

Booking Form

Please reserve me a place on this course... (please tick)

- Microbiology for the Non-Microbiologist** – Tuesday 18 January
 What do the Changes in Annex 11 Mean? – Tuesday 15 February

Courses begin at 08.30 and close at 16:00

Course Fee: £395.00 plus VAT at the prevailing rate (where applicable – see note below)

Includes: tuition, comprehensive course notes, attendance certificate, lunches and refreshments
Excludes: all hotel accommodation and dinners

UK: Under UK law all UK-based applications are subject to VAT at the prevailing rate however most UK VAT registered companies/organisations can reclaim this tax.

EU: With effect from 1 January 2011 applications from delegates whose companies are based in EU countries will not be subject to VAT **PROVIDED THAT** valid VAT ID details are provided at the time of booking, otherwise VAT will be charged.

VAT ID No.

OTHER: With effect from 1 January 2011 applications from delegates whose companies are based outside of the UK/EU will be outside the scope of VAT.

Mr/Mrs/Miss/Ms/Dr (please circle) First Name: Surname:

Job Title: Company:

Full Site Address:

Postcode:

Delegate Tel No: Delegate Fax No:

Delegate Email:

Please indicate any special needs, e.g. Dietary:

Sterling cheques, payable on a UK bank to David Begg Associates (York) Ltd, for the full invoiced amount (net of ALL bank charges) should be attached to this Booking Form and sent to David Begg Associates (York) Ltd at the address below. A VAT invoice (if applicable) will be provided (VAT Reg No. GB 927 3679 85). Payments can also be made by bank transfer online (our company bank details are included on our invoice). Settlement 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. If a Purchase Order number is necessary to effect settlement of our invoice please provide it in the box below.

Purchase Order number:

Authorised Signature: Date: Cheque enclosed:

To aid prompt confirmation of your booking, please ensure you submit a completed application form which bears an authorised signature and Purchase Order number.

The information contained in this brochure is correct at the time of printing and is published in good faith. NSF-DBA reserves the right to make any changes which may become necessary.

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NSF-DBA trading as David Begg Associates (York) Ltd to 31 Dec 2010 then as NSF-DBA Ltd from 1 Jan 2011
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Where to stay...



George and Dragon Hotel, Kirkbymoorside, North Yorkshire

The George and Dragon Hotel is very unique, created by combining the original 17th century coaching inn with the adjoining rectory and cornmill to make a hotel of real charm, a haven of hospitality in the sleepy market town of Kirkbymoorside ('church by the moor').

The hotel is ideally situated on the A170 between Helmsley and Pickering in the heart of the North Yorkshire Moors National Park. Rich in history, heritage and beauty, the George and Dragon has a real 'olde English' pub atmosphere; serving top quality food, local real ales and a great selection of wines. The hotel has a bar, bistro and a fine restaurant, together with 20 en-suite bedrooms.

Visit www.georgeanddragon.net to book and find out more.

Kings Head Hotel, Kirkbymoorside, North Yorkshire

The Kings Head is a 17th century coaching inn, with over four hundred years of history and hospitality. Ideally located for you to enjoy all that Yorkshire has to offer, combined with mouth watering food, tasty ales, log fires and impeccable service. Settle down in front of the wood burning stove, read and play chess in the guests' lounge.

Visit www.kingsheadkirkbymoorside.co.uk to find out more.

To book visit www.northyorkmoors-stay.co.uk and search for the Kings Head, Kirkbymoorside.



How to get to us...

By Rail Take the Intercity service to York. Change at York for Malton (Scarborough line). At Malton take a taxi to Kirkbymoorside (20 minutes).

By Air Local airports are Durham Tees Valley (near Darlington) and Leeds/Bradford. Both of these have connections to London and to Europe (principally Amsterdam and Paris). From the airport take a taxi to Kirkbymoorside (1 hour from Durham Tees Valley and 1 hour from Leeds/Bradford). Manchester airport is also 2 hours by train from York. The train leaves direct from the airport and stops at York station. You can then take a taxi or catch another train to Malton.

By Car **From the south** – from the A1 take the A64 (York and Scarborough). Stay on the A64 past York following signs for Scarborough. At Malton stay on the A64 until you reach the A169 signposted Pickering. Follow the A169 through to Pickering. In Pickering take the A170 at the roundabout (heading towards Thirsk). The A170 passes through Kirkbymoorside. At the roundabout in Kirkbymoorside, turn right heading into the town centre. Halfway up the main street, the White Horse public house is located on the corner on the left hand side. Turn left here into West End. We are about 50 yards down on the right hand side. Parking is either on the street outside or in the main street.

From the north – from the A1 leave at Thirsk and follow the A170 signs for Scarborough or from the A19 follow the A170 signs for Scarborough. Take the A170 through Helmsley continuing to follow the signs for Scarborough. The A170 passes through Kirkbymoorside. At the roundabout in Kirkbymoorside, turn left heading into the town centre. Halfway up the main street, the White Horse public house is located on the corner on the left hand side. Turn left here into West End. We are about 50 yards down on the right hand side. Parking is either on the street outside or in the main street.

Visit www.nsf-dba.com and click on 'Contact Us' for a detailed map.



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25 YEARS OF EXCELLENCE

Introducing In-House at Our House

www.nsf-dba.com

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In 2011 our one day 'In-House – Our House' schedule is on the following topics:

- **Microbiology for the Non-Microbiologist**
18 January • Tutor: Dr Terry Snape
- **What do the Changes in Annex 11 Mean?**
15 February • Tutor: Dr David Selby
- **Management of Customer Complaints and Recalls**
21 March • Tutor: Mr Peter Smith
- **Cleaning Validation – Practical Aspects**
11 April • Tutor: Dr David Selby
- **Microbiological Risk Assessment and Decision Making**
24 May • Tutor: Dr Terry Snape
- **Train the GMP Trainer**
28 June • Tutor: Mr Martin Lush
- **Good Documentation Practices**
19 July • Tutor: Dr David Selby
- **Contamination Control for Non-Sterile Products**
18 August • Tutor: Dr Terry Snape
- **Practical Application of FMEA and HACCP**
12 September • Tutor: Dr David Selby
- **Biotech for the Non-Biotechnologists**
4 October • Tutor: Dr Terry Snape
- **GMP for Engineers**
7 November • Tutor: Dr Terry Snape
- **Basics and Practice of Steam Sterilisation**
13 December • Tutor: Mr Martin Lush

We know how frustrating it can be to find training courses for a topic when you are the only expert within your company and that organising an in-house programme, with all the cost benefits this brings, is not feasible. So we are going to offer you the chance to attend In-House at Our House. That's right, in-house pricing for attendance at our place of work.

With a small group of 12 delegates you will be able to benefit from a chance to share views and network with colleagues in the same position. We recognise that limited resource also means that time out of the office is at a premium, so these courses will be one day training events and, in addition to training at a really good price, you get the chance to spend a day at our premises in the beautiful town of Kirkbymoorside in North Yorkshire.

All our one day courses cost £395.00 plus VAT



Microbiology for the Non-Microbiologist

Tuesday 18 January 2011

About This Course

You don't have to be a microbiologist to manufacture pharmaceutical products – but you do need to understand and sometimes challenge what your microbiologist is telling you in the results of the tests that she/he reports. By the end of this one day seminar you will have the confidence to...

- Interpret reported microbiological data reported to you – or ask the questions to allow you to do so
- Understand the significance of the organisms found and make sound, risk-based judgements on where they came from, how to eliminate them and how best to avoid re-introducing them

Morning Session 08:30 – 12:00

- Basic pharmaceutical microbiology – types and sources of contamination
- Cleaning and disinfection
- Understanding and managing microbiological risk

Afternoon Session 13:00 – 16:00

- Microbiology and your manufacturing environment
- Microbiology and your pharmaceutical water system
- Microbiological in-process control (bioburden management)

Who Should Attend

QA professionals, managers, engineers, auditors and those individuals who need a basic understanding of the challenges of contamination control.

Course Fee £395.00 plus VAT

Course Tutor



Terry Snape, Consultant, NSF-DBA, UK
BA, PhD, CChem, MRSC

First degree in Chemistry from the University of Oxford; PhD in non-Clinical Medicine from the University of London.

Terry has 30 years of senior technical management experience in the manufacture of fractionated plasma products. He has an in-depth knowledge of biologics and biotech products and is an authority on aseptic processing.

What do the Changes in Annex 11 Mean?

Tuesday 15 February 2011

About This Course

IT professionals and engineers develop, manage, maintain and support the systems upon which GMP records necessary for making critical decisions are created and maintained, e.g. batch records, laboratory data and recall systems.

So understanding the regulatory expectations for GMP records, **particularly the newly released Annex 11 on Computerised Systems** from the IT, engineering and QA perspective, is essential.

This course will describe the new Annex 11 Guidance on Computerised Systems and help delegates to identify and resolve any gaps between their current operations and the newly announced expectations.

Morning Session 08:30 – 12:00

- An overview of the new Annex 11
- Identification of the impact of the changes
- Benchmarking current operations against the new Annex

Afternoon Session 13:00 – 16:00

- European expectations on electronic records and signatures
- Identification of the issues in the new Annex
- Open discussion to understand the issues raised

Who Should Attend

- Personnel who work in IT or systems support for GMP applications and who have to understand and comply with GMP and other similar regulations
- Engineers working with control systems in GxP areas
- Quality Assurance personnel, particularly Qualified Persons, who have to know the records that they review have integrity
- Personnel who are involved in the auditing of IT systems, operations and services

Course Fee £395.00 plus VAT

Course Tutor



David Selby, Consultant, NSF-DBA, UK
BSc, PhD, CChem, MRSC, MCQI

David has more than 30 years' experience in the pharmaceutical industry with Glaxo (now GlaxoSmithKline) in a wide variety of senior technical roles including R&D international GMP compliance and auditing, production, factory QA, information technology and General Site Manager for GlaxoWellcome, Barnard Castle.

He was a founding member and Chairman of the GAMP® forum responsible for the internationally accepted 'Supplier Guide for Validation of Automated Systems in Pharmaceutical Manufacture' (GAMP® Guide) and is a Director on the International Board of ISPE.