DBA

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The Journal of David Begg Associates

Issue 6 Summer 2007

How good are you...

really?

The Importance of Performance Measures

David Begg associates

The Pharmaceutical Training Experts

David Begg associates
The Pharmaceutical Training Experts

welcome

This summer, the heat is on.

Mike Bowsher,
Managing Partner
David Begg
Associates

We've seen our fair share of sunshine in the last few weeks. No doubt, like me, you occasionally take an idle moment to picture yourself taking a well-earned summer holiday. And, unlike me, perhaps you've already got everything organised!

But, in the meantime, there's a lot of planning to be done in the world of work. And in this edition of the DBA Journal, we take a look at some of the bigger issues that may affect you in the immediate future.

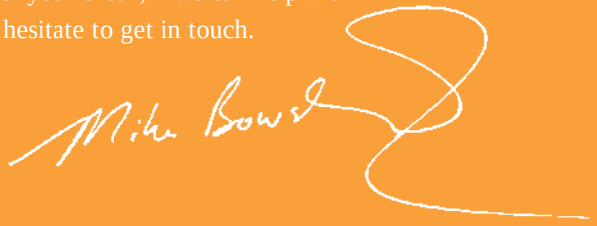
In general, the pharmaceutical industry has never taken Performance Measures to heart – but perhaps it's time we did. We separate the theory from successful practice with some practical guidance.

Eyebrows were raised when Dir. 2004/27/EC not only asked for APIs to be manufactured in accordance with GMP, but also added 'certain excipients' into the bargain. Read about the background to a decision some would regard as an ill-considered afterthought.

Annex 16 covers importation from a third country, and it states categorically that a certifying Qualified Person must ensure that each stage of manufacture meets certain standards. But no one person can do this – so what are the ramifications?

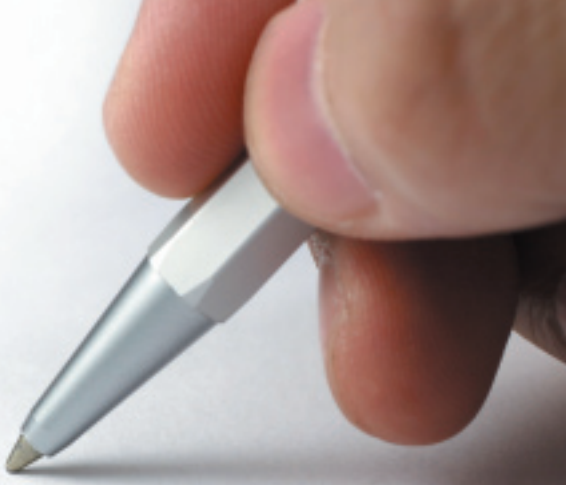
And while everybody's wishing for scorching weather ahead, Martin Lush was wishing for something cooler as he ran one of the hottest marathons London has ever seen. Read how he got on.

Finally, may I wish you an enjoyable summer, in the hope that you can balance your busy work life with some holiday time. And before or after your break, if we can help with training, audits or general consultancy, please don't hesitate to get in touch.



Above:
Clifford's Tower – a focus on York in Location, Location, Location.

Tech talk



Martin Lush explains the crucial importance of setting Performance Measures and provides practical advice on how to implement them successfully.

How good are you…REALLY?

A carpenter friend once offered some very sound advice. "Martin, always remember to measure twice and cut once". Roughly translated this means make sure you have accurate and reliable performance data before making important decisions! With your company facing a level of unparalleled change, the drive to improve every aspect of your business will be unrelenting. The need for making the right decisions at the right time has never been more important.

'Effective decision making requires direct physical measures for operational feedback and improvement. Without these accurate and reliable measures you cannot make accurate and reliable decisions'.

Historically, pharmaceutical companies have been very poor at measuring performance and acting on the data, partly because real and lasting continuous improvement has never been a priority. So do you measure twice and cut once? How accurate and reliable are your performance indicators and your decision making? Ask yourself the following questions:

- Are your 'Key Performance Measures' designed and used by those close to the process?
- Does everyone fully understand what your KPMs actually mean?
- Do your KPMs accurately reflect true performance?
- Are your performance measures clear, concise and unambiguous and not open to 'manipulation' and 'misinterpretation'?
- Is your performance data collected, interpreted and acted upon quickly, within days. Not filed and forgotten?
- Do you present the data in an interesting and understandable way to help and not hinder the reader?
- Is performance data used to encourage and motivate rather than the opposite?
- Does everyone have visibility of your KPMs, or is visibility restricted to the select few?

If you have answered 'Yes' to all of the above, congratulations. Your decisions are probably accurate and reliable! If you had a few 'No's then you should read on.

Quality And Manufacturing Key Performance Measures. Their Purpose:

- To ensure that the requirements of internal and external customers have been met
- To provide standards for establishing comparisons
- To motivate the work force!
- To quickly highlight quality and manufacturing problems and determine which areas require priority attention
- To help you use your resources intelligently
- To provide feedback for continuous improvement
- To provide the QP and Senior Management with visibility of performance
- To actually demonstrate to others, including regulators, that you are 'in control'

Designing And Using Accurate And Reliable KPMs: Key Steps

1. Select your measures with care
2. Get senior management 'Buy In'
3. Think long and hard about presentation
4. Think even harder about who is responsible for what
5. Have a mechanism in place to review, interpret and ACT on the data

Step One: Select Your Measures With Care!

Remember that every measure must

- Reflect true performance
- Accurately and reliably represent the controllable aspects of the process
- Be understood by those using them

It is very important to understand the needs of your readers. Senior and Middle management need to see performance data for the purpose of strategic oversight and planning they are not, however, the main audience. The most important readership are those who understand the process and who are able to quickly interpret and use the data for process improvement. There is one very important thing to remember when selecting any performance measure. Think very carefully about the behaviour each measure triggers. Let's take reducing the numbers of unplanned quality incidents (deviations) as an example. If the KPM forces plants to reduce the number of incidents, there is a risk that some incidents will go unreported. A more intelligent KPM would be one that measures the level of recurrent incidents:

- Each measure must be designed to prevent 'manipulation' or 'misinterpretation'. All must be clear, concise and unambiguous
- Measures must be compatible with any recognition and reward system
- Measures must be timely. To add value, performance measures must be interpreted, communicated and acted upon quickly, within days not months. Before selecting any measure first ask: 'how will we use this information practically?' Our industry is good at collecting lots of data and information and then ignoring it!
- Remember to keep measures up to date and relevant. Some companies, partly through habit, continue to use the same measures year after year, even though their business priorities have changed
- Remember that less is more. Don't collect lots of data; concentrate on the 20% of measures that will provide 80% of the benefit. Do not get carried away!
- When selecting the 20% that actually matter, you must involve the process owners and experts:
    - Process Operators and manufacturing personnel
    - Engineering and Validation specialist
    - QA and QC
    - Qualified Person

Involve them from day one and keep them involved, informed and engaged. They must own the measures, not 'management'.

When involving others be prepared for resistance and apathy. For many companies performance measures have a very bad reputation and many of your people will be very sceptical and distrusting of new ones. Have answers to the following questions beforehand:

- Why do we need them…we have managed successfully without them?
- How will the information be used?
- How will this impact on pay and reward?
- Will there be any additional responsibility?
- What will happen if the data indicates 'poor performance'? Who will feel the 'pain'?
- Will senior management see this data?
- What happens if the regulators ask to see it?
- How will the information be collected, communicated and acted upon?
- Feedback. Who, how and when?

Never, ever use performance measures for political or other 'ulterior' motives.

Step Two: Get Senior Management 'Buy In'

Senior and middle management have been the traditional custodians of performance measures. Historically such measures have been 'accountancy' based, too 'high level', understood only by the select few and often inappropriate. If you're interested in real continuous business improvement we recommend the opposite. The 'local' process owners must own each measure and be responsible for using the data. After you've selected your KPMs make sure you convince your management of their benefit.

Step Three: Think Long And Hard About Presentation

Remember, having generated the data and information you want people to actually read, understand and act on it. Winston Churchill once said "I can tell from the size of this document that you do not want me to read it".

- Keep presentation of data simple and interesting
- Ask the reader what they actually want

Step Four: Think Even Harder About Who Is Responsible For What

Each measure must be 'owned' by someone. You must make someone responsible for collecting, interpreting, reporting and acting on the data. For example…

The Manufacturing Manager could be responsible for measures relating to:

- Manufacturing output and efficiency. This includes operating processes and equipment within their validated/qualified ranges (this obviously includes change control!)
- Good documentation practices and procedural compliance
- Operator training and standards of GMP
- Cleaning and sanitisation
- Completion of Corrective and Preventative Actions relating to the Deviation Reporting and Audit programme

The Engineer could be responsible for measures relating to:

- Planned preventative maintenance of equipment and plant fabric and utilities
- Critical instrument calibration
- Environmental control
- Equipment performance

QA could be responsible for measures relating to:

- The internal audit and self inspection programme
- Deviation and CAPA system
- Trending and interpretation of QC data (Micro and Chemical) probably with the assistance of their QC colleagues!

Without ownership, measures become meaningless.

Step Five: Have A Mechanism In Place To Review, Report, Interpret And Act On The Data

Remember, the whole purpose of Key Performance Measures is to provide accurate and reliable data for accurate and reliable decision making. The data must be reviewed, interpreted and acted upon quickly by the local process owners. Remember:

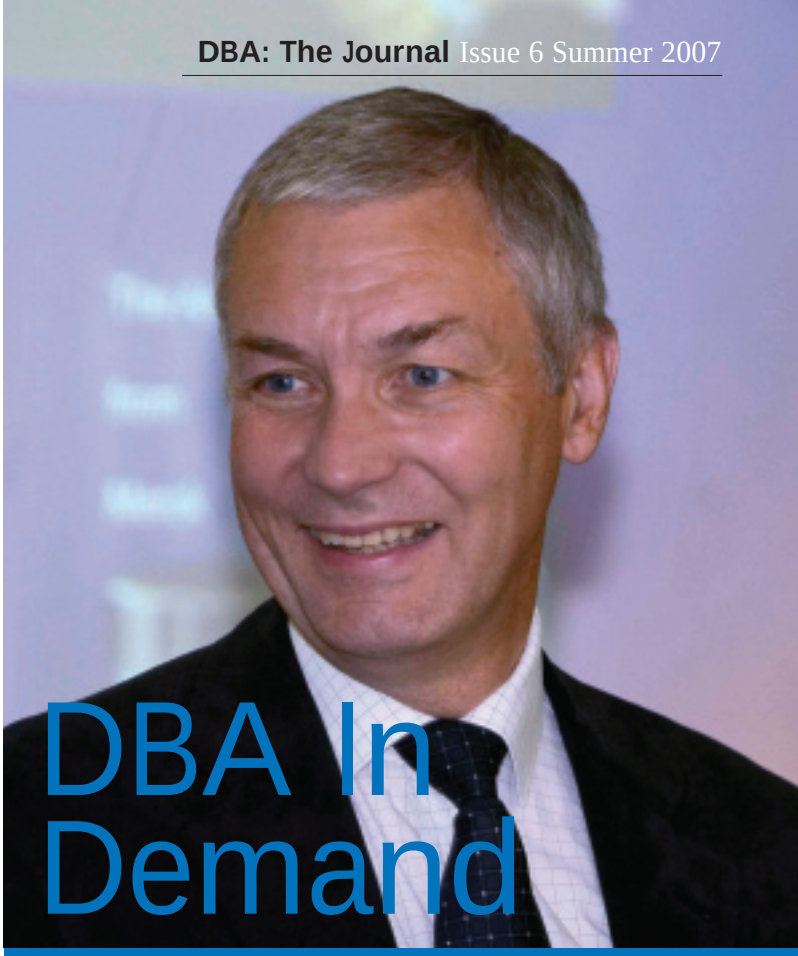
- Keep recording systems simple
- The only way to discuss and interpret key performance measures is face to face
- Meet on a regular basis, at least once every 2 weeks. The shorter the period between data collection and actual interpretation the better. The 'Plant Quality Meeting' is an ideal opportunity to review and act upon the data. This meeting should:
  - Be chaired by the Production Manager
  - Be attended by the 'responsible' QA representative, Plant Engineer and others. Each measure should be discussed:
    - 'Performance' assessed against agreed standards
    - Actions agreed and fully documented
    - A summary of performance fed back to
      - Senior Management
      - Qualified Person
      - Operators
- It is also worthwhile having a system in place to allow for 'escalation of issues'. Remember, senior management do not like surprises.

In Summary:

- You and your company's future will be heavily influenced by the quality of your decision making
- To make good quality decisions you need good quality performance data. You can't manage what you can't measure!
- Measures must be owned by those close to the process
- Select each with care
- Make people responsible
- Think long and hard about presentation and even harder about using the data for continuous improvement

As W. E. Deming once said:

"You don't have to do any of this; survival is not compulsory!"



DBA In Demand

DBA doesn't just host training courses – you may be surprised to learn that we are regularly asked to speak at conferences organised by professional bodies and other groups. Often we have to decline offers because we are already committed to our own clients, but when we can we try and participate in open seminars.

Here are examples of talks we have given in the last year…

June 2006
APIs Europe Conference, Lake Como, Italy
Speaker: David Anderson
Title: The Quality of Drugs in the European Union – What Changes After EC Directive 2004/27?

September 2006
ISPE Conference, Vienna, Austria
Speaker: Pete Gough
Title: Quality Risk Management: Why Now?

November 2006
Joint Professional Bodies QP Symposium, London, UK
Speaker: Pete Gough
Title: Changes to EU Legislation and Guidelines

May 2007
Parenteral Drug Association Conference, Milan, Italy
Speaker: Mike Russell
Title: Risk Assessment and Risk Management of an Aseptic Process: Risk Identification

May 2007
Pharmaceutical Industry Association of Puerto Rico Conference, San Juan, Puerto Rico
Speaker: Bob Pietrowski
Title: EU Pharmaceutical Legislation and The Ever-Increasing Role of the Qualified Person – Implications for Manufacturers in Puerto Rico

Forthcoming Courses

What's planned for the next five months, June to October 2007

Effective Pharmaceutical Audits and Self-Inspections

Marriott Victoria & Albert Hotel, Manchester, UK
4 – 7 June 2007

Learn how to carry out audits with skill and sensitivity, whilst ensuring that you do not overlook important issues. This course will help you to make your audits really value adding.

Course Fee £2065.00 Plus VAT

Active Pharmaceutical Ingredients

Qualified Person & Technical Development Training

Maryborough House Hotel, Cork, Ireland
18 – 22 June 2007

This course will provide you with all you need to know about the application of GMP to the manufacture and control of APIs and bulk biologicals. The course includes visits to a state of the art API manufacturer and one of the largest biotech plants in Europe.

Course Fee £3151.00

Deviation Reporting and CAPA

Clontarf Castle Hotel, Dublin, Ireland
19 – 20 June 2007

This two day course is designed to provide you with the tools and skills to identify, correct and report the root cause of quality problems quickly and efficiently so that you can demonstrate that your CAPA systems work!

Course Fee £1405.00

Key Topics in Sterile Products Manufacture
A Practical Interpretation of Annex 1

NEW course

Marriott Victoria & Albert Hotel, Manchester, UK
25 June 2007

A short course designed to bring you up to date on the latest requirements of Annex 1 of the EU GMP Guide and, more importantly, how to comply in a practical, cost-effective way.

Course Fee £630.00 Plus VAT

Environmental Monitoring

NEW course

Marriott Victoria & Albert Hotel, Manchester, UK
26 – 27 June 2007

This course is designed to help you to understand the methodologies of environmental monitoring, how to use them to design a comprehensive, targeted monitoring programme and how to act upon the results to assure real control.

Course Fee £1195.00 Plus VAT

Process Simulations

NEW course

Marriott Victoria & Albert Hotel, Manchester, UK
28 June 2007

A short course designed to ensure that your process simulations (broth fills) comply with current EU and US requirements. We will also tell you how to deal with problems arising from process simulations.

Course Fee £630.00 Plus VAT

Handling OOS Results

Marriott Manchester Airport Hotel, Manchester, UK
5 July 2007

A clear guide to FDA's final guidance on handling OOS results, including what the regulation covers and how to design practices and procedures which ensure compliances.

Course Fee £630.00 Plus VAT

Role and Professional Duties of the Qualified Person

Qualified Person & Technical Development Training

Marriott Hotel, York, UK
9 – 11 July 2007

This course provides essential guidance not just on the legal duties of the Qualified Person, but also on how the QP should organise themselves, their colleagues and the quality system to ensure that they fulfil their duties with skill and professionalism in the best interests of the patient and their employer.

Course Fee £1710.00 Plus VAT

Pharmaceutical Good Manufacturing Practice

Marriott Victoria & Albert Hotel, Manchester, UK
17 – 20 September 2007

Europe's most popular GMP course! An excellent overview of EU and US GMP regulations and expectations, plus up to the minute guidance on current "hot topics".

Course Fee £2065.00 Plus VAT

Mathematics & Statistics

Qualified Person & Technical Development Training

Hilton Hotel, York, UK
17 – 20 September 2007

Perhaps the only statistics course aimed directly at the pharmaceutical industry! Given the increasing importance of PAT, Quality by Design, trending of in-process data and analysis of data for product reviews, all pharmaceutical professionals need to ensure that their understanding of an ability to use statistical routines is well developed.

Course Fee £2370.00 Plus VAT

Book online at www.david-begg-associates.com

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Sterile Products Manufacture

Marriott Victoria & Albert Hotel, Manchester, UK
24 - 27 September 2007

One of our most popular courses. A comprehensive, four day course on the latest EU and US GMP requirements for sterile products manufacture plus practical advice on how to ensure compliance in a cost-effective and scientifically sound way.

Course Fee £2065.00 Plus VAT

GMP for Clinical Trials Manufacture and Supply

Marriott Victoria & Albert Hotel, Manchester, UK
1 – 4 October 2007

Essential training in current EU and US GMP regulations for the manufacture, testing, importation and distribution of clinical supplies. As last year, we have invited a European regulatory inspector to give a keynote talk on GMP expectations and current regulatory trends.

Course Fee £2065.00 Plus VAT

Good Documentation Practices

Marriott Victoria & Albert Hotel, Manchester, UK
9 – 10 October 2007

This course is essential for anyone wishing to make their documentation system more efficient, cost-effective, user-friendly and compliant with EU and US GMP requirements. The course will be highly participative – you will design key documents and perfect your document writing skills.

Course Fee £1195.00 Plus VAT

Pharmaceutical Law & Administration

Qualified Person & Technical Development Training

Hilton Hotel, York, UK
15 – 19 October 2007

All the prospective Qualified Person or pharmaceutical professional needs to know about EU, UK and US pharmaceutical legislation and regulatory bodies. This course provides the depth of knowledge and understanding you really need to act in a professional capacity in a highly regulated industry.

Course Fee £2960.00 Plus VAT

Good Autoclave Practice

Marriott Victoria & Albert Hotel, Manchester, UK
23 – 25 October 2007

A comprehensive course on the practicalities of autoclave selection, qualification, cycle design and validation, ongoing performance monitoring and management. You will learn current regulatory expectations for steam sterilisation, how to qualify and validate autoclaves effectively, how to troubleshoot problems and best industry practices for monitoring and management of autoclaves.

Course Fee £1580.00 Plus VAT

Chemistry and Pharmacy Registration Requirements

Hilton Hotel, York, UK
29 October – 1 November 2007

Run in conjunction with Regulatory Resources Group, this course is designed to provide you with a clear understanding of technical data requirements for EU and US registration submissions and subsequent manufacture.

Course Fee £2065.00 Plus VAT

Effective Change Control

Marriott Victoria & Albert Hotel, Manchester, UK
30 October – 1 November 2007

The control of planned and unplanned changes is perhaps the greatest challenge facing any pharmaceutical company and its quality management personnel. This highly popular three day course will provide you with practical guidance on how to simplify your change control systems to make them quick and efficient, whilst at the same time ensuring compliance with regulatory expectations.

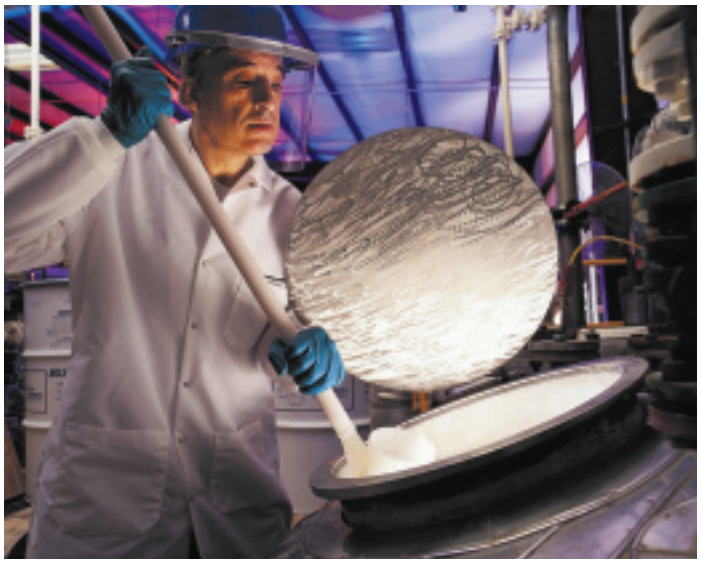
Course Fee £1580.00 Plus VAT

Get in touch now to book your place on any of these courses

Call us on +44 (0) 1751 432999 or email: courses@david-begg-associates.com

Industry News

"Certain Excipients" and GMP – A Solution in Search of a Problem?



As well as the requirement for APIs to be manufactured following GMP, Dir. 2004/27/EC also required "certain excipients" to be made in accordance with GMP. This additional requirement for excipients came as a shock to a pharmaceutical industry that had not been previously consulted on this topic. It would appear to have been added as a last minute, knee-jerk reaction to the problems with contaminated glycerol in Haiti. The problem in Haiti, and subsequently in China, was caused by criminal adulteration of glycerol for financial gain, which no amount of GMP could ever address, so this addition to the Directive was, and remains, wholly unnecessary.

The adoption of this requirement left the industry, and the poor EMEA who have the responsibility for trying to implement it, with numerous problems:

- Firstly, the EU has no adopted GMP for excipients. Whilst the UK Pharmaceutical Quality Group (PQG) and the International Pharmaceutical Excipients Council (IPEC) launched their new joint GMP guide for excipients in early 2006 this is not formally adopted in the EU. In their naiveté the Commission originally thought that ICH Q7A could simply be used for excipients!
- Secondly, many (perhaps most) excipients are not made specifically for the pharmaceutical industry. Many are produced for, and are used in huge quantities by, the food industry. So attempts to impose pharmaceutical GMP are likely to be met with the response that the excipient manufacturer is not going to follow requirements of an industry who only buy a small fraction of their output. Potentially the pharmaceutical industry could lose key elements of its supplier base.

The following is an actual quote from a manufacturer of sucrose during a supplier audit…

"Young man, we sweep up more as waste off the floor in a morning than you buy from us in a year! Do you really expect us to change the way we work to suit you?"

- Thirdly, what message is sent out about the excipients not on the list? Do they not matter?

The above list illustrates some of the absurdities that surround this requirement for certain excipients to be made following GMP. The EU GMP Guide already had sufficient requirements for the necessary controls for excipients specified in Chapter 5 and Annex 8.

In early 2005 EFPIA, IPEC, PDA, AESGP and the UK PQG produced a joint Position Paper recommending that no excipients be listed but this could not be accepted by the Commission lawyers as Directive 2004/27/EC requires a list (as a subsidiary Directive) to be published.

In March 2007 the commission published a draft (which is actually dated 21 December 2006) entitled "Specific Conditions of the Application of the Principles and Guidelines of GMP for Certain Excipients" as a possible basis for a future GMP Directive. This draft lists six categories of excipient that they are considering applying the requirement for GMP to:

1. Excipients prepared from materials derived from a TSE-relevant species (excluding lactose)
2. Excipients derived from human/animal material with potential for viral contamination risk
3. Excipients claimed to be sterile (sold as sterile) and used without further sterilisation

4. Excipients which, due to their nature, origin or manufacturing process are at significant risk of endotoxin/pyrogen contamination and which are used in products which are required to be endotoxin/pyrogen controlled, such as in parenteral products
5. Propylene glycol
6. Glycerol

This draft document then proceeds to give the possible content for the promised Directive on GMP for excipients. This has the following headings:

- Definitions
- Quality management system
- Personnel
- Buildings, facilities, equipment
- Documentation and records
- Materials management
- Production and in-process controls
- Packaging and identification labelling of excipients
- Storage and distribution
- Quality control
- Complaints and excipient retrieval
- Contract manufacturers
- Obligations of the holder of the Manufacturing/Import Authorisation of the medicinal product

The European Commission issued questionnaires to pharmaceutical and excipient manufacturers regarding the application of GMP to excipients in late 2004 and has now issued further questionnaires in early 2007.

Industry has continued to argue that the problems seen with excipients such as glycerol contaminated with ethylene glycol in Haiti were due to criminal activity that the application of GMP would not address and that the existing GMP for finished product already has sufficient control requirements. However, the politicians at the Commission appear to be ploughing on regardless of the fact that this totally unnecessary piece of legislation is likely to further damage the position of the European pharmaceutical industry at a time when it is facing unprecedented competition from places such as India and China.

The latest developments of GMP for APIs and excipients will be covered during our training course “Active Pharmaceutical Ingredients” to be held in Cork from 18-22 June 2007

EU GMP Certificates

The European Medicines Agency, EMEA, has just published a document (EMEA/INS/GMP/871/04) which describes the issue and update of GMP Certificates. Directive 2001/83/EC amended by Dir. 2004/27/EC requires that within 90 days of an inspection a certificate of GMP shall be issued to a manufacturer if the outcome of the inspection shows that the manufacturer complies with GMP. The GMP certificates issued, or information indicating that a manufacturer does not comply, will be entered into the new EudraGMP database.

GMP certificates are used by Member State competent authorities to confirm to a manufacturer that they are complying with GMP. Obviously, the withholding of a certificate sends the opposite message! They can then be used by the manufacturer to communicate their compliance to customers and to support regulatory submissions outside of the European Economic Area (EEA).

EudraGMP is a new database which will contain information on all manufacturing and importation authorisations issued by EEA competent authorities. It will also contain the information on GMP certificates, or the information that a manufacturer does not comply, which Member States will issue following each GMP inspection in the EEA and third countries. EEA competent authorities will have full read/write access to the EudraGMP database and access to the general public will be available for manufacturing and importation authorisations and certain GMP certificates, with the exception of any information of commercially and/or personally confidential nature.

The recently issued EMEA document is intended to give guidance on responsibilities for the issue, renewal and update of GMP certificates. The issue of GMP certificates following an inspection of a manufacturer of IMPs is not defined, however Member States may choose to do so,

This new system should come into operation on 30 September 2007.

Importation from a third country
– are you really complying with Annex 16?

Annex 16 clearly states that prior to certification and release, the certifying Qualified Person must ensure that each stage of manufacture has been conducted in accordance with the relevant marketing authorisation, Good Manufacturing Practice and the laws of the Member State concerned.

The Annex goes on to state that in an industrial situation it is usually not possible for a single QP to be closely involved with every stage of manufacture. Thus, the QP may need to rely in part on the advice and decisions of others.

However, before doing so, the Annex requires the certifying QP to ensure that this reliance is well founded, either from "personal knowledge" or from "the confirmation of other QPs within a quality system which he has accepted".

In the case of products imported from a third country (outside the EU or EEA), the QP clearly cannot rely on other QPs at the site(s) of manufacture and where there is no mutual recognition agreement in place to confirm equivalence of GMP standards, it would seem clear that the certifying QP has no alternative but to build up "personal knowledge" of the manufacturing site(s) and their quality systems – unless of course they have been assessed by another QP in whom the certifying QP has confidence.

Sadly, it is our experience that many certifying QPs do not have the necessary personal knowledge of the site(s) where imported products have been manufactured; preferring to rely on the organisation's corporate auditing system. However, all too often, these corporate audits are not carried out by QPs and do not always put the necessary emphasis on compliance with EU GMP and regulations.

Several times a year, we are called into companies outside the European Union to help respond to EU inspections which have gone badly. In almost every case the company had been audited by the corporate function, which failed to recognise serious non-compliances with EU GMP – usually because of an over-emphasis on local and/or FDA regulations and a lack of familiarity with EU requirements. Invariably we ask "Has the QP at the European releasing site audited your operations?" and the answer is "No".

When the certifying QP does not have the required "personal knowledge" or the ability to rely on other QPs in the system, the organisation is at risk of regulatory censure and so is the QP!

Congratulations to:

in the past four months, DBA has helped the following people obtain QP status:

Vicky Baulch, Novartis Consumer Health, UK; **Jane Colman**, Vericore Ltd, UK; **Mark Dignum**, SSL International plc, UK; **Angela Hoskins**, Health Protection Agency, UK; **Jenni Newcombe**, Actavis UK Ltd; **Bruce Vernon**, Intercell Biomedical Ltd, UK.

Location, Location, Location...

The York Hilton

We at DBA consider ourselves to be very fortunate to live in God's Own County – Yorkshire – and there can be no argument that York is the jewel in Yorkshire's crown!

Founded two thousand years ago by the Romans, and later settled by the Vikings when they "visited" these shores, York has a rich and varied history which residents over the centuries have been at pains to retain. Today, York is one of the finest old cities in Europe, with many medieval buildings and a cathedral to rival Chartres – it has the largest collection of stained glass of any cathedral north of the Alps!

We love living near York and, until fairly recently, almost all our training courses were held there. Then, you told us that you would prefer to attend courses nearer to international airports and we moved our courses to cities such as Manchester, Dublin and Amsterdam.

But our love affair with York remains and we still hold the majority of our Qualified Person & Professional Development training courses in this beautiful old city, along with one or two other selected courses.

The York Hilton Hotel provides an unsurpassed venue in the heart of the city. Just across the street is the magnificent Clifford's Tower – a Norman Castle dating back to the twelfth century and a two minute walk takes you to the main shopping district and the superb cathedral, which we call York Minster.

It is the only 4-star hotel within the ancient city walls and boasts 130 quality bedrooms with high speed internet access (if you can't wait to keep up with events back at work) and a Sony Play Station (if you can!). There is also secure parking for those arriving by car. For our delegates arriving by other means, the nearby railway station has a direct link to

Manchester Airport, London (which takes about the same time!), Edinburgh and most other major cities in the UK.

The Hilton has two very good restaurants which provide superb fayre at breakfast and lunch, though most of our delegates prefer to take a stroll into town each evening to dine in one of York's many excellent bistros and restaurants.

The conference facilities at the hotel are superb and the staff are among the friendliest we deal with. They will ensure that you have a memorable stay. Our Qualified Person trainees really love the hotel – and they are very difficult to please!

So why not come and join us at the York Hilton – and do bring your camera!

We shall be holding the following courses at the York Hilton during 2007…

Mathematics & Statistics
17 – 20 September 2007

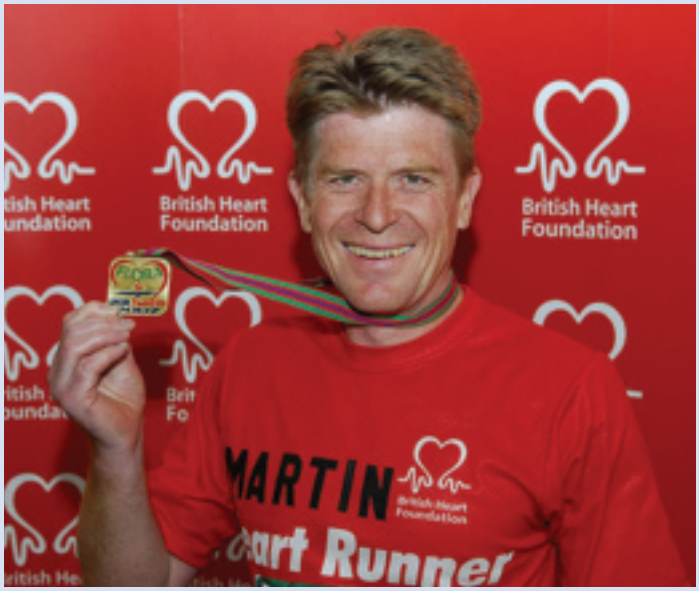
Pharmaceutical Law & Administration
15 – 19 October 2007

Chemistry and Pharmacy Registration Requirements
29 October – 1 November 2007

DBA People

Marathon Man!

In each Journal we spotlight a member of the DBA team so that you can get to know us better. In this issue it's Martin Lush.



On Sunday April 22, Martin Lush set out with around 38,000 other athletes to run the London Marathon.

It was Martin's misfortune to choose to take part in the hottest London Marathon in living memory, with temperatures rising well above 20°C!

Many lesser runners (such as Haile Gebreselassie!) couldn't stand the heat and failed to finish, but not our Martin – despite the unseasonable temperature and the pain which resulted from setting out at a very optimistic pace, he finished in a very creditable 4 hours 15 minutes and 18 seconds.

The race, which is one of the world's top sporting events, has an international reputation for the quality of the course, the London "landmarks" passed en route and, most importantly, the excellent support from the people of London. Martin was completely overwhelmed by the encouragement he received from spectators and this definitely helped to see him through the final 8 miles!

Whilst the elite athletes at the front of the field were running for personal gain, the majority of the participants were competing to raise money for those less fortunate than themselves, and Martin was no exception. His exertion, aches, pains (and two black toenails) were in aid of the British Heart Foundation, for whom he expects to raise around £2,500. Overall, the event will raise £42 million for charity.

Martin would like to thank each one of his sponsors for their very kind donations.

Finally, Martin gives the following advice to any would-be London Marathon runners…

DO	prepare – you can't run a marathon on two weeks of training.
DON'T	set off too quickly – you will pay for it later!
DO	remember the actual race starts at 20 miles – the first 20 miles are purely physical, the last six totally psychological.
DO	take every opportunity to drink and rehydrate during the race.
DO	print your name on your T-shirt – it's really good to hear the crowd cheering you on by name.
DO	enjoy the day – it's a wonderful experience.

If you would like to make a donation to Martin's chosen charity – the British Heart Foundation – visit www.bhf.org.uk

In the next DBA Journal.

Industry News: as ever, we search for regulatory changes so you don't have to, Tech Talk: why are some regulatory agencies so obsessed with air removal in autoclaves? Location, Location, Location:…the Manchester Airport Marriott Hotel DBA People: an obsession with wildlife, Forthcoming Courses: a review of our training courses for the rest of 2007.

If you have any comments or suggestions for the next issue of the Journal, please email us at journal@david-begg-associates.com

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