DBA

The Journal of David Begg Associates

Issue 16 Autumn 2010

Why Training Plans Can Help Performance

Does Quality by Design have the 'X-factor'?

Batch Records and Product Release Procedures *Are you at Risk?*

An NSF International Company

DBA-global.com

welcome

Bob Pietrowski
Managing Partner
David Begg Associates

We hope that you have had an enjoyable summer vacation and are now back at work, ready to make your personal contribution to your company's success and, more importantly, to patient safety.

The summer has been a busy time for us at DBA. As well as preparing for the many educational courses in the second half of this year, we have been working hard to improve our service to you in several important ways…

A Customer Relations Manager for Europe

We are delighted to announce that Anne Davies has joined DBA as Customer Relations Manager in Europe. Anne has a wealth of experience (see article on page 19) and I am confident she will soon become a new friend and colleague to you all.

DBA South Africa

We are also proud to announce that we have opened an office in South Africa, from where Allan Thomas will bring our training courses and services to this growing market and to the whole of Sub-Saharan Africa (see article on page 20).

DBA USA

We are working hard to build up the US team to meet the amazing demand that we are experiencing. Watch this space!

Local Language Representation in Europe

Finally, we soon hope to be in a position to offer DBA's full range of training and consultancy in German, Italian and other European languages, so you don't have to be able to speak English to benefit from the services we have to offer.

We are very excited about the changes taking place at DBA and we hope you will be too.

Bob Pietrowski
Managing Partner

DBA International Healthcare, Consulting & Education Experts

Tech Talk

Does Quality by Design have the 'X-factor'?

by Line Lundsberg-Nielsen & Bruce Davis

1. QbD – Robust Processes and the 'X-factor'!

We are all probably aware of some non-robust processes in the pharmaceutical industry. We also know that our industry rarely operates at a Six Sigma level – a standard many other industries achieve. Why is this? Are we too focused on compliance? Has having the occasional reject batch become the norm?

So, can an 'X-factor' be found to bring back higher efficiencies, create less waste and produce more effective products? Quality by Design (QbD) might or might not be the 'X-factor', but it does provide an opportunity for our industry to do things differently, to do them better and to have more robust processes.

2. QbD – Patient Focus

QbD has become a 'buzzword' to represent the science and risk-based quality paradigm, as expressed by the ICH Q8, Q9 and Q10 guides. The QbD concept focuses on how to develop and manufacture pharmaceutical products by applying a science and risk-based approach throughout the entire product lifecycle, from early development through scale-up, technology transfer and commercial manufacturing to product discontinuation. The key to QbD is product and process understanding based on what is critical to the patient in terms of safety, efficacy and quality.

One might ask "Isn't this what we have always done?" and the answer is probably "Yes and no". Certainly, patient requirements have always been central when developing new medicinal products, as has the application of science. The traditional approach has, in broad terms, involved developing the API and formulated product for early clinical trials and then scaling-up for commercial manufacture with a focus mainly on compliance and end-product testing. Probably lacking has been a continuous thread of key information from early laboratory work to full scale manufacture.

The QbD approach aims at establishing a more comprehensive understanding at all stages by focusing development activities on what is critical to the patient, then controlling these critical aspects during commercial manufacture. Once a product enters commercial scale manufacture, very significant quantities may be produced before errors are detected using conventional end-product testing, or the error may not be detected and reach the patient before being discovered. By enabling real time monitoring of manufacturing the QbD approach offers significantly improved assurance of product quality for patients.

3. QbD – a Science and Risk-based Approach

For developing a new product, the QbD methodology can be described in simple terms as a series of iterative steps as below:

- Defining the Quality Target Product Profile (QTPP) = patient requirements
- Understanding the Critical Quality Attributes (CQAs) = the product attribute specifications
- Defining Critical Process Parameters (CPPs) = the process parameters that impact the CQAs

- Establishing the Design Space = a new way of describing ranges of CPPs and attributes impacting the CQAs. If a process is operated within this space, the CQAs are assured
- Developing the Control Strategy = the actions necessary to ensure the manufacturing process remains within the Design Space
- Enabling Continuous Improvement = making improvements throughout the product lifecycle

These steps are supported by risk assessment, knowledge management, and by PAT tools, which provide techniques to monitor, adjust and control processes in real-time.

4. QbD – Moves Controls Upstream and Introduces Real Time Release Testing (RTRT)

Relying on end-product testing is too late if during manufacturing anything has gone wrong. Both patients and business might be at risk, for example patients could face a product shortage and the manufacturer could lose business. A QbD control strategy ensures the product will comply with CQAs specified. PAT techniques enable the process to be controlled in real-time by using in-process information to predict settings of upstream equipment. This approach has, to a certain extent, always been utilised for aseptically produced sterile products, where meaningful end testing of the sterility CQA is not possible. QbD extends both the depth and scope of this approach, by requiring greater mechanistic understanding of processes and going beyond sterile products to include the manufacture of all dosage forms and other CQAs.

An example is a drying process. Drying time depends on the initial and final required moisture level of the process material. This may seem obvious, but many drying processes have traditionally had a fixed drying time and rely on sampling and off-line QC testing of the moisture level. In QbD the initial moisture level may be used to set the drying process parameters and then on-line NIR used to measure the level and feed this back to the process to enable drying to be stopped when the material has the correct moisture content. By moving these controls upstream in the overall process, it enables these to be used for RTRT and potentially avoid testing at the end. Not only does this create savings in QC activities but also improves production cycle time and hence enables cost efficiencies to be made.

5. QbD – and the Role of the Qualified Person (QP)

At first glance, QbD seems to be much more complex than the conventional approach, for example by applying PAT tools with multivariate data analysis and mathematical models. However, with an enhanced level of process understanding, it becomes easier to assure the quality of the product. The control strategy serves as one of the guiding tools that the QP can use when reviewing batch documentation, to provide them with greater assurance that the CQAs have met specifications.

6. QbD – Impact on Small Companies and Generics

In broad terms 'Big Pharma' companies seem to have embraced QbD and many now take a strategic approach and organise their internal development and manufacturing processes to support QbD. What about smaller and generic companies? Where is the value for them?

Such companies generally do not have resources or time for large R&D investments, as being first in the market place is such a key business driver for them. But to have more robust processes and greater clarity about safety and efficacy are strong business motivators. Smaller companies can gain by 'cherry-picking' the parts of the QbD that give the maximum benefit. For example, it may be too costly to establish the full design space, but investigating a difficult unit operation to make it more robust may create an immediate business benefit.

7. In Conclusion

Whatever the future for QbD, it certainly has brought logic and clarity about how our products should be developed and manufactured. It has also raised the importance of ensuring development and manufacturing departments work closely together.

QbD will not only provide business efficiencies but, most importantly, will continue to benefit patients. Yes, QbD really can provide the 'X-factor'!

A Practical Experience in Scotland with the US Quality Leadership Program, Class of 2011

The DBA US Quality Leadership Program (QLP) consists of 12 modules, 11 of which are run from Boston, with the 12th being a practical module, which delegates have the option of attending at the University of Strathclyde, in Glasgow, Scotland. This module involves practical experience of formulation, manufacture and analytical activities.

Jim Morris, one of DBA's US Partners, describes his first experience of this practical module with the US QLP delegates:

It struck me during a dinner with a cohort of individuals, who I can best describe as the Quality Leadership Class of 2011, that all of these individuals are going to make a significant difference in their respective companies, partly as a result of their participation in the Quality Leadership Program. The group had just finished a week long practical at the University of Strathclyde's facilities in Glasgow, Scotland, and were unwinding after this intensive, yet enjoyable, week. The group had bonded nicely through the shared experience and challenge of the course work required for a Masters degree from a prestigious university.

A total of 34 people attended the week long practical at the University in Glasgow; 11 having traveled over from the USA, narrowly dodging flight cancellations due to the ash cloud. During the week they interfaced with delegates in Europe, who are enrolled primarily to satisfy the educational requirements necessary to get their Qualified Person's eligibility. One delegate, Stefan Verstegen from The Netherlands, had just completed the full QP program in the UK and was recognized for his accomplishment during an evening activity. At the end of an excellent dinner hosted by the University at their estate house overlooking Loch Lomond, Stefan said a few words to the group, mainly wishing everyone luck but also suggesting that this was a fabulous way to get to know one another and recognize everyone's effort and dedication to the program and to the industry that they worked in.

The practical session is designed to introduce delegates to Formulation, Analysis and Oral Dosage Form Manufacturing for Sterile and Solid Products. The University's small scale teaching facilities are equipped with a mix of new and old equipment which provides an opportunity to demonstrate the basic principles that people working in Quality, Manufacturing and other technical functions must appreciate. It is the hands-on approach which adds a crucially important element to the overall program. It exposes participants to new areas and puts them in the role of the formulation scientist, laboratory analyst, and manufacturing operator. The teaching by University staff and DBA experts brings a unique blend of practical experience and wealth of knowledge to the table.

The University professors who teach the course are well known both as teachers and researchers. For instance, Dr Gavin Halbert is one of the UK's leading scientists in the field of cancer research, and Dr David Watson is known for his expertise in analytical chemistry and, as we found out the night of the awards dinner, an excellent singer of Irish brogue!

For the US QLP most of the US delegates have signed up to pursue the Masters degree offered by the University for those delegates who elect to sit each of the module exams and complete a Masters level thesis. In addition some US delegates attend individual modules to build their knowledge base and stay current with industry trends.

For those pursuing the higher degree options, the University of Strathclyde is the second most prestigious school of pharmacy in the UK. The Strathclyde Institute of Pharmacy and Biomedical Sciences is developing a leading Biologics program. It is a perfect partner for DBA, providing the academic bridge to industry.

In August the US QLP Class of 2011 will approach the midpoint of this first series. As I saw in Glasgow and in Boston, the benefits in the knowledge they build through attending each of the 12 modules, and the friendships and networks they establish through the common experience, will continue to grow. We look forward to the forthcoming modules with this group as the first series progresses, and to other newcomers who are joining – either for a full series, or just for individual modules.

DBA will soon promote the second series of QLP, which starts on November 1, 2011. If you are interested in learning more call us on **+1 617 342 3625** or email us at **USinfo@DBA-global.com** We will be offering a FREE information session at the next module held on October 14, 2010 at the Royal Sonesta Hotel, Boston (RSVP by October 8) so you can learn first hand what QLP is all about. You are welcome and we invite you to attend… RSVP to Michelle Evans at **mde@DBA-global.com**

Additionally, we will be running complementary webinars on October 7 and December 6 at 14.00 EST and posting a short video on our website.

Forthcoming Courses

What's planned for September – December 2010

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)

Pharmaceutical Law & Administration

QP

Qualified Person & Professional Development Training

York Marriott Hotel, York, UK

4-8 October 2010

All the prospective QP 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: **£3200.00 plus VAT** (First Booking)
£2560.00 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.

DBA International Healthcare, Consulting & Education Experts

Free Seminar for Prospective QP Trainees

FREE SEMINAR

York Marriott Hotel, York, UK

5 October 2010

Interested in becoming a Qualified Person? Why not attend this free seminar to find out more about what we can offer? Learn about what is required to become a QP and see one of our training modules in action.

QP Free Sponsors' Day

FREE SEMINAR

York Marriott Hotel, York, UK

6 October 2010

Are you currently acting as a sponsor for someone undergoing QP training or are you likely to be in the future? This free seminar, hosted by DBA and including presentations from the Royal Pharmaceutical Society of Great Britain, the Royal Society of Chemistry and the Society of Biology, is designed to help you understand the professional and ethical responsibilities that go with the sponsor role so that you can better fulfil your duties and better support your trainee QPs.

How to Simplify and Improve Your Documentation System

achieve

Manchester Airport Marriott Hotel, Manchester, UK

12-13 October 2010

This course is essential for anyone wanting to make their documentation system more efficient, cost-effective 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: **£1320.00 plus VAT** (First Booking)
£1056.00 plus VAT (Additional Bookings)

Mathematics & Statistics

QL

Quality Leadership Program

Royal Sonesta Hotel, Boston, MA

13-15 October 2010

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

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

Registering Drug Products in the EU: Quality (CMC) Requirements

San Mateo Marriott Hotel, San Mateo, CA

13-15 October 2010

All you need to know about the practicalities of registering your pharmaceutical and biopharmaceutical drug products in Europe, including commonly made mistakes to avoid! Our European experts ensure no other US class comes close to this!

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

GMP for Clinical Trials Manufacture and Supply

Manchester Marriott Victoria & Albert Hotel, Manchester, UK

18-21 October 2010

Essential training in current EU and US GMP regulations for the manufacture, testing, importation and distribution of clinical supplies. As always, we have industry speakers to give a practical interpretation of GMP expectations and current regulatory trends.

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

Risk-Based Decision Making for Quality Professionals and QPs

London Marriott Hotel Kensington, London, UK

19-20 October 2010

The toughest task facing any Qualified Person or Quality Professional is to take decisions regarding the suitability for release of materials when things go wrong. This course is designed to provide you with proven risk management techniques which will help you to make sound, risk-based decisions which benefit the patient, your company and you! Packed with real-life scenarios for you to work on, this course is not to be missed.

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

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 September – December 2010

How to Perform Effective Product Quality Reviews

Manchester Airport Marriott Hotel, Manchester, UK

26 October 2010

Chapter 1 of the EU GMP guide includes a requirement to carry out periodic reviews of all licensed medicinal products. There is a similar requirement under US law. This course will provide you with clear guidance on how to design and perform quality reviews which are efficient, cost-effective and value adding.

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

Pharmaceutical Legislation Update: Continuing Professional Development for Qualified Persons and Technical Personnel

Manchester Airport Marriott Hotel, Manchester, UK

27 October 2010

Your annual top-up!

Current and proposed changes to EU and US legislation and GMP requirements and their impact on QPs and technical managers.

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

Good Autoclave Practice

Manchester Marriott Victoria & Albert Hotel, Manchester, UK

2-4 November 2010

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 practice for monitoring and management of autoclaves.

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

Best Practice for the Control and Supply of Equipment to the Pharmaceutical and Device Industries

NEW COURSE

Manchester Marriott Victoria & Albert Hotel, Manchester, UK

11-12 November 2010

This brand new and unique course is specifically aimed at companies supplying, or wishing to supply, equipment to the pharmaceutical and device industries. We will explain the pharmaceutical and device GMP regulations to you and explain how these create the very special and demanding requirements of companies in these sectors with regard to equipment design, construction, qualification, automation, change control and many more issues. This course will help you sell more equipment to your customers and improve your competitive edge!

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

Medicinal Chemistry & Therapeutics

QP

Qualified Person & Professional Development Training

York Marriott Hotel, York, UK

15-19 November 2010

All the prospective Qualified Person or pharmaceutical professional needs to know about how drugs act on the body, the major therapeutic classes of drugs and how they should be handled in manufacturing.

Course Fee: **£3200.00 plus VAT** (First Booking)
£2560.00 plus VAT (Additional Bookings)

Risk-Based Decision Making

San Francisco Airport Marriott Hotel, Burlingame, CA

16-18 November 2010

Unfortunately, things don't always go according to plan in our industry, and when they don't we have to take decisions about what to do next. Such decisions cannot be based upon emotion or 'gut feel', but rather on the basis of facts, scientific understanding and a clear assessment of RISK. It is fair to say that the regulators judge us by how we behave when things go wrong, not when they go right! We will provide you with tried and tested risk assessment and risk management techniques to ensure you make the right decisions at the right times! What is more, through a series of scenarios and case studies, we will demonstrate to you how your decision making skills have improved during the class.

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

Book online at www.DBA-global.com

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DBA International Healthcare, Consulting & Education Experts

Quality Aspects of the CTD

Hilton York Hotel, York, UK

22-25 November 2010

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

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

Pharmaceutical Water Systems: Troubleshooting and Risk Assessment

Manchester Marriott Victoria & Albert Hotel, Manchester, UK

29 November to 1 December 2010

This three day course will provide you with the latest information on EU and US regulatory expectations for water systems and practical advice on system design, validation, monitoring and management, as well as troubleshooting and risk assessment. In short, all you need to know about water systems!

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

Effective Pharmaceutical Audits and Self-Inspections

Park Hotel, Amsterdam, The Netherlands

29 November to 2 December 2010

Learn how to carry out audits with skill and sensitivity, whilst ensuring 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** (First Booking)
£1820.00 (Additional Bookings)

Practical Application of Quality by Design

Manchester Marriott Victoria & Albert Hotel, Manchester, UK

30 November to 1 December 2010

Quality by Design is a key element of ICH Q8, Pharmaceutical Development, and will be central to ICH Q11, the equivalent guideline for APIs. Important concepts such as Design Space, Control Strategy and, by extension, Process Analytical Technology (PAT) will have an immense impact on the way we design and develop manufacturing processes, how we register those processes and how we control manufacture in the future. Come and learn what it's all about from industry experts and hear how companies are already putting it into practice. This course will be of huge value to those involved in Process Development, Product Registration and the Quality function, especially QPs.

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

Pharmaceutical GMP

Amsterdam Marriott Hotel, Amsterdam, The Netherlands

6-9 December 2010

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

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

Meeting the Regulatory Requirements for Clinical Trials in the EU

London Marriott Hotel Kensington, London, UK

7-8 December 2010

This brand new course, run in conjunction with Regulatory Resources Group, will tell you all you need to know about the regulatory and GxP requirements associated with planning, applying for and conducting a clinical trial in the EU. Essential education for pharmaceutical professionals involved in R&D, regulatory affairs, clinical supplies manufacture and the conduct of clinical trials.

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

Analysis & Testing

Quality Leadership Program

Royal Sonesta Hotel, Boston, MA

7-9 December 2010

An intensive course covering the major analytical techniques used in our industry, allowing you to understand why we select certain types of analysis for certain applications and the validation expectations for them. We will also explain current US and EU GMP expectations for the QC laboratories.

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

Free Seminar for Prospective QP Trainees

Amsterdam Marriott Hotel, Amsterdam, The Netherlands

10 December 2010

Interested in becoming a QP? Why not attend this free seminar to find out what is required to become a QP and how we can help you achieve your goal.

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 Changes

Compilation of Community Procedures

The EU Compilation of Community Procedures on **Inspections and Exchange of Information** has been revised to add a new procedure to ensure a co-ordinated response to serious GMP non-compliance for voiding/suspension of a CEP, as well as updating the 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; therefore action may be taken against the manufacturing or import authorisation or QPs connected with it.

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 email, 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.

The 'Pharmaceutical Package'

This consists of proposed changes in three main areas; pharmacovigilance, falsified medicines and patient information. It was originally hoped to have this completed by April 2010 but as often happens it is taking longer.

Each of the three changes are due to be voted on by the European Parliament in September or October 2010; therefore they are not likely to go to the Council of Ministers before December 2010.

EU GMP Annex 2: Biological Products, Proposals

A first draft revision of Annex 2 was released for public consultation in September 2007. After a long period for consultation (two and a half years), a second draft was issued for comment on 9 April 2010 with a deadline for comments of 15 July 2010.

The currently approved version of Annex 2 is an anodyne document, rarely referenced by people in the field and long

overdue for revision. The latest draft is a major revision, offering sound, practical guidance in most areas and regular observations on the applicability of risk managed decision making. Specific changes include:

- The guidance now takes account of the existence of Part 2 of EudraLex Volume 4 – GMP for Active Substances – which addresses the manufacture of bulk biological products
- The range of regulated biological products has increased significantly since publication of the current Annex, and guidance on 'selected product types' has been included in the revision (summarised in the draft structure outlined below)
- Recent regulation on advanced therapies required the preparation of specific guidelines for so called 'Advanced Therapy Medicinal Products' (ATMPs):
  - ➢ Gene therapy products
  - ➢ Somatic cell therapy products
  - ➢ Tissue engineered products

The draft Annex is structured as follows:

- Scope (including an **illustrative** guide to manufacturing activities 'in scope')
- Principle
- Part A General Guidance
- Part B Specific Guidance on Selected Product Types:
  - ➢ B1 Animal Sourced Products
  - ➢ B2 Allergen Products
  - ➢ B3 Animal Immunosera Products
  - ➢ B4 Vaccines
  - ➢ B5 Recombinant Products
  - ➢ B6 Monoclonal Antibody Products
  - ➢ B7 Transgenic Animal Products
  - ➢ B8 Transgenic Plant Products
  - ➢ B9 Gene Therapy Products
  - ➢ B10 Somatic and Xenogeneic Cell Therapy Products and Tissue Engineered Products
- Glossary

The scope, principles and Part A reflect the structure of the original Annex 2, with updated guidance. Part B, the specific guidance, is a major change (and for the most part an improvement) to the structure and content of the Annex.

EU GMP Annex 6: Medicinal Gases

A revised version of Annex 6, Manufacture of Medicinal Gases, was issued in February 2010 and became 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 GMP Annex 13: Investigational Medicinal Products

This revised guidance was adopted by the European Commission on 31 January 2010 and came into operation on 31 July 2010.

The main changes are:

- Reinforcement of the principle of independence between production and quality control functions in cases where the number of personnel involved is small
- Changes to sections 36 and 37 to supplement the guidance for reference and retention samples given in Annex 19
- An additional note has been introduced to clarify the meaning of 'reconstitution' as referred to in Article 9.2 of Directive 2005/28/EC
- The content of the Batch Certificate referred to in Article 13(3) of Directive 2001/20/EC, agreed following a separate public consultation, has been added as an attachment
- A few editorial changes have been made to sections not consulted upon in the interests of updating references and consistency with terminology used throughout the GMP Guide

Rest of World

Brazil

Brazil has revised their pharmaceutical Good Manufacturing Practice requirements, effective from 19 April 2010. This replaces the GMPs which had been in place from August 2006. GMPs for pharmaceutical products from the Mercado Com'un del Sur (MERCOSUL) areas are incorporated into this revision. MERCOSUL represents a regional trade agreement including the countries of Argentina, Brazil, Paraguay, Uruguay and Venezuela. Bolivia, Chile, Colombia, Ecuador and Peru currently have associate member status.

Industry News

UK Changes

MHRA Guidance on Out-of-Specification (OOS) Results

The MHRA is working to produce a guideline on the investigation of OOS results. They have been sharing a draft of this guidance at a symposia held at their London headquarters. The MHRA has stated their intention to make the guidance compatible with the 2006 FDA Guidance on OOS and, perhaps, form the basis for EU guidance eventually. It is likely to be finalised before the end of 2010 and we will provide a detailed review as soon as it is published.

Maintenance of Active Pharmaceutical Ingredient (API) and Other Sites Named on Marketing Authorisations (MAs)

The MHRA has published a reminder to marketing and manufacturing authorisation holders that as all sites named on approved marketing authorisations can be used for the activity they have been registered for, without further variation or provision of evidence of GMP compliance to the MHRA, it is important that all named sites are fully maintained as approved suppliers and thus available for use.

The MHRA guidance is:

- All API manufacturing sites named on UK marketing authorisations must be actively maintained as approved suppliers (in line with EU GMP expectations)
- The MHRA regards all API manufacturers that are registered on UK marketing authorisations to be approved to supply without further notice and with immediate effect; sites without proven documented GMP compliance status cannot be regarded as an effective back up supply source of starting material
- As a minimum the supplier approval process must be supported by evidence of effective GMP compliance of the API manufacturing site(s). It is expected that this will be confirmed via audit of the API manufacturing site by or on behalf of the relevant manufacturing authorisation holder. Audits should have been conducted at intervals not exceeding three years, by persons with appropriate training and experience, to confirm the current GMP status of the site
- Any API manufacturer listed on a UK marketing authorisation that has not been maintained as an approved supplier, does not meet the EU requirements for starting materials to have been manufactured in compliance with EU GMP requirements
- The MHRA can inspect API sites named on marketing authorisations at any time where GMP compliance status is unknown or suspected to be deficient. Confirmation of non-compliance can result in regulatory action being taken by the MHRA
- Companies not wishing to maintain back up API manufacturers to GMP requirements should remove them from marketing authorisations by submission of a Type 1A variation change code A.7.

FDA

21 CFR Part 11 Focused Inspections

On 8 July 2010 the FDA announced that it is to start conducting inspections that focus on 21 CFR Part 11 (Electronic Records and Signatures).

Although the latest guidance was published in 2003 (Electronic Records; Electronic Signatures – Scope and Application) the agency has not cited any violations against 21 CFR Part 11 since then. The few violations relating to electronic records and signatures that have been recorded since then have always cited 21 CFR Part 211 (the cGMP Regulations).

The reason for the change is that the FDA wants to evaluate the industry's understanding of, and compliance with, Part 11 to help them to decide on the next steps. Depending on the findings from the inspections, options range from taking no action at all to rewriting the regulation and guidance completely.

The new approach has already started (inspectors have been trained) and questions about Part 11 compliance may be incorporated into any FDA inspection (PAI, routine GxP or'for cause' inspection). 'Enforcement discretion' as defined in the 2003 guidance, e.g. related to validation, audit trails, record retention, record copying, and legacy systems continues to apply. The inspections are not expected to last any longer than originally planned.

These Part 11 focused inspections are expected to continue until the end of 2010 when it is anticipated that enough information will have been gathered to enable the FDA to make decisions about the way ahead.

Mandatory Recall Bill

A Bill has been introduced to the US House of Representatives to give the FDA the authority to order mandatory recalls of drugs posing an imminent threat to health. The bill, if passed into US law, would give the FDA power to order immediate cessation of distribution and a recall when it believes a drug could cause serious harm to humans or animals.

Representative Ed Towns introduced the Bill. He is chairman of the US House Oversight and Government Reform Committee and in this capacity has criticised Johnson & Johnson's handling of quality control concerns at its McNeil Consumer Healthcare division.

Medical Devices News

Improvements to the 510(k) Process

The FDA has released two preliminary documents with a series of recommendations on how to improve the 510(k) system [1].

The 510(k), or pre-market notification, process is the regulatory path whereby the FDA clears a device for marketing in the US if a company can prove its device is "substantially equivalent" to one already on the market. The FDA allows devices to take this path, instead of requiring the company to go through the complete PMA process, for devices that are considered less dangerous and/or are part of a well understood class of devices. The 510(k) process is usually faster and less costly for the sponsor than the PMA process, which requires the sponsor to show the device is safe and effective. The PMA process generally requires at least one major clinical trial, while a sponsor can often prove substantial equivalence for a 510(k) with relatively little new clinical data.

In recent years, some agency staff and outside observers have questioned whether the 510(k) system is allowing devices to enter the market without sufficient assurance of safety or effectiveness. Some observers, including critics in Congress, maintain that the rules for 510(k)s have loopholes that allow companies to market new technology in the guise of previously approved devices. On the other side, manufacturers and their lawyers have complained that the agency's handling of 510(k) applications is unpredictable, inconsistent and not transparent, thereby hindering device development and preventing innovative technologies from reaching the market.

The first set of the FDA's preliminary recommendations, announced on August 4, focuses on ways to "strengthen and clarify" the 510(k) process. The second set of the FDA's preliminary recommendations, released the same day, evaluates how the Center for Devices and Radiological Health (CDRH) uses science to make decisions "with an eye towards adapting to new scientific information, while maintaining regulatory predictability necessary for innovation", the agency explains in a release announcing both documents.

The first set of recommendations was created by the 510(k) working group of representatives from across the FDA CDRH, which gathered input from CDRH employees and managers and a range of external constituencies. Among the highlights of the first document is the FDA's acknowledgement that pivotal terms in the definition of "substantial equivalence" are unclear and that the agency should clarify those terms in guidance for industry and new training for its reviewers and managers.

The working group found that "substantial equivalence to a predicate" is generally a reasonable standard to ensure that the device is safe and effective, but that "current FDA regulations and practice may allow for some types of predicate comparisons that are insufficient to consistently provide such assurance". For example, some 510(k)s are predicated on devices that have already been withdrawn from the market due to issues of safety or effectiveness.

Also, some 510(k)s have been cleared based on equivalence to so called "split predicates", whereby the new device is compared with one older device with respect to its intended use and another with respect to its technological characteristics. "The use of a split predicate is akin to combining different attributes of more than one device into a single, non-existent predicate device whose risks and benefits are unknown", the working group concludes.

It recommends that the FDA work with stakeholders to create new rules for when a device can or cannot be used as a predicate and that CDRH consider explicitly disallowing "split predicates".

The second document, written by the CDRH's task force on the utilization of science in regulatory decision making, recommends that the CDRH improve the ability of its staff to access high quality information about regulated products because currently "challenges related to CDRH's current data sources, methods and administrative practices make it difficult for the Center to efficiently and effectively obtain complete information about the risks and benefits of regulated products across the total product life cycle".

The document also stresses the need for the CDRH to address its "staffing needs" and to "enhance processes and systems that support centerwide integration" while also taking advantage of external scientific expertise.

The task force concludes that "In addition to improving its internal co-ordination and communication, the CDRH must improve the communication of its current thinking and expectations to outside stakeholders and remedy the current lack of transparency about the rationale for some of its decisions".

Why Training Plans Can Help Performance

In the current climate, training professionals are being hit hard by both the regulators and their managers as they try to fit the compliance needs of the business with the educational and learning needs of the individuals within the organisation.

On the one hand the business is continually cutting training budgets and trainers' headcount and on the other there is a high expectation from individuals to be developed within the business in order to feel valued and wanted.

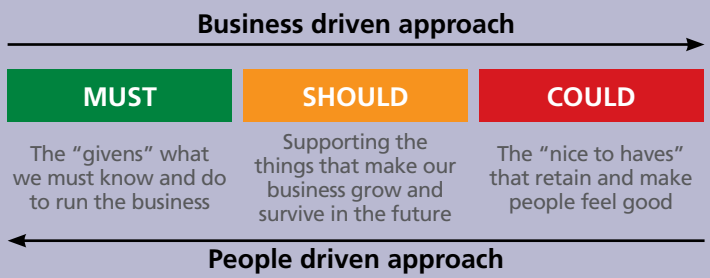
As a result, training in the manufacturing area is a poor reflection of what the business needs or individual requires to perform their role effectively. Managers and supervisors are repeatedly being asked to act as trainer for the process and this leads to restrictions in training for core processes and to SOPs being used for 'Read and Understand' status, with discussion with an experienced operator offered if you're lucky. No wonder QMS topics continue to be high on the list of repeat observations. Understanding of process and technology cannot be given in a 15 minute local briefing.

Regulators demonstrate that they understand the need for education and learning for professionals in the manufacturing and laboratory sectors. They are increasingly asking for evidence of training plans for roles, and for evidence of progress and measurement of effectiveness in performance.

So what does this mean in Practice for your Training System?

The production of an effective training plan for each role requires collaboration between the training function, HR and the line manager for the particular role. Generally QA will need to validate that the right amount of quality and GMP training is included.

Training and education provided within an organisation can generally be categorised in three ways, MUST, SHOULD and COULD training.



1. MUST training for the individual is all of the training and education the individual needs to perform their role effectively. This should be started by the induction to role process and continued until they are performing proficiently. Depending on the complexity of the role this could take up to two years. This level of support for the individual should be monitored by line management and training professionals to ensure training effectiveness and development of skills and knowledge. There should be a combination of training techniques from instruction and demonstration by experienced practitioners to classroom education. This development of the individual fits firmly into the scope of the training plan per role.

   DBA has been supporting this process for the Qualified Person role for many years. The training plan for this role has been established at the industry and regulator level. Attendance and completion of the modules has provided companies with the assurance of performance and effectiveness that is required by the regulators.

   Companies should also consider how these same training and education courses can support the performance levels of other QA professionals, manufacturing supervisors and pharmaceutical technicians, within their training plan.

2. SHOULD training is generally the training and educational topics that are brought into use either for the individual, or for the business, when there is a need to have an extra level of competency. An example would be as part of the individual's PDP, a development project, introducing a new product or piece of equipment.

   Most companies have to invest in this type of training to stay competitive, to keep the business moving and to maintain the high standards required by the industry.

   Stretching and developing individuals is essential for business growth; unfortunately, ensuring that individuals have the right skills and knowledge in their 'kit box' is all too often overlooked as a component that ensures successful completion of the project. In-house programmes and external training by DBA are providing the support companies need to get projects off to the right start or to coach and develop individuals so that they can achieve the targets set by their managers.

If you need help on how to prepare training plans for your organisation contact

3. The last category in the training course menu will be the COULD topics. These are related to strategy and retention of individuals. Having the time and resources to investigate the feasibility of a new direction for the company or the individual will add to the company's ability to anticipate future challenges and plan for the longer term. This information is generally obtained through seminars or journals that talk to the individual rather than engage them in discussion about application.

This last category offers the least payback in terms of today's performance and should be restricted within a company's budget; however this is not always the case. When given the opportunity to select their own development solutions from a list of training providers or external courses/seminars, the individual is likely to choose the seminar or forum where they may not be challenged and can go unnoticed in the crowd. COULDs are associated with the 'next promotion' or being a 'manager', so is more appealing to the individual than to their manager who wants to see improved performance.

The difference between business centred performance and individual centred performance is by planning, preparation and good training solutions. Taking the time to prepare the training plan for the role and considering the best solutions for performance will indeed give the manager more control over how their staff utilise their development opportunities. Staff are paid to fulfil a role; it is critical to get their performance in that role up to a good standard sooner rather than later. Training and educational support provided by DBA has been proven to enhance performance in the workplace, in the job and role for better performance today.

In the next edition Martin Lush will cover "Getting more from your Training Budget"

me on amd@dba-global.com

'HELP'

Human Error Learning Practices Group

Over 600 delegates have benefited from our course on '**Human Error: Causes and Prevention**'. Feedback is consistently outstanding… have a look on our website and see for yourself ('Customer Feedback' tab); delegates tell us our course is unique and the best available. They also tell us that the tools and techniques covered actually work in reducing the frequency and severity of human error!

To help you reduce costly errors and mistakes DBA will launch a 'HELP' group later this year. This will provide a forum for sharing ideas and best practice in 'error reduction'. What's more, **membership is free**. This is how it will work:

- Members will have free access to the latest information, regulatory developments, research, and practical tools and techniques for error reduction via our website
- Free membership is restricted to those who have attended our course on 'Human Error: Causes and Prevention'. Access will be password controlled
- Applying for membership is simple. All you have to do is send us at least three examples of tools, techniques and methods you've used to reduce human error! These will be 'anonymised' and added to the appropriate section on the web page. **If all eligible members apply you will have access to over 3,000 tools and techniques for error reduction.** What a resource! Sections will include:
  - ➢ A 'discussion forum' to post questions and ask for advice
  - ➢ The latest regulatory developments and requirements
  - ➢ The most recent academic research on error reduction
  - ➢ What other industries are doing to reduce human error
  - ➢ Practical tools and techniques submitted by members and proven to work

What next? In the next few months you will receive an invitation to join. If you don't respond don't worry, we won't bother you again!

For those who share our passion for error reduction you will be just a few clicks away from potentially 3,000 solutions!

For further information, please contact mkl@dba-global.com

Batch Records and Product Release Procedures

Are you at Risk?

If ever you want to be jolted out of your early morning slumber just pick up a recent edition of 'The Gold Sheet'. If this publication is new to you get a copy immediately; it provides a sobering reminder of what the FDA is finding in the pharma world and the devastating consequences of 'getting it wrong'.

'Record Drug Recall Totals for 2009 Resulted from GMP Breakdowns' (May 2010)

'Enforcement on Steroids: FDA Delivers Twice the Drug Warning Letters' (April 2010)

Once read, and suitably 'jolted', obvious questions quickly come to mind; "How did this mess happen?" "How can such catastrophic failures go unnoticed?" Any recall also brings into question the security and integrity of the Batch Manufacturing Record (BMR) and Product Release procedures that allowed the batches in question to escape.

The BMR and the Product Release procedure is a critical part of your Quality System. Vital information on the who, what, when, how and where is reviewed and considered before that all important decision is made. "Do I or don't I?" "Do I release, reject or what?" For those involved in this process the pressures are immense. Decisions are rarely 'black and white' or clear cut; more usually a shade of grey. Time and commercial pressures are usually acute and the ever increasing complexity of your supply chain doesn't help. Despite these challenges the Product Release process must be efficient, robust and above all safe.

Based on the worsening recall statistics some companies are clearly falling short of the mark; way short. So how good is your BMR? How safe is your Product Release process? Are you 'at risk'? Consider your responses to the following:

1. Do you release product *just* based on the BMR?... *if you do, start worrying!*

Product can only be released when you are **absolutely sure** that the quality system supporting manufacture is 'in control'. Release can *only* be justified when you *know*, rather than assume, that fully trained operators have used the right materials and components, followed procedures, operated clean, fully calibrated and maintained equipment within its validated state and followed the rules of GMP. To support batch release you simply must have access to Quality System 'performance measures' that tell the truth and nothing but the truth. Releasing product without accurate and reliable performance measures is a bit like a pilot landing 'blind' without dials and gauges; very dangerous. You may get away with it for so long but you will eventually crash. Before any 'yes' decision you must have the data to prove the Quality System is in control. This means having *immediate* access to information such as:

- Audit and self-inspection reports for the entire supply chain
- Change control history: have all changes been implemented successfully? What is the cumulative impact of minor changes?
- Repeat deviations: why have they happened again?
- Equipment calibration and maintenance status and trends: is equipment being operated within validated parameters?
- Contractors: are they being managed and controlled?
- Training and education 'status' of all involved, including contractors and 'temps'
- Performance of key utilities (trend data for water, steam, gases, etc)
- Environmental control
- SOP status: are they all current, available and being followed?
- Cleaning and sanitisation

2. How many double check signatures does your BMR contain?... *if you have lots start worrying!*

Some people have this bizarre, but understandable, notion that lots of double check signatures mean the process is safer and more secure. We now know that the opposite is true.

Signatures are there for a purpose. They tell us who did what and when. Signatures are also very personal, reminding people they are responsible and accountable for their actions. Double or 'check' signatures are also there for a reason. These are reserved for those vital tasks that, if done incorrectly, can have a dramatic impact – weighing and adding materials and components, calculations, line clearances, reconciliations, approval of sterilisation charts and the like. When we insist on *too many* check signatures two things happen. Firstly the importance of the *genuinely* important tasks gets lost when operators are told everything is important. As operators struggle to get the job done there is also the danger that 'signing' becomes a 'tick box' exercise. The second consequence of excessive signatures is even scarier, encouraging *less* accountability and responsibility.

Years ago I was involved in helping a company investigate a costly packaging related recall. The cause was simple enough, an incorrect expiry date. What I found fascinating was that over 80 people had seen and signed to confirm that the expiry date was correct. Not one person picked up the error… I'm convinced many had signed without even checking the label and accompanying documents, assuming that others before them had done the job. So there you have it, the more signatures you have the more worried you should be!

3. Size matters. The bigger your BMR the more worried you should be

We were recently called into a company to help reduce their BMR 'error rate'. Over 38% of BMRs were returned to manufacturing because of mistakes and errors; the usual missing signatures, incorrect calculations and missing data causing costly delays and huge frustration. It became clear that the operators, a disciplined and committed bunch, were actually being distracted by the size and complexity of the 270 page BMR.

BMRs are usually a product of evolution. As the product and process evolves through to Phase 3 Clinical Trials the BMR inevitably gets thicker and more complex before it finally becomes 'registered'. No one sits down and thinks about content, format and design and making the documents easy to use. We helped one of our clients reduce the size and complexity of their BMR, achieving dramatic results… all in three days.

- A 270 page document was reduced to 20 pages in total
- Data entries were reduced by 27% (you will be amazed what you record and don't use!)
- Double signatures were reduced by 68%
- The 270 page BMR took, on average, 60 minutes to review and approve. The slimmer version took only 15 minutes
- Most importantly the BMR 'error' rate reduced dramatically. After six months of use less than 1% of BMRs required correction

So, as far as most BMRs are concerned, less is more.

If you would like to dramatically improve the security and robustness of your BMR and Product Release process please drop me a line at mkl@dba-global.com.

Our intensive two day course:

How to Simplify and Improve Your Batch Record Review Process

23 and 24 September 2010, Manchester, UK

will provide you with the tools and techniques to:

- Decide what should stay in the BMR and what can be removed
- Reduce the number of unnecessary signatures that do more harm than good
- Improve document design to make your BMR user friendly
- Reduce the time required for review and approval
- Reduce the number of errors and reworks
- Improve the security and robustness of your Product Release process

If you can't make the course, don't worry. We can come to you and run this workshop on your premises working alongside your subject experts.

DBA People

Departures and Arrivals

Summer of 2010 has seen the departure of one old friend and the arrival of two new ones.

The End of an Era – Ann Bowley Retires!

Ann Bowley, the longest serving staff member of DBA, retired on Friday 23 July, bringing to an end an association lasting almost 24 years! The Company was established on 16 April 1986 and Ann (as Ann Passey at that time), following some part-time work, became DBA's first full-time secretary in November of that year, making the 'head count' three in all!

The occasion was celebrated with a farewell dinner earlier in July, attended by the partners, associates and Ann's office colleagues. In addition, Dr Lori Bestervelt (Senior Vice-President & Chief Technical Officer, NSF) was able to attend the event.

Bob Pietrowski and former managing partners Mike Bowsher and David Begg all thanked Ann for the outstanding contribution she has made to the development and success of the company and, more importantly, her service to all our clients and customers. Anyone who has attended our training courses or used our other services will have come into contact with Ann. She has been a fantastic ambassador for DBA and, not surprisingly, is well known to many pharmaceutical company personnel world-wide. Ann will be sorely missed from the team, not just as a colleague, but for her enthusiasm, friendliness and professionalism.

For the future, she and husband Peter, who are ardent Francophiles, intend to relax and spend as much time in the warmth of Southern France as possible!

Ann leaves DBA with our heartfelt thanks and we are sure you will join us in wishing Ann and Peter a very long, happy and enjoyable retirement.

Bob (Pietrowski) and David (Begg)

Samantha Clack

We are delighted to announce that we have once again strengthened our Associate Consultant team with the welcome addition of Samantha Clack.

Samantha is a biologist with experience in manufacturing, batch release, auditing and most recently in the management of a quality team for a new solid dose unit.

Samantha has an interest in the development of the quality and pharmaceutical professional, having recently been involved with the Pharmaceutical Quality Group (PQG) as coordinator and mentor for trainee QPs. Before becoming a consultant Samantha worked for Eisai and Eli Lily. She is eligible to act as a QP and we are delighted to welcome her to the team.

Anne Davies joins DBA

We are delighted to announce that Anne Davies joined the DBA team in Kirkbymoorside, as Customer Relations Manager

Anne has 30 years' experience in the Pharmaceutical Industry, with a range of roles under her belt. She joined Fisons in Cheshire as a laboratory technician and progressed on the site, which is now part of the Sanofi Aventis group, through various roles in Quality, Manufacturing and Human Resources, where she developed the role of site Training Manager. Latterly Anne has been working in the Global arena for both Sanofi-Pasteur based in Lyon, and GSK Biologicals based in Belgium.

Outside work Anne enjoys walking, reading, bird watching and fishing. The latter passion she shares with husband Tom, who has patiently supported Anne through relocations and house moves to finally enjoying the wonderful countryside of North Yorkshire. Anne has a daughter, Jenny, who is pleased they are back in the UK so that they get to spend more time together, which could involve some quality shopping time!

Anne brings her experience and knowledge of training systems within a pharmaceutical environment to the team, allowing DBA to align itself to the ever changing needs of the customer. Customer Relations Manager is a new role which, we believe, will strengthen our commitment to achieving the best for the customer.

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.com

Charity and the Lunacy of the Long Distance Runner!

Since our last journal three members of the DBA team have raised, with your support, over £4,300 for charity by putting one foot in front of the other. Martin Lush completed his third London Marathon for Children in Distress and, in true emphatic style, Sharon Bone, Martin's secretary, ran her first 5K race for Cancer Research UK. Bob ran the Edinburgh Marathon, on the hottest day of the year, for Macmillan! So, on behalf of us all, THANK YOU very much for your support and kind words of encouragement!

Also worthy of note is that the Kirkbymoorside 10K, organised and sponsored by DBA, has celebrated its tenth anniversary. Voted one of the best races in the UK, the 'Kirkby 10' has raised over £10,000 to help fund and support two local schools. Long may this continue!

DBA International Healthcare, Consulting & Education Experts

DBA Opens Office in South Africa

We are delighted to announce that on 1 July 2010 DBA opened an office in South Africa, from where we now offer our services of high quality auditing, consultancy and training to the pharmaceutical industry throughout Southern Africa.

The office is led by Dr Allan Thomas, who has been a friend to the Partners of DBA for nearly 20 years and who has an excellent reputation with the local industry in Africa. Allan will be providing DBA's well respected services himself and, where necessary, will call upon the staff of the UK and US offices.

Allan is a pharmacist by training and has over 25 years' experience of pharmaceutical manufacturing as well as pharmacy higher education. He has held executive posts in manufacturing, QA and R&D and has contributed to numerous successful plant design projects. His specialist knowledge of contamination control, pharmaceutical water systems, process validation, plant automation and TQM, allied to his experience and pragmatism, enable Allan to provide world class advice, consultancy and training to pharmaceutical companies in the region. Indeed, he has already consulted widely for pharmaceutical, biomedical, blood fractionation, veterinary and defence contractors and has written training programmes for companies in TQM/GMP and validation of computerised systems.

To find out how Allan and DBA South Africa can assist your company, contact us at…

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Faerie Glen
0043
South Africa

Tel: +27 (0)714 999 614
Fax: +27 (0)86 568 1887
Email: ajt@DBA-global.com

Forthcoming Training Courses

These will be held at the Glenhove Conference Facility, 52 Glenhove Road, Melrose Estate, 2196, Johannesburg, Gauteng, SA

Pharmaceutical GMP
Tuesday 25 to Friday 28 January 2011

Pharmaceutical Risk Management
Wednesday 23 to Friday 25 February 2011

ICH Q10: Pharmaceutical Quality Systems
Wednesday 23 to Friday 25 March 2011

Congratulations to...

In the past few months, DBA has helped the following people obtain QP status:

- Nigel Morton, Norgine Ltd
- Richard Brown, Rosemont Pharmaceuticals Ltd
- Shawn Murtough, Penn Pharmaceutical Services Ltd
- Ian Birch, Roche Pharma AG, Germany
- Claire Montgomery, Brecon Pharmaceuticals Ltd

In the next DBA Journal:

Industry News: As ever we search for regulatory changes so you don't have to; Tech Talk: 2010 Report Card for Quality, Operational Excellence and Improvement in the Pharmaceutical/Biotechnology Industry; DBA People: Exciting new additions to our team to enhance our services worldwide; Forthcoming Courses: A review of our education programmes for early 2011; Plus: All the latest news for Qualified Persons and Technical Professionals in the field of pharmaceuticals, medical devices and nutraceuticals. 25 Years of DBA and Developments on the DBA Website.

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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