose and objectives of archiving.
3. The knowledge and skill to perform the procedures associated with the retention and retrieval of archive data.
4. To critically analyse regulatory controls and appreciate their impact on scientific records management.

Specific topics for discussion will be:

Health and Safety in the Archive

Design and Layout of the Archive

Disaster Plans

Information Technology in the Archive

Regulatory Requirements in GLP, GMP and GCP

Data Management

Archive Procedures

This module will be assessed with a mixture of graded assignments and course work which compile into a portfolio of evidence of achieved learning outcomes:

Module 3

Each student will be asked to undertake a project within the workplace which will have direct relevance to the student and the student's employer. The project will be assessed on the written report which should demonstrate that learning outcomes have been achieved.

The whole DipSAM programme aims to develop the student's knowledge, expertise and experience in the field of Scientific Archiving. Module 3 provides the opportunity to demonstrate that these aims have been achieved. The resulting projects from previous years have been as varied as the students themselves; and have included everything from writing disaster plans to making a presentation to senior management with regard to implementing a new technology system within the archive.

The APU are convinced that distance learning is the way forward and that it is the ideal, modern educational format for individual work-based, flexible life-long learning.

FOR FURTHER INFORMATION CONTACT :

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Short Course Programme Manager
Centre for Professional Development
Anglia Polytechnic University
East Road
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CB1 1PT
Telephone : 01223 363271. Ext. 2493
Fax : 01223 352979. ■

POTENTIAL ADVERTISERS PLEASE NOTE

A fee of £90 - Full page and £70 - Half page will be charged for all Sagacity adverts.

All enquiries regarding advertising must be addressed to the Editor.

Invoices for payment will be sent by the Treasurer. Advertisements; original copy to the Editor with a copy sent 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.

QUALITY ASSURANCE - SANS FRONTIERS

It's all change at the BARQA Newsletter Editorial desk as we say farewell to Nigel Dent. The new editor is Mr. Ramzan Visanji, currently working in the QA area at Hoechst Roussel Vet Ltd., at Milton Keynes, to whom we extend our best wishes.

Nigel, who has been editor for the last ten years, is a scientific consultant and author. As you will see from the following article (reproduced with kind permission from the March 1997 issue of the BARQA Newsletter), Nigel will be continuing his career in the field of QA and we wish him every success.

I thought it worthwhile putting together a small article to follow up on my last trip to India. This discusses the continuing saga of the Good Practices in the Indian sub-continent and QA explorations to the bottom half of the world - New Zealand.

Having just returned from India last month, my ninth trip, I though I would relate some amusing incidence that have happened over the past few trips.

On this occasion I was not flying directly to the JRF Laboratories where I had been working earlier, but was now flying north to the romantic sounding city of Ahmedabad. This basically involved an overnight flight to Mumbai (Bombay no longer exists, neither does Madras due to the new political situation where city names are changing to reflect ethnic pronunciation and culture). Having arrived at midnight, I was awakened at 4 am to return to the domestic airport to catch a plane for Ahmedabad. Arriving at the airport amongst thousands of other hopefuls to join the aircraft, I found I was flying with Jet Airways whose logo is 'the joy of flying'. Upon arrival, I think they should have been renamed 'the relief of arriving'. It is the only airline where, after the usual safety demonstrations, they indicate that those people in Business Class have life jackets and those people in the remainder of the plane, in the event of landing on water, should remove the seat cushion and hold this close to their chest!

After arriving at the airport at 7 a.m. in the morning I was whisked off to a hotel for a four-hour presentation on GLP and GCP followed by in-depth discussions on their new research facility. The following day transportation to Bhat revealed a 30-acre site complete with massive concrete towers, minarets and five circular buildings interlinked with the most enormous and up-to-date animal house that one could imagine. As this was a Bank Holiday and Gandhi's birthday, we finished early and went on a tour of the village where Ghandi was born to look at all the memorabilia. It was quite interesting to see how the Indian culture had basically arrived since the demise of the British Empire.

The following morning, at 5 a.m., again a rude awakening and this time to board the Gujaret Express to Vapi. This must have covered some 300 miles but, unfortunately, took 6½ hours. It was quite interesting initially to go through the various changes in landscape and see the massive herds of buffalo which are farmed for milk and other exotic materials. Stopping at one station I was amused, as a European, to see a little tea stand with the sign 'The Shitty Tea Stand'. I believe that this is quite common as a surname in that area. At another of the stations, ice cream sellers boarded the train giving some exceptionally good ice cream, the main sales supplier being 'Dollops'. Certainly for the European there is a vast amount of amusement to be gained looking at the street and railway signs and activities.

During the trip, which was in a first class air-conditioned carriage, making me feel extremely sorry for those in lower classes (!), I was amused to see that the pre-booked seat syndrome is no different here than in other parts of the world. People come in and sit down, not looking at the seat, and then in violent language and gesticulations move one another to better or more appropriate seats as they see fit.

Arriving in Vapi, we caught the tailend of the monsoon where, in one day, I had seen as much rainfall as we would normally see in the whole of our winter. The temperature was close to 46° and the humidity, I think, was in excess of 100%.

Upon arrival at the hotel, I was pleased to see that the 'dry season' had stopped. This does not relate to the weather in any shape or form, mainly that the last time I was here the elections were taking place and, because of the very over-exuberant reaction of all the people, they banned alcohol. However, on that occasion I was offered whisky provided I had it in a glass with a napkin wrapped round it and had some additive. The only additive available was Coca-Cola and the amusing point about this was that the whisky, which equated to a treble and basically was three-quarters of a glass, then had a small amount of Coca-Cola topped up and the bottle supplied to indicate that what was in the glass was Coca-Cola. The only problem that could be seen immediately was that the glass held approximately 400 ml, but the Coca-Cola bottle had only been depleted by 5 ml!

Turning to the other side of the coin, in May I was invited to go to New Zealand to work with two analytical laboratories and an animal health university hoping to gain GLP compliance. This was a 180° reversal. I departed from London Heathrow in May at 26°, a flight of 12 hours, arriving at Los Angeles where we were on the ground for two hours, followed by a Qantas flight of 13 hours, arriving in Auckland at 5 a.m. in the morning with a temperature of 4° and snow on the hills.

There is just one tip I could give potential travellers to New Zealand who arrive in Auckland airport and then fly onward from the domestic terminal - and that is - remain in the International Terminal for as long as possible. I inadvertently went across for a 9 a.m. flight and then had to fight with 40 other people to sit on the three available chairs with an extremely small café and nothing else.

Two hours later I boarded a very, very small plane to Palmerston North, and upon arriving, was met by my host who asked 'Had I flown with Ansett?' Having indicated in the affirmative, he said, "Well, last week the very flight you arrived on came down too low, put the wheels down too early, crashed and overturned with a loss of five members of the crew and passengers". I arrived in time for lunch, once again eternally thankful that I knew the story after arrival and then prepared for a two-day seminar on GCPV.

During the stay I visited Massey University which is a massive centre with commercial contracts and is aiming for GLP compliance. I conducted a two-day audit amongst thousands of heads of cattle, sheep and companion animals. The facilities were excellent and I think there will be little problem in bringing the facility up to what would be recognised in international terms as a standard equivalent to GLP.

The next day involved a long drive to the south of North Island to Wellington, through snow, sheep, cattle, grass plains and hills, very similar to Southern Ireland. There were some breathtaking scenes of rugged coast line reminiscent of Big Sur just outside San Francisco. Following a one-day review of the analytical laboratory a 20.00 hour flight whisked me from Wellington back to Auckland for another one-day laboratory audit. Discussions on GLP with manufacturers of generic products, a two-hour tour of Auckland with a drive to the top of the hill overlooking Auckland at night, allowed me to return to the airport for, to my surprise, an upgrade to First Class and return to Los Angeles with Qantas.

Overall I was extremely impressed with the very high standards. All laboratories that I visited had ISO accreditation and I think can implement GLP very easily.

GCP work is also being reviewed at this University and has the biggest pool of farm and semi-domestic animals possible in one area.

Coupled with that, the activities and awareness of GCP in the human arena in India means, I think, that we have some very serious contenders in the Indian sub-continent and the Australia/New Zealand areas when it comes to compliance with our Good Practices.

Hopefully, as I return to both New Zealand and India later in the year, I was have some more amusing stories to relate to you on QA without frontiers. ■

Nigel Dent

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Details and registration forms
will follow at a later date

President's Piece

As you know, my main interest for a while has been the training side. As Course organiser, it has been marvellous to be able to say the Diploma in Scientific Archive Management is still running successfully and I know we will be having another presentation ceremony next year from the present students. A big thank you to every one who has helped to get the course up and running and to keep it running. We already have students for 1998-9 DipSAM but welcome more.

The Short Courses have been running since November 1996. We have had six of these and I think there is evidence to prove that they have been a success. All those who have attended have either come on other courses themselves or another member from their company has done so. There have also been students who originally came on a Short Course which was of particular interest to them and as a result, are taking the DipSAM now or will be doing so next year. It is very encouraging and makes all the effort well worth while.

It has also proved to be a popular arrangement that the students are able to pay for the course in three ways:

- The full amount when they register with Anglia
- Pay the registration to Anglia University and then pay for the Short Courses as they take them
- Pay for the Short Courses as and when they are able to take them over two years and pay the registration at the beginning of the second year.

Of course it is good to see the people attending who only want to gain more knowledge on a particular subject. All the attendees have made each Short Course so enjoyable to be a part of - especially when I had my car stolen at the June course! Thank you to all the attendees and particularly to Rick Selfe and Joyce Eakins at Shell who hosted the June course. It was excellent. Is there anyone else out there who would be able to supply a conference room for approximately ten people plus speakers?

The next Short Course is **Staff Administration on 23-24 July at Anglia University, Cambridge**, and will include Health and Safety, COSHH, Job Descriptions and Specifications, Job Training, Recruitment and Budgeting and Costing.

The course in **Cambridge on September 10 - 11 is How Others View the Archive**. This will consist of speakers who do not work in the archive but their work involves them with the work of the archivists. Dr David Moore, the retiring Principal of UK GLP Monitoring, will be speaking and bringing us up to date with all the changes and the new regulations. There will also be speakers from GCP, GMP, QA and a "Customer". This course will be of interest to anyone who has inspections - even if only their company's QA inspections. It is always useful to get an insight into what inspectors are looking for and what they expect from the archive staff.

I am looking forward to seeing you at the SAG Conference in October and hope to be seeing some of you on the Short Course. ■

Kindest regards, Margaret McCabe

GCP UPDATE - EFPIA - INFO DAY ON PERSONAL DATA PRIVACY

23rd April 1997, Brussels

The European Federation of Pharmaceutical Industries' Association represents the interests of the pharmaceutical industry operating in Europe. There are approximately 2200 legally distinct companies located in the EU and EFTA Member States who make up this association.

Pharmaceutical companies have become aware of some problems that the framework Directive 95/46/EC could pose for some of the pharmaceutical R & D activities (such as clinical trials, pharmacovigilance etc) both within the EU and in third countries.

The EFPIA is addressing its concerns primarily to Member States as they are required to implement this Directive into their national laws within three years of its adoption *ie* by 23 October 1998 at the latest.

The European Union adopted Directive 95/46/EC on 24th October 1995. It concerns the protection of individuals with regard to the processing of personal data and the free movement of such data.

During the decision making process the EFPIA identified two particular problems with the Directive and sought, with the help of its member associations, to achieve two basic aims:

* The first aim was to ensure that the Directive did not impede the transfer to third countries of personal data concerning health to be processed for scientific research purposes.
* The second aim was that the Directive should exempt the processing of personal data on health for scientific research purposes (as it exempts personal health services) from the requirement to obtain the explicit consent of the person concerned (under certain circumstances).

As a general principle the Directive states that the Member States shall prohibit the processing of personal data concerning health unless the explicit consent of the person concerned (the "*data subject*") has been obtained.

The Directive does permit Member States to lay down exemptions *"for reasons of substantial interest"* and specifically mentions in this connection that *"important reasons of public interest"* includes areas such as "*public health", "social protection"* and *"scientific research"*, subject to the provision of suitable safeguards.

The main concern in the pharmaceutical industry is that the Directive may be implemented in such a way that pharmaceutical R & D might not be covered by these exemptions, even though it should be.

Ideally, the EFPIA would like to see all pharmaceutical related activities recognised as being of *"substantial public interest"*, because they protect and promote public health. Some pharmaceutical activities are imposed by law in Member States. These include clinical trials concerning the development of new medicines and/or new indications for existing products; drug safety and pharmacovigilance and pharmaco-epidemiology.

Recognition must be given to the global implications of any legislation or codes of practice covering personal health data. Development and pharmacovigilance of new medicines take place internationally and the exchange of relevant data around the world between company and locations, between companies and regulators, and between regulators themselves is essential. In the interest of public health, such transmission of personal data, under the appropriate safeguards imposed by general GCP regulations, should not be impeded.

Implementation of the Directive may have adverse effects on the collection, processing and transmission of clinical trial data, and the secondary use of such data, unless the R & D activities of pharmaceutical companies are exempt. Specifically the following issues should be taken into account:

1) The requirement for consent to be specific and unambiguous raises problems for product safety, pharmacovigilance and pharmaco-epidemiology, particularly with regard to data bases.

2) The right of a data subject to access data could affect the validity of blinded clinical trials and affect the viability and validity of pharmaceutical research in general.

3) The determination of the *"adequacy"* of level of protection granted by third countries does not take into account the possibility that adequacy may exist in some areas *ie* health, but not in others.

4) The obligation to obtain unambiguous consent of the data subject to permit data transfer to a country not offering *"adequate"* protection could extensively complicate and compromise the mutual exchange of important medical information among companies and regulatory authorities.)The removal of patient identifiers once the primary processing purpose has been satisfied, may prevent long term patient management and safety monitoring, may preclude important future linkages of the same patients to different data bases and is in conflict with regulatory requirements for retention of clinical trial data.

6) The obligation to inform the data subject when personal data will be disclosed to a third party not covered by the original consent procedure is an unnecessary and impractical burden.

7) Lastly, the obligation to inform the data subject of all processing activities on his/her personal data and to create the opportunity for him/her to review/rectify data records could be difficult to implement in practice and disproportionate to the objective of the task.

It is essential that all EU Member States implementing Directive 95/46/EC into the national laws make sure that pharmaceutical related activities, such as scientific research and development activities, are recognised as being reasons of *"substantial public interest"* within the Directive justifying this exemption.

Failure to recognise this exemption could result in serious difficulties in complying with existing legal obligations imposed on the pharmaceutical industry at present. ■

USA FDA POSITION ON ELECTRONIC SIGNATURES

Much has been made in the last 6 years about the official and legal acceptability of "signatures" in electronic records. This has significance in the on-line collection of data requiring a GLP signature, and in the signing of documents to be submitted to regulatory agencies in electronic form.

The US Food and Drug Administration have published a Final Rule on this subject, which comes into force on 20th August 1997. The requirements (21 CFR Part 11) are reproduced in the following text, with a comparison with the earlier circulated proposals, for all the technophiles amongst us. For all those Archivists embracing new technology the same information is available on the Internet site:

http://www.fda.gov/cder/esig/pt11pxf.htm ■

A Comparison of the Proposed Rule and Final Rule for 21 Code of Federal Regulations, Part 11; Electronic Records; Electronic Signatures

Proposed Part 11	Final Part 11
Part 11 - Electronic Records; Electronic Signatures	**Part 11 - Electronic Records; Electronic Signatures**
Subpart A- General Provisions	**Subpart A- General Provisions**
Sec.	**Sec.**
11.1 Scope. 11.2 Implementation. 11.3 Definitions.	11.1 Scope. 11.2 Implementation. 11.3 Definitions.
Subpart B - Electronic Records	**Subpart B - Electronic Records**
11.10 Controls for closed systems. 11.30 Controls for open systems. 11.50 Signature manifestations. 11.70 Signature/record binding.	11.10 Controls for closed systems. 11.30 Controls for open systems. 11.50 Signature manifestations. 11.70 Signature/record linking.
Subpart C - Electronic Signatures	**Subpart C - Electronic Signatures**
11.100 General requirements. 11.200 Identification mechanisms and controls. 11.300 Controls for identification codes/passwords.	11.100 General requirements. 11.200 Electronic signature components and controls. 11.300 Controls for identification codes/passwords.
Authority: Secs. 201-902 of the Federal Food, Drug, and Cosmetic Act. 52 Stat. 1040 *et seq.*, as amended (21 U.S.C. 301-392).	**Authority:** Secs. 201-903 of the Federal Food, Drug, and Cosmetic Act;. (21 U.S.C. 321-393); sec. 351 of the Public Health Service Act (42 U.S.C. 262).
Subpart A--General Provisions	**Subpart A--General Provisions**
§ 11.1 Scope.	**§ 11.1 Scope.**
(a) The regulations in this part set forth the criteria under which the Food and Drug Administration considers electronic records, electronic signatures, and handwritten	(a) The regulations in this part set forth the criteria under which the agency considers electronic records, electronic signatures, and handwritten signatures executed to electronic

signatures executed to electronic records, to be trustworthy, reliable, and generally
26 equivalent to paper records and handwritten signatures executed on paper.

(b) These regulations apply to records in electronic form that are created, modified, maintained, or transmitted, pursuant to any records requirements set forth in chapter I of this title.

(c) Where electronic signatures and their associated electronic records meet the requirements of this part, the agency will consider the electronic signatures to be equivalent to full handwritten signatures, initials, and other general signings as required throughout this chapter, unless specifically exempted by regulation that is effective on or after the effective date of this part.

(d) Electronic records that meet the requirements of this part may be used in lieu of paper based records, in accordance with § 11.2, unless paper based records are specifically required.

(e) Computer systems (including hardware and software), controls, and attendant documentation maintained pursuant to this part shall be readily available for, and subject to, FDA inspection.

§ 11.2 Implementation.

(a) For records required by chapter I of this title to be maintained, but not submitted to the agency, persons may use electronic

records, to be trustworthy, reliable, and generally equivalent to paper records and handwritten signatures executed on paper.

(b) This part applies to records in electronic form that are created, modified, maintained, archived, retrieved, or transmitted, under any records requirements set forth in agency regulations. This part also applies to electronic records submitted to the agency under requirements of the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act, even if such records are not specifically identified in agency regulations. However, this part does not apply to paper records that are, or have been, transmitted by electronic means.

(c) Where electronic signatures and their associated electronic records meet the requirements of this part, the agency will consider the electronic signatures to be equivalent to full handwritten signatures, initials, and other general signings as required by agency regulations, unless specifically excepted by regulation(s) effective on or after August 20, 1997.

(d) Electronic records that meet the requirements of this part may be used in lieu of paper records, in accordance with § 11.2, unless paper records are specifically required.

(e) Computer systems (including hardware and software), controls, and attendant documentation maintained under this part shall be readily available for, and subject to, FDA inspection.

§ 11.2 Implementation.

(a) For records required to be maintained, but not submitted to the agency, persons may use electronic records in lieu of paper records or

records/signatures in lieu of paper records/conventional signatures, in whole or in part, provided that the requirements of this part are met.

(b) For records submitted to the agency, persons may use electronic records/signatures in lieu of paper records/conventional signatures, in whole or in part, provided that:

(1) The requirements of this part are met; and

(2) The document or parts(s) of a document to be submitted has/have been identified in public docket (docket number to be determined) as being the type of submission the agency accepts in electronic form. This docket will identify specifically what types of documents or parts of documents are acceptable for submission in electronic format without paper records and to which specific receiving unit(s) of the agency (e.g., specific center, office, division, branch) such submissions may be made. Documents to agency receiving unit(s) not specified in the public docket will not be considered as official if they are submitted in electronic form; paper forms of such documents will be considered as official and must accompany any electronic records. Persons should consult with the intended agency receiving unit for details on how and if to proceed with the electronic submission.

electronic signatures in lieu of traditional signatures, in whole or in part, provided that the requirements of this part are met. 27

(b) For records submitted to the agency, persons may use electronic records in lieu of paper records or electronic signatures in lieu of traditional signatures, in whole or in part, provided that:

(1) The requirements of this part are met; and

(2) The document or parts of a document to be submitted have been identified in public docket No. 92S-0251 as being the type of submission the agency accepts in electronic form. This docket will identify specifically what types of documents or parts of documents are acceptable for submission in electronic form without paper records and the agency receiving unit(s) (e.g., specific center, office, division, branch) to which such submissions may be made. Documents to agency receiving unit(s) not specified in the public docket will not be considered as official if they are submitted in electronic form; paper forms of such documents will be considered as official and must accompany any electronic records. Persons are expected to consult with the intended agency receiving unit for details on how (e.g., method of transmission, media, file formats, and technical protocols) and whether to proceed with the electronic submission.

§ 11.3 Definitions.

(a) The definitions and interpretations of terms contained in section 201 of the act apply to those terms when used in this part.

(b) The following definitions of terms also apply to this part:

(1) Act means the Federal Food, Drug, and Cosmetic Act (secs. 201-902, 52 Stat. 1040 et seq., as amended (21 U.S.C. 301-392).

(2) Agency means the Food and Drug Administration.

(3) Biometric/behavioral links means a method of verifying a person's identity based on measurement of the person's physical feature(s) or repeatable action(s).

(4) Closed system means an environment in which there is communication among multiple persons, where system access is restricted to people who are part of the organization that operates the system.

(5) Electronic record means a document or writing comprised of any combination of text, graphic representation, data, audio information, or video information, that is created, modified,

§ 11.3 Definitions.

(a) The definitions and interpretations of terms contained in section 201 of the act apply to those terms when used in this part.

(b) The following definitions of terms also apply to this part:

(1) *Act* means the Federal Food, Drug, and Cosmetic Act (secs. 201-903 (21 U.S.C. 301-393)).

(2) *Agency* means the Food and Drug Administration.

(3) *Biometrics* means a method of verifying an individual's identity based on measurement of the individual's physical feature(s) or repeatable action(s) where those features and/or actions are both unique to that individual and measurable.

(4) *Closed system* means an environment in which system access is controlled by persons who are responsible for the content of electronic records that are on the system.

(5) *Digital signature* means an electronic signature based upon cryptographic methods of originator authentication, computed by using a set of rules and a set of parameters such that the identity of the signer and the integrity of the data can be verified.

(6) *Electronic record* means any combination of text, graphics, data, audio, pictorial or other information representation in digital form, that is created, modified, maintained, archived,

maintained, or transmitted in digital form by a computer or related system.

(6) Electronic signature means the entry in the form of a magnetic impulse or other form of computer data compilation of any symbol or series of symbols, executed, adopted or authorized by a person to be the legally binding equivalent of the person's handwritten signature.

(7) Handwritten signature means the name of an individual, handwritten in script by that individual, executed or adopted with the present intention to authenticate a writing in a permanent form. The act of signing with a writing or marking instrument such as a pen, or stylus is preserved. However, the scripted name, while conventionally applied to paper, may also be applied to other devices which capture the written name.

(8) Open system means an environment in which there is electronic communication among multiple persons, where system access extends to people who are not part of the organization that operates the system.

retrieved or distributed by a computer system.

(7) *Electronic signature* means a computer data compilation of any symbol or series of symbols, executed, adopted or authorized by an individual to be the legally binding equivalent of the individual's handwritten signature.

(8) *Handwritten signature* means the scripted name or legal mark of an individual, handwritten by that individual and executed or adopted with the present intention to authenticate a writing in a permanent form. The act of signing with a writing or marking instrument such as a pen or stylus is preserved. The scripted name or legal mark, while conventionally applied to paper, may also be applied to other devices that capture the name or mark.

(9) *Open system* means an environment in which system access is not controlled by persons who are responsible for the content of electronic records that are on the system.

Subpart B--Electronic Records

§ 11.10 Controls for closed systems.

Closed systems used to create, modify, maintain, or transmit electronic records shall employ procedures and controls designed to ensure the authenticity, integrity, and confidentiality of electronic records, and to

Subpart B--Electronic Records

§ 11.10 Controls for closed systems.

Persons who use closed systems to create, modify, maintain, or transmit electronic records shall employ procedures and controls designed to ensure the authenticity, integrity, and, when appropriate, the confidentiality of

ensure that the signer cannot readily repudiate the signed record as not genuine. Such procedures and controls shall include the following:

(a) Validation of systems to ensure accuracy, reliability, consistent intended performance, and the ability to conclusively discern invalid or altered records.

(b) The ability to generate true copies of records in both human readable and electronic form suitable for inspection, review, and copying by the agency. Persons should contact the agency if there are any questions regarding the ability of the agency to perform such review and copying of the electronic records.

(c) Protection of records to enable their accurate and ready retrieval throughout the records retention period.

(d) Limiting system access to authorized individuals.

(e) Use of time stamped audit trails to document record changes, all write to file operations, and to independently record the date and time of operator entries and actions. Record changes shall not obscure previously recorded information. Such audit trail documentation shall be retained for a period at least as long as required for the subject electronic documents and shall be available for agency review and copying.

(f) Use of operational checks to enforce permitted sequencing of events, as appropriate.

(g) Use of authority checks to ensure that only those individuals who have been so authorized can use the system, electronically sign a record, access the operation or device, alter a record, or perform the operation at

electronic records, and to ensure that the signer cannot readily repudiate the signed record as not genuine. Such procedures and controls shall include the following:

(a) Validation of systems to ensure accuracy, reliability, consistent intended performance, and the ability to discern invalid or altered records.

(b) The ability to generate accurate and complete copies of records in both human readable and electronic form suitable for inspection, review, and copying by the agency. Persons should contact the agency if there are any questions regarding the ability of the agency to perform such review and copying of the electronic records.

(c) Protection of records to enable their accurate and ready retrieval throughout the records retention period.

(d) Limiting system access to authorized individuals.

(e) Use of secure, computer-generated, time-stamped audit trails to independently record the date and time of operator entries and actions that create, modify, or delete electronic records. Record changes shall not obscure previously recorded information. Such audit trail documentation shall be retained for a period at least as long as that required for the subject electronic records and shall be available for agency review and copying.

(f) Use of operational system checks to enforce permitted sequencing of steps and events, as appropriate.

(g) Use of authority checks to ensure that only authorized individuals can use the system, electronically sign a record, access the operation or computer system input or output device, alter a record, or perform the

hand.

(h) Use of device (e.g., terminal) location checks to determine, as appropriate, the validity of the source of data input or operational instruction.

(i) Confirmation that persons who develop, maintain, or use electronic record/electronic signature systems have the education, training, and experience to perform their assigned tasks.

(j) The establishment of, and adherence to, written policies which hold individuals accountable and liable for actions initiated under their electronic signatures, so as to deter record and signature falsification.

(k) Use of appropriate systems documentation controls including:

(i) Adequate controls over the distribution, access to, and use of documentation for system operation and maintenance.

(ii) Records revision and change control procedures to maintain an electronic audit trail that documents time- sequenced development and modification of records.

§ 11.30 Controls for open systems

Open systems used to create, modify, maintain, or transmit electronic records shall employ procedures and controls designed to ensure the authenticity, integrity and confidentiality of electronic records from the point of their creation to the point of their receipt. Such procedures and controls shall include those identified in § 11.10, as appropriate, and such additional measures as

operation at hand.

(h) Use of device (e.g., terminal) checks to 31
determine, as appropriate, the validity of the source of data input or operational instruction.

(i) Determination that persons who develop, maintain, or use electronic record/electronic signature systems have the education, training, and experience to perform their assigned tasks.

(j) The establishment of, and adherence to, written policies that hold individuals accountable and responsible for actions initiated under their electronic signatures, in order to deter record and signature falsification.

(k) Use of appropriate controls over systems documentation including:

(1) Adequate controls over the distribution of, access to, and use of documentation for system operation and maintenance.

(2) Revision and change control procedures to maintain an audit trail that documents time-sequenced development and modification of systems documentation.

§ 11.30 Controls for open systems

Persons who use open systems to create, modify, maintain, or transmit electronic records shall employ procedures and controls designed to ensure the authenticity, integrity and, as appropriate, the confidentiality of electronic records from the point of their creation to the point of their receipt. Such procedures and controls shall include those identified in § 11.10, as appropriate, and such

document encryption and use of established digital signature standards acceptable to the 32 agency, to ensure, as necessary under the circumstances, record authenticity, integrity, and confidentiality.

§ 11.50 Signature manifestations

(a) Electronic records which are electronically signed shall display, in clear text, the printed name of the signer and the date and time when the electronic signature was executed.

(b) Electronic records shall clearly indicate the meaning (such as review, approval, responsibility, and authorship) associated with their attendant signatures.

§ 11.70 Signature/record binding

Electronic signatures and handwritten signatures executed to electronic records shall be verifiably bound to their respective electronic records to ensure that the signatures cannot be excised, copied or otherwise transferred so as to falsify another electronic record.

Subpart C--Electronic Signatures

§ 11.100 General requirements.

(a) Each electronic signature shall be unique to one individual and shall not be reused or reassigned to anyone else.

(b) Before an electronic signature is assigned

additional measures as document encryption and use of appropriate digital signature standards to ensure, as necessary under the circumstances, record authenticity, integrity, and confidentiality.

§ 11.50 Signature manifestations

(a) Signed electronic records shall contain information associated with the signing that clearly indicates all of the following:

(1) The printed name of the signer;

(2) The date and time when the signature was executed; and,

(3) The meaning (such as review, approval, responsibility, or authorship) associated with the signature.

(b) The items identified in paragraphs (a)(1), (a)(2), and (a)(3) of this section shall be subject to the same controls as for electronic records and shall be included as part of any human readable form of the electronic record (such as electronic display or printout).

§ 11.70 Signature/record linking

Electronic signatures and handwritten signatures executed to electronic records shall be linked to their respective electronic records to ensure that the signatures cannot be excised, copied or otherwise transferred so as to falsify an electronic record by ordinary means.

Subpart C--Electronic Signatures

§ 11.100 General requirements.

(a) Each electronic signature shall be unique to one individual and shall not be reused by, or reassigned to, anyone else.

(b) Before an organization establishes,

to a person, the identity of the individual shall be verified by the assigning authority.

assigns, certifies or otherwise sanctions an individual's electronic signature, or any element of such electronic signature, the organization shall verify the identity of the individual.

(c) Persons utilizing electronic signatures shall certify to the agency that their electronic signature system guarantees the authenticity, validity, and binding of any electronic signature. Persons utilizing electronic signatures shall, upon agency request, provide additional certification or testimony that a specific electronic signature is authentic, valid, and binding. The certification should be submitted to the agency district office in which territory the electronic signature system is in use.

(c) Persons using electronic signatures shall, prior to or at the time of such use, certify to the agency that the electronic signatures in their system, used on or after August 20, 1997, are intended to be the legally binding equivalent of traditional handwritten signatures.

(1) The certification shall be submitted in paper form, and signed with a traditional handwritten signature, to the Office of Regional Operations (HFC- 100), 5600 Fishers Lane, Rockville, MD 20857.

(2)Persons using electronic signatures shall, upon agency request, provide additional certification or testimony that a specific electronic signature is the legally binding equivalent of the signer's handwritten signature.

§ 11.200 Identification mechanisms and controls.

(a) Electronic signatures which are not based upon biometric/behavioral links shall:

(1) Employ at least two distinct identification mechanisms (such as an identification code and password), each of which is contemporaneously executed at each signing;

§ 11.200 Electronic signature components and controls.

(a) Electronic signatures that are not based upon biometrics shall:

(1) Employ at least two distinct identification components such as an identification code and password.

(i) When an individual executes a series of signings during a single continuous period of controlled system

access, the first signing shall be executed using all electronic signature components; subsequent signings shall be executed using at least one electronic signature component that is only executable by, and designed to be used only by, the individual.

(ii) When an individual executes one or more signings not performed during a single continuous period of controlled system access, each signing shall be executed using all of the electronic signature components.

(2) Be used only by their genuine owners; and

(2) Be used only by their genuine owners; and

(3) Be administered and executed to ensure that attempted use of an individual's electronic signature by anyone other than it's genuine owner requires collaboration of two or more individuals.

(3) Be administered and executed to ensure that attempted use of an individual's electronic signature by anyone other than its genuine owner requires collaboration of two or more individuals.

(b) Electronic signatures based upon biometric/behavioral links shall be designed to ensure that they cannot be used by anyone other than their genuine owners.

(b) Electronic signatures based upon biometrics shall be designed to ensure that they cannot be used by anyone other than their genuine owners.

§ 11.300 Controls for identification codes/passwords.

Electronic signatures based upon use of identification codes in combination with passwords shall employ controls to ensure their security and integrity. Such controls

§ 11.300 Controls for identification codes/passwords.

Persons who use electronic signatures based upon use of identification codes in combination with passwords shall employ controls to ensure their security and integrity.

shall include:	Such controls shall include:
(a) Maintaining the uniqueness of each issuance of identification code and password.	(a) Maintaining the uniqueness of each combined identification code and password, such that no two individuals have the same combination of identification code and password.
(b) Ensuring that identification code/password issuances are periodically checked, recalled, or revised.	(b) Ensuring that identification code and password issuances are periodically checked, recalled, or revised, (e.g., to cover such events as password aging).
(c) Following loss management procedures to electronically deauthorize lost tokens, cards, etc., and to issue temporary or permanent replacements using suitable, rigorous controls for substitutes.	(c) Following loss management procedures to electronically deauthorize lost, stolen, missing, or otherwise potentially compromised tokens, cards, and other devices that bear or generate identification code or password information, and to issue temporary or permanent replacements using suitable, rigorous controls.
(d) Use of transaction safeguards to prevent unauthorized use of passwords and/or identification codes, and detect and report in an emergent manner any attempts at their unauthorized use to the system security unit, and to organizational management.	(d) Use of transaction safeguards to prevent unauthorized use of passwords and/or identification codes, and detect and report in an immediate and urgent manner any attempts at their unauthorized use to the system security unit, and, as appropriate, to organizational management.
(e) Initial and periodic testing of devices, such as tokens or cards, bearing the identifying information, for proper function.	(e) Initial and periodic testing of devices, such as tokens or cards, that bear or generate identification code or password information, to ensure that they function properly and have not been altered in an unauthorized manner.

March, 1997

SPACE : A FINAL FRONTIER.....?

A Voyage through the Regulatory Support Unit

Good Friday 1997 saw the closure of the Glaxo Wellcome site at Beckenham. This original Wellcome site was one of the casualties of the merger of Glaxo Wellcome in the early 90s. The last few years have been eventful for the staff who have been occupied in transferring services and resources to other UK and worldwide sites, none more so than the archive staff.

Much of the Beckenham site which cannot be sold will now be bulldozed and cleared to make way for re-development.

In 1994 Fil Manuguid of the Wellcome Regulatory Support Unit offered her personal view of Scientific Archives, which we are re-printing in memorial to all the Scientific Archivists who worked at Beckenham, many of whom have gone on to other careers within the Pharmaceutical industry, we wish them well.

"Oh, they archive", said one scientist on introducing a new member of staff to the Division. One cannot help the triviality of this statement nor the miscon-ception of others. Maybe it is because we do not wear T-shirts proclaiming clear and definite job roles that leads to this misapprehension? And therefore the problem lies not in ignorance but in the lack of advertisement. Or maybe it is the 'Quasi modo' effect that hinders others to comprehend the sphere or diversity of what it is we exactly do; for one must admit that a Scientific Archivist is a rare and select breed! What is it in Shakespeare's play that Henry V said? "We happy few, we band of brothers"??

If one were to proceed on the premise that all we do is stick a specimen or a bunch of papers into a "black hole" or as the Latin word origin 'archivum' suggests, in 'a strong chest', then, what do we do with the other 99% of the day?

Well, I'll tell you what we get up to in the vast reserve of the Kent countryside.

Some 18 months ago, 5 Departments from 2 different Divisions were combined to form 4 new Departments into one new Division! Confused? Don't worry, we were too. It was hard enough for a hundred scientist to conform to one consensus, but a hundred more!? Thus it is from this abyss, that a little over a year ago, the "Regulatory Support" section gradually emerged. We comprise at team : diligent, youthful, energetic souls with innovative ideas (pay me later guys) to support all 18 different Sections in ensuring that all GLP records, procedures and study related data conform to the accepted regulatory principles in the Division. This also means in turn to maintain Company and regulatory documentation in support of Divisional business - Needless to say this involved:

1. Being responsible for the Divisional archives and all associated procedures.
2. The collation of Divisional study data.
3. The management of the Divisional Policies, Standard Operating Procedures (SOPs) and Safety Assessments including distribution; maintenance of records, reviews and related performance measures.
4. Controlling/maintaining/creating/standardising / stream-lining GLP systems and procedures, such as: Company Laboratory Notebooks, Divisional Equipment, Log Books, Manuals, Equipment Verification and associated records, equipment and data indexes which assist with the consequent archival and certainly any subsequent retrieval.
5. Being responsible for records management within the Division.

So how far have we got with all the above, why does it take such a long time?

Let's start with the actual archive areas, which until our emergence looked like a scene from Star Trek's, "Space, a final frontier...".

One of the notorious facets of inheriting ten archival areas lend an acquired appreciate of Detective Agencies. Frankly, there must be some talent in deciphering cryptic messages labelled on slides, study files and odd pieces of paper. Just imagine the art of investigating what the item is, its origins, and its purpose? Mind boggling.

One of our staff's recent travels must have helped to interpret or translate such hieroglyphics because she manage to enter details of all physical samples generated over the last 50 years onto a database so they could be sensibly grouped. We then had to obtain permission to dispose of these samples, which was easier said than done, considering about half the people's names now appeared on headstones instead of the company 'phone directory.

Departments had changed, areas of the Company had been sold off, yet nobody would allow these samples to be disposed of! Beam me up Scotty!

Our blue eyed fluttering or dumb blonde (that's our only male colleague) exercise did work on some people, enabling work to commence on our disposal mission. This involved sorting through literally tens of thousands of boxes, piled 6 high and 3 deep on bowing shelves. Why is it, that the box you want is *always* the one on the top shelf, at the bottom of the stack and right at the back, not to mention those backache after effects??

In the meantime we set up a Divisional Retention Policy for Physical Samples and are in the process of reviewing all samples we know belong to the Division. These have been but a few of the voyages of the RSU enterprise.....to seek out old life forms, and boldly go where no woman and man has ever gone before!

Then we have Contract Houses. One fringe benefit of working in the pharmaceutical industry is..... discount on aspirins (Oops, no offence folks!) The irony of the situation is that they want to return your data or get fee charges for continued storage. We didn't even know what was being stored, let alone what was coming back! A questionnaire was sent out and from the responses we now realise just how difficult it was going to be to keep control of data at so many different Contract Houses when we all use different size boxes/containers, have different "free" retention periods, charge different prices for additional storage, with different payment terms. Will a day ever come when all Contract Houses conform to one archiving standard? No need to worry though, luckily we also have the benefit of Stress Management Courses.

Another minor problem we faced was the demolition, this year, of 6 of our archive areas which are all filled to capacity. New smaller archives are not planned for construction until 1996 (Sorry, no bonus this year for Site Planners). Hence we carried out a detailed cost analysis for off site storage as opposed to on-site archives - what's a Scientific Archivist becoming, Isaac Newton the Second?? I do hope we got our sums right because we've now ordered and all singing, all dancing 'Mobile Archive' fully equipped to BS 5454 standards with an FM200 Fire Extinguishing System.

The only thing we have to do now is turn into Arnold Schwarzneggar and move all the contents of the archives from one side of site to the opposite corner!

Furthermore, as we all know, technology plays a vital role in our industry. We all look for the quickest, most efficient and user friendly systems available. The energy and time spent in the Section on understanding the needs of our Division has been critical to choosing the various software, databases and imaging systems on the market (thanks to all the Sales Reps for all the delicious lunches). We are also constantly trying to improve the use of our databases by creating new data programmes and/or remodelling old ones. It is thus not surprising to find us as a source for study status information or as a central area for communication between different Sections.

Then there are the Archive Disaster Control Plans: a growing concern to many factions. The quantity and scientific value of data becomes an important issue for compliance. Flood, fire and natural occurrence? Just how prepared would you be to tackle the possibility that your sacred archive may look like the second coming or 'The Lost Civilisation of Atlantis'? The value of material, the amount of damage, the restoration and the cost are some of the assessments that need to be taken into consideration. In any case, are we ready to take on the dual courageous roles of the adventures of the "Last Action Hero" and "Casualty" if the eventuality (cross our fingers) ever arises?

So, you've heard it all before, you're in the same position etc - OK I'll tell you about the collation of study files then. As we all know the four basic components of collection management are inventory, appraisal, cataloguing and storage. The collating of study files for auditing and subsequent placement in the 'black hole' envisages certain feats of ingenuity. Subsequently our talent for 'moonlighting' is often called upon. here we play pivotal roles of the fearless circus juggler, and 'the wake-up call' telephonist. Why is that you may ask? Well, surely we have all been through the scenario of catching, indexing, recording and filing 2 or 3 different study data from the smiling histologist, toxicologist, pathologist... all in the same rotation; while calling the friendly bio-analyst (with our feet) "to please bring down his data because the pleasant QA auditor is desperately waiting for it" - in all cases it lends itself to another profession.

Perhaps I should start on a book because the above only takes account of 10% of our time. Or, perhaps there will be further exciting adventures in a later news letter!! (order your copy today to avoid disappointment when stocks run out).

Anyway, the tendency of others to describe our duty as only 'to archive' leads one to a pious and penitent view. Should we just sit idly by, nodding our heads with a sweet semi-smile upon assumed conceptions? Perhaps the answer to this problem of being taken for granted is solely in attitude. We are employed in the pharmaceutical industry "dedicated to the discovery and marketing of products that promote human health and the quality of life", and therefore our foremost goals whether we be study directors, technicians, administrators, or scientific archivists should ALL be to adopt a good attitude towards providing a good service. ■

FORTHCOMING EVENTS

■ GOOD MANUFACTURING PRACTICE FOR THE CHEMICAL SYNTHESIS OF PHARMACEUTICAL ACTIVE INGREDIENTS FOR CLINICAL TRIALS.

July 16th 1997, The Møller Centre, Churchill College, Cambridge.

■ GOOD MANUFACTURING PRACTICE FOR THE BIOLOGICAL SYNTHESIS OF PHARMACEUTICAL ACTIVE INGREDIENTS FOR CLINICAL TRIALS.

July 17th 1997, The Møller Centre, Churchill College, Cambridge.

GMPs were initially established only for the commercial manufacture of sterile drug products. Since then their scope has inexorably expanded to encompass non-sterile drug products, drug substances and investigational materials. So how are the rules, which were designed for the routine production of drug products, to be translated and sensibly applied to the evolving processes used for the production of drug substances for incorporation into clinical trials supplies?

These two seminars set out to establish the current best practice. Following presentations and syndicate sessions, participants should have gained a fuller understanding of why R&D requires different rules, what levels of GMP to apply to each stage of development, the need for verification, validation and qualification and how the innovation of development and the constraints of GMP can be balanced.

The seminars are intended for QA/QC staff in research and development, Qualified Persons and other quality professionals in production areas who are, or will be, responsible for the release of drug substances for clinical trials and for chemists, biochemists, chemical and bio-engineers involved in drug substance synthesis, scale-up and pilot plant operation.

The first seminar deals with chemical synthesis of drug substances which the second explores biological synthesis. The have been arranged on successive days to give delegates the opportunity to attend one or both seminars.

Seminar fees

Associate Members £170 Non Members £195

Seminar fees include: lectures, discussions, workshops, lunch, coffee and tea.

For further information on any BARQA course, please contact David Weller at:

British Association of Research Quality Assurance

PO Box 37, St Ives, Huntingdon

Cambs PE17 3UJ, England

Tel +44(0) 1480 461 1465 Fax +44(0) 1480 461 1889

e-mail: barqa@zetnet.co.uk

■ SAG SHORT COURSE ON STAFF ADMINISTRATION

Woodville Hotel, Nottingham

23-24 July 1997

Cost : £150 non residential £195 residential

This short course will include the topics:

Health & Safety in the Archive

Control of Substances Hazardous to Health

Budgeting and Costing

Job Descriptions and Job Training

Workshop on Personnel and Recruitment

For further information contact:

Margaret McCabe
SAG Short Course Organiser
20 Banksfield Crescent
Yeadon
W Yorkshire
LS19 7JY
☎ (01943 879731)

■ RMS SUMMER SCHOOL
CHANGE MANAGEMENT

Records Management Society

3-5 August 1997

The fourth RMS Summer School will include the topics:

- What major changes are we likely to seen in organisations in the next five to ten years?
- How people react to change and how to manage those reactions effectively
- The importance of good project management in the management of change
- Stress in yourself and your staff - identification and management
- Managing the change of downsizing
- Managing change in a merger situation
- The reality of change
- The role of records management in organisational change
- Training and development of staff in the context of change
- Training end users, customers etc.
- Taking responsibility for one's own career, one's own development - an essential factor in today's world of work

Fee: £240 + VAT (RMS members)
£300 + VAT (Non-members)

Contact : Jude Awdry
RMS Admin Secretary
Woodside, Speen,
Princes Risborough
Bucks HP27 0SZ

Tel: 01494 488599
Fax: 01494 488590

■ SAG SHORT COURSE ON HOW OTHERS VIEW THE ARCHIVE

Anglia University, Cambridge

10-11 September 1997

Cost : £150 non residential £195 residential

This course is designed to give archivists the opportunity to see how others view the archive.

The following people will be discussing their connection with the archive; how they view the archive; its function and its staff.

- A Regulatory Inspector
- A Quality Assurance Auditor
- A Customer
- An External Auditor

For further information contact:

Margaret McCabe
SAG Short Course Organiser
20 Banksfield Crescent
Yeadon
W Yorkshire
LS19 7JY
☎ (01943 879731)

■ THE MANAGEMENT OF ARCHIVES AND RECORDS: THE IMPACT OF ELECTRONICS AND THE INTERNET

The British Council

Liverpool

2-12 November 1997

Topics covered in the seminar will include:

- progress in developing standards and performance measurement in archives and record management: recent changes
- managing electronic records and archives: developments and standards
- archives and the Internet : SGML, HTML
- the impact upon training of new technologies and changes in the status of archives services
- the user interface: technical services in the archives
- the user interface: training users
- archival description and finding aids in the electronic context
- international experience of archives and records management in development

Fee: £1,680

Contact : Promotions Manager
International Seminars
The British Council
1 Beaumont Place
Oxford OX1 2PJ

Tel: 01865 316636 Fax : 01865 516590/557368

email : international.seminars@britcoun.org

■ 4th INTERNATIONAL RECORDS MANAGEMENT CONGRESS

IRMC/RMS

Edinburgh

27-30 April 1998

Records management into the next millennium - the global perspective.

- Business trends into the next millennium
- Trends in information management
- Trends in records management
- The records management standard
- Professional development for records managers
- Global records management
- International records retention
- Records managers and their users
- The way ahead

Fee : TBA

Contact : Jude Awdry (previously stated)

■ RESEARCH QUALITY ASSURANCE AND GOOD LABORATORY PRACTICE

October 7-8 1997

Madingley Hall, Cambridge

Contact : David Weller at:

British Association of Research Quality Assurance
PO Box 37, St Ives, Huntingdon
Cambs PE17 3UJ, England

Tel +44(0) 1480 461 1465 Fax +44(0) 1480 461 1889
e-mail: barqa@zetnet.co.uk

■ 12th INTERNATIONAL CONGRESS 'MULTI-SITE AND MULTI-NATIONAL STUDIES

November 5-7 1997

DeVere Grand Hotel, Brighton

Contact : David Weller at:

British Association of Research Quality Assurance
PO Box 37, St Ives, Huntingdon
Cambs PE17 3UJ, England

Tel +44(0) 1480 461 1465 Fax +44(0) 1480 461 1889
e-mail: barqa@zetnet.co.uk

■ 13th INTERNATIONAL CONGRESS
' COMPLIANCE AND COMPUTERS'

May 6-8 1998

Moat House International Hotel, Glasgow

Contact : David Weller at:

British Association of Research Quality Assurance
PO Box 37, St Ives, Huntingdon
Cambs PE17 3UJ, England

Tel +44(0) 1480 461 1465 Fax +44(0) 1480 461 1889
e-mail: barqa@zetnet.co.uk

SCIENTIFIC ARCHIVISTS GROUP

The objectives of the Scientific Archivists Group are:

To develop a professional status for Members.

To improve the science of archiving.

To ensure Archives meet business, scientific and regulatory needs.

To encourage a high profile with regulatory authorities.

Membership entitles you to attend the bi-annual conferences of the group, which promote the exchange of information on the role of the Archive and Archivists, and encourage members to keep abreast of developments within the industry. You will also receive copies of the biannual magazine. A copy of the SAG membership list is available on request, but should not be used for commercial purposes.

Full membership is open to individuals with an interest in Archives of Scientific records. To apply, complete the application form and send it with a cheque for £30.00 made payable to the Scientific Archivists Group to:

Lesley Almond
DowElanco Europe
Letcombe Laboratory
Letcombe Regis
WANTAGE
Oxon
OX12 9JT

While the SAG is always ready to welcome new members, the committee reserve the right to refuse applications.

MEMBERSHIP FORM

Personal Details

Name .....
Job Title .....
Company .....
Address .....
.....
.....

Telephone No.....Ext.....

Archive Details

Is the Archive associated with other functions (e.g. QA). If so, please state:
.....
.....
.....
Number of Archive Staff:.....

Types of data submitted (Please Tick):

☐ Document ☐ Magnetic Tapes/Discs
☐ Wet Tissues ☐ Microscopic Slides
☐ Wax Blocks ☐ Dispensary Samples

Is the Archive computerised: .....

Is the Archive compliant with:

GLP..... GCP.....GMP..... Other.....

Do Archive Staff Back-up Data? YES/NO
If YES do you:

Microfiche ☐ Electronic Storage ☐
Image/Scan ☐ Off-site Storage ☐
Other ..... ☐

Do you have any objection to the above details being held on computer for use by the SAG for mailing purposes only? YES/NO

How did you hear about the group?
.....
.....
.....
.....

SIGNED:..... DATE:.....