DBA

The Journal of David Begg Associates

Issue 15 Spring 2010

Simple ways to improve your CAPA systems

The new EU Variations Process

Implementation of revised Directive 2007/47/EC

– what it means for you!

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welcome

Bob Pietrowski, Managing Partner David Begg Associates

A very warm welcome to this latest edition of the Journal. As usual, we provide you with the very latest information regarding regulatory changes in our industry – we hope you find these regular updates useful. We also try to find articles on latest trends in quality management to give you food for thought as you consider practices in your own organisation. Again, we hope you find these interesting.

Managing Quality the Toyota Way

Many of you must have been amused to see that in the last Journal we included an article on best practices for quality management from Toyota – just as the company embarked upon a worldwide recall which has severely damaged their reputation for quality and reliability. We have to admit to very bad timing! However, we believe that the general approach to quality management and increasing ownership of quality by staff is the right approach to take and we stand by our article. What destroyed Toyota's reputation was a failure to listen and respond to the legitimate concerns of the people who matter most – the customers – and there is a lesson there for us all.

DBA People

In this issue we say goodbye to an old friend and welcome three new team members. Together, we are committed to providing you with a top quality service worldwide.

DBA USA

We are delighted to report that our US office is performing way ahead of expectations this year – with revenues more than double those of the equivalent period last year. We are clearly doing something right and providing a service which clients recognise as both top quality and unique in the marketplace!

QP Training

October sees the beginning of our eleventh series of Qualified Person training in the UK and Europe. To celebrate we are making a number of improvements to the series of modules, including the chance to gain a Postgraduate Certificate award by attending six or more classes.

Haiti Earthquake Appeal

Thanks to you, we have been able to donate over £4,000 to the Haiti Earthquake Appeal. We are truly grateful for your support.

We are dedicated to providing the very best consulting, auditing and education services to the healthcare industry and we have big plans for the future. We hope you like what we are doing.

Bob Pietrowski
Managing Partner

DBA International Healthcare, Consulting & Education Experts

Tech talk

Deviation and CAPA Systems

Dispelling some myths that will transform your system!

If you think you've already read one article too many on this subject, *please* don't turn the page until you've considered how you feel about the following:

- When investigating deviations please make sure you *don't* focus on finding '*root cause*'… it simply doesn't exist. The concept of a single root cause is a myth
- Never treat every incident the same. To do so is actually dangerous!
- If your policy allows 30 days to 'close out' investigations hang your head in shame…you clearly don't take deviations seriously
- Do your metrics actually *encourage* people to report incidents? If so, great…you clearly *do* understand their importance!
- If you routinely complete investigations from behind a desk one thing is guaranteed…your diagnosis of the problem and prescription for those CAPAs are probably wrong
- One last question for those of you involved in deviation investigations…do you *really* have expert, almost intimate, knowledge of your products and processes? If you don't, investigating 'quality incidents' is a risky business – a bit like a surgeon wielding a scalpel without an expert understanding of human anatomy

'How to Simplify and Improve Your Deviation and CAPA System' is one of DBA's most popular 'in house' courses. Why? Well, our clients tell us they actually get what it says on the tin. Not only do we provide simple tools and techniques that dramatically improve efficiency, we also dispel a few myths. Here is just a sample:

Myth 1: Every deviation has a 'root cause'

Fact: There is no such thing as root cause. Most incidents are due to multiple 'contributing factors'

One of the biggest failings in most deviation investigations is the tendency to look just for one 'root cause'. A single event that led to the deviation; 'human error' or 'procedural non-compliance' are two of the most common. This is very rarely the case; there is seldom only one single root cause or single event but rather a number of *contributing factors* that must queue up in a particular pattern before the incident happens. To prevent the incident happening again you need to remove as many of the contributing factors as possible, not just one 'root cause'.

Contributing factors may include:

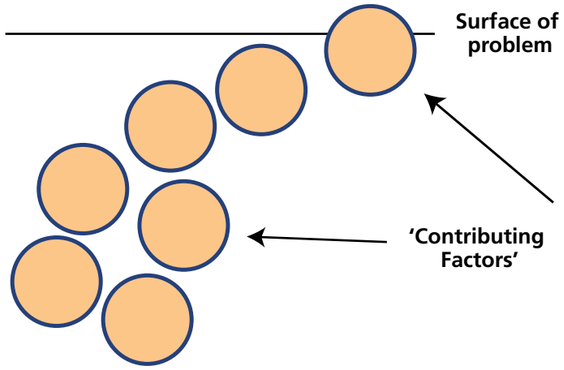
- Physical (poor plant layout, working conditions, multiple distractions)
- Procedures that are too long, poorly designed, complex, written for the regulator not the user and therefore totally unworkable
- People who are poorly trained, managed, demotivated and disengaged
- Processes that are poorly designed and unreliable

Hints – so remember:

- Think about multiple contributing factors, NOT one single root cause. Deviations are never that simple!
- Start digging and don't stop at the first and most obvious contributing factor. The devil really is in the detail

Tech talk

- First list the contributing factors supported by data or scientifically sound assumptions
- Is there an obvious sequence of events?
- Focus your attention on those contributing factors which have the biggest impact, NOT on those easiest to solve
- Remove the term 'root cause' from your vocabulary and your procedures!



Myth 2: 'One size fits all'. Your system should treat every deviation the same way

Fact: Don't! Deviations must be investigated proportionate to risk

Treat every incident the same and you're likely to suffer from deviation 'blindness', the symptoms of which are familiar to many:

- Deviation 'overload'
- Lots of repeat incidents
- *Really* important incidents going unnoticed
- Human error often seen as the most probable and convenient 'root cause'
- Periodic, corporate-led initiatives such as a 'war on deviations' to close out reports and balance the books. At least for the short term

Failure to 'risk prioritise' incidents is not only inefficient but dangerous. Although you must rally your troops to focus on the 'major' deviations, those that pose greatest risk, you can't afford to ignore those of lesser importance, the 'quality incidents'. They also have to be addressed but in a way that is proportionate to risk.

Hint:

Every incident must be 'triaged' based on risk, and the sooner the better. On our course we demonstrate how this can be done quickly and efficiently using very simple, easy to use, customised 'impact assessments'. Designed with care, these ensure the right questions are asked and data gathered before decisions are made. Our clients tell us this approach has dramatically improved the accuracy and speed of their decision making, vital in the triaging process. The result? Faster, more thorough investigations and less repeat incidents.

Myth 3: 'Close out within 30 days'

Fact: Allowing 30 days is *at least* 25 days too long!!

Just imagine you're jetting off to your holiday destination, 'ash cloud' permitting. The cabin crew complete their usual welcome and mention a few 'technical problems' to boot. They reassure you that fixes have been identified (CAPAs in pharma speak) and that these will be 'closed out' in 30 days. I think most of us would be running for the emergency exit! In other industries, where deviations and failures can impact on customer safety as well as cost, the number one imperative is to get them sorted, and quickly. The fact that many pharma companies allow the luxury of 30 days is, quite frankly, staggering. A 30 day limit says to people "don't worry, this isn't *that* important…take your time". And they do. In practice we want the complete opposite. Incidents must be investigated sooner rather than later to minimise risk, prevent recurrence and improve the process. All are achievable providing the investigation is done quickly.

Hints:

- Make sure every 'quality incident' is reported immediately and triaged within hours using customised impact assessment forms
- Lower risk 'quality incidents' need to be closed out within hours, 1-2 days maximum, whilst those intimately involved with the incident are around, available and interested. Leave it any longer and both memory and interest fade, resulting in a superficial investigation generating CAPAs that fall way short of the mark
- Deviations that require a more extensive investigation should be closed out within 3-4 days for the very same reasons. These will clearly take longer since they are broader in scope and potentially present greater risk to your patients and business. Longer yes, but not *too* long. Remember, the longer the close out period the greater the risk to your business. Memories fade, interest is lost and risk increases. Sometimes dramatically

Myth 4: Metrics that encourage people to reduce deviation numbers are good!

Fact: They are NOT!! Such measures potentially encourage the wrong behaviour

We all know that we need accurate 'performance measures' to make the right decisions. What most people don't know is that *before* selecting any performance measure you must first decide on what behaviour you wish to encourage…then select the most appropriate measure. When encouraged to 'reduce deviation incidents' people usually oblige and incidents *appear* to decrease in number. Often overnight. Such a measure may encourage under-reporting of incidents, particularly if a blame culture is alive and kicking.

Hints:

- If you want a good 'performance measure' for deviation systems, one that drives the right behaviour, consider one or more of the following:
  - Number of repeat incidents (these should be few and far between)
  - Time taken to raise, report and investigate (the quicker the better)
  - The ratio of 'quality incidents' to 'deviations'. Fix the incidents and the number of deviations will fall…hence the ratio change
- Change your attitude! Deviations are *good* news, not bad, *providing* you learn from the experience
- If you really want performance measures that drive business improvement, why not consider coming to our course 'KPIs and Performance Measures for Quality Systems'?

Myth 5: Deviations can be solved from behind a desk

Fact: They can't! Never, ever

If you want to fix incidents for good you must go to where the action took place and the sooner the better. Although 'desk based' investigations are quick and convenient, the resulting CAPAs are usually based on assumption with a bit of good old fashioned guessing thrown in. The incident ultimately happens again and you end up paying dearly for this false economy.

In Kaizan language the Japanese have a term for this called 'Genchi Genbutsu' ('Go to where the action is'). In North Yorkshire, where people are refreshingly blunt, we call it 'GOYA'…..Get Off Your A*se.

In Summary

Deviation and CAPA systems exist for two very simple reasons. When 'stuff happens' we rely on the system and the people operating it to assess risk and protect our patients. These unplanned incidents also provide a fantastic opportunity to not only prevent recurrence but to actually learn from the experience and improve business processes. Unfortunately, this is often not the case…some myths seem to have confused our thinking and compromised our ability to manage deviations intelligently.

If you would like help in dispelling a few more myths and dramatically improve the effectiveness of your deviation system, why not give us a call? We can help you to…

- Prevent incidents happening again
- Design impact assessments to triage incidents quickly
- Report and risk prioritise incidents in hours so you focus resources where they are needed
- Identify CAPAs that hit the mark
- Close out reports quickly
- Track and trend open CAPAs to ensure prompt closure of reports
- Make sure your deviation system drives continuous improvement

If you would like us to come to your company to help you improve your deviation and CAPA programme, either by focussed consultancy or through training of your key staff, please call us.

Our residential training course on KPIs and Performance Measures for Quality Systems will be held in Manchester on 21 and 22 September 2010. Please see our website for details.

Forthcoming Courses

What's planned for May – September 2010

DBA International Healthcare, Consulting & Education Experts

Medical Device CE Marking – The Latest Requirements

NEW COURSE

Manchester Marriott Victoria & Albert Hotel, Manchester, UK

17-19 May 2010

This course will provide you with all you need to know to be able to understand, interpret and apply the latest EU directives and requirements for medical device CE marking.

Course Fee: **£1000.00 plus VAT (First Booking)**
£900.00 plus VAT (Additional Bookings)

Pharmaceutical GMP

Manchester Marriott Victoria & Albert Hotel, Manchester, UK

17-20 May 2010

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

Course Fee: **£2275.00 plus VAT** (First Booking)
£1820.00 plus VAT (Additional Bookings)

Human Error: Causes and Prevention

Crowne Plaza Hotel, Philadelphia Center City, PA

18-20 May 2010

Human error is a commonly quoted cause of problems and deviations in our industry, but it is often not the real reason – just a convenient excuse – and so corrective actions such as "retraining" are doomed to failure. You know that and so do the regulators! This unique course will help you to see beyond "human error" as the root cause of problems. We will show you why people make mistakes and provide you with practical ways to reduce errors in the workplace.

Course Fee: **$2675.00**
$2140.00 (Early Bird and Additional Bookings)

Post Market Surveillance and Vigilance Requirements for Medical Devices

NEW COURSE

Manchester Marriott Victoria & Albert Hotel, Manchester, UK

20-21 May 2010

Learn the very latest requirements for post market surveillance and vigilance, including recently introduced changes and associated guidelines.

Course Fee: **£800.00 plus VAT** (First Booking)
£720.00 plus VAT (Additional Bookings)

Effective Pharmaceutical Audits and Self-Inspections

Manchester Marriott Victoria & Albert Hotel, Manchester, UK

24-27 May 2010

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. Plus, you have the opportunity to become a DBA certified auditor.

Course Fee: **£2275.00 plus VAT** (First Booking)
£1820.00 plus VAT (Additional Bookings)

Pharmaceutical Microbiology

QL

Quality Leadership Program

Royal Sonesta Hotel, Boston, USA

2-4 June 2010

A comprehensive course which provides all you need to know about microorganisms, the threat they can pose to product quality and patient safety, how to implement an effective microbiological control strategy and how to assess microbiological risk.

Course Fee: **$2700.00**
$2160.00 (Early Bird and Additional Bookings)

Cleaning Validation

Manchester Marriott Victoria & Albert Hotel, Manchester, UK

7-8 June 2010

This ever-popular course will provide you with what you need to know to be able to design, execute and audit cleaning validation studies to current EU and US standards. There will be industry case studies on validation experiences for APIs, biotech products and solid dosage forms.

Course Fee: **£1320.00 plus VAT** (First Booking)
£1056.00 plus VAT (Additional Bookings)

Human Error: Causes and Prevention

Manchester Marriott Victoria & Albert Hotel, Manchester, UK

14-16 June 2010

Human error is a commonly quoted cause of problems and deviations in our industry, but it is often not the real reason – just a convenient excuse – and so corrective actions such as "retraining" are doomed to failure. You know that and so do the regulators! This unique course will help you to see beyond "human error" as the root cause of problems. We will show you why people make mistakes and provide you with practical ways to reduce errors in the workplace.

Course Fee: **£1740.00 plus VAT (First Booking)**
£1392.00 plus VAT (Additional Bookings)

Contamination Control for Non-Sterile Production

Manchester Marriott Victoria & Albert Hotel, Manchester, UK

15-17 June 2010

This course will provide practical advice on how to design, maintain, operate, clean and monitor manufacturing facilities, equipment and utilities to minimise the potential for physical, chemical and microbiological contamination of non-sterile dosage forms by practical application of a risk-based approach. We will help you to add quality, not just add cost!

Course Fee: **£1740.00 plus VAT** (First Booking)
£1392.00 plus VAT (Additional Bookings)

Investigational Medicinal Products

QP

Qualified Person & Professional Development Training

York Marriott Hotel, York, UK

21-22 June 2010

Designed to provide the prospective Qualified Person or pharmaceutical professional with an up to the minute understanding of EU regulations for the conduct of clinical trials, the GMP expectations for the manufacture and control of clinical supplies and the role of the QP.

Course Fee: **£1242.00 plus VAT** (First Booking)
£993.60 plus VAT (Additional Bookings)

Design, Development and Performance Evaluation of Medical Devices

NEW COURSE

Manchester Marriott Victoria & Albert Hotel, Manchester, UK

21-22 June 2010

This course will provide you with the necessary tools and techniques to design and develop devices and provide good design assurance in compliance with ISO 13485:2003 and FDA 21 CFR Part 820.

Course Fee: **£800.00 plus VAT** (First Booking)
£720.00 plus VAT (Additional Bookings)

Supply Chain Assurance

Manchester Marriott Victoria & Albert Hotel, Manchester, UK

22-24 June 2010

The hottest topic in pharmaceutical quality management right now! Come and learn about the international initiatives to assure the integrity of the supply chain and how these initiatives will impact on Quality Leaders, Qualified Persons, Auditors, Quality Control staff, Purchasing staff and all others connected with the supply of medicines to the patient.

Course Fee: **£1740.00 plus VAT** (First Booking)
£1392.00 plus VAT (Additional Bookings)

The Role and Professional Duties of the Qualified Person

QP

Qualified Person & Professional Development Training

York Marriott Hotel, York, UK

23-25 June 2010

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

Course Fee: **£1863.00 plus VAT** (First Booking)
£1490.00 plus VAT (Additional Bookings)

Risk Management for Medical Devices Implementing ISO 14971:2007

NEW COURSE

Manchester Marriott Victoria & Albert Hotel, Manchester, UK

23-25 June 2010

This course will provide you with all you need to know to enable you to adopt and implement risk management procedures to cover design, validation, manufacture, use, service and disposal of medical devices in compliance with ISO 14971:2007.

Course Fee: **£1000.00 plus VAT** (First Booking)
£900.00 plus VAT (Additional Bookings)

Engineering Aspects of GMP

Manchester Marriott Victoria & Albert Hotel, Manchester, UK

28 June - 1 July 2010

This highly popular course is designed to provide engineering staff with the knowledge to apply GMP principles to their work and to provide QA staff with an understanding of the special challenges faced by engineering staff.

Course Fee: **£2275.00 plus VAT** (First Booking)
£1820.00 plus VAT (Additional Bookings)

Book online at www.DBA-global.com

Course details and prices are correct at the time of printing and are published in good faith. DBA reserves the right to make any change which may become necessary.

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

Call us on: +44 (0) 1751 432 999 or email: courses@DBA-global.com

Forthcoming Courses

What's planned for May – September 2010

DBA International Healthcare, Consulting & Education Experts

Medical Devices Lead Auditor Training

NEW COURSE

Manchester Marriott Victoria & Albert Hotel, Manchester, UK

5-9 July 2010

Essential expert training to become a medical devices lead auditor from two of the best lead auditors available!

Course Fee: **£1250.00 plus VAT** (First Booking)
£1125.00 plus VAT (Additional Bookings)

Electronic Documentation and Annex 11

London Marriott Hotel Kensington, London, UK

6 July 2010

EU regulators have totally re-written their guidance on GMP requirements for computerised systems (Annex 11). Come and learn how the new Annex impacts on key areas such as electronic records and records retention.

Course Fee: **£695.00 plus VAT** (First Booking)
£556.00 plus VAT (Additional Bookings)

How to Simplify and Improve Your Computer System Validation

London Marriott Hotel Kensington, London, UK

7-8 July 2010

Computer validation doesn't have to take an age and consume vast amounts of resource! We will show you how to keep it simple and quick, whilst at the same time meeting EU and US requirements. **This course will save you money!**

Course Fee: **£1320.00 plus VAT** (First Booking)
£1056.00 plus VAT (Additional Bookings)

Active Pharmaceutical Ingredients and Supplier Assurance

QL

Quality Leadership Program

Royal Sonesta Hotel, Boston, USA

3-5 August 2010

This module will teach you what you need to know about APIs (including biopharmaceutical APIs), their manufacture, critical process steps and quality challenges. Additionally we will provide you with practical advice on how to assess and assure the quality and integrity of your suppliers and supply chain.

Course Fee: **$2700.00**
$2160.00 (Early Bird and Additional Bookings)

Human Error: Causes and Prevention

San Mateo Marriott, CA, USA

10-12 August 2010

Human error is a commonly quoted cause of problems and deviations in our industry, but it is often not the real reason – just a convenient excuse – and so corrective actions such as "retraining" are doomed to failure. You know that and so do the regulators! This unique course will help you to see beyond "human error" as the root cause of problems. We will show you why people make mistakes and provide you with practical ways to reduce errors in the workplace.

Course Fee: **$2675.00**
$2140.00 Early Bird and Additional Bookings)

Pharmaceutical Law

QL

Quality Leadership Program

San Mateo Marriott, CA, USA

16-18 August 2010

By popular demand, a repeat of our first Quality Leadership Program module covering all aspects of US, EU and international pharmaceutical legislation and its impact on Quality Leaders and Pharmaceutical Professionals. Not to be missed!

Course Fee: **$2700.00**
$2160.00 (Early Bird and Additional Bookings)

Free Seminar for Prospective QPs and Sponsors

FREE SEMINAR

London Marriott Hotel Kensington, London, UK

24 August 2010

Interested in becoming a Qualified Person? Planning to act as a Sponsor? Why not attend this free seminar to learn more about the roles and what we can offer?

Process Validation for Medical Devices

NEW COURSE

Manchester Marriott Victoria & Albert Hotel, Manchester, UK

7-9 September 2010

All you need to know to design, execute, review and document process validation studies in compliance with international regulations for medical devices.

Course Fee: **£1000.00 plus VAT** (First Booking)
£900.00 plus VAT (Additional Bookings)

Analysing and Trending Data to Drive Quality Improvement

NEW COURSE

Manchester Marriott Victoria & Albert Hotel, Manchester, UK

14-15 September 2010

How statistical analysis can help you to understand your processes better and exert better control to save money and improve quality! "Numb3rs" for the pharmaceutical industry – with our own mathematical genius, Professor George Gettinby.

Course Fee: **£1320.00 plus VAT** (First Booking)
£1056.00 plus VAT (Additional Bookings)

KPIs and Performance Measures for Quality Systems

achieve

Manchester Marriott Victoria & Albert Hotel, Manchester, UK

21-22 September 2010

This course will help you to set effective KPIs and performance measures for your Quality Management System and will teach you how to review them, interpret them and act upon them to maintain a world class quality system with maximum assurance of product quality and safety.

Course Fee: **£1320.00 plus VAT** (First Booking)
£1056.00 plus VAT (Additional Bookings)

Practical Application of Quality Risk Management

Manchester Marriott Victoria & Albert Hotel, Manchester, UK

21-23 September 2010

A real "hot topic" with the regulators! They expect you to adopt risk-based quality systems based on ICH Q9 (now Annex 20 of the EU GMP Guide). Come and learn current best industry practice from someone who wrote the document.

Course Fee: **£1740.00 plus VAT** (First Booking)
£1392.00 plus VAT (Additional Bookings)

How to Simplify and Improve Your Batch Record Review Process

achieve

Manchester Marriott Victoria & Albert Hotel, Manchester, UK

23-24 September 2010

This focused two day course will show you how to make your batch record review process effective and value-adding, not just time-consuming. We will show you how to organise the batch disposition/ product release process for maximum effectiveness and security.

Course Fee: **£1320.00 plus VAT** (First Booking)
£1056.00 plus VAT (Additional Bookings)

Sterile Products Manufacture

Manchester Marriott Victoria & Albert Hotel, Manchester, UK

27-30 September 2010

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: **£2275.00 plus VAT** (First Booking)
£1820.00 plus VAT (Additional Bookings)

Practical Aspects of Controlled Temperature Storage and Distribution

London Marriott Hotel Kensington, London, UK

27-29 September 2010

An intensive three day course designed to help you comply with EU and US requirements for the design, qualification, validation and ongoing control of all systems associated with controlled temperature storage and shipment of pharmaceuticals and biopharmaceuticals.

Course Fee: **£1740.00 plus VAT** (First Booking)
£1392.00 plus VAT (Additional Bookings)

Anti-Counterfeiting Measures: Implications for Quality Professionals and QPs

London Marriott Hotel Kensington, London, UK

30 September 2010

Counterfeit medicines represent perhaps the biggest current threat to patient safety and company reputations. That is why the regulators are so active in enacting legislation on the topic and companies are putting in place sophisticated anti-counterfeiting measures. Come and learn what all this means in practice for Quality Professionals and QPs!

Course Fee: **£695.00 plus VAT** (First Booking)
£556.00 plus VAT (Additional Bookings)

Book online at www.DBA-global.com

Course details and prices are correct at the time of printing and are published in good faith. DBA reserves the right to make any change which may become necessary.

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

Call us on: +44 (0) 1751 432 999 or email: courses@DBA-global.com

Industry News

EU

New Variations Process

The Commission approved the new Variations (comitology) Regulation 1234/2008 on 24 November 2008. This new Regulation, binding in its entirety and directly applicable in all Member States, applied from 1 January 2010 onwards for all products registered through centralised or MRP/DCP procedures.

In late December 2009 the Commission published two guidance documents:

- Variations Procedural guidance on the handling of the different classes
- Variations Classification guidance

Directive 2009/53/EC amending Directives 2001/82/EC and 2001/83/EC, as regards variations to the terms of marketing authorisations for medicinal products, was published in the Official Journal on 30 June 2009. This implements the changes to the co-decision part of the Variations process. Member States have until 20 January 2011 to "bring into force the laws, regulations and administrative provisions necessary to comply with this Directive".

This Directive requires that Regulation 1234/2008 on the Variations procedure shall apply where a medicinal product that is subject to national provisions but is subsequently granted a marketing authorisation in another Member State. This represents a significant change to the legal basis of the Variations Regulations, so that virtually all authorised medicinal products, including those authorised at a purely national level, are subject to the same criteria for the evaluation, approval and administrative handling of changes, regardless of the procedure under which those medicines were initially authorised.

A Member State may only continue to apply national provisions on variations to marketing authorisations granted before 1 January 1998 to medicinal products authorised only in that Member State. If a Member State chooses to continue to apply national provisions to qualifying products they must inform the Commission of their decision to do so before 20 January 2011.

A majority of Member States implemented the change so that all national variations used the process defined in Regulation 1234/2008 as soon as it became effective on 1 January 2010. The Member States who did **not** implement this change on 1 January 2010 were Austria, Czech Republic, Germany, France, Lithuania, Malta, Poland, Portugal and Romania. This means that there will be a period from 1 January 2010 until 20 January 2011, at least, where individual Member States may, or may not, be applying the Regulation 1234/2008 process to their national variations, which is likely to be a recipe for some confusion.

In January 2010 the Coordination Group for Mutual Recognition and Decentralised Procedures issued a question and answer list for the submission of variations according to Commission Regulation (EC) 1234/2008.

Process Validation

In February 2010 the EMA released a Concept Paper that proposes to revise the existing CHMP Guidances on Process Validation (CPMP/QWP/848/96 and EMEA/CVMP/598/99). Comments on this proposal are due to the EMA by 31 May 2010.

The changes are being proposed to bring EU guidance in line with ICH Q8, 9 and 10. The FDA issued a draft guidance on this topic in November 2008 and this proposal is the EU's first step catching up with the thinking in the USA.

The development of the guideline will be carried out by a Quality Working Party, in co-operation with EU/EEA competent authorities the GMDP Inspectors Working Group, the EMA PAT Team, the Biologics Working Party (BWP), the Immunologicals Working Party (IWP) and the Herbal Medicinal Products Committee (HMPC).

It is anticipated that the draft guideline could be published for six months external consultation nine months after the adoption of the Concept Paper by CHMP and CVMP (Q3 2010) and that it could be finalised within six months after the expiration of the external consultation period (Q4 2011).

Real Time Release

In February 2010 the EMA released a draft CHMP note for guidance (NfG) on Guideline on Real Time Release Testing. This is intended to replace the previous guidance on parametric release (CPMP/QWP/3015/99). The existing guidance only applies to the release of terminally sterilised products without performing a sterility test. The new draft retains the previous guidance but extends the concept to other sorts of product along the lines described in ICH Q8, 9 and 10.

This draft states in its introduction:

> *"Medicinal product must comply with the requirements stated in the authorised specifications for release and shelf life. Real Time Release (RTR) is a system of release that gives assurance that the product is of intended quality, based on the information collected during the manufacturing process, through product knowledge and on enhanced process understanding and control. RTR recognises that under specific circumstances a comprehensive set of in-process controls (Real Time Release testing (RTR testing)) may provide greater assurance of product quality than end-product testing. The RTR principle is already authorised for use as an optional alternative to routine sterility testing of products terminally sterilised in their final container i.e. parametric release. Enhanced product knowledge and process understanding, the use of quality risk management principles and the application of an adequate pharmaceutical quality system, as defined within ICH Q8, Q9 and Q10 provide the platform for establishing RTR testing mechanisms for other applications, for new products as well as established marketed products."*

A key point made in this draft is that when RTR testing has been approved this should be routinely used for batch release and if the RTR testing fails or results are trending towards failure RTR testing may **not** be substituted by end-product testing.

When RTR testing is applied, the attribute that is indirectly controlled (e.g. sterility, uniformity of content) together with a reference to the associated test procedure, should still be included in the specifications. The relationship between end-product testing and material attributes and process monitoring, including acceptance criteria, should be fully explained and justified, including the use of any prediction models.

With respect to re-testing of products imported into the EU from 'third' countries the draft guidance states the following:

> *"For products coming from third countries into the EU it is a requirement in Directive 2001/83/EC "that each production batch has undergone in a Member State a full qualitative analysis, a quantitative analysis of at least the active substances and all the other tests or checks necessary to ensure the quality of medicinal products in accordance with the requirements of the marketing authorization". This normally means a complete re-analysis of the product according to the approved specifications. When a company has got approval for RTR testing for one or more tests in the specifications, these tests would not be considered a "necessary test or check to ensure the quality of the medicinal product in accordance with the requirements of the marketing authorization". Therefore a relief from this testing will be accepted."*

Comments on these proposals are due to the EMA by 31 May 2010.

EU GMP Guide Part 1, Chapters 1 and 2

The EU has at last started to implement ICH Q10. They have issued draft revisions of Chapters 1 and 2 of Part 1 of the EU GMP Guide. Both drafts give the date of "Release for Public Consultation" as 18 November 2009 but they did not appear on the internet until 4 January 2010. Comments are due by 31 May 2010.

These changes have been made to Chapters 1 and 2 in order to integrate the principles of "Pharmaceutical Quality System" as described in the ICH Q10 tripartite guideline, which will be added to the EU GMP Guide as Annex 21.

Industry News

The following sections have been added to Chapter 1:

- Quality Management System
- Process Performance and Product Quality Monitoring System and Product Quality Review
- Management of Outsourced Activities and Purchased Materials
- Management Review of the Quality Management System
- Monitoring of Internal and External Factors Impacting the Quality Management System
- Outcomes of Management Review and Monitoring

The following sections have been added to Chapter 2:

- Consultants
- Management of Change in Product Ownership

Further amendments to existing sections of the text of both Chapters have been made in order to align with the concepts described in ICH Q10; e.g. in Chapter 1 there are new requirements for deviations and CAPA and in Chapter 2 for consultants (which are virtually identical to US 21 CFR 211.34).

It should be noted that there is an error in the numbering of both the revised Chapter 1 which has two sections numbered 1.8 and in Chapter 2 where two sections are numbered 2.3.

The proposed changes to both Chapters include direct quotes from ICH Q10; these are particularly extensive in the proposals for Chapter 1. This means that there is a large amount of duplication between the proposed revisions to these Chapters and the new Annex 21, which seems to be totally unnecessary. The selective quoting of parts of ICH Guidelines breaks ICH rules and so may well be challenged by industry. Also by adding these new requirements to Chapters 1 and 2 it will make them apply to veterinary medicinal products, as well as human products, in the EU even though ICH Q10 has not been adopted by VICH.

EU GMP Guide, Part III

On 4 January 2010, the European Commission published a proposal for Part III to the EC GMP Guide. Part III does not deal with requirements for pharmaceutical excipients, as many had anticipated, but represents an informational part.

In the future, Part III is meant to include documents that are not GMP guidelines but which amend GMP guidelines or describe regulatory procedures. An explanation for pharmaceutical manufacturers on the preparation and contents of a Site Master File has been published as a first document in Part III. The Site Master File concept had been developed by the PIC/S and is expected as a standard in many EU GMP inspections today. PIC/S has fairly recently revised the requirements on Site Master Files. This new version is now published unchanged in Part III of the EC GMP Guide.

EU GMP Annex 6: Medicinal Gases

A revised version of Annex 6, Manufacture of Medicinal Gases, was issued in February 2010 and becomes effective on 31 July 2010.

One of the major drivers for this revision is the need to more clearly define what is to be considered a starting material and what is a bulk medicinal product, when dealing with medicinal gases. The revised annex states *"Normally, the production and purification steps of the gas belong to the field of manufacture of active substances. Gases enter the pharmaceutical field from the first storage of gas intended for such use."*

Other changes include the need to train sub-contractors and tanker drivers, more detail on requirements for storage of cylinders and mobile cryogenic vessels, the conduct of risk management on tankers used to transport medicinal gases and other measures to address cross-contamination concerns.

EU CoP Revisions

On 17 March 2010 several of the EU Compilation of Community Procedures (CoP) were updated to include a new procedure to ensure a co-ordinated response to serious GMP non-compliance for voiding/suspension of a CEP, as well as updated procedures on the "Handling of reports of suspected quality defects in medicinal products", "Handling Rapid Alerts and Recalls Arising from Quality Defects" and "GMP Inspection report – Community format".

The new Procedure on dealing with serious GMP non-compliance for voiding/suspension of Certificate of the European Pharmacopoeia (CEP) deals with all circumstances of serious GMP non-compliance, whether found at a manufacturing or import authorisation holder, third country manufacturer or active substance manufacturer is necessary to ensure a co-ordinated approach to potential risks to public/animal health. It stresses that some actions may lead to consequential actions. For example, if a manufacturing authorisation is revoked or suspended or a CEP is voided or suspended it will have an impact on one or more marketing authorisations. Serious GMP non-compliance found at an active substance manufacturer means that manufacturing authorisation holders using the active substance in question as a starting material have failed to fulfil their legal obligations and therefore action may be taken against the manufacturing or import authorisation or QPs connected with it. The actions that may be taken include:

A Community notification of GMP non-compliance

- Withdrawal of GMP certificate or issue of GMP certificate with restricted scope
- Action against a manufacturing or import authorisation
- Voiding or suspension of CEP
- Action in connection with marketing authorisations
- Impact on clinical trials
- Issuing of a Rapid Alert
- Prohibition on supply
- Disciplinary measures against the Qualified Person(s)

The CoP on Handling of Reports of Suspected Quality Defects in Medicinal Products was revised to extend the scope to include active substances/active pharmaceutical ingredients and falsified medicines.

The CoP on Rapid Alerts and Recalls was revised to change the mechanism of transmission of notifications from fax to e-mail, with Class I and II defects being circulated to all contacts on the notification list. The scope was extended to include active substances/ active pharmaceutical ingredients and investigational medicinal products.

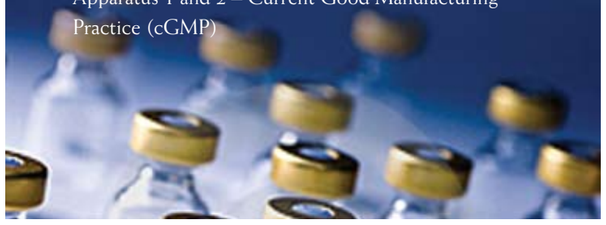
The Community format for GMP Inspection reports was revised to align the format with activities and amendments made in order to enable summary reports for European Medicines Agency inspections to be discontinued.

Note: it is this document that provides the definitions for the classifications used in EU GMP Inspection reports; i.e. Critical, Major and Other.

USA

FDA has recently issued two new "Guidance for Industry" documents…

- Characterization and Qualification of Cell Substrates and Other Biological Materials used in the Production of Viral Vaccines for Infectious Disease
- The use of Mechanical Calibration of Dissolution Apparatus 1 and 2 – Current Good Manufacturing Practice (cGMP)



WHO

The World Health Organization (WHO) published a draft guideline for comment, entitled "Guideline for the Production and Control of *Specified Starting Materials*", in March 2010.

WHO defines these 'specified starting materials' as any substance which is primarily or mainly used as a starting material for the production of an API, but which itself could be used directly as an API.

WHO is concerned that if a material that itself could be an API is used as a 'specified starting material' then applying full API GMP and other requirements may be unnecessary and counter productive. For example if, in practice, the GMP regulations and pharmacopoeia monographs are effectively applied for the 'specified starting materials' to some manufacturers in some countries but not in others, this could lead to a wide price differential between countries. If access to the drug is limited due to the price, pricing level will always be driven by the lowest quality standards. The replacement of a drug product by cheaper and sometimes dangerous substitutes, which may even cause deaths (less active drugs, false medicines), is the risk driven by high prices.

If the material is used in the production of an API then the quality attributes and specifications should be determined by the API manufacturer and the material should be fit for its intended use. Viral safety and TSE data should be carefully considered if the starting material is animal derived.

Quality Control for compounds used as 'specified starting materials' should address impurity profiles, isomers, residual solvents and other impurities that may be carried through to the resulting API.

API manufacturers are encouraged to take a risk-based approach in setting specifications for these materials, considering the number and type of unit operations between introduction of the material and production of the resulting API.

Industry News

UK

API 'Pedigrees'

The MHRA is developing the idea of the introduction of a '**Pedigree**' document for APIs. This Pedigree document would require all APIs to be able to demonstrate full upstream traceability for all 'critical' starting materials as well as downstream traceability of the finished API from site of manufacture to the finished product manufacturer's site. These Pedigree documents will need to be more detailed than just a simple flow chart with proof that the sourcing/supply routes have been confirmed.

The QP will be responsible for assuring the accuracy of the Pedigree document as an extension of the QP declaration of GMP conformity. In order to decide the extent of the Pedigree the API manufacturer should define 'critical materials'. For semi-synthetic/synthetic APIs; critical materials are those that contribute to the structure of the API molecule. For animal/plant/human origin APIs; original tissue is considered critical material. A registered route of synthesis should cover all such critical materials.

The Pedigree is proposed to comprise of:

- All manufacturers/suppliers of critical raw materials/intermediates concerned with manufacture of API up to the point of release of final API
    - ♦ Includes contractors, traders, consolidators
- Suppliers/sites acting from the point of release of final API from the manufacturer to receipt by the finished product manufacturing site
    - ♦ Includes re-packagers, re-labellers, brokers, importers

The Pedigree is proposed to be either:

- An Annex to QP declaration: as part of an application for MA, renewal or variation

or

- A GMP requirement (in revised Chapters 1 & 5 of EU GMP)

The MHRA is currently discussing these ideas for a Pedigree within various EMA groups.

In addition the MHRA is proposing to introduce an extension of the Sunset Clause to APIs whereby if an API source named on a license has not been used for a defined period (proposal is five years) it will automatically be considered as no longer in operation in terms of the license and be de-listed/removed.

The MHRA is also considering introducing a requirement that a formal risk assessment is conducted for new API sources that are not based in the EU or countries with an MRA (USA won't need a risk assessment). If deemed workable this will later be expanded to excipient supply as well.

MHRA GMP inspections will increase their focus on Supplier Audit Programmes with specific regard to assurance of the total supply chain for APIs. Adequacy of supplier audits is a major concern for the MHRA at the moment. QPs need to be able to demonstrate clearly the basis of any GMP declarations that they sign. MHRA is increasingly applying sanctions and disciplinary actions against the manufacturer and/or the QP where they find deficiencies in this area.

Where GMP inspections of API manufacturers are performed by regulatory bodies and they consequently remove or fail to issue a GMP certificate, all the manufacturers who have the API supplier named on a marketing authorisation will be contacted to inform them they are no longer considered to be of the required standard and cannot be used. In parallel, all QP declarations that have been generated relating to that API manufacturer will be challenged and legal action may be taken against the approving QP and their employer if it is found the declaration has been generated without proper assurance that the supplier meets the required API GMP standards.

Medical Devices

Revised Directive 2007/47/EC came into force on 21 March 2010

March 2010 saw the implementation of the revision of the Medical Devices and Implantable Medical Devices (AIMD) Directive.

Some of the revisions simply clarify existing practice, but new guidance has been produced in certain areas:

Clinical Data

- Manufacturers must justify the lack of clinical data if none is available
- Similarly, manufacturers must justify the absence of a clinical investigation for high risk devices
- If the literature route is followed, the manufacturer must establish equivalence between their device and that covered by the literature
- The manufacturer must justify any absence of post-market clinical follow up

Custom-Made Devices

- Manufacturers of custom-made devices are now required to follow other devices and review and document experience gained in the post production phase and to implement a post market surveillance system
- Additionally, the 'statement' which accompanies the device must be made available to the named patient

Crossover with Personal Protective Equipment

- Manufacturers can now CE mark products both as medical devices and as personal protective equipment

Machinery Directive

- Devices which are also machinery must now meet any requirements of the machinery directive which are more specific than those for devices

Standalone Software

- Standalone software is now considered to be a medical device in its own right

Labelling

- Devices intended to administer and/or remove medicines, body fluids or other substances from the body and which contain phthalates must be labelled accordingly
- If such devices are used in the treatment of children, pregnant or nursing women, the manufacturer must provide a justification for the inclusion of phthalates

Access to Registration Data

- The following data is no longer considered confidential:
    - ♦ information on the registration of persons responsible for placing devices on the market
    - ♦ information to users sent out by a manufacturer, authorised representative or distributor
    - ♦ information contained in certificates from Notified Bodies

Reclassification of Some Devices

- The definition of the central circulatory system has been amended to include arcus aorta and aorta descenders, which will reclassify some devices to Class III
- Devices in contact with the central nervous system are now Class III
- Devices for disinfecting invasive devices are now Class IIb
- Devices for recording X-Ray images are now Class IIa

Sampling of Class IIa and IIb Devices

- There are now specific requirements for detailed technical reviews by Notified Bodies during quality assurance assessments

Authorised Representatives

- All manufacturers outside the EU/EEC must have an Authorised Representative

Declarations of Conformity

- These must now clearly identify devices by name, code or other reference

DBA will discuss these and many more issues in our training course "Medical Device CE Marking – The Latest Requirements" to be held in Manchester from 17 to 19 May 2010.

Latest Guidance on a Medical Devices Vigilance System

To coincide with the implementation of Directive 2007/47/EC, the European Commission has published Revision 6 of MEDDEV2.12-1, its guidelines on a medical devices vigilance system. Whilst the document is largely unchanged, it incorporates technical modifications to Annex 3 (Report Form - Manufacturer's Incident Report).

These requirements will be discussed in detail in our training course "Post Market Surveillance and Vigilance Requirements for Medical Devices" to be held in Manchester from 20 to 21 May 2010.

Congratulations

to the first graduates from the Genentech Quality Certification Program

As well as launching our external modular US Quality Leadership Program from Boston in the fall of 2009, we have seen a continuing trend for Pharmaceutical/Biotech companies to use DBA to run in-house Quality Leadership style programs.

The value of DBA in-house programs to companies has previously been confirmed by senior industry leaders such as Gerry Migliaccio of Pfizer and David Watson of Sanofi-Aventis.

Even in the current economic climate this trend indicates that there are still leaders around within the more forward-thinking companies who recognise the need to champion such programs and develop their people – an essential factor in the culture change needed to drive science and risk-based approaches to Quality as part of the drive to better business efficiency and Operational Excellence.

The in-house Quality Leadership programs that DBA run are customized to meet the client's needs and…

- develop key individuals and equip them with the relevant knowledge and skills to make the right quality-related decisions in development, manufacturing and supply chain for the business and the patient
- drive internal culture change to deliver the science and risk-based approaches expected in today's regulatory environment and move away from the 'blind compliance' approaches that have over-complicated our industry
- help break down the silos that exist between different functions and sites, and facilitate them working towards harmonized best practices
- integrate the shared ownership for Quality in all employees – not just the Quality unit
- enhance the credibility of the Quality unit – to one being seen as a professional, value-adding part of the business
- establish a network of 'catalysts for change' across the business

In the USA, DBA are now accredited with Continuing Pharmacy Education Provider Accreditation Program Accreditation Council for Pharmacy Education (ACPE) as a provider of courses.

Our clients have chosen a range of options for these in-house programs, ranging from 4-6 modules up to 12 modules, delivered over a period of 1-2 years, usually with 20-30 core participants. Different locations in the company are often selected as venues for different modules. We are happy to fit in with the needs of our individual clients.

Examples of the typical modules selected by clients include:

- Pharmaceutical Law for a Global Market
- Investigational Medicinal Products
- Modern Quality Management Systems
- Formulation and Processing Fundamentals
- Pharmaceutical Microbiology
- Sterile and Aseptic Processing
- Supply Chain and Active Pharmaceutical Ingredients
- Bulk Biopharmaceuticals
- Maths and Statistics for the Pharmaceutical User
- Pharmaceutical Packaging
- Pharmaceutical Analysis

The Genentech GQCP

One of DBA's most enthusiastic clients has been the biotech giant Genentech. DBA and Genentech have partnered to design and deliver the **Genentech Quality Certification Program** (GQCP) – aimed at technical professionals from a range of different functional areas and site locations across the company.

The pilot program ran throughout 2009 with 11 assessed modules plus work assignments and culminated in the delegates participating in a panel session with senior Genentech leaders and DBA.

The attached photograph shows the great relief of some of the class of 2009 graduates (and DBA's Neil Wilkinson) on completing the program! They later attended a graduation event presided over by John Pinion, Head of Global Quality for Genentech/Roche, and other key leaders.

In today's business climate, DBA see Genentech as visionaries – equipping their people and organisation with the future leaders needed to tackle the increasingly complex and difficult Pharmaceutical Industry climate.

Well done to the class of 2009 …and good luck to the 2010 GQCP class just starting the journey!

So what did the class of 2009 think about the GQCP program?

"My participation in the Genentech Quality Certification Program has been an eye opening experience which has provided me the knowledge and tools necessary to look at the Quality industry in a whole new light. It has provided me the opportunity to interact with industry experts and thought leaders from around the world, as well as my peers throughout the Genentech network. Together, we have explored the current quality challenges we are facing in our business today, and have discovered the challenges we must prepare for to enable continued success in the rapidly evolving industry of pharmaceutical quality assurance."

Aron Yaeger, QA Specialist, Vacaville Quality Assurance

"As a participant this year the program has been great. I have learned a lot at every session and feel more confident in my job and role. It is a great opportunity because you are able to get quality training from DBA who is a world class company and the benefit of real world Genentech situations as well as exposure to our sites. You won't find this opportunity anywhere else in the industry. So it's worth it. I rely on things I have learned from the program every day with my job."

Lori-Anne Boville, Global Product Steward

"The guidance and direction around the ICH Guidelines has been invaluable. Our instructors have been authors and co-authors of the guidelines. Their level of insight around the movement away from blind compliance to risk based continuous improvement is extremely exciting. The program positions the participants extremely well to help translate the ideas of the thought leaders to practical implementations for field investigators."

Scott Zimmerman, Associate Director, Operational Excellence

"The Quality Certification Program has been a phenomenal experience! This program is perfect for those who have a thirst for current industry trends, scientific knowledge, guidance on regulations (domestic and ROW), and understanding how we apply it all to our business. The course content was thoughtfully constructed and delivered. It's wonderful to work for a company that invests in its employees…thank you for offering such a cutting edge program! I appreciate all this program has to offer…from knowledge to networking!"

Bethany McElroy, QA Specialist, Hillsboro Quality Assurance

The advantages of a DBA program

The DBA in-house approach is appropriate for companies in a range of circumstances including:

- Where your own routine refresher training approach needs revitalising
- Where your company is growing to a different size and complexity
- Where you have been part of merger or acquisition activities
- When you need to make a sustainable culture change
- When you are implementing a Q8/9/10 approach

In addition to in-house Quality Leadership style programs, DBA is able to offer in-house versions of the majority of the individual courses from its wide portfolio of education and training programs.

If you are interested in changing the culture in your organization and in preparing for the challenges ahead, call us to explore how an in-house program similar to that adopted by Genentech or the Boston-based series of modules can benefit you.

DBA People

Departures & Arrivals

Spring of 2010 has seen the departure of one old friend and the arrival of three new ones.

David Anderson

After ten years as DBA's specialist consultant for active pharmaceutical ingredients (APIs) David has taken the decision to retire and spend more time with his wife and family.

David has been a key part of the DBA team and his pragmatic approach to compliance and quality management has brought him immense respect from our clients.

We wish David a long and very happy retirement.

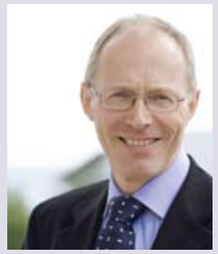
David Inglis

David Inglis joins us to fill the technical gap left by David Anderson's departure. A chemist by training, David spent many years in API manufacture and control with Glaxo before becoming an independent consultant around 5 years ago.

David has a strong interest in training as well as consulting, and we are delighted to welcome him to the team.

Line Lundsberg

Line joins us as a specialist in ICH Q8 and all aspects of Quality by Design and PAT. Before becoming an independent consultant, Line worked for many years with Novo Nordisk and Lundbeck in Denmark. She holds the distinction of being our first non-British consultant in Europe – the first, we hope, of many!



Bruce Davis

Bruce is a professional Engineer and, like Line, is an acknowledged expert in the field of Quality by Design. He has a particular interest in marrying QbD and PAT with facility and process design and commercial scale production. Before becoming an independent consultant, Bruce held senior positions with AstraZeneca.

The arrival of David, Line and Bruce not only strengthens our Associate Consultant team, it allows us to provide you with expert advice and training in the increasingly important area of development and Quality by Design.

If you would like to benefit from our enhanced experience and knowledge base, please call us on +44 (0) 1751 432 999 or email us at mail@DBA-global.com

London Marathon

By the time you've read this, Martin Lush, one of our Partners, will have completed the London Marathon on behalf of 'Children in Distress'. Completed, yes. Fully recovered…probably not!

CID is a UK-based charity that provides medication and support for children with HIV in Romania. Without their support these children would die.

If you would like to make a small donation, just go to http://justgiving.com/Martin-Lush. Every penny really matters!!

On behalf of the children, thank you very much indeed.

Series 11 begins in October and promises to be our best Series ever!

In October this year we commence our eleventh Series of training for the Qualified Person and Pharmaceutical Professionals. It is now twenty years since we and the University of Strathclyde hosted our first training courses for QPs and we plan to make some significant improvements to the coming Series to make the training even more relevant and attractive to you.

Introduction of a Postgraduate Certificate Award

From our very first Series we have offered students attending all modules the opportunity to gain a Postgraduate Diploma and Master of Science Degree.

Now, for the first time, we offer students attending a minimum of six modules the chance to gain a Postgraduate Certificate award from the University of Strathclyde.

More on Investigational Medicinal Products

In response to requests from the growing number of clinical trials QPs, we are increasing the duration of our Investigational Medicinal Products module to four days. This will allow us to cover the unique issues pertaining to these products in the level of detail that the prospective QP really needs.

And remember – even if you are not currently working with IMPs, it is highly likely that you will at some point in your career.

More on the Roles and Responsibilities of the Qualified Person

Every year, the European Commission places extra responsibility on the shoulders of the QP, and this is unlikely to stop! That is why we plan to expand this module to allow more time to discuss and debate these responsibilities, as well as to devote more time to helping QPs to see their role as leaders and change agents for the future.

We will, of course, retain all those traditional elements of our QP training which have made us the most popular and most respected training provider for QPs.

Our free evening sessions covering essential non-technical aspects of the QP role will be retained and strengthened. Topics to be covered will include…

- Presentation techniques
- Team building and team working
- Assertiveness training
- Rapid learning techniques
- Relaxation techniques

…and numerous others.

Free Seminars in London and Amsterdam

We plan to hold free information seminars about the coming Series in London and in Amsterdam later this year. Why not come along with your Sponsor and see what we have to offer you?

Interest in the new Series is already very high, with delegates from the UK, Ireland, several mainland European countries and even Australia already signed up. If you would like to join them, call Stella Pearson-Smith on +44 (0) 1751 432999 or email her at qp@DBA-global.com.

You only take QP training once, so make sure you do it right!

Congratulations to...

In the past few months DBA has helped Rachel Evans of AstraZeneca Pharmaceuticals to obtain QP status

DBA International Healthcare, Consulting & Education Experts

NEED TO REDUCE COSTLY ERRORS *...HERE'S HOW*

I was at a company recently who suffered from procedural non-compliances big time. Not surprising really when you looked at what the operators relied upon for guidance and clarity, namely their SOPs.

Even for simple tasks they had to wade through pages of 'purpose', 'scope', 'definitions' and other 'blurb' before they got to what really mattered; the specifics of 'how to do'. Even then, hopes of clear, concise and readable instructions were dashed because of:

- Too many 'filler words'
- Complex and lengthy sentence structure. In fact, almost Shakespearian
- Multiple cross references to other documents most of which were unavailable
- No pictures, just boring words

Yes, the error rate was high but it should have been higher. The operators were truly heroic in getting anything out the door.

What alarmed me most was that SOPs, designed to provide clarity and **improve** consistency, did the complete opposite.

Operators were distracted and confused by the very things sent to help them.

There is however a very simple answer. A very simple alternative...the humble checklist.

When faced with difficult and complex tasks, we humans are up against two main difficulties.The first is the fallibility of the human memory and attention; especially for routine tasks. Even more insidious is the tendency for people to skip steps, often with serious consequences.

Used widely by medics and pilots alike, instructions provided in checklist format prevent failures and non-compliances. SOPs written for the user by authors with a checklist mindset work, providing you know what rules to follow.

You may be just one step away from dramatically reducing your error rate by simplifying your key SOPs and giving your operators some hope and save yourself a fortune. If you would like to find out how, come along to one of our popular courses on 'Human Error' – details below:

Human Error: Causes and Prevention
18-20 May 2010
Crowne Plaza, Philadelphia Center City, PA, USA

Human Error: Causes and Prevention
14-16 June 2010
Manchester Marriott Victoria & Albert Hotel, Manchester, UK

If you would like further information just drop me an email mkl@dba-global.com

Haiti Earthquake Appeal

Following the tragic earthquake in Haiti in January of this year, we decided to donate 1% of our professional fees for January and February to the Haiti earthquake appeal.

We are delighted to be able to report that, thanks to your support of DBA through attendance at training courses and requesting our consulting skills, we were able to donate £4,280 (€4,700, $6,420) to Unicef to help provide much needed assistance to orphaned and displaced children.

We would like to thank you all for helping us to help the children of Haiti.

In the next DBA Journal: Industry News: As ever we search for regulatory changes so you don't have to; Tech Talk: Quality by Design – how it will affect you; DBA People: Exciting new additions to our team to enhance our services worldwide; Forthcoming Courses: A review of our education programmes for the rest of 2010; Plus: All the latest news for Qualified Persons and Technical Professionals in the field of pharmaceuticals, medical devices and nutraceuticals.

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

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