JOURNAL OF THE SCIENTIFIC ARCHIVISTS GROUP

SAGACITY

In This Issue:

JANUARY 1999

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EDITORIAL:

Tell the Truth?

It is an undisputed fact that millions of people owe their lives and health to animals. We have heard many arguments from animal rights campaigners seeking the abolition of testing on animals. In recent weeks this argument has been openly debated. It began with a discussion programme on Channel 5, hosted by Kirsty Young, called "Tell the Truth". The format of the programme is to invite leading figures from opposing sides of a particular subject to air their views with an invited audience consisting of 'for and against' supporters, and at the end of the hour long debate to have a telephone vote from viewers. The subject of the programme in question was "Should we ban all medical experiments using animals?"

The vote was 48% for a ban and 52% against.

The debate continued with an interview with Desmond Lynam, on Radio 2, when Sir Paul McCartney described the dilemma he faced when he realised that the treatment his wife received for breast cancer has been tested on animals. He admitted, "I'm finding out now that there is quite a lot of animal experimentation. Some of it I suppose is absolutely necessary when you come down to the final tests before people." Paul and his late wife Linda were staunch vegetarians and animal rights campaigners, his comments were subject to much comment and media coverage.

Hard as it may seem, we must all be aware that to abolish animal research would severely hinder medical progress and ultimately cost human lives.

I wish you all a happy and healthy New Year.

Regards,

Karen Box

SAG Editor

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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

Thank you to everyone who attended the SAG Autumn Conference sponsored by Hays Information Management, at Nailcote Hall Hotel, Berkswell, on the 15th-16th October 1998. The Committee was especially pleased to meet the new members present. Our thanks go to Liz Tribe, Liz Hooper and Hays Information Management, for making the conference a success. The SOP Workshop on the 15th was well attended and appeared to meet the needs of the members present.

The Committee have been approached by BARQA to collaborate on a paper on Archiving (draft index and contents are included elsewhere in this publication). I feel it is really important for the Group to participate in this publication, The Committee already has a heavy workload, and therefore I call for volunteers to undertake this project on behalf of the Group. All those who feel they have the time and are willing to write, proofread, comment etc., please contact me as soon as possible.

Arrangements for the Spring Conference 1999 are currently underway. The theme will be Disaster Contingency Planning and the workshop will be on Archive Design, Procedures etc. You will be informed of venue and date as soon as these have been finalised. Suggestions for Conference and Workshop themes are always welcome, please contact any Committee Member if you have and ideas.

On behalf of the Committee may I take this opportunity to wish you and your families a Prosperous New Year.

MEDICAL RECORDS MANAGEMENT

By Ian Young of Hays Information Management

Ian Young is the Business Manager in the Public Sector and Healthcare Division of Hays Information Management (HIM). His experience in the medical records field and the solutions that HIM has provided could be the answer to similar problems faced by many regulatory archivists within the SAG.

Healthcare as a sector is more dependent than most on high technology, from scanning equipment to patient-care systems. So why is it, given the array of records and information management solutions now available, that hospitals and health authorities are struggling harder than ever with problems of space availability?

The answer lies partly in a perennial shortage of money, and partly with the associated inability to plan effectively for the long term.

Ironically, both issues are being addressed by a phenomenon that many hospitals fear will bring more disruption than they can bear, the PFI (Private Finance Initiative).

PFI offers an opportunity for the healthcare sector to obtain not only much needed short-term funding, but longer-term strategic input on how to address precisely such problems as the worsening hard–copy archive situation.

The problems associated with physical records for hospital trusts may well sound familiar to you all as archivists and records managers:

- Volume of records growing.
- Multiple locations.
- Poor accounting.
- Poor quality.
- High cost/maintenance collection.
- Mislaid documents.
- Poor tracking of documents on loan.
- Delays in delivery.
- Limited 'opening' hours.
- No destruction/document 'management' policy.

Electronic imaging, at first glance, appears an attractive and space-saving option. But it immediately becomes apparent that the question is not whether to digitise – but what?

The difficulty is basements full of hard copy archives, of various status, for which there is often no coherent policy of lifecycle management or even a formal destruction policy – a situation which may be exacerbated by consultants' insistence on retaining records for research purposes, or for protection against litigation

Throwing technology at the problem may not be the answer. HIM tends to recommend that if a hospital wants to move towards electronic imaging, they should aim at a future point after which all new records will be stored on optical disk and this would apply to your own archive as well.

In the meantime, parallel programmes of rationalisation (backward-looking) and *ad hoc* digitisation (forward-looking) can help to unblock the immediate bottleneck, spread the cost and prevent unfeasible large batches of data being out of commission while they are in the 'imaging queue'.

Offsite storage (remote for deep archives, local for files in daily use) and barcode-based tracking systems can virtually eliminate the currently all-too-common hazard of mislaid records.

Such a programme doesn't come cheap, as hospitals will be the first to point out. But as more hospitals undergo market-testing, they are coming to recognise the hidden cost of their present solutions, in terms of resource allocation (physical and human), wasted time and consequent effects on patient care.

The following statistics illustrate the scale of the problem the average hospital is facing, as found by the Audit Commission's three-year review:

- 75% of hospital records contained duplicate notes.
- 30% of records were unavailable at any one time.
- 11% of medical tests were redone because the original notes were missing.
- 36% of case notes were not immediately available.
- 40% of records were not up to date.
- 4000-8000 records were out on loan/in circulation in an average hospital at any one time.
- 64% of records are in the Archive at any one time.
- 32% of records on loan. (Records on loan took four times longer to locate).
- 4% of all records were 'lost'.

HIM has developed and marketed the product MedRec as a solution to the problem of migration from paper to electronic records.

Planning for such a major change can take up to three years and includes implementing computer/VDUs for users and training staff in the use of the new system.

MedRec offers a flexible approach so that hospitals can 'buy' into the concept in stages, or to any combination of the stage:

Step One - Offsite storage of older records.

Step Two - Electronic scanning of all new records.

Step Three - Gradual progression to total e-archives.

The key elements of the MedRec system are:

- Centralised Electronic Hardware/Software
- Ability to phase in the system.
- It provides a Hospital/Trust wide solution.
- The technology has already been tried and tested in the US.

The key benefits achieved by the MedRec system are:

- Reduced handling/movement costs.
- Faster and more relevant point of access.
- **NO** missing records.
- Greater security.
- Phased migration from paper to electronic system.
- Payment for service can be revenue driven.

MedRec is a solution that HIM has provided for one area of the health sector, but it is not the only service or product we offer – as I am sure many of you are aware as existing customers. HIM offers practical, long-term solutions designed and implemented in line with your own company strategic guideline.

Hays capacity to invest in the future makes us an excellent long-term proposition. As a discipline, information management is being transformed – but, whether in the form of paper, magnetic media or optical technologies, as long as you are in business, you'll need to manage those records. And as long as you need record management facilities, Hays Information Management will be happy to supply them.

For any further information about Hays Information Management products and services please contact:

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Managing the Document Life-cycle
Gordon D. Gove, Marketing Manager, Xerox Business Services

Like many international companies, The Document Company Xerox has gone through much change over the years. From being *The Copier Company*, Xerox has become a leader in innovation and a partner in new frontiers working with many technological companies such as Microsoft, Sun, Novell, Compaq and others. It has gained recognition for its *Leadership through Quality* activities and is now approaching the new millennium with a structure to meet the modern demands of discerning customers.

The constantly changing market place creates business issues. In a recent survey of European Chief Executive Officers, four common major issues were cited:

1. Global complexity
2. New customer demands
3. Increased competition
4. Organisational change

Global complexity – As organisations begin to deal international so the working processes become more difficult. Furthermore, entering new markets often means *going to market* with new partners and establishing these relationships can be difficult, complex and taxing.

New customer demands – Customers are becoming more sophisticated and wanting more from their suppliers. It is no longer enough to offer a quality service. Banking customers, for example, want banks to be open when it is convenient for the customer, not the bank.

Increased competition – More and more, customers are looking for a good deal. They are prepared to move their business to another supplier if the price is right. Loyalty is a frail consumer commodity.

Organisational change – In an effort to become more competitive and gain benefit from economies of scale, reorganisation and merger is taking place in many industries. Furthermore, organisations use new structures to become less bureaucratic.

These four issues are being addressed by many organisations as all of them use people, processes and documents which in turn consume resource. Collectively they make up productivity and thus by making these resources more efficient, productivity can be increased. Documents, in this scenario, follow cycles and if we manage these cycles better then better it will be for the enterprise. **In other words, proper management of the document lifecycle can make companies more profitable.**

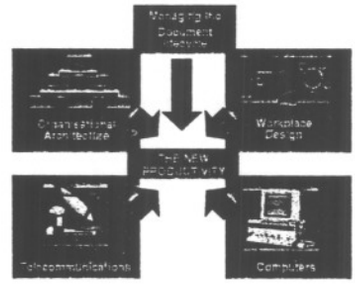

Figure 1 – Productivity improvement options

There are, of course, other ways to improve productivity – workplace design, organisational architecture, computers and telecommunications can all play a part. *(Figure 1 – Productivity improvement options)*

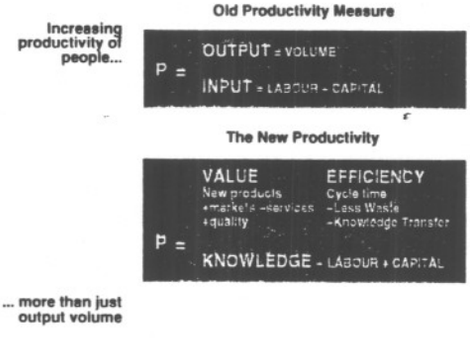

Figure 2 – Old versus the new productivity

However, at Xerox, we believe that adding knowledge to labour and capital brings value and efficiency to the traditional calculation of productivity. This, we believe, is the new productivity that

companies should be considering *(Figure 2 – Old versus the new productivity).*

When we consider how we can manage the document lifecycle, we should also consider what a document is. At Xerox, we believe that documents *present information where; when and how the user needs it* and of course, it comes in many forms. Video, voice, CD-Rom, graphics, text, multimedia and paper all are forms of documents imbedded within an organisation's processes managed by people. We should also understand the importance of documents. Following are some dimensions:

- To register a new drug, on average, 300,000 pages are used
- Dun & Bradstreet prints over eight million forms per month
- Boeing 747 documentation weighs more than the plane itself
- Document preparation and composition varies between £10 and £260 per page

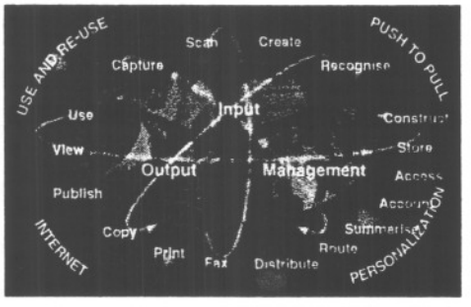

Figure 3 - Adding value to the document

The activities associated with the document lifecycle (*Figure 3 – Adding* for organisations to improve their performance as well as giving customers what they want. This can be demonstrated in the following ways:

Push to Pull – by making documents available in a digital form through networks, customers and organisations can pull documents and information into their own domains thus obtaining the information that they want.

Personalisation – Organisations can personalise documents that are sent to their customers. This can make the documents more friendly and may elicit a more positive response from a customer.

Internet – The use of the Internet is becoming a way of life with more and more people expecting information from it and to transact business using this network. The use of standard documents from business to business is growing substantially.

Use and re-use – The use of workflow systems and image processing is improving the office environment immensely. Major productivity savings are being realised using these systems.

So, with the importance of documents to business understood and confirmation that documents

- Support business processes
- Support products
- Are the products themselves

it follows that if you

- Make documents better
- Are making better documents
- Are using documents better

then your productivity will increase as will your bottom line. You will also make your stakeholders happy!

In managing the document lifecycle, it is useful, perhaps, to take a different look at documents. Consider documents as:

- Helping people work with people
- Connecting a business with its customers
- The knowledge base of a business process
- Vital links in the value chain
- Collectors and communicators of knowledge
- Records of information and actions

To summarise the above considerations, **documents should support the way people want a business to run, not determine the way a business is run.**

Company	Benefits	How delivered
Panasonic	User guide price reduced from £2.55 to £1.55. TTM reduced from 12 weeks to 2 days	Print on demand, elimination of obsolete stock
Gartner Group	Research test production time from 10 to 4 days	Digital document management
European Patent Office	99.999% accuracy of output from variable quality input.	Scanning technology, rigorous QC.
Norwich Union	Reduce costs and space. Planned savings £600k pa	Fully managed print service - commence early 1998
Eastern Electricity	30% savings on mail discounts. Billing much improved.	Better quality documents
Ericsson	Document retrieval improved from 6 weeks to 2 days. Document packs produced in 3 weeks instead of 10.	Document management systems for Engineering drawings.
Royal Bank of Scotland	VAT savings of £60k pa. Reduced storage costs. In house magazine production time reduced by 60%.	Digital printing. Print on Demand.

Figure 4 – Value from changing documents

Many Xerox customers have gained value from changing the way they process and use documents. *Figure 4 – Value from changing documents* offers a list of such companies, the benefits gained and how the benefit was delivered.

To illustrate the importance of *Managing the Document Lifecycle*, it is worth considering the results of research commissioned by Xerox:

- 90% of an organisation's information resides in documents
- People in business spend 60% of their time with documents
- Organisations spend up to 15% of their revenue managing documents

Clearly documents are an integral part of business and, as the research suggests, extremely important in business. We would suggest that documents are as important as your Information Technology. **Indeed, we know you have an Information Technology strategy. Shouldn't you have a document strategy?**

The importance of managing the document lifecycle is further enhanced by the increase in *the digital document*. Did you know that in 1993, 20% of all documents in an enterprise were created in digital form? **It is estimated that by the end of 1998 65% of all documents will be in digital form.** Further reason why consideration should be given to creating a document strategy.

One way of managing the document lifecycle is to give the problem to someone else through outsourcing or facilities management (FM).

Using an outsourcing or FM company allows you to:

- Improve business focus
- Gain access to world class capabilities
- Gain accelerated re-engineering benefits
- Share risk
- Free resources for other purposes

In conclusion, organisations are looking for productivity gains and, thereby, increases to the bottom line. The document is a fundamental part of business; it holds knowledge enabling and instructing people to undertake business processes. It follows that if you can manage the document lifecycle, with a document strategy, then your company will be a more efficient enterprise and a more profitable one too.

About the author

Following a career in computing and consultancy in the financial services sector, Gordon Gove joined Xerox (UK) Limited in 1995. Initially working at the Xerox Technical Centre in Welwyn Garden City where he helped develop a new business venture, he moved to Xerox Professional Document Services to undertake document management consulting.

Earlier this year, Gordon moved to Xerox Business Services to concentrate on developing the facilities management and outsourcing activities of Xerox.

Prior to joining Xerox, Gordon spent some 10 years at the Woolwich Building Society.

A graduate in Business Studies, Gordon is married with two children and lives in Maidstone in Kent. He is a keen football and cricket fan (watching these days) and admits to be a long suffering Gillingham F.C. supporter

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MANAGING POLICIES AND STANDARDS ON A GLOBAL BASIS

A Presentation by Dr Sandy Chalmers of Glaxo Wellcome to the SAG Autumn 1998 Conference

Glaxo Wellcome feels that information policies and standards are sufficiently important to the business to have a small international group, of which I am a part, to address information and records management issues, to ensure that information flows easily around the company and that it is compliant with legal and regulatory obligations.

So my talk today will be based on our efforts, after the merger, to bring a cohesive approach to establishing corporate information and document policies across a multi-site organisation. I will therefore cover the following topics:

- What are they and why do we need them?
- What are the issues involved in creating them?
- How do you implement and maintain them?
- Some Glaxo Wellcome examples.

I will begin by defining what I mean by the document terminology, which I will be mentioning today:

Policy

A high level statement of fundamentals that need to be achieved i.e. a statement of intent or position describing agreed course or action.

Procedure

A document describing a process critical to achieving high product quality of regulatory compliance.

Standard

A clearly defined minimum level of quality which must be achieved, and against which all procedures and guidelines should comply.

Guidelines

A description of recommended best practice for a process or activity, but which may not be mandatory.

So why are the above document types so important to the business? We believe that they help to improve the flow of information around the company, while at the same time ensuring that any legal or regulatory needs are met. Compatibility between electronic documents and systems will save resources and allow reuse of information in a convenient form. Demonstrating standardisation also gives confidence to staff that their information resources are under control, and will allow efficient information retrieval.

Developing a Policy

When a corporate policy is to be established, one of the first decisions to be made is on the scope of the document. In a company such as mine, a key question is - will the policy apply to all sites carrying out R&D, or will it also include manufacturing areas worldwide? This must be clear from the start, so that the appropriate staff are involved in the discussions.

Another question to be asked is whether the policy will be rolled out simultaneously to all agreed regions, or if there will be a phasing programme. All parties need to be aware of the intent. On some occasions, it may be desirable for parallel but similar policies to be developed, particularly where there may be a specific local need or activity; however, the final product or outcome is normally internationally consistent.

Most policies and standards are mandatory but, on occasions, Glaxo Wellcome aims for a 'hearts and minds' approach where a desirable set of outcomes is described and recommendations made to users to change their practices. This is usually carried out through a Green Paper/White Paper system, where the users have an opportunity to influence the direction of the policy. Whatever the type of document being produced, users agreement on the content is very important, and focus groups with empowered users are essential. These users must be able to speak for their area and reflect back their own and their colleagues' views.

Approval

Once the policy has been agreed, senior staff approval is required. Extensive lobbying prior to this stage with senior people may have already been necessary. It is also desirable that directors not only sign up to a document, but that they are committed to it, and in some cases a specific short statement committing to a process needs to be issued; this is very helpful for compliance.

Quality

One of the most critical issues to be decided about a policy is to assess how 'perfect' it should be. Striving for perfection, i.e. excessive debate over detail may lead to delays in launching – or even being overtaken by other events, resulting in no launch at all.

A more pragmatic approach aiming for 80% or 90% may still serve the purpose, and will allow delivery on time. In this context, it should also be remembered that certain regulatory or legal

obligations may need to be met, and care must be taken to ensure this, without at the same time overdoing it in an attempt to impress a regulatory inspector or a lawyer when they are reviewing the policy. A balance needs to be struck.

Implementation

For implementation of a policy to be successful, the co-operation with users must continue; commitment by all is essential, and it will help greatly if the policy can be rolled out at the same time as other ongoing initiatives or projects. Using these other initiatives as a vehicle gives it added weight. This is not always possible and success may have to rely on good promotion, training and education.

Changing the Culture

Critical to all this is that not only should benefits be gained for the company as a whole but that individuals should see a direct advantage. It also helps if the timing can be arranged so that peer groups can all migrate to new practices together, thus giving a sense of team approval.

Communication

As you will understand with a multi-national company, communications are vital to the success of the policy, particularly if there is a transition period in moving from one policy to another to be endured. In addition to the use of electronic mail and face to face meetings, tele- and video-conferencing are now popular, and save travel costs. Newsletter articles, Web sites announcements and publicity materials are all important, as are direct presentations to specific groups of staff.

Maintenance

Once the policy has been launched and implemented, the story is not finished. The much forgotten maintenance phase then begins, where feedback on the success or otherwise is sought, and queries responded to and collected for the next review and update of the policy. Changes may be agreed through a change control process, and refresher promotions are likely to be needed to ensure that all sections of the community are using the policy or standard to the same operating level.

Build-as-you-go document compilation

Glaxo Wellcome, like many of you, has the problem that we have very large submission compilations that have to be sent to regulatory authorities to gain marketing approval or clinical trial approval. These often take years to complete, and are a rate-determining step in getting pharmaceuticals to the market.

Glaxo Wellcome is now running an international project to look at the compositions of submission reports and compilations to break them up into smaller modules which can be built up like a jigsaw into different outputs maximising re-use and speeding up the process.

An information plan identifies which modules should go into the compilation, and the modules are created in a build-as-you-go framework. They are held within an electronic, version-controlled repository and are then approved for release for building into different outputs. Some publishing software will then finalise and assemble the aggregated modules for publication. Change control and version control is instrumental in making this work.

The project is well on its way, and these modules are being built from are templates ready for compilation. This is being done on a large scale and we believe this particular application is just the start of a new kind of text and data management applicable to other document types to be implemented in the next millennium.

In this scheme, modules like documents and records should have their own lifecycles. Does this mean that modules should be treated as documents with their own retention times, archiving policies etc? The answer is likely to be yes, but with an added amount of complexity.

Information Classification Scheme

Within Glaxo Wellcome, a policy on information classification is being developed to assign levels of confidentiality to paper and electronic documents according to their value to the company. These are:

Level 1 - Confidential, secret.

Level 2 - Company confidential, intellectual assets.

Level 3 - Internal information.

Level 4 - Approved for release outside the company.

Once the user groups have decided into which of the agreed levels a document should go, a User Guide is consulted which will indicate the way that a particular document should be handled, stored, distributed etc. These recommendations, which are aimed at assigning the greatest protection to the most confidential material, apply to all formats i.e. paper, electronic records, e-mail, fax etc. The policy is very much a 'hearts and minds' project and has been prototyped in the US, with roll out in Europe and elsewhere

planned for the near future. As you can imagine this policy will impact on all Glaxo Wellcome documents and has the approval at an executive level in the company.

R&D Reports Management Policy

R&D reports are key documents in the pharmaceutical industry, and at Glaxo Wellcome a world-wide policy is in place to ensure that:

- They are created using a standard Word Template
- An international numbering system is used to allocate the number
- Reports are approved and distributed in an agreed way
- Satisfactory rules for revision of documents apply reports are officially archived for regulatory and litigation reasons
- A software system allocates the numbers, but in some countries a Web-based request form is used to assign these remotely.

The policy was implemented in the UK and US first, with other world-wide sites adopting the policy in stages.

Publications Approval Policy

It is critical for a pharmaceutical company to ensure that journal articles and presentations are cleared for publication, otherwise there may be a
loss of intellectual property. Glaxo Wellcome R&D has a world-wide policy which ensures that review is undertaken by the author's line management, Global Intellectual Property and in some cases, therapeutic areas. This ensures that inadvertent disclosure is avoided, and that all disclosures are in line with strategic publication plans for any particular therapeutic area.

This policy was particularly difficult to establish, as there are differing views from a variety of disciplines within the company, which needed to be reconciled.

I close with the comment that policies and standards are there to help the business, not to impede it. The challenge is to ensure that these policies are focussed on the needs of the business, and not become out of date and irrelevant. ■

(Dr Chalmers also presented this paper at the 4th International Records Management Congress earlier this year).

GLP UPDATE

At the October technical meeting of the Good Laboratory Practice Consultative Committee Contract archiving was once again under discussion.

At the present time the GLPMA do not consider that contract archives can enter the Compliance Programme. It is much more difficult for management of the test facilities which generated the study data to demonstrate that data storage is adequately controlled. Also, the GLP Principles require prompt retrieval system and this could be a problem if the contract archive is geographically remote from the test facility that is the subject of regulatory inspection. As contract archives do not generate study data the GLPMA might not have a legal mandate under the Statutory Instrument to inspect such facilities.

The use of archive facilities belonging to a contract research organisation is different from the use of a contract archive facility. Essentially, as the contract research organisation is a member of the Compliance Programme the GLP compliance of archiving activities has been verified.

It has been suggested that archive related matters could form the basis of an OECD initiative which could also consider aspects of electronic records. The GLPMA have proposed that interested parties should contact their members and establish the extent or desire for contract archives. They could then produce a "position paper" to be tabled at the next meeting in February 1999. A representative from the Scientific Archivist Group could be invited to this meeting. ■

UNDERSTANDING THE COSTS OF DATA CAPTURE

Presentation by Caroline Jarrett, of Effortmark Ltd to the SAG Autumn Conference 1998.

Introduction

Organisations have sometimes been surprised and disappointed when they re-engineer a forms-based data capture process but fail to achieve their anticipated savings.

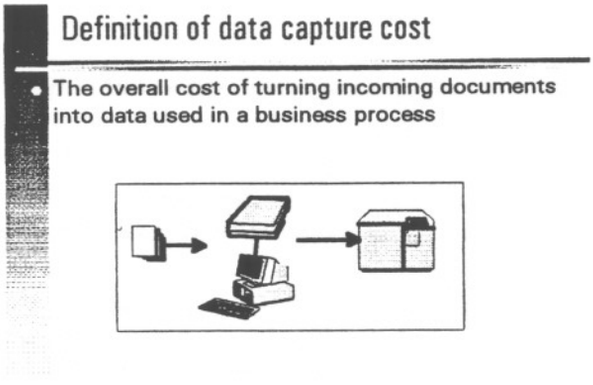
My paper will explain:

- how capture costs are built up from data entry **plus** dealing with problems
- the effect on costs of dealing with problems. Are you sending forms back to the respondent for extra information? Are your staff having to look up missing information elsewhere in your organisation?
- what happens to the costs if you speed up data entry by introducing an automated capture system
- how to find out whether your own new data capture process will achieve the savings you want.

THE COSTS OF DATA CAPTURE

The cost of data capture is the overall cost of turning incoming documents into data used in a business process.

If you are considering automated data capture in your organisation, you may have seen schematics like this:



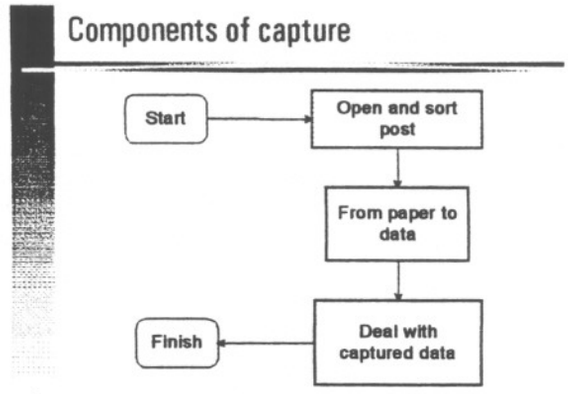
Documents arrive at a scanner, are captured, and end up on your organisation's database. The problem with these schematics is that they leave out one major element of your costs: the staff who operate the technology. I will not be considering the technology in this paper. Instead, I will be considering the human element: what your staff have to do at each stage to achieve the overall business purpose.

The components of cost - what people have to do at each stage when turning paper into data

Understanding average cost - how to analyse these costs when you are considering your investment

Investigating your costs - four techniques for investigating your own data capture costs

THE COMPONENTS OF CAPTURE



Opening the post

Figure 3.1 Incoming post, courtesy of the Open University (author's photo)

Your documents do not arrive at the capture process by themselves. The post has to be opened and sorted.

When you start scanning your documents, rather than reading them, you have to be more careful when you open the post. For example, one of my customers complained that the scanner would not work. I found that they were opening the envelopes with an automatic letter opener which sliced each form into two pieces. Then the data capture department was sticking the pieces back together with sticky tape which was too thick for the scanner.

Sorting the post

Your incoming post probably includes some of these:

- items marked 'personal and confidential'
- post for a different office
- a quantity of items which are wholly unsuitable for scanning, such as samples

and various other items which may or may not have an impact on the process you are automating. Somewhere you will need to have a post sorting station like this:

Figure 3.2 Form sorting desk, courtesy of Open University (author's photo)

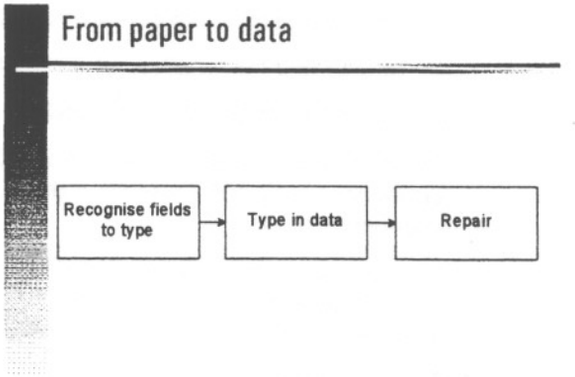
Your post team will need to know what to do with all your forms. Are you going to get them to remove the forms that are too torn or crumpled to go into the scanner? What about forms which arrive on the old version of the stationery? What are you going to do if an incoming form is attached to a letter? Are you going to deal with it as a letter or a form first? What if the letter modifies the contents of the form?

There is also a considerable problem if your forms are multi-part. If you have many pages, are they all attached to each other? If so, how are you planning to cut them up in order to scan them? Conversely, if they are separate sheets, there is the opposite problem of checking that they are all in the same place and arrive together.

Inevitably, a batch of multi-part forms will get dropped and muddled up. You will need some identifying marks which allow them to be sorted out again.

FROM PAPER TO DATA

Once you have got your forms to your data capture staff, the next step is turning paper into data.



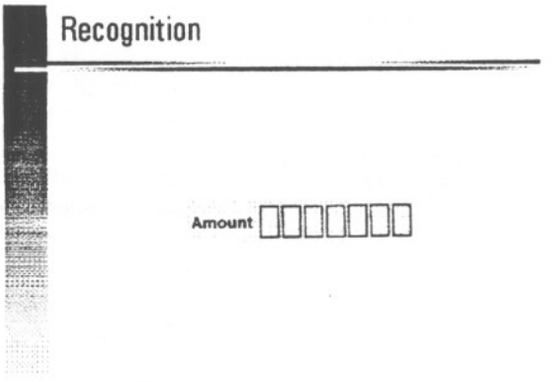
The staff have to recognise what to type in - to understand the marks on the paper as figures or numbers to be put into the computer.

Then the figures or numbers have to be typed - keying the figure or number into the appropriate field.

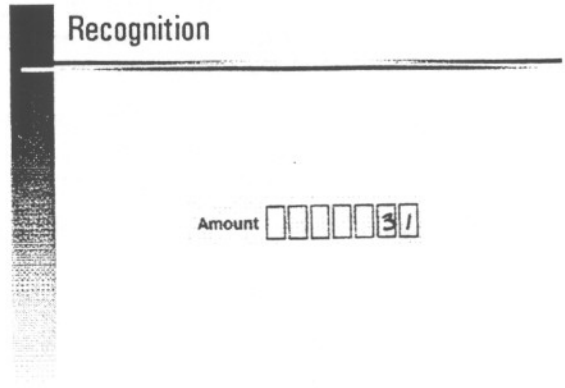
Finally, your computer system is likely to validate the data. The staff have to decide what to do if the data keyed is not acceptable as an input. Repair is the process of dealing with the validation failures and any other problems on the form.

Recognition

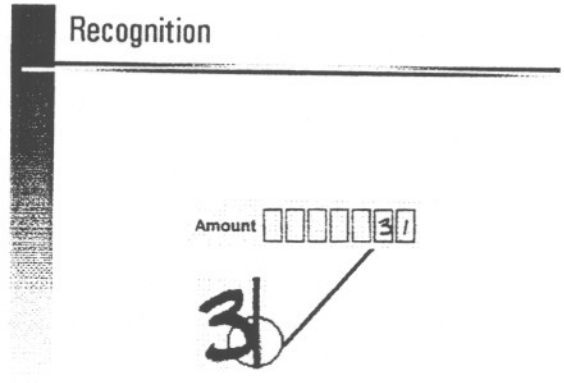
To explain where the costs come from, I will use an example: an amount field. I have not seen a typical clinical form, but I guessed that you often require the amount of a drug dispensed or similar information.



Here it is as completed. There are some marks on it.



The process of recognition is understanding the two squiggles on the right as numbers. Humans are rather good at this, and most of us will interpret these squiggles as the number '31'. You might not even notice that the 3 has been written across part of its box.

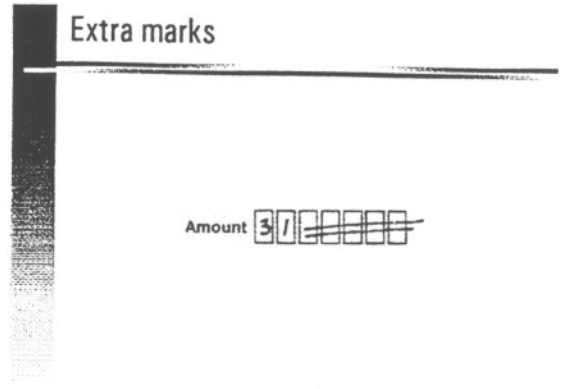


When character recognition experts - OCR, ICR or whatever - talk about recognition, this is what they mean. Their equipment will look for the squiggles, separate them from the boxes, and turn them into numbers. They prefer to have the boxes printed in drop-out colours so that they do not need to deal with problems like my '3', but some recognition engines will sort this out for you.

When they talk about 90% recognition rates, they usually mean that 90% of *characters written in the boxes* will be recognised correctly.

Now let us look at some other ways your respondent - maybe a doctor, nurse, patient, representative - might tackle this box.

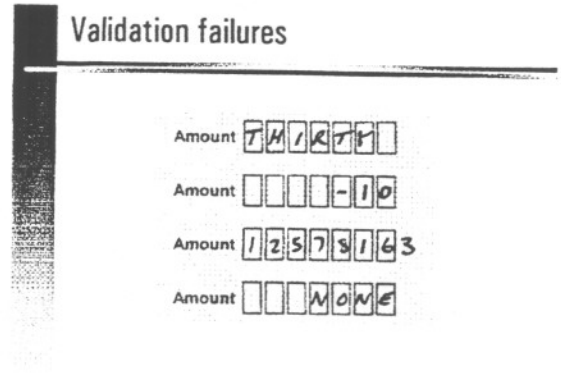
Extra marks



This time, we have another '31' but the respondent has felt obliged to indicate 'zero' with two horizontal slashes. Some OCR engines may fix this. Mostly, your engine will report this as a recognition failure.

Validation failures

Your computer system is likely to have validation on the input. For example, the amount field might only accept numbers in the range 0-9,999,999 and the validation will reject all of these:

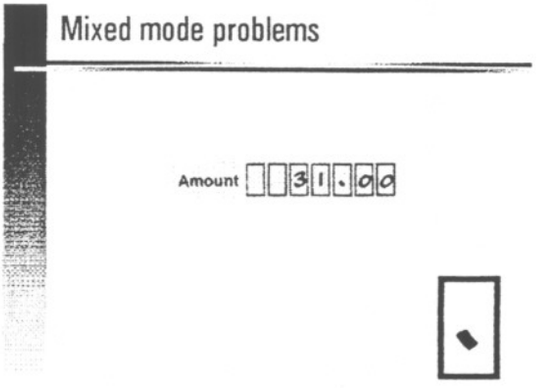


Your staff will sort these out when they see them. It is likely that a recognition engine, with appropriate definitions and validation, will also refer them to the operator although there is a risk that you capture 1,257,816 rather than 12,578,163. (I will consider the issue of what an amount of 12,478,163 might actually mean later in this talk).

Mixed mode problems

In this case, the respondent has added a decimal point and two zeros. What happens here depends on the validations and the engine.

You may have a recognition failure on:



- If you are in luck, you will get '31.00' back from the engine and you can then strip off the ".00" to put 31 into your database.
- If your engine and validations are not working in harmony, you may end up with '31100" in your database.

Multiple entries and messages

Quite often, your respondent will do something like this:

Whatever did they mean?

A good OCR engine will give up on these - and is unlikely to count them as part of the 10% recognition failure. If the OCR tries too hard to understand the writing, you may get strange results: '300211'.

Repair

'Repair' is dealing with recognition and validation failures. A person has to view each one, and decide what to do at one of these levels:

Visual	You can repair the problem just by looking at the field. The 'extra marks' example is a visual repair.
Validation	You may need to know the validations as well, as in most of the 'validations' examples.
Internal fix	You can solve the problem with information on the document or within your organisation.
Go back	You have to obtain more information from your respondent to solve these problems.

Let's look a bit more closely at the 'internal fix' and 'go back' levels.

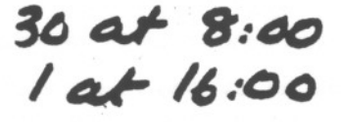
Internal fix

I have concentrated on a numeric field, but frequently your respondent will forget to supply some information you need: maybe a trial number, some form of reference, their own address. Quite often, you can look these up in your existing records.

You may need to know some business rules to fix some validation errors. For example, your staff will probably know if you can deal with an amount of 12,578,163 - or whether the respondent really meant something else, maybe 25,781.63, or a range from 12.57 to 81.63.

Go back

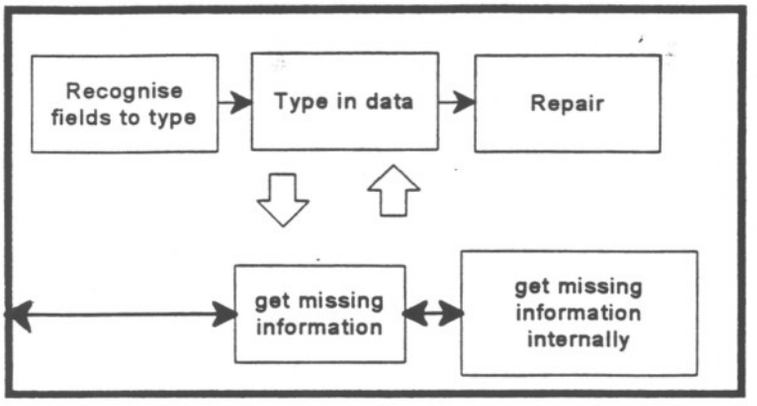
Organisations are reluctant to send forms back to the respondent, but you may have to - for example, if a signature is missing. Or there could be some vital information which might make the difference between the case being acceptable or rejected for the particular experimental protocol. You may have to ask the respondent what was meant, or for extra information to solve a problem.



The extra information supplied in this example might make all clear: perhaps you can just enter

'31' into the database. On the other hand, you may need to go back to the clinician to ask what was meant.

Combining processes



The diagram shows three separate processes of recognise, type in and repair. In fact, your staff will look ahead and choose a repair strategy before typing anything. They will read the marginal comments and deal with them first. And they will also know a lot of the validation rules. A human is unlikely to type '31100' in my 'wrong format' example. 'THIRTY' would be translated to '30'. A human would probably never realise that they have seen an 'extra marks' problem.

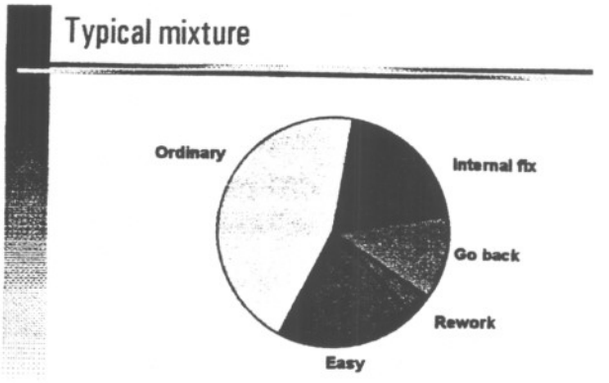
When you use an automatic data entry process, there is much less flexibility in the process. Recognition always comes first: the engine has to try to reconcile the squiggles into letters and numbers. You can only proceed to the validation stage when you have actual data. The 'internal fix' and 'go back' problems, which should have been tackled before you tried to do anything with the form, may get left until the end or missed altogether.

Rework

So that leads me on to my final category of problem: rework. If you miss problems at the initial capture stage - whether because your staff got it wrong, or your automated process got it wrong - then you have to solve the problem later.

People make mistakes all the time. You may find out that the capture process has gone wrong when you deal with the information. Or you may get subsequent information - maybe you send out a follow-up form which is only aimed at a certain sub-group in your population, and the respondent realises that something has gone wrong because the form is discussing the wrong type of case.

To simplify the calculations, I have grouped all of these into one overall category: rework.



COMPARING COSTS

Let us now look at how repairs influence costs for dealing with forms.

These figures are taken from a typical process for dealing with a multi-part form which asks for a variable range of data based on circumstances. I must admit here that I have no figures at all for a typical scientific study, but I hope that the categories I have used are recognisable for you.

In the processes I have observed, I have usually found a range of difficulty. To keep the calculations manageable for this talk, I have simplified them into two types:

Ordinary	The run-of-the-mill work. 'Typical' forms with an average amount of repair. Time to process = 1 unit.
Easy	The simplest forms - less data and no complications. Time to process = about half the time of an 'ordinary' form = .5 unit

We also identified three types of problem forms. Your own figures may be rather different, but these ones are also typical of the processes I have observed.

Internal fix	Repair from information you already hold. Same basic time as an ordinary form, plus about the same again to deal with the problems. On average, these take about twice as long as an 'ordinary' one = 2 units.
Go back	Need to go back to the respondent

during initial processing. Same basic time as 'ordinary' plus time to contact respondent, retrieve information, and finish. A working assumption: 4 times as long as an ordinary form = 4 units.

Rework — Someone points out a problem later. Has to be re-worked plus there will be additional care and attention needed. Some of these will take a long time to sort out, but to keep the calculations simple we will assume 2 units more than a 'go back'. Total time = 6 units.

The mix of work will vary according to the application, but the next table shows a typical split and the effect on process time.

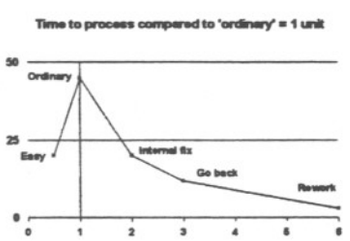
For each type, I have worked out:

typical percentages in the overall mixture

the time for processing the form

split overall time into post handling, keying, and problem handling.

Before automated process



An automated process

Let us now consider the effects on these times of an automated capture process. You will now be scanning your forms, so:

post handling time	probably doubles - now 6% of unit time
scanning time (new)	typically 10% of the previous unit time

The automated data capture product will remove the need for keying most of your data. The original keying time is replaced by:

recognition failures	10% of the data will need repair because of not being recognised - 10% of previous keying time for the form

However, from the earlier discussion of errors you will recall that there are other reasons for repair. The automated data capture product will not deal with 'extra marks' or 'wrong format' errors. So we need to add:

validation failures	maybe 10% of previous keying time
extra marks	maybe 10% forms will have this problem throughout, but to keep it simple we will use 10% of previous keying time per form

On top of that, we will actually increase the time for dealing with our problem categories of documents. With the manual process, we could recognise the problems and start to deal with them immediately. With an automated process, these problems get left until the recognition and validation problems have been identified. This increases the time to deal with each problem: the 'problem penalty'.

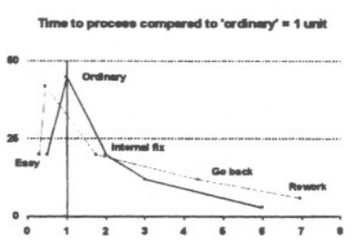
There is also a probability that problems get missed during the data capture stage, as some forms will no longer be getting as much scrutiny as they used to. Therefore some work has to be put right at the later stage. The effect is spread among all the forms, but to keep the calculations simple I have just assumed that 'ordinary' forms are affected.

The overall effects will depend on your particular process, but as a first estimate let us assume:

- time to deal with problems increases by 30% (problem penalty).
- 3% of forms move from the 'ordinary' into the 'rework' category

New automated process

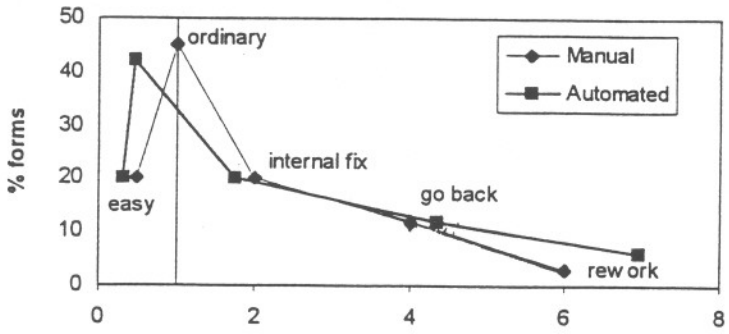
With automated process



Comparison of costs:

manual and automated process

So now let us compare the manual process costs with the new automated process.



This is rather a successful implementation of an automated data capture process. The new process is a bit more problematic for the difficult forms, and there are a few more of them. But 85% of our forms are being dealt with more quickly.

The table puts this into numbers.

Manual process and automated process

Total time to process

	Manual	Automated	Time saved
Easy	10	6	40%
Ordinary	45	19	58%
Internal fix	40	35	13%
Go back	48	52	-8%
Rework	18	42	-133%
Total time	161	154	4%

But what has this done to the bottom line, the overall cost of dealing with all the forms? The time saved on dealing with the easy and ordinary forms is offset by the increased time on the problem forms. Our new technology has achieved (161-154) / 161 = 4% saving.

The final question to ask is: what are you actually capturing at the moment? When you bring in your automated process, you may find that costs go up because you start to capture data that you did not capture in the manual process.

This may seem strange. If you have a box on the form, and the respondent has completed the box, why would you ignore it?

WHAT ARE YOU CAPTURING

Form tells you what you already know

Consider this example.

The customer here has filled in his name (and goes on to fill in his address) even though the name and address are the same as the ones already printed at the top of the form. There is no need to capture anything. 'Change' of name and address boxes are notorious for this - in one study, I found that half of the entries in the change of address box were the same as the current address. Often, the form asks the customer to fill in the whole name and address even if only one part of it has changed: you may be processing 50 to 100 characters of information when the only change is a single digit in the post code.

I have chosen name and address because so many forms ask for them. But the problem of asking for information you already hold is much more pervasive than just name and address. In the example above, not a single field had changed from the previous year's data.

Information arrives more than once

The second hidden cost I want to remind you about is the cost of getting the same information from two sources. For example, you may issue multi-part forms which need to be returned in a specified order. But sometimes they will come in all together, or in the wrong order.

For example, it is quite common for the second form in a series to contain all the data from the first form, plus a bit extra. If you have already processed the second form, you will add nothing (except possible confusion) if the first form arrives afterwards and you just go ahead as if you never received the first form.

Although you may try to discourage them from doing this, you do not really want to put off processing the second form until the first one arrives: maybe it never will. So how are you going to reconcile this with any off-line capture system?

All boxes on the form are not equal

Finally, I have been discussing forms as a whole. But when you consider the individual boxes, you may find that:

Some are crucial to your business: perhaps the

signature box, or the procedure reference number. We will assume that you capture these.

Others are for more general purposes: market research, future mailing lists, a description which helps to confirm the general details of the case, something that someone thought 'we may as well ask this'. Your manual process might only capture these for some forms, or for certain special events, or if other information is missing.

Some may just be left over from an earlier version of the business process and are no longer used at all.

If you simply start to capture all the boxes on the form when you introduce your automated process, you may be using a lot of staff time on recognition and repair for boxes you are not going to use.

It is important to distinguish between these boxes when you design your automated process. A validation which accepts almost anything on a vague box about 'please indicate any leisure interests' might be inappropriate for a box, similar layout, asking 'please indicate if any of these conditions exist'. If a box is only used under certain circumstances, it might be more efficient to ignore recognition errors on it until the point it is needed.

ESTABLISHING THE RISKS

I have spent a lot of time explaining what might go wrong and how those problems might end up giving you trouble on your own project.

Against that, there are many success stories and the opportunity to remove tedious work. So how can you find out what the risk factors are on your own project?

The data you need

My calculations used:

- categorisation of forms into 5 types: 'easy', 'ordinary', 'internal fix', 'go back' and 'rework
- percentage of each type in the overall workload
- post handling time
- keying time
- recognition rate for properly completed boxes
- percentage of validation failures
- scanning time
- percentage of recognition failures because of improperly completed boxes ('extra marks' and other errors)
- penalty percentage on dealing with problems in a different order because of automated process
- increase in rework category.

and I also warned you about capturing data you already know, data that arrives twice, or data which you may not use.

Four techniques to help you

The four techniques are:

1. Cohort tracking
2. Exceptions analysis
3. Usage analysis
4. System calibration

Cohort tracking

Cohort tracking will define:

- your own types for categorisation of forms
- your own percentage of each type in the overall workload
- the post handling time

The steps are:

1. Make an appointment with your post room.

   Find out when they open the post, and what the pattern of post is from day to day and week to week. Choose a typical day for your first cohort.

2. Count the unopened envelopes.

   You may need to start selecting at this point. If you have thousands of items, it will be hard to track them all, so you may need to compromise by picking every tenth, or every hundredth envelope.

3. Watch your envelopes being opened.

   Note how many items are removed for separate handling

   Note how many of the items arrive with or without supporting information. Establish how much work gets done on your items.

4. Mark each item you are interested in.

   You could use a small rubber stamp, or a dot of highlight pen, on the reverse of the item.

5. Take note of some identifying detail for each item.

   This could be a reference number or some other identification.

6. You now have a cohort of items.

The idea is to check back to see how many have been dealt with and what happened to them. Who sorts them, and why? How many

are finished with by the end of day 1, of week 1, of month 1? Did any of them turn into problems?

By tracking your cohort through the process, you should be able to create your own split of your documents into the 'easy', 'ordinary', 'internal fix', 'go back' and 'rework' - or a more complex selection of categories.

Depending on the overall time for your process, you may need to check on your cohort over days, weeks or even months. If you do not do it, you may miss the really time-consuming examples that eliminate any savings from an automated process.

If the typical cohort shows encouraging figures - low percentages in the 'go back' and 'rework' categories - then you may need to track more cohorts, choosing them from the extreme or unusual: end of the month, the day after bank holiday, extra orders after a big promotion.

Exceptions analysis

Cohort tracking identifies the overall fate of a batch of items. Exceptions analysis is its opposite: it looks at the work of a single day, or even of a single hour, and identifies the full range of problems encountered during that particular session of processing.

Exceptions analysis will define:

- keying time
- percentage of validation failures
- percentage of recognition failures because of improperly completed boxes ('extra marks' and other errors)

This time, you start with the forms as they arrive at the point of capture. You may need to enlist the help of the staff who deal with the form. For each form and every field on the form, you note:

- if you find the writing on the form difficult to read
- whether there are extra marks
- if any field is completed in a way which might fail validation
- if anything mandatory is missing
- if there are internal contradictions, for example two items both completed, when only one is allowed
- if there are any marginal notes, additional information, or accompanying letters to explain entries on the form.

By the end of this, you should be able to identify:

- the percentage of forms with extra marks
- the rate of validation errors
- the rate of internal fix errors
- the rate of 'go back' errors

Of course, you could do the exceptions analysis on the cohort. But often the cohort gets split up during its various sorting phases - and you find that you can only look at exceptions with particular members of staff who do certain types of work. The cohort tracking gives you the overall mixture, whereas the exceptions analysis gives you the detail on elements of the mixture.

Usage analysis

The third step is usage analysis. This tells you how you use the information you ask for on the form.

Do not try this step until you have your cohort and exceptions information. If you use a blank form, you will find that there are unrealistic expectations about the standard of accuracy in the information written on the form.

Armed with the data about what actually gets put onto the form by your respondents, you convene a meeting - or it may have to be a series of meetings - of your computer team, your processing team, and the overall owner of the business process. For every box on the form, you find out:

- what gets put into the computer system by the processing staff
- what the computer system does with that information
- the consequences for the business of the exceptions you have identified.

The meeting should discover the discrepancies between what you ask for and what you need.

System calibration

By the end of the cohort tracking, exceptions analysis and usage analysis, you should be able to judge whether your data process is sufficiently straightforward to allow you to consider an automated process. My broad criteria would be:

- 20% or fewer forms have exceptions
- you are using all the information you ask for, and
- more than 90% of forms fall into the 'easy' or 'ordinary' categories.

You can now prepare a realistic pack of test forms to discuss with your chosen vendors. The pack should include the same mixture of types of documents as your overall mix, discovered during the cohort tracking. Remember to put

them into the appropriate envelopes: the folding is important.

During system calibration, you will discover:

- effect on post handling time
- scanning time
- recognition rate for properly completed boxes
- percentage of recognition failures because of improperly completed boxes ('extra marks' and other errors)
- penalty percentage on dealing with problems in a different order because of automated process
- increase in rework category.

Test the proposed scanner by getting the forms out of their envelopes, sorting them as required by your vendor, and scanning them.

Ask your vendor to provide you with the recognition rates and recognition failures on your test pack of forms. Do not accept rates produced on any other test pack.

Finally, check the output data you are likely to obtain. Will this be sufficiently accurate to prevent any increase in rework?

SUMMARY

Every data capture application has to accept that people will make mistakes. Your new automated system will just expose the problems that your current manual system avoids by using the perceptual and judgmental skills of your staff.

Often, these skills come as a surprise. Your post-room staff and data entry clerks are often some of the lowest-paid employees in the business. Despite this, they are making hundreds of decisions every day. They may be relatively tiny decisions, but the cumulative effect can be fundamental to your business.

What you learn should help you to win, not lose, from implementing your new technology. Or you might decide to improve some of the old technology. How about some hand-cream for the staff who open the post? ■

WRITING A STANDARD OPERATING PROCEDURE

Workshop presentation by Elaine Stott and Liz Tribe made to the SAG Autumn Conference 1998.

The aim of today's presentation is to give participants encouragement and help to start writing SOPs.

Firstly it is important to define what a procedure is:

- A description of the steps to be followed to achieve the objectives defined in the procedure.

In other words:

- What needs to be done to perform a task or activity and when it should be done.

Why do we need SOPs?

- To ensure a quality standard.
- To ensure consistency.
- To encourage improvements in efficiency.
- To support training.
- As an historical reference.

A well-written SOP will have some fundamental characteristics:

- Reflects the activity being described.
- Unambiguous.
- Logical, clearly defined objectives.
- Easy to interpret.
- Simple in language.

Preparation

Before your start writing your document it is essential to determine the scope of the procedure. It might be useful to start with a flow diagram of the process; this will help you to establish exactly what relevant information you will need to collect.

It is also important to recognise the primary user or audience of the procedure to ensure the language and terminology you employ is correct.

Writing the Draft Procedure

When writing the draft procedure the key points to remember are:

- Language should be clear and concise.
- Process should be logical.
- Must be accurate.

Once the draft procedure is complete the next stage is the review process. This will entail asking a series of questions to establish that the written document will fulfil its objective:

- Is the process GxP compliant?
- Does the procedure read well?
- Is it logical?
- Is it correct?
- Is it complete? (Who,What,When)
- Can it be followed?

If the answer is yes to all of the above questions, write the final version and present for approval.

SOP Content

The following is a list of recommendations for the content of a SOP:

- Title
- Author
- Management Approval
- Implementation date
- Status
- A reason for the new version
- Scope
- Applicability
- Table of Contents
- Abbreviations
- Definitions
- References
- Responsibilities
- Page Numbering
- Section Numbering
- Various fonts and font styles to high-light points
- Description of the procedure
- Appendices
- Flow Charts

Summary

To conclude this presentation here are a few helpful tips to remember:

- Define the purpose and scope
- Appoint a suitable author (usually the operator)
- Know your user

- Collect all the information you need
- Write clearly and concisely (not lengthy)
- Write logically
- Use simple language
- Create a flow chart to reflect the procedure
- Only include relevant details
- Test the procedure for accuracy at the draft stage
- Get comments from users on acceptability of the SOP

We have also included a list of some of the archiving functions where a SOP could be written:

- Storage procedures
- Security and access to archive
- Retrieval of archived material
- Document Microfilming
- Document Scanning
- Safety in the archive
- Loan procedures
- Location and management of archives
- Environmental conditions of the archive
- Retention of archive material
- Purchasing policy for archive storage materials

And many more...

SUCCESSFUL DIPLOMATES!

Congratulations are extended to Rachel Simerly of Amgen and Beth Stevens of British Biotech, pictured here (left to right) with Liz Tribe, SAG Training Officer, Lesley Almond, SAG Chairman and Margaret McCabe.

Congratulations also to Rick Selfe of Shell UK Ltd who has also graduated but was unable to attend the presentation.

MANAGEMENT OF STANDARD OPERATING PROCEDURES

Workshop presentation by Karen Box and Mary Paul at the SAG Autumn Conference 1998.

Introduction

SOPs are practical tools that define what should be done, when and by whom.

The Statutory Instrument No 654 on Good Laboratory Practice Regulations 1997 Part VII states that:

(1) A laboratory should have written standard operating procedures approved by management that are intended to ensure the quality and integrity of the data generated in the course of the safety study.

(2) Each separate laboratory unit should have immediately available standard operating procedures relevant to the activities being performed therein.

A SOP documents a series of actions that need to be performed so that the result achieved is of the necessary quality - this includes in addition to laboratory procedures any administrative procedures undertaken.

The above definitions of SOPs promote the theory that reliable data can be produced only if there is a controlled standardisation of procedure. A SOP can demonstrate this control because the written format helps to prevent slight alterations in procedure as it is conveyed from one person to another. An effective SOP system will also provide documented evidence of management control.

SOPs have other purposes too:

(1) Historical Record – by archiving every SOP as it is produced it is possible to reconstruct past research techniques, to demonstrate development of a process and to help identify any problems that may emerge in historical study data.

(2) Critical Appraisal of Procedures – SOPs enable an organisation to analyse working practices and rationalise variations in procedures.

(3) Training – SOPs can be used as a training aid for new staff members.

(4) Health & Safety – SOPs can demonstrate and document compliance to health and safety regulations i.e. COSHH.

(5) Company Commitment – SOPs can also demonstrate commitment of staff and management to GLP/GCP/GMP. Short, vague, poorly controlled or unused SOPs are clear indicators to regulatory authorities, auditors and customers of lack of commitment.

Management of SOPs

The management of any SOP system, whether paper or electronic, includes certain key elements; these are preparation and review; approval and authorisation; distribution and administration; review and revision; and archving. In this workshop we are concerned only with the basic SOP management requirements; specific details of electronic SOP management are covered in a separate workshop.

Preparation and Review

All SOPs should:

- Conform to a standard, company format.
- Be uniquely identifiable.
- Each version of a SOP should be sequentially numbered.
- Each SOP should be prepared by one named individual. Usually the most suitable person is the one conducting or supervising the procedure on a daily basis.
- Draft SOPs should have a limited life span. Concerned parties are then able to comment and reply within an agreed time scale. It is not usual to archive a copy of any draft documents. It is essential that draft documents can be easily identified from SOPs in general use.

Approval and Authorisation

Once prepared the SOP should be authorised for use by management.

This ensures the procedure will comply with company policy and any other regulations that may impact on the procedure. Examples of such regulations are Health & Safety at Work Act, COSHH Regulations, Ethics committee approval etc. SOPs are usually formally authorised with a dated signature (or a series of signatures) on the document to be issued.

Distribution and Administration

SOP administration needs to ensure that the approved documents are made available in a controlled manner to their intended users.

It is usual for SOPs to be administered in a central location.

The administrator will alert users when a new SOP or a new version of the SOP has been approved and will prepare the necessary copies of the document for distribution.

To maintain a controlled system it is essential to

have documented evidence of individual SOP distribution, location of each individual copy of the SOP, and the date of production and issue.

Procedures need to be in place to ensure that only the latest version of a document is readily available and in circulation. It may be necessary to provide controlled access to historical SOPs but these need to be easily identifiable from SOPs in general use.

Documented evidence is required to support the notification and removal of superseded and withdrawn SOPs.

Review and Revision

SOPs should be reviewed on a periodic basis and procedures need to be in place to ensure regular review of all documents. It is important to document that the review procedure has taken place, even though there may be no revision.

SOPs should be given the next sequential version number on amendment.

It is a good idea for all changes to existing documents to be identified on the cover or in the introduction of the new version.

Archiving

A copy of all SOPs should be archived as they are produced. Some companies maintain a complete set of historical SOPs, which are exact duplicates of documents issued to the laboratory, as well as a 'wet ink' master set of SOPs from which the copies were made.

LETTER TO THE EDITOR

Dear Editor,

A Regulatory View from the GCP Compliance Unit

Thank you for publishing your account of my talk to the Spring Conference in Chester. May I please make two small comments? Firstly the diagram showing the structure of the MCA omits the Executive Support and Finance Divisions. Secondly page five incorrectly states that the unit has yet to conduct and 'for cause' type inspections. In fact there have been several. I apologise if these errors arose due to any lack of clarity in my presentation. But I would be grateful if you would bring them to the attention of your readers.

Many thanks for your invitation to the meeting and for your hospitality. I enjoyed the occasion very much and hope we will meet again in the future.

Yours sincerely,
Pamela C Nichols
Head of GCP Compliance

FOOTNOTE:
Pamela C Nichols is no longer Head of GCP Compliance Unit but has become an independent consultant for GCP Compliance. The GCP Inspectorate is still continuing with its voluntary inspection programme and the Management vacancy within the GCP Inspection Unit is unlikely to be filled until the middle of next year.

SAG WELCOMES NEW MEMBERS

Mr John Ambler	Novartis
Mrs Jacqueline Botten	Phoenix International
Ms Karen Brutnell	Astra Charnwood
Ms Patricia Ferguson	Moredun Scientific Ltd
Ms Estelle Jacquin	Vetoqinol
Ms Georgial Lazari	Covance
Ms Christine McBride	Irish Equine Centre
Ms Rachel Stewart	Zeneca CTL
Mr C J Urmson	Scottish National Blood Transfusion Service

PAPER v ELECTRONIC STANDARD OPERATING PROCEDURES

Workshop presentation by Andy Hollis and Lesley Almond at the SAG Autumn Conference 1998.

The workshop began with a poll to establish the percentage of delegates who used paper SOPs, electronic SOPs and a hybrid system using both. The majority of systems employed a hybrid with some wholly paper.

INTRODUCTION

It is important to note that irrespective of the medium of your own SOP system there are key elements that are applicable to all. These are:

Descriptive title

Authorised by signature

Effective/operative data

Edition/version number

Available to use

Locatable

Retained historic copies

Controlled distribution

Good practical text

ELECTRONIC SOPS

An electronic SOP has the same content as a paper SOP, but with production, retention, use, distribution, authorisation etc. managed electronically.

The author and approver of a document must sign the SOP, and for an electronic SOP this will entail the use of a unique user ID/password or manual electronic signature, *eg.* stylus, or biometric signature *eg.* fingerprint.

All review procedures for electronic SOPs will also take place by electronic means in a digital form.

Even with an electronic system it is still necessary to establish an administrative process for issue of SOPs, replacing the previous version on the effective date of the SOP. Only the current version of the SOP must be available for use.

Similarly, an administrative process needs to be in place for review and removal of discontinued SOPs. The previous version of the SOP must be retained in an 'Archive' for 'x' years.

For any electronic system to work effectively it is necessary for the current version of the controlled documents to be immediately available to the appropriate users. PCs or terminals must be available in the place of work.

If SOPs are to be printed off the system to increase flexibility of use then a 'banner' must be available across the SOP to indicate a limited life span i.e. 'x' days.

HYBRID SOPS

Hybrid SOPs are those which are produced electronically but include various elements of a manual/paper system. For example:

- SOPs generated in WORD
- Master SOP is a paper, signed version
- Paper distribution and copy control
- User access to electronic versions for update, controlled so that only approved versions are available to users electronically.

PAPER SOPS

With a paper system the following key elements need to be in place:

- Issue new SOP numbers
- Initiate SOP review process
- Chase up SOPs under review, which are falling behind review time scale.
- Keep track of SOP status i.e. under review, issue withdrawn etc.
- Issue and withdraw SOPs as necessary
- Control copies of SOPs to ensure superseded and withdrawn copies are removed from manuals
- Keeping track of SOP manuals i.e. location and holder
- Archived superseded master SOPs
- Keep track of destruction of superseded SOP copies.

BENEFITS OF ELECTRONIC SOPS

An electronic system does have benefits over a paper SOP system:

- Easier access
- Easier review process and copy control
- Reduces administration
- Reduces ambiguity of versions
- Increases security (if set up correctly!)
- Saves trees

The benefits could also include an increase in efficiency of SOP production, review, distribution, destruction and tracking. ■

W.W.W. UPDATE

The following appendix is provided by Alan McQuitty from Eli Lilly Ltd and lists some useful websites for archivists and records managers.

(If you know of any others please e-mail the SAG editor with details and watch out - the next website could be for the SAG).

NAME	ENTRY	WEBSITE
ABPI	Y	www.abpi.org.uk/
Adobe Systems	Y	www.adobe.com
Advanstar	Y	www.advanstar.com
American Association Of Pharmaceutical Scientists	Y	www.aaps.org/
Anglia Polytechnic University	Y	www.anglia.ac.uk
Apex Data Services	Y	www.apexinc.com
Applied Clinical Trials Online	Y	www.actmagazine.com
Archer Management Services	Y	www.yes-archer.com/home.htm
Archives Of Australia	Y	www.aa.gov.au/
Archivex	Y	www.archivex.com
ARMA - Disaster Recovery	Y	www.arma.org/hq/disaster.html
ARMA Home Pages, List of	Y	www.arma.org/index.html
ARMA - HQ Site	Y	www.arma.org/hq/armainfo.html
ARMA - HQ Job Hotline	Y	www.arma.org/hq/jobshot.html
Association for Information and Image Management International	Y	www.aiim.org
Australian Archives	Y	www.aa.gov.au/
Automated Records Management Systems, Inc.	Y	www.arms4rim.com/
BIDS	Y	www.bids.ac.uk
British Data Management	Y	www.BDM.co.uk
CAIT	Y	www.cait.wustl.edu/cait/infosys.html
Cap Gemini	Y	www.capgemini.co.uk
Cardamation	Y	www.cardamation.com/
Cave Tab plc	Y	www.cavetab.plc.uk/
CDI Vaults	Y	www.cdivaults.com/
Central Records Services, Inc.	Y	www.centralrecords.com/
Chicago Records Management, Inc.	Y	www.chicagorecords.com/home.htm
Datafile	Y	www.datafile.com
Datavault Limited	Y	www.datavault.co.uk
Documentum	Y	www.documentum.com
Electronic Evidence Discovery, Inc.	Y	www.eedinc.com
European Union Drug Regulatory Authorities	Y	www.eudra.org/
Excalibur Technologies	Y	www.excalib.com
FACS Records Centre	Y	www.facsrecords.com/
FDA	Y	www.fda.gov/
FDA CDER Approvals List	Y	www.fda.gov/cder/da/da.htm
FDA ICH Guidelines for GCP	Y	www.ifpma.org/pdfifpma/e6.pdf
FDA Information Sheets	Y	www.fda.gov/oc/oha/toc.html

NAME	ENTRY	WEBSITE
Financial Times Healthcare	Y	www.fthealthcare.com/
First American Records Management	Y	www.firstam.com/farm
GLP Statutory Instrument 1997	Y	www.hmso.gov.uk/si/si1997/97065401.htm
GMB	Y	www.gmb.com.au/index.html
Government Information Service	Y	www.open.gov.uk/
GTESS	Y	www.gtess.com/
Hayes	Y	www.hayes.co.uk
History Associates, Inc.	Y	www.historyassociates.com
Information Requirements Clearinghouse	Y	www.irch.com/
Input Center	Y	www.inputcenter.com
INSCI	Y	www.insci.com
Institute Of Historical Research	Y	www.ihr.sas.ac.uk/
International Council on Archives	Y	www.archives.ca/ica/english.html
International Council on Archives - Electronic Records - Guide For Managing Electronic Records	Y	www.archives.ca/ica/p-er/guide_0.html#top
International Council on Archives - Electronic Records	Y	www.archives.ca/ica/p-er/english.html
International Council on Archives - Electronic Records - Literary Review	Y	www.archives.ca/ica/p-er/literev_acs.txt
Joint Information's Systems Committee	Y	www.niss.ac.uk/education/src/
MCA	Y	www.open.gov.uk/mca/mcahome.htm
Metadata Specifications	Y	www.lis.pitt.edu/~nhprc/meta96.html
National Pharmaceutical Association (NPA)	Y	www.npa.co.uk
OPAC	Y	http://opac.unn.ac.uk
Preserving The Intellectual Record	Y	http://ukoln.bath.ac.uk/%7elisld/hedstrom.htm
Provenance Systems, Inc.	Y	www.provsys.com/
Public Record Office	Y	www.open.gov.uk/pro/prohome.htm
Royal Commission On Historical Manuscripts	Y	www.hmc.gov.uk/
Specialised Research Collections In Humanities (NFF)	Y	www.kcl.ac.uk/projects/srch
Staffware	Y	www.staffware.com/
TASC	Y	www.tasc.com/
TDK	Y	www.tdk.com
Technology Guides	Y	www.techguide.com
US National Archives	Y	www.nara.gov
UK Patent Office		www. patent.gov.uk
Association of British Pharmaceutical Industry		www.abpi.org.uk

BARQA ARCHIVE PAPER

The group has the opportunity to collaborate with BARQA with the production of a paper on Archiving.

The Draft index and contents are reproduced in the journal and anyone who feels able to write, proof read, comment etc., should contact Lesley Almond who is co-ordinating the SAG efforts. All volunteers are welcome.

DRAFT - Index and Contents Notes

TABLE OF CONTENTS

CONTENT NOTES

I. DEFINITIONS AND ROLES OF THE ARCHIVE (Design/Option)

(including historical descriptions)

- Corporate Archive
- Regulatory Archive
- File Centre
- Information Bureau
- Inventory Registration Service
- Record Centre
- Reference Library

II TYPES OF CONTENTS

- Paper Documents
- Microfilms
- Magnetic Media
- Magneto-Optical Media
- Chemical Samples
- Biological Specimens

III ENVIRONMENTS

eg. At CRO, Sponsor, INV SITE, hospital etc., are different policies recommended?

IV REGULATIONS, POLICIES AND GUIDELINES

Identify existing GCP, GLP and GMP tenets

V ISSUES TO CONSIDER IN A DATA AND DOCUMENT MANAGEMENT PLAN

- Retention control
  - WHAT material is to be stored?
  - WHY does it need to be retained?
  - WHEN should it be sent to Archive *eg.* Archive Schedule - when does transferral occur?
  - HOW does material need to be identified, collated, indexed, stored and retained? ....."With regards to recording media, electronic media are currently unsuitable for long-term storage due to rapid and constantly changing technology. Most data and documents are therefore currently recorded and stored on paper with microfilm copies necessary (only) for references or security copy purposes."
  - WHERE does material need to be stored?
  - WHO is responsible?
- Disposal Control
- Access Control (*ie.* easy retrieval but restricted to authorised personnel only)
- Environmental Control
- Media Maintenance
- Storage Planning

- Media Planning
- Contingency Planning
- Disaster Planning
- Technology Planning
- Transfer Options *eg.* CRO to Sponsor and Sponsor perhaps to Internal or External Archive
    - Transfer of physical storage media
    - Transfer of electronic files between storage media
    - Transfer of access control authority
    - Transfer of retention control authority
    - Transfer of disposal control authority

VI STRATEGIC ISSUES (examples)

- Licensing involvement
- Company acquisitions, mergers, closures, responsibilities etc., relating to:
    - Ownership of data
    - Integrity of data
    - Accessibility of data records
    - Quality of data

VII RECOMMENDATIONS (examples)

(to organisations for establishment and maintenance of archives)

1. Establish corporate (organisational) policies and formalise in procedures or SOPs leading to the development of a DATA AND DOCUMENT MANAGEMENT PLAN.
2. Commit to appropriate resourcing.

VIII AUDIT GUIDES (sample - HOW to audit archives)

(include checklists for GLP, GCP and GMP or by ENVIRONMENT which incorporates GxPs).

CONTRIBUTIONS/SOURCES (CONTACTS??)

- Input from QA audit personnel and own company (MOF) - Biogen personnel
- RAPS - including national monitors
- BARQA Committees
- EFGCP Audit Working Party
- ACRP
- Archivists - *eg.* from Novartis??
- Central Laboratory Personnel - *eg.* MDS Clinical Trial Laboratories
- Other types of companies - *eg.* radiopharmaceuticals - MDS Nordion
- BARQA course developers
- Inter-company group representatives who meet to develop industry proposals (Novartis etc.)

FORTHCOMING EVENTS

ELECTRONIC DOCUMENT MANAGEMENT MASTERCLASS
JANUARY 1998
Records Management Society, London
This popular masterclass will look at the following topics:

- What is document management?
- Getting started -case study- identify the needs: where are the current and future problem areas?
- Feasibility study – case study – anticipated benefits – costs – winners and losers.
- Potential solutions
- Implementation – case study - managing change –risks and risk management

Fee: RMS Members £100 + VAT
Non-members £150 + VAT

Contact: Jude Awdry
RMS Administration
Secretary, Woodside,
Coleheath Bottom, Speen,
Princes Risborough,
Bucks HP27 0SZ
Telephone: 01494 488599
Fax: 01494 488590
E-mail: newsletter@rms-gb.org.uk

INTRODUCTION TO ICH GCP

27-28 JANUARY 1999
Rostrum, London

MONITORING TO GCP
20-21 APRIL 1999
Rostrum, London

SAG SPRING CONFERENCE

APRIL 1999

DISASTER PLANNING AND RISK ASSESSMENT
The Copthorne Hotel
Nr. Gatwick

(Details will be circulated nearer the date to all SAG Members)

GCP FOR CLINICAL TRIAL ADMINISTRATORS AND SECRETARIES

29 APRIL 1999
Rostrum, London

HOW TO AUDIT EFFECTIVELY

11-12 MAY 1999
Rostrum, London

USE OR THE INTERNET IN CLINICAL RESEARCH: A LAYMAN'S GUIDE

22 JUNE 1999
Rostrum, London

For details of all Rostrum courses contact:
Rostrum
Mildmay House
St. Edwards Court
London Road, Romford
Essex RM7 9QD

Fax: 01708 734 876/725413

ABOUT THE SCIENTIFIC ARCHIVISTS GROUP

The objectives of the SAG are:

- ***To improve the science of archiving.***
- ***To ensure Archives meet business, scientific and regulatory needs.***
- ***To encourage a high profile with regulatory authorities.***
- ***To develop a professional status for Members.***

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

TO APPLY :

Full membership is open to individuals with an interest in 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, DowAgrosciences Europe, Letcombe Laboratory, Letcombe Regis, WANTAGE, Oxon, OX12 9JT

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: .....

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: .....

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Datacare Business Systems Ltd	CLARKE, R	DATACARE BUSINESS LTD	FEBRUARY 1995
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What is a Record? or Life Cycle of a Record	SYNDICATE SESSION REVIEW PAPER	SAG	AUGUST 1998
Standard Operating Procedures	SYNDICATE SESSION REVIEW PAPER	SAG	AUGUST 1998
SAG - The Future?	SYNDICATE SESSION REVIEW PAPER	SAG	AUGUST 1998

Articles from back copies of Sagicity are available from the SAG Secretary