DBA

The Journal of David Begg Associates

Issue 13 Autumn 2009

Steam Quality

What's all the fuss about?

DBA Devices

A New Service to the Medical Devices Industry

An NSF International Company

DBA-global.com

welcome

Bob Pietrowski, Managing Partner David Begg Associates

Doing More With Less

So, the summer break is now just a distant memory, the days are getting shorter and you are back at work to face the usual challenge – how to do more with less!

As former industry employees, we know exactly what that is like. In fact it's the major reason we left industry to build DBA – not to run away from the challenge of doing more with less, but rather to use our skills and experience to help you to save time, money and hassle by doing more with less.

I can see some of you smiling sarcastically, thinking "How can we save money by giving it to you?" But we honestly believe that our training, audits and advice will save you much more than they cost.

Take our training, for example. Our courses are specifically designed to develop your people, streamline your systems and eliminate wasteful practices.

Then there is auditing. Our **pre-inspection audits** can save you many thousands through first time approvals and the extra sales that result, while our unique **benchmarking audits** allow you to compare your quality systems with the industry's best. We will tell you where more effort is needed, but more importantly we will tell you where you can save valuable effort, money and resource, so you can improve your compliance, your efficiency and your competitive edge.

So why not let us help you? We know that you will benefit from our assistance and we will get the professional satisfaction of having improved your business – for you and for the patient.

Bob Pietrowski
Managing Partner

DBA The Pharmaceutical Training Specialists

DBA Analytical

Dietary Supplements cGMPs – How DBA Analytical is helping industry achieve cost-effective compliance

More and more people around the world are taking dietary supplements as part of a personal wellness program. These consumers have a right to know that the supplements they purchase have been produced in a quality manner, do not contain contaminants or impurities, and are accurately labeled. To help ensure this, FDA ruled in June 2007 that, in the interests of public safety, compliance with its current good manufacturing practices (cGMP) regulations for dietary supplements (21 CFR Part 111) will become mandatory for all manufacturers. However, to limit disruption to supply, especially for small manufacturers, FDA opted for a three year phase-in of compliance. Thus, companies with more than 500 employees had to be compliant by June 2008, those with 20-500 employees by June 2009 and small businesses with fewer than 20 employees by June 2010.

The path to compliance is by no means easy and requires knowledgeable and dedicated personnel at all levels within the business. Fortunately, DBA Analytical recognized this need for cGMP training and guidance nearly ten years ago by working collaboratively with NSF's Dietary Supplements Program, which offers GMP registration, as well as product and ingredients certification.

So far this year, DBA Analytical has offered two extensive training classes on 21 CFR 111, the Current Good Manufacturing Practices in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements. Each class has taken place at NSF's headquarters in Ann Arbor, MI, USA and, to date, courses have been well attended with enormous praise for the knowledgeable trainer and relevance of information.

Here is what one participant thought of the training

"I attended a Dietary Supplement GMP training course with DBA Analytical at NSF headquarters in Ann Arbor in January 2009. I found the course material to be very relevant and the instructors to be quite knowledgeable. The course was very helpful in attaining our certification through NSF in May of this year. I would highly recommend this course to any of my peers looking to bring their companies into a state of compliance"

Martin Frazzini, QA Manager, Ashley-Martin Mfg. LLC, USA

The 2-day course features Dr. Norm Howe as trainer and is designed for individuals involved in a range of activities in the dietary supplements industry, including manufacturing, auditing, quality control/assurance, laboratory operations, labeling, suppliers and distributors, as well as regulatory affairs. Course participants learn about the history of cGMPs, the Code of Federal Regulations, Pharmacopoeias and Guidance, FDA background information including what to expect during an FDA audit, not to mention specific information on GMPs for dietary supplements and guidance on implementation into a facility.

DBA Analytical plans to hold a cGMP course on the East Coast later this year – please watch for details. If you can't wait that long, we would be happy to offer you an in-house course. Please contact Casey Coy for more details **ccoy@dba-global.com**.

Finally, DBA Analytical will be exhibiting at one of America's most prestigious dietary supplements trade shows, Supply Side West, which will take place in Las Vegas, November 9th – 10th. If you are planning to attend, please drop by and see all that we have to offer.

For additional information on NSF GMP Registration, Product Certification or Ingredient Certification, please visit www.nsf.org/business/dietary_supplements or contact David Trosin at 734-827-6856 or by email at dtrosin@nsf.org.

Tech Talk

Steam Quality – *What's all the Fuss About?*

Whenever we carry out audits of sterile products manufacturers we invariably ask questions regarding approaches to steam sterilisation, which leads inexorably to discussions on steam quality.

If we are auditing a manufacturer outside the European Union (or, more precisely, outside the United Kingdom and Ireland) and we ask how the quality of steam used for sterilisation purposes is confirmed, we almost always get an answer something like this …

"We regularly sample condensed steam and analyse it for compliance with water for injection standards."

Whilst such a sampling and testing procedure can confirm the **purity** of the steam, it fails to answer questions regarding the **quality** of the steam for sterilisation purposes. To do this, it is necessary to assess certain other physicochemical attributes: namely…

- superheat
- dryness fraction
- non-condensable gas content

In this article we will try to answer the two most important questions concerning steam quality…

- why is steam quality so important to achieving effective sterilisation?
- if it is so important, why don't the regulators demand regular steam quality testing?

Why is Steam Quality so Important?

To answer this question, we must first understand how steam under pressure kills microorganisms, and this requires an understanding of the thermodynamic properties of steam.

Cast your mind back to your schooldays and the first time you placed a bunsen burner under a beaker of water and measured the water temperature with a thermometer. As the bunsen burner imparted heat (energy) to the beaker of water, so the temperature rose until the water reached boiling point. Then what happened? The bunsen burner continued to put energy into the water, but the temperature remained the same (100°C if you were at sea level). So what was happening to all this energy, if the temperature was no longer rising? The answer is that the energy was bringing about a **phase change** in the water; it was converting it from a liquid (water) to a gas (steam).

The energy required to raise the temperature of 1 gram of water by 1°C is 1 calorie (4.2 kilojoules). By contrast, the energy required to convert 1 gram of water into 1 gram of steam without any increase in temperature is 540 calories (2268 kilojoules). This energy is known as the **latent heat of vaporisation**.

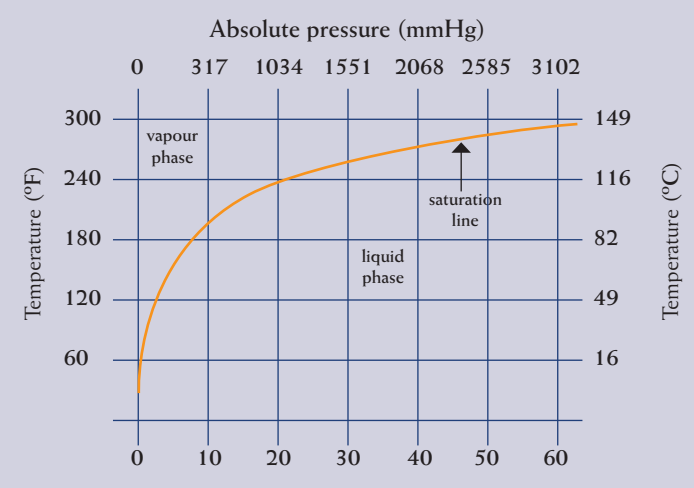
Thus, steam contains two types of heat…

- **sensible heat**, which you can measure with a thermometer
- **latent heat**, associated with the phase change

When steam comes into contact with a cool object it condenses, releasing the latent heat of vaporisation and the sensible heat associated with the drop in temperature. Hence, steam under pressure at 1.1 barg has a temperature of 121°C. When it meets a cool object, for example an item of equipment in an autoclave, and condenses and cools to 120°C, it gives up 1 calorie of sensible heat and 540 calories of latent heat. It is the energy associated with the latent heat which is largely responsible for the killing effect of steam.

But this energy release and subsequent killing effect only occurs if the steam is on the point of condensing – it is what we call **dry, saturated steam** or **phase boundary steam**.

Figure 1.
Relationship between *temperature* and pressure for steam saturation



Steam above the phase boundary line (see Figure 1) is **superheated**. It is not on the point of condensing and so will not give up its latent heat of vapourisation on contact with a cooler object until the temperature drops to that of the phase boundary – which may never happen during the sterilisation phase of an autoclave cycle. Thus, superheated steam is a very ineffective sterilising medium.

Common causes of superheated steam are…

- additional external heating, for example by an autoclave jacket which is hotter than the chamber
- rapid expansion of steam from a narrow distribution pipe into a large autoclave chamber – so-called adiabatic expansion

Although steam will not exist below the phase boundary line, steam containing droplets of water will be **wet**, which will both reduce its efficiency as a sterilising medium and may also result in wet loads.

Common causes of wet steam include…

- failure to remove entrained water droplets in the steam generator
- inadequate condensate removal from the steam distribution system – infrequent or inappropriately placed condensate valves

Finally, if steam contains significant quantities of **non-condensable gases** (air or other gases which don't condense into water when steam is cooled) then these gases can accumulate within equipment to be sterilised and insulate against the sterilising effects of steam by stopping steam from coming into direct contact with a non-sterile surface and releasing its latent energy.

Common causes of non-condensable gases include…

- poor steam generator design or performance
- ingress of air into steam distribution systems via faulty pipework or faulty valves

From all the above, it should be clear that, for steam to be an effective sterilising medium, it should be…

- saturated, and not superheated
- not too wet
- free of significant levels of non-condensable gases

If Steam Quality is so important, why don't the Regulators take a greater interest in it?

This is a difficult question to answer. Perhaps it is due to lack of education. Perhaps it is due to an understandable desire to place emphasis on microbiological confirmation of sterilisation efficiency (via bioindicators) rather than on less direct, physical measures.

However, at least two European regulatory authorities do demand steam quality testing. They are the UK's MHRA and Ireland's IMB. Both make reference to two important sources of guidance relating to testing and acceptance criteria…

- Health Technical Memorandum 2010, "Sterilization"
- European Standard EN 285: Sterilization – Steam Sterilizers

Failure to conduct steam quality tests or to comply with the acceptance criteria contained within these documents is considered to be a serious GMP failure by these regulatory agencies.

It is our firm belief that companies should regularly test their steam for superheat, dryness fraction and non-condensable gases, not because the regulators demand it, but because it is a central component of a Quality Assurance system for our steam sterilisation procedures. So just because your regulatory agency doesn't demand it, it doesn't mean that you shouldn't do it.

This and many other issues relating to steam sterilisation will be discussed in detail during our ever-popular training course **"Good Autoclave Practice"**, to be held in Manchester on 3-5 November 2009.

Industry News

Pete Gough reviews the latest international regulatory changes and proposals

EU NEWS

"Certain Excipients"

Directive 2004/27/EC amended Directive 2001/83/EC to state that, in addition to APIs, "certain excipients" must be made in accordance with GMP. Moreover, it stated that a list of the "certain excipients" would be published as a separate Directive. This was a ridiculous piece of legislation that could never have worked (see DBA Journal issue 6). It is no surprise, therefore, that the EU has backtracked.

In February 2008 the Commission published an independent analysis of their survey of manufacturers and users of certain categories of excipients on various policy options. In total, 285 validated responses were assessed and summarised by an external contractor, Europe Economics. The report concluded that a Commission Directive on GMP for excipients, as currently foreseen in legislation, would lead to increased costs and no benefit to patients. This report would seem to support the strongly argued industry position that the problems seen with excipients such as glycerol contaminated with ethylene glycol in Haiti were due to criminal activity that the application of additional GMP regulation would not address.

In early June 2009 the Commission stated "Following the publication of the report on an impact assessment study by an external contractor DG Enterprise and Industry has taken the decision not to continue with the preparation of a Commission Directive on GMP for certain excipients as originally foreseen in Article 46(f) of Directive 2001/83/EC. The results of a public consultation conducted by DG ENTR have confirmed concerns previously raised by stakeholders and experts from Member States regarding the lack of flexibility of the current legal basis, which stipulates for a list of certain excipients for which conditions of GMP should be applied and which should be established in implementing legislation."

So there will be no list of "certain excipients" that must be made in accordance with GMP. However, the Commission went on to say, in a rather long winded way, that the concept of requiring appropriate controls on the manufacture of excipients is a good one. Their view is now that those appropriate controls should be determined and ensured by *the user* (not the producer) using a risk-based approach following Annex 20 of the EU GMP Guide (ICH Q9).

Concerns regarding counterfeiting and adulteration of pharmaceutical starting materials will mean that there will continue to be a focus on controls for excipients, even though the Directive requirement for "certain excipients" is going away. The focus will, rightly, be on all excipients rather than a certain, special few. It is likely that the baseline GMP standard for excipients will be the IPEC/PQG guide that was first published in 2006.

UK NEWS

MHRA GMP Inspection Findings

The MHRA has published several documents giving details of recent inspection findings on their website at: http://www.mhra.gov.uk/Howweregulate/Medicines/Inspectionandstandards/GoodManufacturingPractice/FAQ/Commondeficiencies/index.htm

On the same web page they give the number of critical and major deficiencies reported and identify the top five serious issues from the 40 classifications used for 2007 and 2008. These are:

For 2007

- Number of relevant Inspections (total): 598
- Number of critical deficiencies reported: 28
- Number of major deficiencies reported: 838

The top five deficiencies:

- Investigation of anomalies
- Documentation (QMS, procedures)
- Quality management
- Supplier audit and technical agreements
- Change control/management

For 2008

- Number of relevant Inspections (total): 369
- Number of critical deficiencies reported: 34
- Number of major deficiencies reported: 793

The top five deficiencies:

- Investigation of anomalies
- Quality management
- Quality management (change control)
- Complaints and product recall
- Corrective action/preventive action (CAPA)

Thus, change control, investigation of deviations, CAPA plans and overall Quality Management continue to be major areas of regulatory criticism by MHRA. Perhaps the only surprise here is that industry does not seem to be improving.

If you have concerns about the effectiveness of your change and deviation management systems, the following DBA courses may be just what you need….

Essential Elements of a Quality Management System

Manchester, UK
9-12 November 2009

How to Simplify and Improve Your Change Management System

San Juan, Puerto Rico
19-20 November 2009

Concept Paper project to consolidate and simplify UK medicines legislation

A Concept Paper to bring about much needed consolidation and simplification of UK medicines legislation was published by the MHRA in early January 2009. Numerous amendments to the UK Medicines Act since its adoption in 1968 and the growing number of Statutory Instruments (SIs) – some to amend previous SIs – have resulted in a very complex and fragmented set of legal provisions which are unwieldy to use and complicated to explain or understand. This creates difficulties and burdens both for MHRA as the regulator and for the regulated industry.

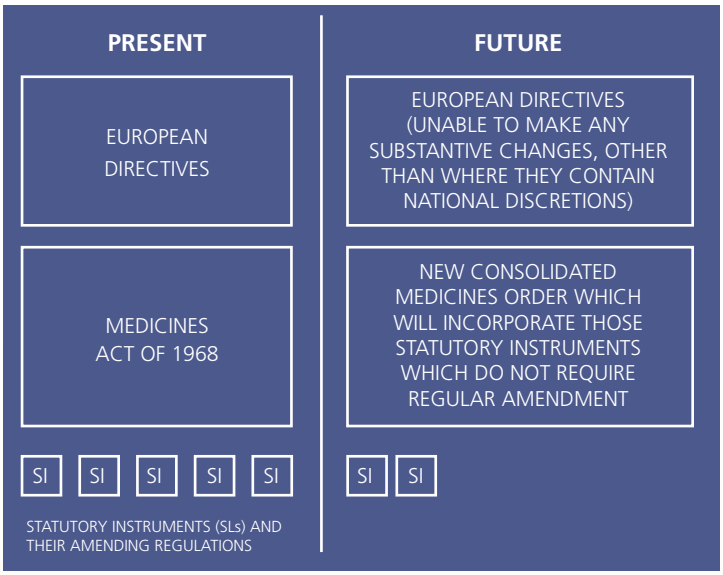
The proposal is for a project consisting of two strands running, where possible, in parallel. Strand 1 will focus on the **consolidation** of existing national legislation; Strand 2 will focus on the potential **simplification** of legislation.

The project will cover all national legislation governing medicines for human use, including homoeopathic and herbal medicines. European Community medicines legislation will be included within the scope of the project; however, the MHRA will not be able to make any substantive changes to the Community law, other than where it contains national discretions. Therefore, in terms of possible reforms and simplification, the focus will be on national legislation.

The MHRA propose to achieve the consolidation (Stage 1) by way of a Legislative Reform Order (LRO). This is a new type of legislative measure that can be used to amend primary legislation. This is a significant benefit because it can avoid the need to secure a place for a new Bill in the legislative programme, so speeding up the overall process. However, as it is not suitable to introduce significantly new or controversial legislative measures, some of the proposals that emerge from the review may require other types of legislative change. The MHRA hope to have a consolidation Order prepared, by the spring of 2010.

Industry News

The present and potential future structures for UK medicines legislation are shown below:



Stage 2 of the project will be to conduct a review of the legislation with a view to simplifying it. The Concept Paper states, "The review stage of the project will be characterised by numerous consultations and analysis of responses on these priority issues. We envisage that this period of consultation will extend well in to 2010."

Something of an underestimate, we think!

Veterinary Product Licences

Effective 1 April 2009, the responsibility for veterinary only licences moved from the Medicines and Healthcare products Regulatory Agency (MHRA) to the Veterinary Medicines Directorate (VMD).

This change applies to any new applications or variations to existing Veterinary Manufacturing Authorisations and Veterinary Wholesale Authorisations naming only sites which deal with Veterinary Products.

Licensing activities now covered by the VMD include:

- Receipt, processing and issuing applications for new authorisations
- Receipt and processing of variations for existing authorisations
- Invoicing and collecting fees

Inspection activities cover:

- All inspection activities relating to new applications for new authorisations
- All inspection activities relating to variations for existing authorisations
- Routine re-inspection
- Issuing post-inspection Good Manufacturing Practice (GMP) Certificates
- Updating European Medicines Agency (EMEA) systems which require information relating to Manufacturing/Importation authorisations and post-inspection GMP certificates
- Any other activity relating to authorisations or inspections

USA NEWS

US "Responsible Person"

The "US Draft S882 Drug and Device Accountability Act of 2009" is before the US Senate for consideration. One fascinating concept that this draft introduces is that of a "Responsible Person". The legislation would require that each drug and device submission be certified by the "Responsible Person" defined as a "senior officer or director of the sponsor of such submission with knowledge of, and management responsibility for, such submission".

It will be intriguing to see how this concept develops, both in the USA and, if successfully implemented, elsewhere.

ICH NEWS

Q8, 9 and 10 Implementation Working Group (IWG)

A formal Question and Answer document was published in April 2009 and is available from the ICH website. It covers the following topics:

- Quality by Design:
- Design Space
- Real Time Release Testing
- Control Strategy
- Pharmaceutical Quality System
- ICH New Quality Guidelines' Impact on GMP Inspection Practices
- Knowledge Management
- Software Solutions

Some of these issues will be discussed in detail in our new course **"Practical Application of Quality by Design"**, to be held in Manchester, UK, on 1-2 December 2009.

Q11 API Development

The Expert Working Group met again in Yokohama, Japan, in June 2009 but no draft has been produced yet.

OTHER WORLD NEWS

Canada updates its GMPs

Health Canada has finalised their revised GMP guidance document (GUI-0001). This new document was issued on 8 May 2009 and becomes effective on 8 November 2009, superseding the 2002 edition.

The principle changes include measures that seem to introduce expectations similar to those for EU Qualified Persons:

- In section C.02.006, Personnel, new expectations have been delineated for the individuals in charge of the quality control department for all establishments.
- Section C.02.014 (1) states the Regulation that: "No lot or batch of drug shall be made available for sale unless the sale of that lot or batch is approved by the person in charge of the quality control department." The following Interpretation 1 states "All decisions made by the quality control department pursuant to Regulation C.02.014 are signed and dated by the person in charge of the quality control department or by a designated alternate meeting the requirements described under Section C.02.006."

Other changes include:

- In section C.02.004, Premises, some interpretations have been modified to highlight expectations, and some interpretations have been clarified with respect to the facility requirements for highly sensitising drugs.
- In sections C.02.025 and C.02.026, Samples, some interpretations have been modified to highlight expectations regarding sample containers, and retention within Canada.
- Minor changes to several other sections.

In addition, the Canadian Health Products and Food Branch Inspectorate have issued notification of their intention to adopt the EU requirements pertaining to sterile vial crimping. The revised crimping requirements will be implemented as of 1 March, 2010, following the release of a second version of the GMP guideline (GUI-0001).

ASEAN Sectoral Mutual Recognition Arrangement

At the April 2009 14th ASEAN Summit and Related Summits in Pattaya, Thailand, the ASEAN Economic Ministers signed the ASEAN Sectoral Mutual Recognition Arrangement (MRA) for Good Manufacturing Practice (GMP) Inspection of Manufacturers of Medicinal Products.

This MRA will permit the mutual recognition of GMP certifications and/or inspection reports issued by ASEAN region inspection bodies who are parties to the MRA. These certificates and/or inspections reports will then be used as the basis for regulatory actions.

The benefits include reduced business costs for manufacturers since they do not need to subject their products to repetitive testing or certification process.

All these new developments and more will be discussed in much more detail during our one day *"Pharmaceutical Legislation Update"* course, to be held in Manchester, UK, on Wednesday, 28 October 2009.

Forthcoming Courses

What's planned for the rest of the year

Mathematics & Statistics

Qualified Person & Professional Development Training

York Marriott Hotel, York, UK

14-17 September 2009

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: **£2524.00 plus VAT** (First Booking)
£2019.20 plus VAT (Additional Bookings)

Free Seminar for Prospective QP Trainees

FREE SEMINAR

York Marriott Hotel, York, UK

15 September 2009

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.

Qualified Person Sponsor Seminar

FREE SEMINAR

York Marriott Hotel, York, UK

16 September 2009

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 Institute 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.

Applying ICH Q10: Pharmaceutical Quality System

Marriott Philadelphia West, Philadelphia, PA

21-22 September 2009

ICH Q10, Pharmaceutical Quality System, is an industry-led initiative to provide much needed, modern day guidance on the design, implementation and operation of a relevant and effective Quality Management System. Its adoption will have a profound impact on the way we work in the future. Learn how best to apply this groundbreaking philosophy by someone who wrote it!

Course Fee: **$1775.00** (First Booking)
$1420.00 (Additional Bookings)

Applying ICH Q10: Pharmaceutical Quality System

Marriott San Mateo, San Mateo, CA

24-25 September 2009

ICH Q10, Pharmaceutical Quality System, is an industry-led initiative to provide much needed, modern day guidance on the design, implementation and operation of a relevant and effective Quality Management System. Its adoption will have a profound impact on the way we work in the future. Learn how best to apply this groundbreaking philosophy by someone who wrote it!

Course Fee: **$1775.00** (First Booking)
$1420.00 (Additional Bookings)

Pharmaceutical GMP

Manchester Marriott Victoria & Albert Hotel, Manchester, UK

21-24 September 2009

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: **£2210.00 plus VAT** (First Booking)
£1768.00 plus VAT (Additional Bookings)

Human Error: Causes and Prevention

EXTRA COURSE

Hilton Manchester Deansgate Hotel, Manchester, UK

28-30 September 2009

An extra course added to our programme by popular demand following our sell out course in May! 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 methods to reduce errors in the workplace.

Course Fee: **£1690.00 plus VAT** (First Booking)
£1352.00 plus VAT (Additional Bookings)

Sterile Products Manufacture

Manchester Marriott Victoria & Albert Hotel, Manchester, UK

28 September – 1 October 2009

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: **£2210.00 plus VAT** (First Booking)
£1768.00 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 The Pharmaceutical Training Specialists

Practical Aspects of Controlled Temperature Storage and Distribution

NEW COURSE

London Marriott Hotel Kensington, London, UK

28-30 September 2009

An intensive three day course designed to help you to understand current EU and FDA requirements for the design, qualification, validation and ongoing control of all systems associated with controlled temperature storage and shipment of pharmaceuticals, from manufacture to the patient.

Course Fee: **£1690.00 plus VAT** (First Booking)
£1352.00 pus VAT (Additional Bookings)

Linking Pharmaceutical Quality and Pharmacovigilance Systems

NEW COURSE

London Marriott Hotel Kensington, London, UK

2 October 2009

Recent legislation and guidelines on pharmacovigilance places clear responsibilities on the Quality function, and the Qualified Person, and not just upon the Clinical professionals within pharmaceutical companies. This one day seminar will explore the role of Quality staff and QPs in ensuring that pharmacovigilance systems are effective and meeting the full requirements of the regulators.

Course Fee: **£675.00 plus VAT** (First Booking)
£540.00 plus VAT (Additional Bookings)

Pharmaceutical Law

Quality Leadership Program

NEW COURSE

Royal Sonesta Hotel, Boston, MA

5-7 October 2009

The launch of our ground-breaking Quality Leadership Program in the USA. This first module covers 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** (First Booking)
$2160.00 (Additional Bookings)

Senior Management Seminar

By Invitation Only

The Future of Quality Management

London Marriott Hotel, Kensington, UK

6-7 October 2009

Two day senior management seminar – by invitation only.

How to Simplify and Improve Your Documentation System

achieve

Manchester Airport Marriott Hotel, Manchester, UK

13-14 October 2009

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

Course Fee: **£1280.00 plus VAT** (First Booking)
£1024.00 plus VAT (Additional Bookings)

GMP for Clinical Trials Manufacture and Supply

Manchester Marriott Victoria & Albert Hotel, Manchester, UK

19-22 October 2009

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

Course Fee: **£2210.00 plus VAT** (First Booking)
£1768.00 plus VAT (Additional Bookings)

Pharmaceutical Law & Administration

Qualified Person & Professional Development Training

Hilton York Hotel, York, UK

19-23 October 2009

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: **£3105.00 plus VAT** (First Booking)
£2484.00 plus VAT (Additional Bookings)

Satisfying EU GMP Requirements for Sterile Products Manufacture

Hilton Boston Financial District, Boston, MA

20-22 October 2009

Current EU GMP requirements for sterile products manufacture are the most stringent and probably the most confusing on the planet! We will explain the GMP regulations to you, describe the rationale behind them, and advise you on how to comply with them in a pragmatic and cost-effective way.

Course Fee: **$2675.00** (First Booking)
$2140.00 (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 the rest of the year

How to Perform Effective Product Quality Reviews

Manchester Airport Marriott Hotel, Manchester, UK

27 October 2009

Chapter 1 of the EU GMP guide now includes a requirement to carry out periodic reviews of all licensed medicinal products. 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: **£675.00 plus VAT** (First Booking)
£540.00 plus VAT (Additional Bookings)

Pharmaceutical Legislation Update:

Continuing Professional Development for Qualified Persons and Technical Personnel

Manchester Airport Marriott Hotel, Manchester, UK

28 October 2009

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: **£675.00 plus VAT** (First Booking)
£540.00 plus VAT (Additional Bookings)

Human Error: Causes and Prevention

San Francisco Marriott, Fisherman's Wharf, San Francisco, CA

3-5 November 2009

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

Course Fee: **$2675.00** (First Booking)
$2140.00 (Additional Bookings)

Good Autoclave Practice

Manchester Marriott Victoria & Albert Hotel, Manchester, UK

3-5 November 2009

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: **£1690.00 plus VAT** (First Booking)
£1352.00 plus VAT (Additional Bookings)

EU GMP and Inspection Readiness

San Juan Marriott Resort & Stellaris Casino, San Juan, Puerto Rico

3-5 November 2009

We will explain to you the key differences between US cGMP regulations and EU GMP requirements and provide you with clear advice on how to prepare for an EU inspection, how to manage the inspection to a successful conclusion and how to respond to any inspectional findings.

Course Fee: **$2675.00** (First Booking)
$2140.00 (Additional Bookings)

Essential Elements of a Quality Management System

Manchester Marriott Victoria & Albert Hotel, Manchester, UK

9-12 November 2009

Designed to provide the prospective Qualified Person or any pharmaceutical professional with all they need to know to be able to design, implement, monitor and maintain a cost-effective quality management system to current international regulatory requirements, including the imminent ICH Q10, "Pharmaceutical Quality Management Systems".

Course Fee: **£2210.00 plus VAT** (First Booking)
£1768.00 plus VAT (Additional Bookings)

Risk-Based Decision Making

San Juan Marriott Resort & Stellaris Casino, San Juan, Puerto Rico

16-18 November 2009

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: **$2675.00** (First Booking)
$2140.00 (Additional Bookings)

Analysis & Testing

Qualified Person & Professional Development Training

Hilton York Hotel, York, UK

16-20 November 2009

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 EU and US GMP expectations for the QC laboratory.

Course Fee: **£3105.00 plus VAT** (First Booking)
£2484.00 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.

A Practical Interpretation of Annex 1

Marriott Philadelphia West, Philadelphia, PA

17 November 2009

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

Course Fee: **$900.00** (First Booking)
$720.00 (Additional Bookings)

Environmental Monitoring for Sterile Products Manufacture

Marriott Philadelphia West, Philadelphia, PA

18-19 November 2009

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

Course Fee: **$1775.00** (First Booking)
$1420.00 (Additional Bookings)

Aseptic Simulations

Marriott Philadelphia West, Philadelphia, PA

20 November 2009

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

Course Fee: **$900.00 (First Booking)**
$720.00 (Additional Bookings)

How to Simplify and Improve Your Change Management System

San Juan Marriott Resort & Stellaris Casino, San Juan, Puerto Rico

19-20 November 2009

The control of planned and unplanned changes is perhaps the greatest challenge facing any pharmaceutical company and its quality management staff. We will provide you with proven techniques to simplify your change control systems, making them quick and efficient whilst at the same time ensuring compliance with regulatory requirements.

Course Fee: **$1775.00** (First Booking)
$1420.00 (Additional Bookings)

Quality Aspects of the CTD

Hilton York Hotel, York, UK

23-26 November 2009

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: **£2210.00 plus VAT** (First Booking)
£1768.00 plus VAT (Additional Bookings)

Medicinal Chemistry

Quality Leadership Program

Royal Sonesta Hotel, Boston, MA

30 November-2 December 2009

The second module of our groundbreaking Quality Leadership Training in the USA. In this module you will learn how the body works and how the major classes of drugs interact with the body to cure or alleviate disease. Plus, key drug interactions and contra-indications – essential to planning cleaning and cross-contamination strategies.

Course Fee: **$2700.00** (First Booking)
$2160.00 (Additional Bookings)

A-Z of Pharmaceutical Water Systems

Manchester Marriott Victoria & Albert Hotel, Manchester, UK

30 November-3 December 2009

This four 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 will ever need to know about water systems!

Course Fee: **£2210.00 plus VAT** (First Booking)
£1768.00 plus VAT (Additional Bookings)

Practical Application of Quality by Design

Manchester Marriott Victoria & Albert Hotel, Manchester, UK

1-2 December 2009

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 Testing (PAT) will have an immense impact on the way we design and develop manufacturing processes, how we register those processes and how we control manufacturing 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: **£1280.00 plus VAT** (First Booking)
£1024.00 plus VAT (Additional Bookings)

Pharmaceutical GMP

Amsterdam Marriott Hotel, Amsterdam, The Netherlands

7-10 December 2009

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: **£2310.00** (First Booking)
£1848.00 (Additional Bookings)

EU GMP and Inspection Readiness

San Francisco Marriott, Fisherman's Wharf, San Francisco, CA

15-17 December 2009

We will explain to you the key differences between US cGMP regulations and EU GMP requirements and provide you with clear advice on how to prepare for an EU inspection, how to manage the inspection to a successful conclusion and how to respond to any inspectional findings.

Course Fee: **$2675.00** (First Booking)
$2140.00 (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

DBA USA

Neil Wilkinson transfers to Boston Office

We are delighted to announce that Neil Wilkinson has transferred from the UK to our US office in Boston.

Neil joined us a little over a year ago from AstraZeneca in the UK, where he was Senior Director, Global Quality, but it was always our intention to transfer him to Boston. He is currently moving to New England – his partner Janeen is based at Pfizer's Groton facility in Connecticut – and he will work out of our Boston office from 1 September.

Neil and Jim Morris make a formidable team of experienced pharmaceutical industry consultants who, along with our growing number of Associates, have the breadth and depth of knowledge to be able to add value to your organisation – as our rapidly expanding North American client base will readily confirm.

If you are attending the PDA/FDA meeting in September, why not come along to our stand and meet Jim and Neil? They will be happy to explore how DBA can help **you.**

Quality Leadership Program

A Masters degree in Pharmaceutical Quality Assurance and GMP for less than Temple charges for in-State students!

The first module of our groundbreaking Quality Leadership Program takes place in Boston in early October. Interest so far has been fantastic – not surprising when you consider that we offer delegates from all over the USA the opportunity to gain a Masters degree for less than Temple University charges its Pennsylvania students.*

What is more, you will receive top quality education from seasoned industry professionals and academics from one of the finest universities in the United Kingdom.

Graduates from our program in Europe – as well as those from in-house programs in the USA – have gone on to take up senior posts within their companies as a result of the skills they have obtained with us.

There is still time to register. Why not be a part of something special?

For more information, email infoQL@DBA-global.com or call our Boston office on 617-342-3625.

*If you take advantage of all the incentives on offer.

DBA USA adds three more Consultants to the Team

We are delighted to announce that we have added three more Associate consultants to our growing team. Glenys Foster Roberts, Norman Goldschmidt and Joe Habarta are all independent consultants in their own right, but are happy to be associated with the DBA brand and are looking forward to sharing their experience and skills with us – and of course with you.

Glenys Foster Roberts, PhD

Glenys is an Analytical Chemist with senior QC experience on a global scale and with generics industry background. She was the VP of Global QC at Barr until its acquisition by Teva. Glenys has extensive experience managing large scale QC laboratories, with a focus on compliance combined with effectiveness. Recent project work includes leading PAT initiatives and she has authored papers on the topics of PAT as it applies to the generics industry.

Glenys brings a wealth of technical and regulatory QC experience to the DBA USA team.

Norman Goldschmidt, BS

Norman is a Mechanical Engineer with over 25 years' experience primarily with Bristol-Myers Squibb where his last role was Senior Director of Global Engineering. Norman has managed teams of engineers and large capital projects including the installation of barrier syringe and vial filling lines, new laboratories, and R&D facilities worldwide. He has been the author on several ISPE Guides including the HVAC Guide, Biotech Guide and a reviewer on ISPE Water System Guide, and is an active instructor on pharmaceutical engineering related topics.

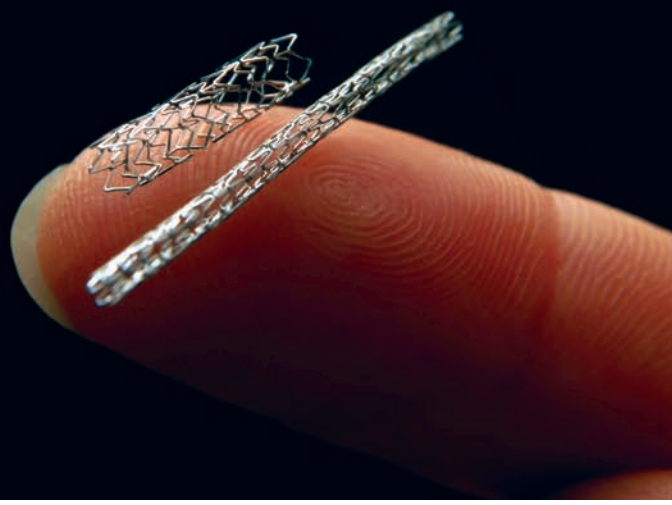
Joe Habarta, PhD

Joe has more than 35 years' experience in the healthcare, pharmaceutical and biopharmaceutical industries specializing in quality assurance, quality control and regulatory compliance in all phases of drug development, from pre-clinical to post-marketing.

Prior to establishing his private consultancy, Joe held numerous senior quality management positions for biopharmaceutical and international pharma companies, including Transkaryotic Therapies, Inc. (now Shire Human Genetic Therapies), and at Serono S.A. (now Merck-Serono S.A.), Astra Pharmaceuticals, Inc. and Ortho Biotech, Inc.

We believe that, overall, the quality of our staff in the US and in Europe cannot be matched by any other pharmaceutical consulting and training organization. Why not try us? We know you won't be disappointed!

DBA Medical Devices



Since our foundation in 1986, we have risen to become Europe's largest provider of pharmaceutical consultancy and training. We have an outstanding international reputation in the fields of pharmaceutical quality management and regulatory compliance.

This reputation has been built on two fundamental cornerstones…

- the quality of our people
- sticking to what we know best

We believe that a business like ours stands or falls on the quality of the people we employ. That is why we take great care to ensure that all the consultants at David Begg Associates have extensive pharmaceutical industry experience at senior technical manager level. Additionally, several of our staff have regulatory agency experience with MHRA. All our people have the experience and the skill to provide sound, practical advice and can benchmark our clients' systems against the very best.

Secondly, we strongly believe that if we cannot offer the quality of service that our clients have come to expect from us, then we won't tender for a project. We believe that admitting we are not the best people to use works in our favour in the long run. That is why we have historically turned away work from the medical devices sector. Although we have several staff with experience of devices, we have felt that we do not have the breadth of expertise in this area to offer the same quality of service as we provide to the pharmaceuticals sector…

UNTIL NOW!

After months of detailed preparations, we are delighted to announce that we have entered into a collaboration with Pink Associates of the United Kingdom to provide expert training and consultancy in the field of medical devices.

Pink Associates have the same philosophy towards quality of personnel and service as DBA and they stand out from the crowd in the devices world because of their industrial experience and unique approach to training. It is hard to envisage a better partner for us.

Pink Associates will from now on perform all their training and consultancy as David Begg Associates and we will be working closely together to develop new services for our pharmaceuticals and devices clients on a worldwide basis. We have already been accepted into the BSi UK Associate Consultant Programme and we intend to grow from a great start.

Right now, we can assist you and your company by providing expert consulting and training to help you…

- register your products internationally
- implement quality systems in compliance with ISO 13485:2003, Ordinance 169 and 21CFR Part 820
- prepare for a regulatory inspection
- implement cost effective product and process validation strategies
- benchmark your systems against industry best practice
- develop product specific design control and risk management strategies
- conduct supply chain audits

and in many other ways.

Meet The Team

James Pink, Principal Associate

James has 12 years' experience in the medical devices industry. He has extensive experience of auditing medical device manufacturers through his active involvement as a medical device lead auditor with the British Standards Institute. James is considered as an expert in medical device quality and risk management having undertaken extensive research relating to the modes of failure and their controls within high risk medical devices.

James has held senior technical management positions, notably as engineering and regulatory affairs director for Symmetry Medical Inc. where he was responsible for engineering and quality teams providing design and manufacturing solutions to the orthopaedic, cardiovascular and dental sectors. James provides significant expertise in the European medical device regulations, electro-mechanical testing (including ISO17025), risk management (ISO14971) and quality systems implementation (ISO13485, CFR21 Part 820 and Ordinance 169.

Ian Revie, Associate

Ian has over 15 years' medical device experience in various roles within Johnson & Johnson, covering product development for the hip implant business and developing new business opportunities through the development of technologies, products and markets in minimal access and computer assisted surgery. Ian has developed a passion for medical technology, conducting hospital based orthopaedic research at the point of care, developed regulatory strategies for new products in new clinical areas, worked through regulatory classification of high tech electronic high risk active devices with regulatory specialists and led regulatory high risk implant approvals during his career. His main areas of expertise include general high risk medical device design control, implementing quality management systems to ISO13485:2003 and the preparation and management of regulatory technical documentation in accordance with international regulatory requirements.

Bernard Sweeney, Associate

Bernard has over 25 years' experience in the medical device industry. He has a wide commercial, R&D and regulatory affairs background in international markets, gained from working with Becton Dickinson Ltd, Beiersdorf AG, Huntleigh Technology Inc. and Femcare Nikomed Ltd. Most recently he has been in charge of British Standards Institute (BSi) Healthcare Division, which included the Notified Body. During this period he set up operations in the USA and Asia for the division and has been actively working with a number of Asian regulatory bodies including India, China, Hong Kong and Malaysia to assist in introducing new regulations. Bernard is considered to be an expert on global regulations with an emphasis on Asia and has the background necessary to assist in developing a strategic approach to product launches within the new regulatory environment.

Janette Benaddi, Associate

Janette has more than 20 years' experience of managing pre and post market clinical studies in both devices and pharmaceuticals. Prior to founding Medvance 11 years ago, Janette worked in Paris for a medical device consultancy group as project director in clinical/regulatory affairs. Janette has also worked with several multinational organisations in various clinical, regulatory and marketing roles. Janette is a registered nurse, has a BSc in management studies, a Diploma in company direction, a Diploma in management studies. She holds a teaching certificate and is a chartered scientist. Janette is a board director of the Institute of Clinical Research and is also a chair elect. Janette has published several articles and sits on a number of committees involved in the regulation and standardisation of medical device studies.

Chris Weatherall, Associate

Chris has over 20 years' experience in the medical device and in vitro diagnostic industry. He began his career as a project engineer for Abbott Laboratories and has since held many senior engineering and quality positions within both major international and start up companies across the globe concentrating upon implementing and validating manufacturing operations through to the planning, implementation and management of medical device regulatory strategies and their supporting quality and regulatory requirements. Chris is a considered expert in product development, regulatory strategies, process validation and quality systems implementation, having over 10 years working with medical device manufacturers as a contract based consultant.

John Lang, Associate

John has over 25 years' in the pharmaceutical and medical device industry. He was corporate product safety assurance manager for the Smith & Nephew Group for 11 years and previously head of experimental biology, for 5 years. His career focus was initially in drug metabolism and pharmacokinetics and then expanded to include safety/toxicology assessment of medical devices, pharmaceuticals, tissue engineered products, and consumer products. John has been involved in the development of European and International Technical Standards for 17 years including ISO 10993, EN 12442 and ISO 22442, BSI RGM/1, ISO TC 194 SC1, ASTM F04 on Tissue Engineered Medical Products and ISO TC 229 on Nanotechnologies.

We will be adding to this formidable team in the coming months in order to provide our medical devices clients with the most comprehensive training and consultancy service available and we will shortly be advertising a series of specialised technical training courses for industry sectors. Please watch this space!

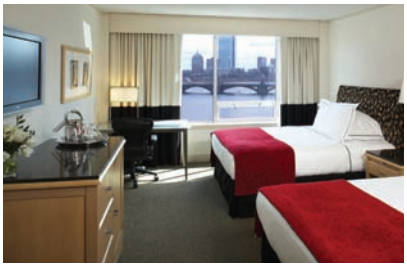
If you would like to take immediate advantage of our offerings, email us at Info@DBA-global.com We are here to help in whatever way we can.

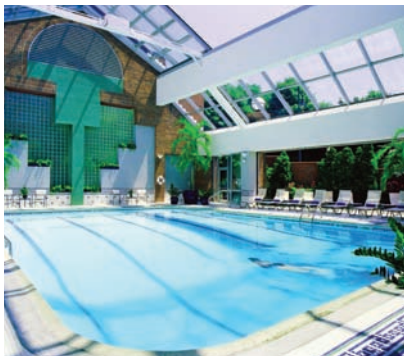
The Royal Sonesta Hotel **Boston**

The Royal Sonesta Hotel, Boston, will be the venue for our Quality Leadership Program, which begins October 5.

Once we had decided to offer our prestigious Quality Leadership Program in the US, choosing a home for the series of educational courses was relatively quick and simple. Boston is in many ways the ideal location for these courses: it has a long and impressive history and yet is vibrant and relevant to today – just like the Quality Leadership Program.

Boston has a wealth of excellent business hotels well suited to our needs, but the Royal Sonesta stands out. Situated on the Cambridge side of the Charles River and providing breathtaking views of the Boston skyline, it benefits from the relative calm of Cambridge during the day and easy access to the city and Cambridge/Harvard attractions in the evening.





Conference facilities at the Royal Sonesta are excellent and all bedrooms have high speed internet access to keep you in touch with the outside world. To help you unwind at the end of a strenuous day there is a superb Health Club and fitness center with a full range of exercise equipment and an indoor/outdoor pool.

The hotel boasts two riverfront restaurants, but just across the street is the Cambridge Side Galleria, where you will find a broad range of restaurants, as well as over 100 retail outlets where you can shop till you drop!

All in all, the Royal Sonesta Hotel represents a top quality but affordable venue for our flagship Quality Leadership Program. We know you will be blown away by both!

The DBA Quality Leadership Program starts October 5 at the Royal Sonesta Hotel. The Program comprises a series of 12 linked but independent modules to be held in Cambridge over a 2 year period, leading to a Postgraduate Diploma or Masters Degree in Pharmaceutical Quality Management and GMP. Students can join the series at any time during the series – you don't have to start on Module 1 and finish on Module 12. Nor do you have to attend every module, unless you specifically choose to work towards the Diploma or Masters.

The GMP/Pharmacovigilance Interface: Are you Fulfilling your Obligations?

Pharmacovigilance and the Pharmacovigilance Qualified Person

Pharmacovigilance is the surveillance of medicines in use to ensure that the **safety**, **quality** and **efficacy** of medicines are confirmed in clinical practice.

All pharmaceutical companies have a legal obligation to report adverse reactions associated with their products. Adverse reaction reporting applies to:

- EU Licensed marketed products - reactions occurring in the EU
- EU Licensed marketed products - reactions occurring abroad
- Products within a clinical trial taking place within the EU

There should be a nominee/group within each company to monitor adverse reactions and each company is required to have a "Qualified Person" responsible for ensuring that an effective pharmacovigilance system is in place. This pharmacovigilance QP is not the same as the QP for the manufacturing operations, although the use of the same term " QP" has caused confusion.

Companies within the EU are now receiving regulatory inspections that are solely reviewing the pharmacovigilance systems, often with unhappy consequences!

The Manufacturing Qualified Person

Chapter 8 of Part 1 of EudraLex Volume 4 (the EU GMP guide) states that all complaints and other information concerning potentially defective products must be reviewed carefully. A person should be designated responsible for handling complaints and deciding the measures to be taken. If this person is not the Qualified Person, then the QP should be made aware of any complaint, investigation or recall.

Thus, it is clear that the EU authorities expect the manufacturing QP to take a keen interest in all customer complaints so that potential manufacturing and/or quality issues associated with a batch or batches of product or products can be recognised and appropriate actions taken.

Relationship between the Pharmacovigilance QP and the Manufacturing QP

The Pharmacovigilance QP and the manufacturing QP have entirely different roles and responsibilities within a company; however, they cannot act independently.

- Adverse reactions may be caused by manufacturing or quality issues
- Trends in adverse reactions and side effects may possibly be related to manufacturing issues e.g. small amounts of contamination, impurities, changes to excipients or components etc
- Quality Complaints may be linked with an adverse reaction e.g. "This product doesn't taste or smell like it usually does and it made me feel dizzy"

In the latter case, the QC department may analyse the product and find it meets its specification and fail to report it into the pharmacovigilance system.

Therefore there is an essential need for both QPs to be aware of each other's responsibilities and areas of interest.

The Qualified Person in the manufacturing operations must ensure that he/she is familiar with the obligations of a company for ADR reporting and should understand how the system works at their own company.

It is an expectation by a number of EU Regulators that the manufacturing QP and the pharmacovigilance QP have some communication and interaction and means of assessing whether reported ADRs could be quality or manufacturing related, or indeed vice versa, where quality related complaints could be causing ADRs.

Exchanging summaries of complaints and ADRs and looking for common trends may be beneficial to both QPs.

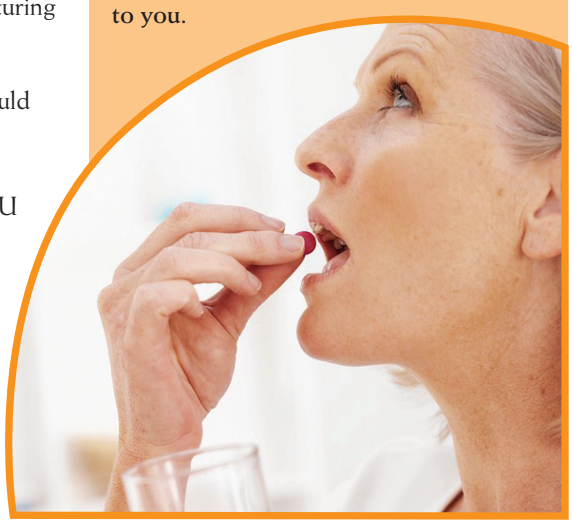
In Summary

- **EU is strengthening pharmacovigilance provisions**
- **Pharmacovigilance systems are subject to Regulatory inspections**
- **There is a clear need to ensure robust links exist between complaints and pharmacovigilance systems**

The message to both the GMP QP and the PV QP is to communicate with each other and find ways of sharing summaries of relevant data.

Are you fulfilling your obligations in this respect?

This and many other related issues will be discussed in detail during our new training course "Linking Pharmaceutical Quality and Pharmacovigilance Systems", to be held in London on Friday 2 October 2009. If you are unsure whether your current procedures meet EU expectations, this course will be of immense value to you.



Congratulations to...

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

Justin Ahern DDD Limited	Robert Clayton Warner Chilcott Ltd	Phillip Millward BOC Gases	John Tognarelli Roche Products Ltd

DBA The Pharmaceutical Training Specialists

PQG publications available from DBA

The UK Pharmaceutical Quality Group (PQG) publications, monographs and the PS9000 series, may now be ordered through DBA. We will have copies of all the publications available for viewing during our training courses and they may be ordered using the order forms which will also be available at courses or online via a link on the DBA website.

PQG Monographs on Pharmaceutical Quality Assurance

The PQG, together with many expert professionals in the industry and volunteers with many years experience, publish a series of globally acclaimed monographs.

The monographs are written by PQG members who are skilled and experienced within their own fields of interest and activity. They provide a collection of contemporary experience which is intended to be of assistance to the Pharmaceutical Industry by giving a wide practical background to Good Manufacturing Practice and Quality Assurance.

These monographs will be of particular interest to management and supervisory personnel engaged in the manufacture and supply of medicines, especially where they are involved in the training and education of staff.

Currently available monographs are:

- Pharmaceutical Auditing
- Cleaning Validation
- Pharmaceutical Packaging Validation
- Pharmaceutical Premises and Environment
- Pharmaceutical Manufacturing (Processing and Packaging)
- Elements and Philosophy of Pharmaceutical Quality Assurance
- Pharmaceutical Distribution
- Contract Manufacture and Analysis
- Pharmaceutical Documentation
- Good Control Laboratory Practice
- Microbiological Control for Non-sterile Pharmaceuticals (new March 2009)

PS 9000 Series for suppliers to the Pharmaceutical Industry

These standards are of particular interest to management and supervisory personnel engaged in the manufacture and supply of excipients and packing materials, especially where they are involved in the training and education of staff.

The series currently contains the following documents:

PS 9000

PS 9000:2001 is an application standard developed by the PQG for the manufacture of packaging materials for medicinal products. The document defines specific requirements and guidance for GMP integrated with ISO 9001.

PS 9004 Pharmaceutical Packaging Materials – A Guide to PS 9000.

The guide provides in clear language, the appropriate reason for each critical requirement contained in PS9000:2001 together with details of sources of further useful reference information. The guide is intended primarily to help with the education and training of supplier's staff but will also be useful for the training of appropriate pharmaceutical industry staff.

PS 9100

PS 9100:2002 is an application standard developed by the PQG for the manufacture of excipients for medicinal products. This code of practice defines specific requirements and guidance for GMP integrated with ISO 9001.

In the next DBA Journal

Industry News: As ever, we search for regulatory changes so you don't have to; Tech Talk: Combination Products – does a new category of products require a new approach to Quality Management? Location, Location, Location …: York – home to our Qualified Person training courses; DBA People: Helping you to get to know us better. Forthcoming Courses: A review of courses in early 2010. Plus: All the latest news for Qualified Persons and what's new at our UK and US offices.

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

David Begg Associates

Europe The Georgian House, 22-24 West End, Kirkbymoorside, York, UK, YO62 6AF
Tel: +44 (0)1751 432999 Fax: +44 (0)1751 432450 Email: mail@DBA-global.com

USA Suite 19, 101 Federal St., Boston, MA 02110, USA
Tel: 617-342 3625 Fax: 617-342 3623 Email: USinfo@DBA-global.com

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