

# Quality Leadership Program

Webinar  
July 8th 2009

# Webinar Agenda

- Welcome
- Who are David Begg Associates?
- Background to Program
- Quality Leadership Program Description
- Benefits – Why should you attend QLP?
- Questions and Answers

# Webinar 'Domestics'

- 30-40 minute presentation
- Opportunity for Q & A
  - Email to [njw@DBA-global.com](mailto:njw@DBA-global.com)
  - Via Webinar chat feature
- Materials available post webinar at [www.DBA-global.com](http://www.DBA-global.com)
- PLEASE MUTE YOUR PHONES

# Who are DBA?

- Founded by David Begg MHRA 1986
- The leader in Europe for Pharmaceutical Quality Consultancy and Training
- Premier provider of education program to meet EU Qualified Person requirements
- Global reach – including major US client base
- Purchased by NSF International 2007
- Boston office opened in 2008



# Partners & Consultants

- 6 Partners
- 18+ Consultants
- Offices in Kirkbymoorside UK and Boston USA
- Includes Pharmacists, Chemists, Biologists
  - An average of 30 years' industry experience, including senior management roles
  - API, Pharmaceutical, Biotech, Vaccines, Devices
  - Some ex-inspectors
  - Mostly QPs
  - ICH Q Industry Topic Leaders

# Partners & Associates



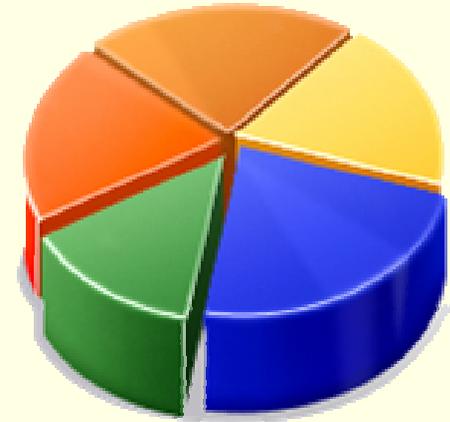
# The DBA Business

External training 36%

Internal training 34%

Consultancy 14%

QP training 16%



# Who are our Customers?

- Diverse customer base
- Multinationals
- Large and small companies
- CROs
- Originators and Generics
- Virtual start-ups
- IMPs and Commercial
- Pharma, Biotech, Vaccines
- EU, USA, Asia, ROW



# External Training

## *Strong Portfolio Delivered by Subject Experts*

### *May to Jun*

- Contamination Control for Non-Sterile Production
- EU GMP and Inspection Readiness
- Human Error: Causes and Prevention
- Engineering Aspects of GMP
- Satisfying EU GMP Requirements for Sterile Products Manufacture
- Preparing for the Future: Successful Implementation of ICH Q8, 9 and 10
- Effective Pharmaceutical Audits and Self-Inspections
- A Practical Interpretation of Annex 1
- Environmental Monitoring for Sterile Products Manufacture
- Process Simulations
- Active Pharmaceutical Ingredients
- Pharmaceutical Packaging GMP
- Achieving Operational Excellence: Effective Training: How to Improve Business Performance
- Supply Chain Assurance



### *Jul to Sep*

- EU Requirements for Clinical Trials
- Role & Professional Duties of the Qualified Person
- Preparing for the Future: Successful Implementation of ICH Q8, 9 and 10
- Mathematics & Statistics
- Pharmaceutical GMP
- Sterile Products Manufacture
- Practical Aspects of Controlled Temperature Storage and Distribution

# External Training

## *Strong Portfolio Delivered by Subject Experts*

### *Oct*

- Anti-counterfeiting Measures: Implications for Quality Professionals and QPs
- Linking Pharmaceutical Quality and Pharmacovigilance Systems
- Pharmaceutical Regulations
- Senior Management's Role in Driving Quality Improvement for Business Benefit
- Achieving Operational Excellence: How to Simplify and Improve your Documentation System
- GMP for Clinical Trials Manufacture and Supply
- Pharmaceutical Law & Administration
- Satisfying EU GMP Requirements for Sterile Products Manufacture
- How to Perform Effective Product Quality Reviews
- Pharmaceutical Legislation Update: Continuing Professional Development for Qualified Persons & Technical Personnel

*...in seven*

*different worldwide locations*

### *Nov to Dec*

- Human Error: Causes and Prevention
- EU GMP and Inspection Readiness
- Good Autoclave Practice
- Essential Elements of a Quality Management System
- Analysis & Testing
- Risk-Based Decision Making
- How to Simplify and Improve Your Change Management System
- Quality Aspects of the CTD
- A-Z of Pharmaceutical Water Systems
- Medicinal Chemistry
- Pharmaceutical GMP
- EU GMP and Inspection Readiness



# Internal Training

Some 60 to 70 courses in-house per year, 10 to 100s of delegates per course (including in-house QP programmes)



# Consultancy

Global support to the pharmaceutical industry:

*We don't just identify the issues –  
we provide pragmatic solutions and advice*

- Advice
- Pre audit preparation – EU & FDA
- Mock PAI
- Audits of suppliers and subcontractors
- Remediation plans after failed inspections

# EU Based Qualified Person Training

- 13 modules running over 2 years
- Currently in its 20<sup>th</sup> year (10<sup>th</sup> series)
- Typically 40-50 delegates per module
- 15,000+ delegate days of training so far !



# Background to the DBA Quality Leadership Program

- What are the key drivers?
- What do companies need?
- What are we offering in our unique program?

# The Pharma Environment Today

- True globalization
- Increased competition
- Cost constraint
- Demands for efficiency
- Developing international regulation

The companies which prosper will be those which can best adapt to a changing environment



# The Pharma Environment Today

- Supply Chain Complexity
- Product and Process Complexity
- Role of the Qualified Person not well understood outside EU and of increasing importance
- Principles of QP role equally applicable and desirable elsewhere



The companies which prosper will be those which best develop their people to lead within a changing environment

# Successful Companies Will Need

High caliber **Quality and Technical Professionals** throughout the organization (not just the Quality Unit) to...

- interpret international regulations
- take sound, risk-based decisions
- facilitate change
- drive Business benefit

**CREDIBILITY MATTERS!!**



# DBA's EU Qualified Person Training

- Provided in EU by DBA and University of Strathclyde since 1990
  - UofS is one of top 3 UK Pharmacy Schools
- Unrivalled reputation
- Trained over 200 QPs from all over Europe
- Over 3000 delegates attended individual modules



# US In-House Programs

- Offered as in-company training since 2004
- Based on elements of EU QP education program
- Past and current clients include forward thinking companies such as...

*Pfizer*

*Wyeth*

*Sanofi Pasteur*

*Genentech*

- Has it been successful?

# Client Feedback

“We decided that our US QA colleagues could benefit from the same formalized training as required for QPs in Europe. The results surpassed our expectations. The QA leaders who participated in the training have much greater confidence in their decision-making ability. DBA provided training that could immediately be used in their daily activities.”

**Gerry Migliaccio,**  
**VP Global Quality, Pfizer Inc**



# Client Feedback

“DBA’s course has made a difference in the short term by allowing our delegates to be more efficient in their daily jobs. Most importantly, DBA has provided them with the skills they will need in the long term to manage change and meet future challenges.”

**David Watson,**  
**Senior VP of Global Industrial Operations,**  
**Sanofi Pasteur**



# US Quality Leadership Program

## NOW PUBLICLY AVAILABLE FOR THE FIRST TIME

- Based on our tried and tested Qualified Person training
  - Greater emphasis on US issues
- Tutors as for QP training program
  - Additional US tutors
- Structure of training essentially similar as EU QP training
  - 12 modules over ~2 yrs
- Same University of Strathclyde involvement
  - Academic certification



# US Quality Leadership Program

- How is the US environment changing?
- Why is this important to your company?
- Why should you attend?

# US Quality Leadership Program

- Effective Quality Management is now already becoming a major focus of the regulators
  - FDA
  - EMEA
- For Good Business reasons it should also be a major focus of Senior Management
  - Focusing on Compliance only is not enough
  - It is a real Business advantage
- QLP provides a unique means of educating and developing key staff to facilitate this

# US Quality Leadership Program

- Drug and Device Accountability Act 2009
- Draft legislation from US Congress proposes drug and device submissions require certification by a “responsible person”
  - *“senior officer or director of the sponsor with knowledge of, and management responsibility for, such submission”*
- Proposes sanctions (sponsor and/or individual) if inaccurate or untruthful submissions made
- QLP program can educate Quality and Technical professionals to contribute to senior management governance processes

# US Quality Leadership Program

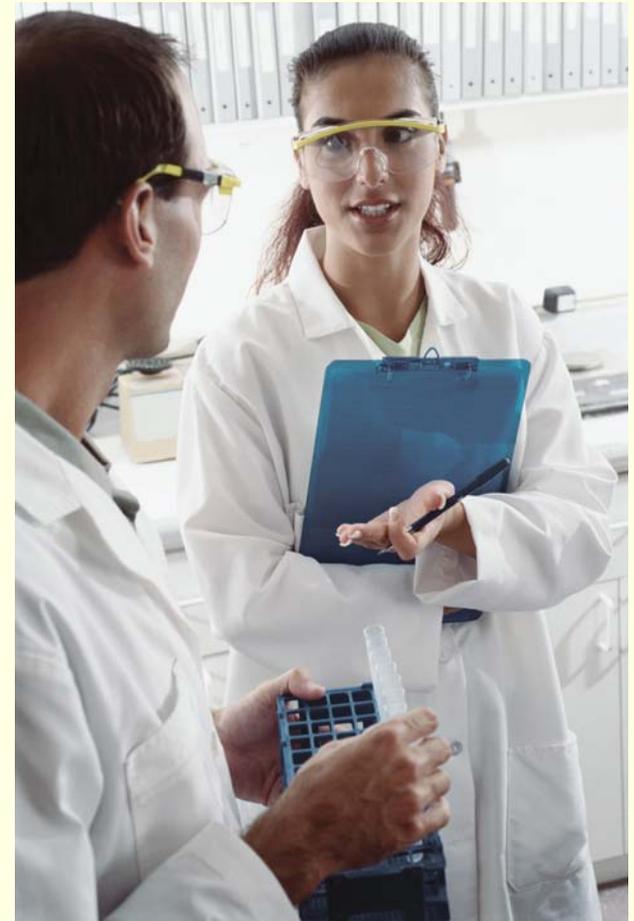
## The Modules

- Pharmaceutical Law
- Medicinal Chemistry & Therapeutics
- Formulation & Processing (2 modules)
- Pharmaceutical Microbiology
- Active Pharmaceutical Ingredients/Supplier Assurance
- Mathematics & Statistics
- Analysis & Testing
- Pharmaceutical Packaging
- Quality Management Systems
- Practical Module
- Investigational New Drugs
- Role of the Quality Leader

# QLP Benefits

Provide the key ingredients for individual and company success...

- KNOWLEDGE of laws, guidances, standards, products and processes
- EXPERIENCE in pharmaceutical manufacture and testing AND understand the business
- SOFT SKILLS - including team building, assertiveness, decision making, negotiations and professionalism
- LEADERSHIP - an ability to draw the line, take responsibility, take initiative and show true CONFIDENCE!



# QLP Advantage

## Postgraduate qualifications

- Students attending all modules can register for a postgraduate qualification...
  - Postgraduate Diploma
  - Masters degree

Awarded by the University of Strathclyde,  
Glasgow, UK

# QLP Advantage

## DBA and University of Strathclyde input

- Delegates are encouraged to select thesis topics which are relevant to their work
- Advice and counsel is provided as required by DBA and UoS
- QLP Alumni network

# QLP Advantage

## Flexibility

- **Core and non-core delegates**
  - Don't have to attend all modules in a single series
  - Can start and finish whenever you like
  - Freedom to attend individual modules for non-core delegates as 'one-offs'

# US Quality Leadership Program

## Summary

- Proven, effective development program for Quality Leaders, Manufacturing Leaders and Technical Professionals
- Delivered by seasoned industry professionals and academic experts
- Designed to improve the competitive edge of your business
- Flexibility to meet your needs

# US Quality Leadership Program

## Summary

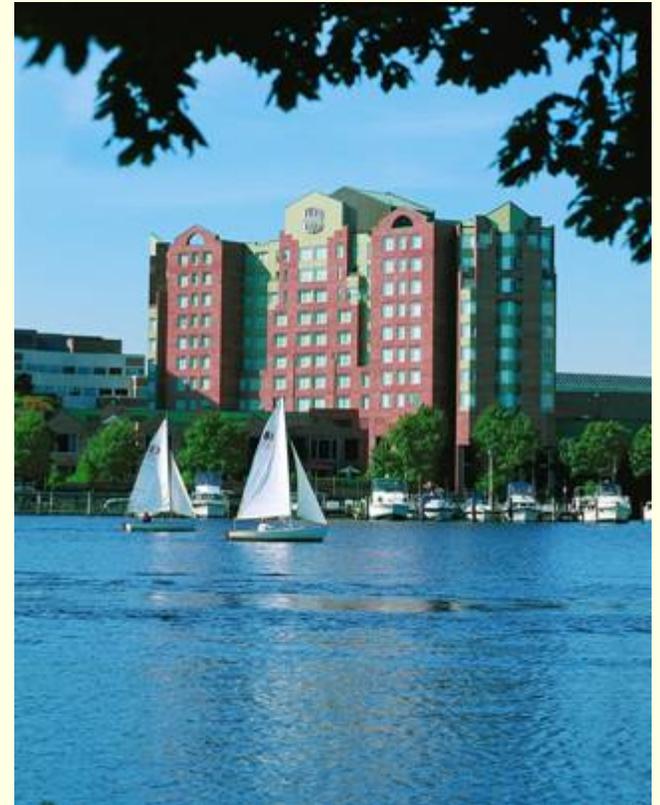
- Significant development opportunity for key individuals
- **Delivers** a broad Pharmaceutical knowledge base for the modern environment
  - Technical aspects of medicinal products
  - Regulations and Guidances
  - Quality Management Systems
  - Improvement tools and techniques
  - Leadership skills

**ALL IN ONE PROGRAM**

# FAQ

## Where and When

- Classes to be held at the Royal Sonesta Hotel, Boston
- Classes commence October 2009
- Series 1: October 5th 2009  
> October 2011



## How can I learn more? How do I register?

- Email [USinfo@DBA-global.com](mailto:USinfo@DBA-global.com)
- Call 617 342 3625
- Register at [www.DBA-global.com](http://www.DBA-global.com) for Module 1 Pharmaceutical Law today!!

Thank you

**DBA**

David Begg Associates

[www.DBA-global.com](http://www.DBA-global.com)

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