

Introducing
for 2005



The School for the Pharmaceutical Supply Chain

For training in materials supply and distribution

- Offering** Choice of economical half day modules
- With** Small groups to maximize interaction
- And** High level of 'hands on' activity
- At** Regional venues to save travel and hotel costs
- From** Tutors with extensive practical experience

About the Pharmaceutical Supply Chain School

The school has been set up to provide a focal point for training in the key area of supply to and distribution from the pharmaceutical and biotech industry. This area is developing rapidly and attracting increasing interest from EU regulators and global organisations such as WHO, as it is now widely recognised that the supplied materials and distribution practices contribute enormously to the quality of medicines. The primary objective of the school is to provide up to date training in this field for personnel from both the pharmaceutical and supply industries.

Courses offered.

No.	Course Title	Courses will be of interest to
SPSC 1	Good Sampling Practice for Pharmaceutical Materials	Materials QC Managers, Technicians involved in sampling in either Supplier or Pharmaceutical plants.
SPSC 2	Developing Effective Packaging Specifications	Materials QC Managers and their staff, Packaging Development staff.
SPSC 3	Good Distribution Practice for Pharmaceutical Manufacturers, Wholesalers and Agents	Warehouse Managers, Qualified Persons, Materials QC Managers and their staff, QA Managers.
SPSC 4	The GMPs for Suppliers of Excipients and Packaging Materials	Supply industry personnel, Supplier auditors, QA Managers.
SPSC 5	Practical Workshop for new Supplier Auditors	New and trainee auditors.
SPSC 6	The Manufacture and Control of Printed Packaging Materials	Pharmaceutical Production & Purchasing personnel, Materials QC Managers and their staff
SPSC 7	Reduced QC Testing of Supplied Pharmaceutical Materials	Materials QC Managers and their staff, Supplier auditors, QA Managers.
SPSC 8	Supplying Materials to the Pharmaceutical Industry - The Regulatory Framework	Materials QC Managers and their staff, Qualified Persons
SPSC 9	Developing Better Relationships in the Supply Chain - to control the risks	Materials QC Managers and their staff, Purchasing Managers.
SPSC 10	Practical Workshop for the Validation of Cold Chain Systems	Warehouse Managers, Qualified Persons, Validation Managers.

The School for the Pharmaceutical Supply Chain

Our tutors



Afshin Hosseiny. PhD, MInst Pkg, CChem, MRSC. Afshin has over 20 years experience of Pharmaceutical Quality Assurance management across a wide range of disciplines. This included global responsibility for the development and implementation of a product supply strategy to maintain compliance with regulatory requirements.

Michael Hickey. Market Manager UK & Ireland, Laminar Medica Ltd. Mike is a professional engineer with many years experience of design and implementation of a variety of engineering projects. Within Laminar Medica, Mike is now responsible for the design and implementation of customised cold chain solutions for the pharmaceutical industry.

Ashley McCraight BSc, MChemA, FRSC, MIQA. Ashley has 20 years experience in pharmaceutical management with roles in QA, Production and Materials Management. He currently leads the development of the PQG's supplier GMP standards and training guides.

Mark Hassall. Production Services Manager, Medica Packaging, UK. Mark has over 10 years experience in the supply of Printed Materials to the Pharmaceutical industry. He is currently responsible for Procurement, Planning, Pre-Press, Computer to Plate and Distribution. Prior to this Mark gained 10 year experience within Rolls Royce Motors.

Norman Randall. PhD, CChem, FRSC, FIQA. Thirty years experience in Quality Management of Ethical and Generic Medicines including global responsibility for Supplier Assurance and Development has given Norman an excellent grasp of this important subject arena.

Norman Sadler. BSc, F.Inst. Pkg, Dip. RSA. NVQL5. Over 17 years in pharmaceutical supplier quality management with GSK & Unilever. Experience of medical devices, quality systems development and Purchasing at a global level.

Steve Wood. Production & Technical Director, Medica Packaging, UK. Steve has over twenty three years experience in the Print industry and has held senior roles in Procurement, Quality Assurance and Production which are underpinned by the professional Diploma in Printing.

Our Prices

All modules are priced
at £ 195 + VAT and
include

- Snack lunch
- Refreshments
- Course Certificate
- Replacements possible

Our course venues

Cheshire 1 & 2 March 2005 : University College Chester, Warrington
Campus, WA2 0DB
14,15,16 June 2005 : Sanofi-Aventis Training Centre, Holmes Chapel,
CW4 8BE

**Both of our Cheshire locations are within 5 minutes of
the M6 and have good rail connections**

London Institute of Quality Assurance, 12 Grosvenor Crescent,
London, SW1X 7EE

**The IQA is within 5 minutes walk of Hyde Park Corner
Underground station**

Full details of the location will be provided with the joining instructions.

If you would like to attend either of these courses or request course data sheet please complete the enclosed booking form or ring Tel No 01494 818159 for more information.

We reserve the right to cancel a course if there are insufficient registrations.

**On site options—All courses can be delivered at your premises even more
economically. Phone 01277 228530 to discuss options**

What the courses cover



Each course will have a maximum of 15 participants which combined with the high level of practical activity is designed to provide excellent environment for learning.

- SPSC 1 Good Sampling Practice** Tutors - Ashley McCraight or Norman Randall
 Introduction to regulatory expectations of sampling at all stages of the supply chain
This course will provide guidance and advice on the implications of EU GMP and the CFR and its relationship to the international sampling system ISO 2859 (BS 6001). It will also cover the requirements for sampling at supplier's premises and the value of Square Root Plus One sampling
- SPSC 2 Developing Effective Packaging Specifications** Tutor - Norman Sadler
 Practical advice on developing meaningful packaging specifications for pharmaceutical products
Participants of this course will learn how to develop specifications for primary and secondary packaging materials, which comply with the current regulatory standards and very importantly meet supplier's practical needs
- SPSC 3 Good Distribution Practice for Pharmaceutical Manufacturers, Wholesalers and Agents** Tutor - Afshin Hosseiny
 How to develop supply chain strategy in line with requirements expressed within EU GDP and specific guidance issued by the MHRA (for temperature control) and the World Health Organisation (for Agents)
Led by a tutor with international experience of this subject, this course will provide practical guidance on solutions to develop supply chain for ambient and cold chain products
- SPSC 4 The GMPs for Suppliers of Excipients and Packaging Materials** Tutors – Ashley McCraight or Norman Randall
 GMP requirements for suppliers of packaging materials and raw materials to pharmaceutical manufacturers
This course will explain the GMPs that are specified for Packaging Materials Suppliers in PS 9000 and for Excipients suppliers in PS 9100. Explanations of the need for these GMPs will be provided throughout the course.
Note : This course can also be delivered as separate shorter modules on either Packaging or Excipients in your premises.
- SPSC 5 Practical Workshop for New Supplier Auditors** Tutors - Afshin Hosseiny or Norman Randall
 A workshop designed to provide tools and skills for new auditors conducting supplier audits
This is a practical workshop, led by experienced auditors, during which participants will learn and practice the key foundation skills needed for successful auditing.
- SPSC 6 The Manufacture and Control of Printed Packaging materials** Tutors – Steve Wood or Mark Hassall
 How the manufacture of printed packaging materials is managed to satisfy the pharmaceutical industry
On this course participants will learn, from print industry professionals, how printed materials are made and controlled to meet the rigorous requirements of the pharmaceutical industry
- SPSC 7 Reduced QC Testing of Supplied Pharmaceutical Materials** Tutors – Ashley McCraight or Norman Randall
 How to implement reduced testing of supplied materials, while maintaining compliance and control.
The objectives for this course are to provide participants with sufficient knowledge of EU and US GMP and industry practice that they will be able to institute reduced QC testing within their companies.
- SPSC 8 Supplying Materials to the Pharmaceutical Industry - The Regulatory Framework** Tutors - Norman Randall or Ashley McCraight
 Understanding the regulatory requirements for supply of packaging and raw materials to pharmaceutical manufacturers
This course, delivered by experts in this field, is aimed at providing an overview of the EU and US legal requirements for starting materials supplied to pharmaceutical manufacturers
- SPSC 9 Developing Better Relationships in the Supply Chain** Tutor - Norman Sadler
 Deciding when and how, to develop a partnership with your suppliers that will mitigate risks to quality
Participants will learn, from a tutor with global experience in this subject, which supplier relationships should be developed and how this might be done based on a risk assessment process.
- SPSC 10 Practical Workshop for the Validation of Cold Chain systems** Tutor – Mike Hickey
 A workshop providing practical guidance on how to ensure your Cold Chain system works effectively.
Participants will learn, from an engineer currently practising this methodology, how to plan and carry out the validation of storage and distribution of products requiring Cold Chain control

Booking Form - "The School for the Pharmaceutical Supply Chain"



Please register the following person :

Title :	First name :	Surname :
Job title:		
Company :		
Address :		
		Post Code :
Telephone :	Fax :	

Please note that your contact details will be included in our mailing list enabling us to advise you of other courses that we may offer. If you prefer not to be added to this list please tick here

If you like to receive information by email please tick here and complete your email address :

Email address : _____

Price £195 + VAT = £229 for each course. Please note that this is not a residential course but price includes refreshments and buffet lunch.

Please circle the course(s) you would like to attend :

No.	Course Title	Cheshire	London
SPSC 1	Good Sampling Practice for Pharmaceutical Materials	P.M : 14 June	P.M : 11 Oct
SPSC 2	Developing effective Packaging Specifications	P.M : 1 March	P.M : 19 April
SPSC 3	Good Distribution Practice for Pharmaceutical Manufacturers, Wholesalers, and Agents	A.M : 16 June	A.M : 13 Oct
SPSC 4	The GMPs for Suppliers of Excipients and Packaging Materials	A.M. : 15 June	A.M : 12 Oct
SPSC 5	Practical Workshop for new Supplier Auditors	P.M : 2 March	P.M : 20 April
SPSC 6	Manufacture & Control of Printed Packaging Materials	A.M : 14 June	A.M : 11 Oct
SPSC 7	Reduced QC Testing of Pharmaceutical Supplied Materials	A.M : 2 March	A.M : 20 April
SPSC 8	Supplying Materials to the Pharmaceutical Industry - - the regulatory framework	A.M : 1 March	A.M : 19 April
SPSC 9	Developing Better Relationships in the Supply Chain - - controlling the risks	P.M : 15 June	P.M : 12 Oct
SPSC 10	Practical Workshop for the Validation of Cold Chain Systems	P.M : 16 June	P.M : 13 Oct

How to pay - Tick the appropriate box :

I agree to make BACS payment to HSBC Bank, 86 Main Street, Frodsham, WA6 7AS. Sort code 40-21-28. Account No. 51405780, trading as "The School for the Pharmaceutical Supply Chain".

Please supply remittance advice to address shown below.

I enclose a cheque payable to "The School for the Pharmaceutical Supply Chain" for the full amount of each course selected.

Full refunds will only be given for cancellations made in writing to Dr N Randall four weeks before the course is scheduled. 50% is payable between 1 to 4 weeks and no refunds for less than one week's notice. However substitution of delegates is acceptable but please tell us in advance. In the event of unforeseen circumstances SPSC reserves the right to alter the programme, speaker(s), course date or venue. We reserve the right to cancel a course if there are insufficient registrations.

Please post to the address shown below :

School for the Pharmaceutical Supply Chain, 20 Crescent Drive, Shenfield, Brentwood, Essex, CM15 8DS
Tel : 01277 228530 e-mail : bookings@spsc.uk.com

Want know more before you book?

If so, we can provide a data sheet for each course. Just e-mail your interest at :
our e-mail address — info@spsc.uk.com for the attention of Afshin Hosseiny
or Phone : 01494 818159