GMP Auditor Training, 7 & 8 April 2008

Participants will learn about the key techniques and thought processes which may be used by auditors to maximize the benefits of each type of audit. These include planning and preparation, the audit team, structuring the audit, close out, CAPAs and follow up.

How to Audit API Manufacturers, 9 April 2008

This seminar is aimed at QA staff in drug products manufacturers especially QPs who have specific responsibilities under directive 2004/27/EC.

Integrated Tablet Formulation Development, 8-10 April

- **Preformulation 8 April 2008**
- **Formulation, 9 April 2008**
- **Process Development and Validation 10 April 2008**

This unique 3 day course introduces and integrates the key elements of tablet development based on the principles of Quality by Design (QbD) set out in ICH Q9 and explains the important links between each of these.
The course is structured to enable participants to choose to attend one or all of the 3 days

Active Pharmaceutical Ingredients -Development, Supply and Commercial Manufacture 10 & 11 April 2008

This 2 day course is designed to give an overview of the development of chemical processes for the supply of active pharmaceutical ingredients for human consumption both in clinical trials and commercial manufacture

Speakers:

Dr David Inglis, Ulverston GMP Consulting
Dr Ron Scott, PharmaAnswers
Dr Michael Gamlen, Pharmaceutical Development Services

Holding these courses together enables participants to meet and network with participants on other courses, as well as offering the opportunity to attend more than one course.
A reception will be held each evening for the participants on all courses to socialise and learn from each other.

Radisson SAS Hotel
Little Island, Cork, Ireland
Monday 7 to Friday 11 April 2008

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PharmaTraining Services

PharmaTraining Services
1st Floor
77 Leonard Street
London EC2A 4QS
UK

Tel: +44 20 7613 7232
Fax: +44 20 7681 3582

judy@pharmatrainingservices.co

GMP Auditor Training
7 & 8 April 2008

This 2 day course is aimed at Quality Assurance auditors and production management for Level 2 internal audits and supplier auditing.

To be a business benefit rather than a drain on resources, your auditing programmes must be integral to continuous improvement. The key to effective internal auditing and auditing of suppliers is the training of both auditors and auditees in the purpose and relevant techniques of the audit and how these techniques can be channeled to achieve business and compliance improvements.

Participants will learn about the key techniques and thought processes which may be used by auditors to maximize the benefits of each type of audit. These include planning and preparation, the audit team, structuring the audit, close out, CAPAs and follow up.

Who should attend

- QA auditors and trainees
- Production managers who receive internal QA and corporate GMP audits
- Engineering managers who receive internal QA and corporate GMP audits
- Production supervisors who lead Self Inspection audits
- Auditors of suppliers and contractors

How to Audit API Manufacturers
9 April 2008

This one day seminar is aimed at QA staff in drug products manufacturers and especially their QPs who have specific responsibilities under directive 2004/27/EC.

QPs are required to declare that the active materials used in each of their products have been manufactured to GMP as interpreted by the EU.

Participants will learn about the legislators' perspectives and the key differences between APIs and products, which lead to different audit techniques and thought processes when auditing API manufacturers.

The seminar includes:

- the background to current GMPs for APIs
- FDA and EU interpretation of GMPs for APIs
- specific opportunities from the guidelines that API manufacturers may exploit
- specifics of what to look for when auditing an API site.

Who should attend

- Supplier auditors for drug products manufacturers
- QPs in manufacture of drug products
- QA managers who support the QP / declaration
- QC managers of drug products manufacturers
- Production managers of drug products manufacturers

Course Speaker

DR David Inglis is director of Ulverston GMP Consulting Ltd, specialising in GMP/Quality Assurance for the manufacturing sectors of the pharmaceutical and consumer healthcare industry. He has extensive experience in assessment and improvement of QA/GMP systems, auditing, GMP training, inspection preparation and plant cleaning / decontamination, especially in bulk intermediates and APIs. He has a Ph.D. degree in enzyme chemistry (affinity chromatography).

During more than 29 years in Quality Assurance in the pharmaceutical industry, Dr Inglis has gained extensive experience of Quality Management, through roles in QA laboratories, GMP compliance and regulatory compliance. He successfully pioneered automated HPLC methods, then managed all aspects of QC laboratories before spending the following 11 years managing and developing Quality Assurance, including documentation, control of change, auditing and routine regulatory compliance to cGMP. He is a Qualified Person under EU Regulations, formerly for bulk sterile antibiotics and now for bulk product intermediates for use in clinical trials.

Dr Inglis is an experienced international auditor of suppliers and contractors and has successfully prepared several sites for FDA/MHRA inspections, including FDA "Systems" based inspections. He has extensive experience of being the lead spokesman during major regulatory audits.

Dr Inglis is a specialist in cGMP training and QA system improvement. His flagship improvement package details a system of secure GMP compliance at competitive cost. For conceiving and developing this package, Dr Inglis received the highest level of recognition for excellence from a

Programme
GMP Auditor Training

Day 1

Auditing basics

- Reasons for audits and audit models (overview)
- The Purpose of Audits
- Role Characteristics of the Auditor
- Audit Types
- Audit Classification
- Audit Methods
- General Themes for All Audits

Auditing Tools and Techniques

- Basic tools
- Audit Techniques
- Audit Planning

The course will include three or four Work-shops on specific aspects of the programme

Wine Reception

DAY 2

The audit process

- Audit scheduling
- Conducting the audit
- Managing the Audit Team
- The Exit Meeting
- Audit Reporting
  Audit Closeout

Improving the audit system

- Adding Value from the Audit programme

Added Value from Self Inspections (Level2 – QA Led)

- A practical Level 2 inspection programme (based on Auditor Training)
- Purpose of the self inspection programme
- Establishing the programme
- Setting up and training the inspection team

Wine Reception

Programme
How to Audit API Manufacturers

Why audit API Manufacturers?

EU Directive 2004/27/EC (Regulator's view)
What are the requirements?
What are the similarities with the FDA GMP requirements for APIs?
What are the expectations from API Manufacturers?
What role should secondary manufacturers play?
How will regulators assess compliance with these requirements?

Background to ICHQ7a and EU Guide Part II (formerly Annex 18)

History of GMP for APIs
What role these documents play
How they will be enforced
GMP expectations outlined
How to go about implementing the requirements

FDA GMP expectations of API manufacturers

FDA draft guidance
Legal basis of ICH Q7a
Details of what is required
How is it enforced?
Differences and similarities with EU requirements
How would manufacturers comply with both regulators' requirements?

Workshop I:
How to identify and select a GMP compliant API supplier

Preparing for GMP assessment of an API site

- identifying the GMP relevant activities
- assessing the rational for GMP relevance of activities
- identifying the processing steps
- list of key documentation
- identifying the critical steps impacting your secondary product

Lunch

Implications of EU Directive 2004/27/EC on Drug Manufacturers

- what role manufacturers of the secondary products should play on enforcing these requirements
- what is the impact on manufacturers?
- how to apply the requirements to non EU API sites
- what impact this will have on cost of APIs?

Workshop 2:
Handling Manufacturing Deviations

Basis of proactive deviation management
Identifying and documenting GMP non-compliance incidents
Monitoring and reporting
Key aspects of knowledge management
Framework of critical deviation management
Continuing governance of critical deviations management

Auditing of an API site (I)

Documentation and systems review
Facilities and support services
Validation
Materials control

Auditing of an API site (II)

SOPs and SOP training
Calibration
Testing laboratories
Packaging and labelling
Storage and distribution

Summary of Key Issues

Close of Seminar

Wine Reception

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UK
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Fax: +44 20 7681 3582

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Active Pharmaceutical Ingredients

Development, Supply and Commercial Manufacture

10 & 11 April 2008

This 2 day course is designed to give an overview of the development of chemical processes for the supply of active pharmaceutical ingredients for human consumption both in clinical trials and commercial manufacture. Each step from the selection of a new candidate from Discovery into Development through to commercial launch is covered. Particular emphasis is placed on the differences between a laboratory procedure and an economically viable manufacturing process.

These include:

- Process economics.
- Process safety.
- Environment protection.
- Quality of product.
- Specialised facilities for highly potent substances.

Who will benefit from the course?

Chemical and Process Engineering Scientists involved in the design, development and technical support of chemical manufacturing processes in the pharmaceutical industry. Chemical Analysts providing process analytical support to laboratory, pilot plant and full scale manufacturing operations. Formulation Scientists and Health, Safety and Environment professionals seeking a more detailed knowledge of the operational aspects of process chemistry. Those involved in technology transfer from laboratory to pilot plant to full scale plant and from manufacturing plant to other manufacturing locations.

Course Speaker

Dr Ron Scott is a Director of PharmaAnswers, an independent consultancy in all aspects of the development of chemical processes and manufacture of active pharmaceutical ingredients. He has a First Class honours B. Sc. in Chemistry and a Ph. D. in Synthetic Organic Chemistry and is a Fellow of The Royal Society of Chemistry.

During a 25 year career he has worked in leading contract manufacture and contract R&D organisations including Oxford Asymmetry and Almac Sciences where he held senior management positions in technical operations up to Vice President level.

He has had responsibilities for New Product Development, Process R&D, Process Safety, Quality Control, Quality Assurance, Production and Environmental Compliance.

He specialises in the design and optimisation of robust and economical chemical processes for the supply of new chemical entities for clinical development and subsequent commercial manufacture. A particular niche area of expertise is the design and safe use of facilities for handling highly potent active pharmaceutical ingredients, typically for oncology applications.

Programme
Active Pharmaceutical Ingredients -
Development, Supply and Commercial Manufacture

9.00am registration and coffee

Medicinal Chemistry
- Molecular Screening
- Hit Identification
- Hit to Lead Compound Selection

Pre-Clinical Development
- Lead Compound Route Selection
- Viability of Process for Future Material Supply
- Availability of Raw Materials
- First Material Supplies to Pharmaceutical Development
- Outsourcing Versus In-House manufacture
- 500g non-GMP
- 5kg GMP
- 50kg GMP
- Moving Chemical Development off Project Critical Path

Highly Potent Active Pharmaceutical Ingredients
- Special Classifications of Active Pharmaceutical Ingredients
- Dedicated Handling Facilities
- Occupational Hygiene
- Medical Surveillance

Clinical Supply
- Phases I, II and III
- Chemical Process Development
  - Yields
  - Quality
  - Process Economics
  - Process Safety
  - Environmental Compliance
- Process Analytical Technology
- Process Transfer from Laboratory to Pilot Plant
- Process and Analytical Documentation
  - Product Polymorphs
  - Product Stability
  - Validation of Plant, Process and Analytical Techniques
- Chemical Manufacturing and Control Dossier

Pre-Approval Inspection
- ICH Q7A
- Requirement for Marketing Approval of a New Drug Substance
- Rigorous Inspection of Good Manufacturing Practice
- Reporting of Violations

Commercial Manufacture
- Site Selection for Process
- Low Cost Economies
- Protection of Intellectual Property
- Drug Substance Economic Life Cycle

Wine Reception each evening

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Integrated Tablet Formulation Development
Preformulation 8 April 2008
Formulation 9 April 2008
Process Development and Validation 10 April 2008

This course can be attended for one or all of the three days

This unique 3 day course introduces and integrates the key elements of tablet development based on the principles of Quality by Design (QbD) set out in ICH Q9:

- **Preformulation studies**
- **Formulation development**
- **Process development and validation**

and explains the important links between each of these. Proper integration of these elements is essential to achieve "Quality by Design" because data from each phase of development is used to control the next step in the development process. By achieving proper integration based on sound scientific principles, many development and production problems can be avoided. The course includes case studies of tablet development at the preformulation and formulation development phases as well a detailed, step by step analysis of all elements of the tablet manufacturing process. Key process parameters and their control are identified.

Who will benefit from the course?
The course is designed for people new to tablet and process development, and those requiring a refresher in the area. It will also benefit Process Development experts wishing to extend their understanding of why processes can go wrong, and regulatory and quality personnel who need to understand the development process.

Programme

Registration each day is at 8.45 and course proper starts at 9.15am

Day 1: Preformulation

- Quality by Design in preformulation - preformulation studies in context
- The Research/Development interface – selecting the best compound
- Key techniques in preformulation
- Lunch
- Excipient and process compatibility testing
- Case studies – preformulation data in practice. How small can you go with the product formulation process?
- Tablet components and their function

Day 2: Formulation development

- Quality by design in formulation development.
- Tablets in early development – opportunities and pitfalls. Developing formulations with minimal quantities of material
- Key manufacturing techniques. How formula and Process interact
- Lunch
- Formulation optimisation case studies in wet granulation and direct compression
- Stability testing in product developent
- Material characterisation – compression science and when to use it

Day 3: Process development and validation

- Quality by design in process development.
- Key manufacturing processes and their effect on process scale-up
- Applying experimental design in process development
- Lunch
- Process development case studies
  - Blend uniformity assessment
  - Wet granulation
- Process Validation protocols and how to develop them

A CD-ROM with the relevant reference sources will be supplied to each participant, including full course notes.

Course Speaker

Dr Michael Gamlen is Managing Director of Pharmaceutical Development Services Ltd, a Guildford-based technical consultancy. Dr Michael Gamlen has over 30 years experience of tablet development. Awarded a First Class Honours degree in Pharmacy, specialising in Pharmaceutical Engineering, he studied for a PhD at Nottingham University. He was Head of Tablet Development at the The Wellcome Foundation for 15 years, and has since worked for Vanguard Medica Ltd and as a consultant. He specialises in managing product development, formulation, tablet and process development studies. He has been teaching professional tabletting courses for many years.

PDS Pharmaceutical Development Services

Venue

Radisson Hotel, Little Island, Cork, Ireland
Offering a high standard of style and service, the newly opened Radisson SAS Hotel & Spa is located just 10 minutes from the centre of Cork and Cork International Airport.

Further information is available on website www.cork.radissonsas.com

Course Materials and Numbers

Numbers will be limited to give participants the opportunity for thorough discussion of the issues to be covered by the programme and one on one consultation with speakers.

Terms and conditions

Delegate fees
Fees for this programme or suite of programmes are shown overleaf. Delegate fees are inclusive of course documentation, refreshments, lunch and evening reception

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
PharmaTraining Services 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.

PharmaTrainingServices will not be responsible for any airfare, accommodation or other travel costs incurred.

Reduced rates are available for delegates registering for more than one course.

We also offer reduced rates for more than 2 delegates attending from the same company.

Please Contact **Judy Callanan** by email or telephone to take advantage of this offer.

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77 Leonard Street
London EC2A 4QS
UK

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Fax: +44 20 7681 3582

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REGISTRATION FORM

I wish to register for the following:	Please tick
GMP Auditor Training—7 & 8 April, 2008: £1160.00	
How to Audit API Manufacturers, 9 April 2008: £ 600 .00	
GMP Auditor Training *and* How to Audit API Manufacturers 7, 8 & 9 April 2008 *at the reduced rate of* £1584.00	
Active Pharmaceutical Ingredients—Development, Supply and Commercial Manufacture, 10 & 11 April 2008 £1160.00	
Integrated Tablet formulation Development, 8, 9 & 10 April *at the reduced rate of* £1584.00	
Preformulation, 8 April 2008 £ 600.00	
Formulation 9 April 2008 £ 600.00	
Process development & Validation, 10 April 2008 £ 600.00	
Preformulation & Formulation, 8 & 9 April 2008 £ 1160.00	

Total payable £_____

Title (Mr/Mrs/Ms/Dr/Prof): _____ First name_____

Surname: _____

Position: _____

Company:_____

Address: _____

_____

Post Code:_____Country: _____

Email address: _____

Tel: _____ Fax: _____

Signature: _____

Method of Payment

☐ Cheque **(Please make cheque payable to "JA Conference Management")**

☐ Bank transfer **Quoting Reference No. 801**
JA Conference Management
Barclays Bank, Muswell Hill & Crouch End Branch
Sort Code: 205851 **Account No:** 10245038

☐ Credit/Debit Card

Card Number: _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _

Expiry Date: _ _ _/_ _ _/_ _ _

Cardholder: _____

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Please send completed registration forms and payment to: Judy Callanan at:

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1st Floor
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