PharmaTraining

Technology Transfer

11, 12 & 13 December 2013

Hotel Russell, Bloomsbury London UK

Course overview:

This three-day interactive workshop is intended to provide an overview of the challenges that must be overcome in transferring manufacturing technology and to highlight some proven techniques for overcoming those challenges.

The focus of the course is on small-molecules and their formulations rather than biological products, although many of the issues faced and techniques discussed will be equally applicable.

Some of the benefits to be derived from this workshop include:

- An appreciation of where TT fits in the life cycle of a pharmaceutical product.
- An appreciation of the importance of planning and project management in TT.
- An overview of the potential complexity of technology and product transfer.
- An outline of proven best practice in technology transfer.
- An opportunity to discuss current issues and challenges in technology transfer with peers and with an expert faculty.
- A consideration of "where next" as we move from traditionally-developed products to a world where products are developed using QbD techniques and controlled by PAT.

Course Leader:

Chris Barnett is an independent GMP and compliance consultancy. Chris has a talent for coaching and explaining complex regulations in a straightforward manner.

An expert in quality management, technology transfer and new product introduction, Chris specialises in Quality Management, Technology Transfer and New Product Introduction.

Chris has a background as an analytical chemist and over 20 years experience in QA roles, with the Wellcome Foundation and GlaxoSmithKline. He has had QA management posts in India and Mexico, as well as new product introduction project management roles in pharma manufacturing. Chris graduated from Cambridge in natural sciences, with an MSc in analytical chemistry, and subsequently an MBA from Greenwich University.

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www.pharma-training-courses.com

Technology Transfer
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Who should attend?

Pharmaceutical technologists, Quality Assurance staff, Regulatory staff, Engineering staff, Project Managers and anybody else involved in the transfer of products or technology from one location to another.

PROGRAMME

Start time:
Coffee and registration will be available from 8.30am, course proper will commence at 9.00am. We anticipate the course will finish at 5.00pm.

Day 1
Why Transfer Technology?

- Pharmaceutical Product Life Cycle
  - Development
  - Innovative
  - Mature
  - Generic
- Product Transfers and Technology Transfers
  - IP
  - Technology
  - Techniques
  - Regulatory Considerations
- Registration Procedures
  - Europe
  - Non-European
- Variation Procedures
  - Types of Variations
  - Advantages and Disadvantages

Day 2
Technical Challenges

- Manufacturing processes
- Validation
- Stability
- Packaging processes

Logistical Challenges

- Label Changes
  - Text
  - Physical
- Timing
  - Project Plan
  - Phase in/out

Day 3
Technical Challenges (2)

- Risk Management and Technology Transfer

Human challenges

- Push versus Pull
- Team membership and team roles
- Cross-Cultural Issues
- Progress Reporting and breaking bad news

Comments from previous attendees:

"Very good, informative, gave a good overview of all aspects of TT"

"Good with experienced lecturer, lots of questions could be answered"

"Technical aspects of the course were well covered"

Venue:

Hotel Russell, Russell Square, Bloomsbury London, UK, WC1B 5BE
http://www.hotelrussellllondon.co.uk/location/

The course does not include accommodation, hotel details are available from our website http://www.pharma-training-courses.com/pharma-training-venues.htm

Numbers are limited to give participants the opportunity for thorough discussion of the issues to be covered by the programmes and one-to-one consultation with speaker(s)

COURSE PROGRAMME 2013

Stability Testing in Pharmaceutical Development and Manufacture
14 & 15 May, London

GMP Auditor Training for Quality Systems *11 & 12 June, Amsterdam*
25 & 26 November 2013, London

HPLC Analytical Method Development and Validation
13 & 14 June, Amsterdam, 28 & 29 November 2013, London

Tablet Process Development, Validation and the application of QbD
12, 13 & 14 June, London

QbD and Lifecycle Management for Analytical Methods
20 & 21June 2013, Edinburgh

Technology Transfer *26, 27 & 28 June, 11, 12 & 13 December, London*

Pharmacokinetics in Drug Development – for the Non-Specialist
1 & 2 July, London, 31 Oct and 1 November Bucharest Romania

Pharmaceutical Packaging - an introductory course *2 July, London*

Hands-on Tablet Development, including Pre-Formulation, Formulation and Process Development
11, 12 & 13 September, 4, 5 & 6 December, Beckenham UK (near London)

OOS Investigations in a GMP Environment *10 & 12 October, London*

Pharmaceutical Documentation *14 & 15 October, London*

Developing Pharmaceutical Tablets for Low Cost Manufacturing,
15 & 16 October, Beckenham UK (near London)

Oral Solid Dosage Manufacturing Technology *18 October, London*

Check out the benefits, content, details, dates and times of our range of training programmes:

We deliver a range of expert programmes in pharmaceutical development, quality assurance and regulatory topics, plus a new range of industry awareness courses. We employ speakers/trainers with a high degree of expertise, completely up to date with industry trends.

REGISTRATION DETAILS:

Technology Transfer: 11, 12 & 13 December 2013, London

Early-bird rate for registering and paying by 22 October 2013
£1593.00 (+ VAT £318.60 if applicable, see VAT rules)

Full Fee: 3 day course £1770.00 (+ VAT £354.00 if applicable, see VAT rules)

VAT RULES:

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.

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, ie no VAT is charged or payable.

Reduced fees available for multiple bookings:

- 15% 2 courses or 2 delegates
- 20% for 3 courses or 3 delegates or any combination thereof
- 30% for 4 or more courses or 4 or more delegates or any combination thereof

Payment to be made in a timely manner

Contact Judy Callanan to discuss a bulk booking
Phone: ++44 2071937703 Email: info@pharma-training-courses.com

Methods of Payment available:

☐ Cheque (**Please make payable to "PharmaCourses Ltd")**

☐ Bank transfer ☐ Credit/Debit Card

Please Register Online at:
www.pharma-training-courses.com

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Terms and Conditions

Delegate fees: Fees for this programme or suite of programmes are shown overleaf. Delegate fees are inclusive of course documentation, refreshments and lunch. Payment of the registration fee must be paid within 14 days of commencement of the course. Upon receipt of payment, a proof of payment will be sent to you. **Cancellation Policy:** Full refunds less a handling fee of £100 will be made for cancellations received in writing within 28 days of the commencement of the course. Refunds of 50% will be made for cancellations received in writing between 28 and 7 days prior to the commencement of the course. Regrettably no refunds will be made after 7 days prior to commencement of the course. Substitutions can be made at any time. **Liability:** PharmaCourses reserves the right to change the programme, speakers, date or venue without notice or cancel the event. If cancellation occurs delegates will be notified as soon as possible and will receive full refund of fees paid. PharmaCourses will not be responsible for any airfare, accommodation or other travel costs incurred. **Data Protection:** PharmaCourses gathers personal data in accordance with the UK Data Protection Act 1998 and we may use this to contact you by telephone, fax, post or email to tell you about other products and services. If you have any queries or want to update any of the data that we hold then please contact us.

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