

# DBA

An NSF International Company

**Q** Quality  
Leadership  
Program

## Module 1

Monday 5 to Wednesday 7 October 2009

Boston, MA

## Pharmaceutical Law



University of  
**Strathclyde**

# Pharmaceutical Law

## About this Module

Pharmaceutical Law is a key knowledge requisite for the Quality Leader and Technical Professional. A thorough understanding of the laws and legal processes in the US, Europe and beyond is essential in today's global environment. Regulatory requirements drive many decisions during product development and during commercialization and managing changes in compliance with regulatory guidelines and the product license is often extremely complex. Decision makers must understand this context and think strategically.

This extremely popular module sets the tone for the Quality Leadership Program. It is designed to provide a thorough and detailed understanding of....

- The basis of pharmaceutical law – why it exists and what these laws seek to achieve
- The laws and legislative processes in the USA, EU, Canada, Japan and other key markets
- The regulatory framework for APIs, biological products, combination products and Investigational New Drugs
- The Role of the Quality Leader and the Qualified Person in Europe
- Latest developments and trends – what are the current hot button issues?

## Examples of the Course Content

- The Product Lifecycle from a Regulatory Perspective
- Pharmaceutical law as consumer protection legislation
- A comparison of international pharmaceutical legislation
- Structure of the FDA and EMEA
- Key GMP differences between Europe and the US and why these differences exist
- Definition of contract services and technical agreements
- Role of the Pharmacopeias, PICs, and ICH
- Regulatory submissions and the CTD
- Post Approval Changes in the US and Europe
- Impact of ICH Q8, Q9, Q10. and how businesses will benefit

Reserve your place today email: [infoQL@DBA-global.com](mailto:infoQL@DBA-global.com)



## Course Tutors



Neil Wilkinson  
David Begg Associates, UK



Pete Gough  
David Begg Associates, UK

## Module Format

The module consists primarily of lectures and case studies, but delegates are required to carry out some study in advance of each module using pre-read material provided by DBA. This material will be available 5 weeks before the start of the course. A pre-read review session is scheduled for the evening before commencement of the module. This is an optional session, but is highly recommended for delegates planning to take the exam associated with this module.

<b>Key Dates</b>	October 4	5 – 7 pm	Module 1 Introduction and Pre-Read
	October 5	8 am	Module 1 Opening
	October 7	5 pm	Module 1 End

**Venue** Boston Royal Sonesta Hotel tel: 617-806-4200  
40 Edwin Land Boulevard, Cambridge, MA 02142

# How This Training will Benefit You

Pharmaceutical Law is the first of 12 modules which constitute DBA's Quality Leadership Program. It is the cornerstone for the modules which follow and is the foundation upon which sound leadership is built.

It will provide the background and knowledge needed by every Quality Professional and Technical Leader whether in Production, Quality, R&D, Validation, Engineering, or any other technical discipline. As with all of DBA's QLP modules, it is led by industry and academic experts; frequently incorporating case studies and small group sessions to facilitate learning.

DBA's format of extended days and pre-work ensures that both you and your company benefit from the learning experience in an efficient way and with minimal time away from the workplace.

The Quality Leadership Program and this module on Pharmaceutical Law is based upon a key component of the Qualified Persons instruction which David Begg Associates offers in Europe. It sets a new standard for practical, results oriented instruction.

A Certificate is granted by DBA for attendance. Higher degree options – a Diploma and a Masters in *Pharmaceutical Quality and Good Manufacturing Practice* from the University of Strathclyde can be obtained by attending the full series.

## A Look at the Full Quality Leadership Program Series

Module 1	Pharmaceutical Law	Oct 5-7, 2009
Module 2	Medicinal Chemistry & Therapeutics	Nov 30 - Dec 2, 2009
Module 3, Part I	Formulation Processing Part I (non-sterile product)	Feb 2-4, 2010
Module 3, Part II	Formulation Processing Part II (sterile product)	April 7-9, 2010
Module 4	Pharmaceutical Microbiology	June 2-4, 2010
Module 5	Active Pharmaceutical Ingredients/Supplier Assurance	Aug 3-5, 2010
Module 6	Mathematics & Statistics	Oct 13-15, 2010
Module 7	Analysis & Testing	Dec 7-9, 2010
Module 8	Pharmaceutical Packaging Technology Operations	Feb 1-3, 2011
Module 9	Quality Management Systems	April 4-6, 2011
Module 10	Practical	May 10-14, 2010
Module 11	Investigational Medicinal Products	Aug 2-4, 2011
Module 12	Role of the Quality Leader	Oct 3-5, 2011

## Who Should Attend

This course is designed for technical professionals in Quality, Manufacturing, Regulatory Affairs, Validation, R&D, or other key pharmaceutical development and supply functions.

## To Book this Module

You may register online at [www.DBA-Global.com](http://www.DBA-Global.com) under US Residential Courses. Credit cards are accepted.

Or you may register by completing the back page of this brochure and returning this form by mail, email or fax to David Begg Associates (USA), LLC.

## University/Government Discount

Individuals with university/government or other not-for-profit affiliation are entitled to a 50% discount on the full course module fee.

## Incentives

Bookings received at least 8 weeks prior to the course start date will receive a 20% discount on the full module fee. After that date, if several bookings are received from the same site, the second and subsequent bookings shall receive a 20% discount on the full module fee. Discounts are not cumulative. In other words the second person from the same site booking 8 weeks in advance is entitled to a 20% discount only.





# The Venue

The course will be held at the Royal Sonesta Hotel in Cambridge (Boston), including the review session to be held the evening prior.

The Royal Sonesta hotel is minutes from downtown Boston. Located along the Charles River, it is close to many of the Boston historic sites, the Boston Science Museum and there is excellent shopping nearby.

## Hotel Accommodation

David Begg Associates has a negotiated a preferred rate with the Royal Sonesta Hotel. A limited number of rooms are available at this rate.

Hotel reservations and payment is the delegates' responsibility. We will be happy to help but final confirmation and bill settlement is the responsibility of each delegate.

There are a number of other hotels located within minutes from the Royal Sonesta Hotel including the Marriott Hotel in Cambridge, the Courtyard Inn Cambridge and the Le Meridien Hotel, Cambridge. Downtown Boston hotels are within 15 minutes by taxi or public transportation of the meeting venue.

## Cancellations

Cancellations within 25 working days for the module start date are subject to charges equivalent to half the course fee. Cancellations within ten days of the module start date will not be refunded. Substitutions may be made at any time.

## Booking your place couldn't be easier!

**Phone** 617-342-3625 **Email** [infoQL@DBA-global.com](mailto:infoQL@DBA-global.com)

**Fax** 617-342-3623 **Online** [www.DBA-global.com](http://www.DBA-global.com)

**Post** David Begg Associates USA LLC,  
Suite 19, 101 Federal Street, Boston MA 02110

# Booking Form

## Quality Leadership Program

### Module 1 - Pharmaceutical Law

October 5 - 7, 2009

- course starts Monday 8:00 am and closes Wednesday 5:00 pm
- optional review session on pre-read material offered Sunday 5 - 7 pm

**First / only delegate attending: \$2700**

**Additional delegate(s) from same site: \$2160**

**Early Booking deadline August 5, 2009 \$2160**

- Discount Policy: a 20% discount applies to second and subsequent delegates from the same site or if bookings are received by August 5, 2009. Discounts are not cumulative.
- Includes: tuition, comprehensive course notes, attendance certificate, lunches and refreshments
- Excludes: all hotel accommodation and dinners

Last Name ((Circle) Mr./Mrs./Ms./Dr.)		
First Name	Job Title	
Company		
Full Street Address		
City/Town	State	Post Code
Delegate Tel No	Delegate Fax No	
Delegate Email		

Will attend the review session Sunday 5 – 7 pm at the Royal Sonesta	Yes or No
Will be interested in taking the exam for Module 1	Yes or No
Accommodation Required Please Circle	Yes or No

Please Note: There are a limited number of rooms booked at a preferred rate at the Royal Sonesta Hotel and these will be allocated on a first come first served basis. Any last minute room cancellations charges remain the delegates' responsibility.

**Payment Information:** *Payment must be received at least 10 working days prior to the course start date. Cancellations within 25 working days of the course start date are subject to charges equivalent to half the course fee. Cancellations within ten days of the course start date will not be refunded. If a Purchase Order number is necessary to effect payment of an invoice, please provide below.*

Credit Card Number	Expiration Date
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**Check – Payable to David Begg Associates USA LLC for the full amount. Please attach to the booking form and send to David Begg Associates USA LLC, Suite 19, 101 Federal Street, Boston, MA 02110, Reference # - QLP1.**

**Bank Transfer – Transfer the full course fee to David Begg Associates bank account: National City Bank, Swift Code – NATCUS33, Routing # 072000915, Beneficiary Acct Name – David Begg Associates USA LLC, Beneficiary Acct # 987358181, Reference # - QLP1.**

Purchase Order # -
Authorised Signature

**David Begg Associates USA LLC**

Tel 617-342-3625 Fax 617-342-3623

Email: [USinfo@DBA-global.com](mailto:USinfo@DBA-global.com) Website: [www.DBA-global.com](http://www.DBA-global.com)

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