Forward to a colleague who would benefit from training

Stability Testing in Pharmaceutical Development and Manufacture – an update for the 21st Century

Dates: ***6 & 7 June 2019, London UK***
Fee: £1200.00 (+VAT if applicable)
Early-bird fee: £1080.00 (+VAT if applicable) If booked and paid by 3 April 2019 **Expert Speaker:** Dr Michael Gamlen

Course Overview
This course has been updated to reflect the changes in the pharmaceutical stability testing world. The course content will provide a comprehensive update on current trends which offer substantial potential savings in time and resources in a traditionally costly testing area. It will include opportunities for review of specific participant problems.

The course will cover:
Recent regulatory changes affecting stability including
- The implications of implementation of ICH Q7, Q8, Q9, Q10 and Q11 for stability testing
- Changes to European GMP guidance with impact on stability testing including Annexe updates affecting product development, outsourcing and application of Quality Risk Management (QRM)
- Product Quality Reviews and the interpretation of stability data.

Recent scientific developments with implications for stability, with a particular focus on cost reduction, shortening of development timelines, and improvements on existing interpretation systems
- ASAP - using short term high stress testing to get accurate predictions of shelf life with a high degree of confidence – Freethink Technologies' ASAPprime®
- Low level impurities and their impact on product stability
- Manipulation of tablet internal pH to improve product stability

'Course content good, clear explanations given with examples of real life studies'

Development of Stability-Indicating HPLC Methods

Dates: ***14 October 2019, London UK***
Fee: £600.00 (+VAT if applicable)
Early-bird fee: £540.00 available (+VAT if applicable)
Expert Speaker: Dr Mark Powell

Course Overview
A Stability Indicating Method (SIM) is defined as a validated analytical procedure that accurately and precisely measures active ingredients (drug substance or drug product) free from process impurities, excipients and degradation products. High Performance Liquid Chromatography (HPLC) is the favoured method of detecting possible degradants and impurities.

Upon completion of this course, delegates will have learned what is necessary to develop and validate methods for drug substance and drug product to comply with international regulatory guidelines.

The course will cover:
Overview of developing a stability-indicating method
· Regulatory framework
· What can go wrong on storage?
· Real-time, accelerated and forced degradation
· Chemical and photochemical decomposition
· Requirements for a stability-indicating analytical method
· Stress testing objectives
· Anticipation of likely degradation products
· Common degradation pathways
· Are degradation products likely to be isomers, enantiomers or diastereoisomers?

Workshop: Anticipation of likely degradation products
· Forced degradation (stress testing) of drug substance, as per ICH guidance
· How much degradation is enough? When do we stop?
· Note findings of stress-testing industry comparison

HPLC Methods
· Brief overview of HPLC theory
· Common modes of HPLC: Reversed and normal phase HPLC
· Different approaches to stability analysis using HPLC
  * Determination of degradants and HPLC assay calculation
· Mass balance

Essentials of the stability-indicating HPLC method
· Is the method doing everything I need?

Workshop: Selecting the Separation Mode for a Stability Indicating HPLC Method and Consideration of Detection Issues

Pharmaceutical Packaging - an introductory course

Dates: ***17 & 18 June, 2 & 3 December 2019, London UK***
Expert Speaker: Chris Penfold **Fee:** £620.00 (+VAT)

Pharmaceutical Packaging is a very specialised area with its own unique issues and problems. This two day course will provide delegates with a good basic grounding and appreciation of what is required for the packaging of pharmaceutical and healthcare products. Whether you know nothing, have a basic understanding or are familiar with the area, this course will provide you with the useful knowledge and insights from an expert who has worked in the industry for over 25 years

What it covers?
- Packaging component and material selection
- Key properties of various packaging materials/systems
- Pack testing and evaluation
- Packaging component specifications
- Printing processes and controls
- Artwork generation and control
- Regulatory requirements eg MA packaging requirements, Braille, 2D Data Matrix barcodes, Child resistance, Tamper Evidence, Readability and others
- Transit packaging
- Trade/Supply Chain requirements

Who should attend:
- Account Managers
- Artwork Producers
- Auditors
- Business Developers
- Clinical Trial Suppliers
- Logistics Personnel
- Packaging Design/Labelling Personnel
- Project Managers
- Purchasers
- Quality Assurance and Control Personnel
- Regulatory Personnel
- Suppliers to the industry
- Technical Writers

HPLC Analytical Method Development and Validation

Dates: ***15 & 16 October 2019, London UK***
Fee: £1200.00 (+VAT if applicable)
Early-bird fee: £1080.00 available (+VAT if applicable)
Expert Speaker: Dr Mark Powell

Analytical methods must be validated to provide reliable data for regulatory submissions. These methods are essential for a number of purposes, including testing for QC release, testing of stability samples, testing of reference materials and to provide data to support specifications.

This course provides a comprehensive coverage of the method development and validation requirements that are essential to progress a pharmaceutical compound, at each stage of product development. Upon completion of this course, delegates will have learned what is necessary to develop and validate methods for drug substance and drug product to comply with regulatory guidelines.

The course is designed for
Scientists working with HPLC who need to further their understanding of the technique in order to develop better methods faster. Scientists who have to validate HPLC methods in accordance with current internationally-accepted guidance. HPLC technicians working in R&D laboratories, quality control laboratories and stability testing laboratories. Managers with a responsibility for generating regulatory submissions.

BOOK with 'Development of Stability-Indicating HPLC Methods' 14 October for a reduced rate

Parenteral Products

Dates: ***21, 22 & 23 October 2019, London UK*** **Fee:** £1720.00 (+VAT if applicable)
Early-bird fee: £1548.00 (+VAT if applicable) if booked and paid by 28 August 2019

Three Day Intensive Course Covering Formulation, Product Development, Sterile Manufacture and Quality Assurance with Special Emphasis on Formulation, Biotechnology Products, Operational and GMP Issues and Sterilisation Processes.

Compared to other dosage forms, Parenteral Products present unique challenges in both their development and manufacture as their method of administration requires sterile and pyrogen free products. During formulation and development studies, products need to be formulated to meet solubility and stability requirements, as well as ensuring compatibility with manufacturing operations and the intended administration route. Biological products present additional formulation and analytical challenges often including the need for freeze drying to facilitate long term storage. Primary packaging is particularly critical for parenteral products as sterility and efficacy needs to be maintained throughout the product's shelf life. In recent years there has been increasing emphasis on devices to facilitate the administration of parenteral products and enable products suitable for self-administration to be developed.

From a manufacturing perspective, the need to achieve sterile, pyrogen free products that also have extremely low particulate levels is paramount. Facilities, equipment and utilities must all be appropriately designed and validated to ensure that microbial, chemical and physical contamination is prevented. Sterile product operations are considered the highest risk category amongst the main pharmaceutical dosage forms by the regulatory authorities and subsequently, are the focus of detailed licence application review and frequent inspections.

Course Objectives
This Course will provide an overview of the design and manufacture of a range of parenteral products, with a mixture of lectures, case studies and workshops. The workshops are designed to encourage interaction between delegates and presenters and to enhance participants understanding of specific key aspects of parenteral products. The course will cover routes of parenteral administration, types of parenteral product, common formulation strategies and relevant regulatory guidelines. The formulation of biological and freeze dried products will also be discussed as well as primary packaging and delivery devices.

The discussion of parenteral product manufacture will include problems encountered in the production environment, sterilisation, depyrogenation, media simulations and the quality assurance of parenteral products. The Course will also outline the use of isolators and access barriers for aseptic processing and discuss the quality criteria for water for injections. GMP requirements and regulatory expectations specific to parenteral products and sterile processing will be discussed throughout the course

A feature of the Course is the Workshops designed to enhance participant's understanding of specific aspects of Parenteral Products

Who Should Attend
Graduates, Managers, Scientists and Technical staff in industry or hospitals who wish to develop an overall understanding of the formulation and manufacture of parenteral products. This includes scientists in QA/QC and Regulatory Affairs. The course will be particularly useful for staff that are transferring or changing responsibilities to a role involving the development and manufacture of parenteral products

Pharmaceutical Aerosols, Dry Powder Inhalation Systems and Nasal Delivery Devices

Dates: ***25, 26 & 27 November 2019, London UK*** **Fee:** £1720.00 (+VAT if applicable)
Early-bird fee: £1548.00 (+VAT if applicable) If booked and paid by 23 September 2019

A Three Day 'Team Taught' Intensive Course for Scientists, Managers and Technicians

Course Background
Pharmaceutical aerosols, (particularly as metered dose inhalers (M.D.I.'s) and dry powder inhalation systems, have over recent years, shown a steady growth in conjunction with nebulisers and nebulisation systems. More recently nasal delivery devices are increasingly being used as novel drug delivery systems. The advantages and disadvantages of all these devices will be compared, with M.D.I's and dry powder inhalation systems being covered in detail from development through marketing, launch and patient use. The increasing demands of the world's regulatory authorities in terms of product performance, safety and quality and how this has led to more sophisticated testing procedures together with a rational approach to product evaluation and supporting documentation will be reviewed.
The purpose of the Course is to provide a sound background in aerosols generally and metered inhalers and dry powder devices, specifically. Since none of these product administration systems can be developed in isolation, a high level of integration is required between product, pack/device so that an adequate performance and shelf life can be achieved by effective testing procedures. This involves a thorough knowledge of formulations and the materials (metal, plastics, rubbers, etc.) from which the pack/device component may be produced. The aim of the Course is to provide information across these diverse areas.

The course will cover -
Aerosol Introduction Aerosols and aerosol technology
Formulation of Aerosols General formulations and formulations for MDI's. Challenges for formulating proteins and peptides
Aerosols, Valves and Containers Understanding valve systems, drawings, properties of materials and functional features
pMDI Performance, Testing and Issues
Aerosol Filling, Facilities and Equipment A review of methods, equipment, facilities and environmental needs.
Who Should Attend? The Course is designed to provide a broad knowledge base on aerosols and dry powder devices with limited reference to nebulisers. It is therefore intended for those who require an overview of the technologies involved as well as those who require specialised knowledge of more specific areas, ie. R & D, Development, Production, QA, QC and Regulatory Affairs.

GMP Auditor Training for Quality Systems

Dates: ***29, 30 & 31 October 2019 London UK*** **Expert Speaker:** Susan Rocca

This 3 day course is aimed at Quality Assurance auditors and production management for Level 2 internal audits and supplier auditing

Current GMP legislation requires that there are internal and external audit programmes operating as part of an integrated quality system. Effective auditing should provide evidence of operational compliance status and identify opportunities for continuous improvement and improved supply chain control and relationships. Both internal auditors and supplier auditors need to have in-depth, interactive training in audit techniques and understand how audit activities complement quality and risk management processes to ensure business compliance and identify quality improvements. Participants will learn about the key techniques and thought processes which can be used by auditors to maximize the benefits of each type of audit. These include planning and preparation, structuring the audit, managing the audit team, classifying observations, close out and reporting, CAPAs and follow up.

The course includes role play sessions to practice auditor/auditee communications. There is also a session on Data Integrity and implications of the US—EU MRA
The course will also *compare and contrast paper and electronic documentation, electronic batch records and all quality systems items on an electronic system called Trackwise*

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 ***"Fantastic course which gave a good overview of what is required"***

Introduction to the Formulation & Stabilisation of Protein and Peptide Drug

Dates: ***16 & 17 September 2019, London UK*** **Expert Speaker:** Dr Mark Cornell Manning
Fee: £1595.00 (+VAT if applicable) **Early-bird fee:** £1436.00 (+VAT if applicable) If booked and paid by 31 July 2019

Two-Day Course with the Emphasis on Formulation and Dosage Form Design Strategies, Mechanisms of Degradation and Excipient Choices

Pharmaceutical macromolecules, whether proteins or peptides, are highly susceptible to degradation throughout the development process. From the time the active pharmaceutical ingredient is synthesized, it is subjected to stresses that can induce damage. For example, the processes of isolation, purification, formulation, packaging, and storage each provide opportunities for chemical and physical changes to occur with potentially disastrous consequences to the final product.

This course will provide a detailed overview of the common methods of degradation for proteins, as well as the most current strategies for stabilisation and formulation of pharmaceutical macromolecules. Emphasis will be placed on a mechanistic, rather than a phenomenological approach, towards stabilisation of peptides and proteins. Special emphasis will be given to the differences between peptides and proteins.

The Objective of this course is to provide attendees with:

- A perspective on the importance of formulation development in the biopharmaceutical industry
- An understanding of the most common mechanisms of protein degradation
- An overview of where pharmaceutical macromolecules are most likely to be damaged during handling and storage
- The physical basis for the aggregation and solubility behaviour of polypeptides
- Descriptions of the most important analytical tools needed in formulation development
- Detailed strategies for stabilization of peptide proteins and chemically modified proteins

Who Should Attend Anyone involved in the development of pharmaceutical macromolecules as commercial therapeutic agents, whether for human or veterinary use. This course is intended for those new to the field and those who simply wish to obtain an overview of this important discipline. This would include those involved in research & development, production, purification, formulation, manufacturing, and delivery of peptides and proteins. Those involved in overseeing these operations would benefit as well as those working at the bench.

Latest Advances in the Stabilisation and Formulation of Protein and Peptide

Dates: ***18 & 19 September 2019, London UK*** **Expert Speaker:** Dr Mark Cornell Manning
Fee: £1595.00 (+VAT) **Early-bird fee:** £1436.00 (+VAT) If booked and paid by 31 July 2019

Two-Day Intensive Course with the Emphasis on Formulation and Dosage Form Design Strategies, Analytical Methods and Excipient Choices

Pharmaceutical macromolecules, whether proteins or peptides, are highly susceptible to degradation throughout the development process. From the time the active pharmaceutical ingredient is synthesized, it is subjected to stresses that can induce damage. For example, the processes of isolation, purification, formulation, packaging, and storage each provide opportunities for chemical and physical changes to occur with potentially disastrous consequences to the final product.

Course Background and Objectives

To provide attendees with

- A solid understanding of the most common mechanisms of protein degradation;
- An overview of where pharmaceutical proteins are most likely to be damaged during bioprocessing and storage
- The physical basis for the aggregation and solubility behaviour of polypeptides:
- Descriptions of the most important analytical tools needed in formulation development, especially for aggregate quantitation and characterisation;
- An overview of the latest advances in protein formulation development
- An appreciation of the importance of packaging in product performance
- Detailed strategies for stabilization of peptides as well as proteins

This course will provide a detailed overview of the common methods of degradation for proteins, as well as the most current strategies for stabilisation and formulation of pharmaceutical macromolecules. Emphasis will be placed on a mechanistic, rather than a phenomenological approach, towards stabilisation of peptides and proteins. Special emphasis will be given to the differences between peptides and proteins.

Who Should Attend - Anyone involved in the development of pharmaceutical macromolecules as commercial therapeutic agents, whether for human or veterinary use. This would include those involved in research & development, production, purification, formulation, manufacturing, and delivery of peptides and proteins. Those involved in overseeing these operations would benefit as well as those working at the bench. *This course is intended for those currently working in the field and presumes a basic working knowledge of protein structure.*

BOOK BOTH COURSES FOR A REDUCED RATE – email: info@pharma-training-courses.com

Pharmacokinetics in Drug Development

Dates: ***October/November 2019, London UK*** **Expert Speaker:** Dr Graham Blakey
Fee: £1200.00 (+VAT) **Early-bird fee:** £1080.00 (+VAT) *Advise if you are interested in this course*

In drug development clinical pharmacology is tasked to ensure that patients receive the right dose at the right time. This ensures that the new medicine is safe and effective throughout the patient population. To achieve this goal, it is necessary to recognise the factors that can alter drug response. Knowledge of pharmacokinetics (PK) and pharmacokinetic/pharmacodynamic (PK/PD) relationships is at the heart of this endeavour. For many drugs, clinical pharmacology information accounts for almost 50% of the final drug label, further emphasising the importance of PK understanding in drug development.

Course Objectives:

To provide participants with an overview of the principles of PK and PK/PD modelling and how, together with regulatory guidances, they can be used to effectively deliver drug development programmes

What will participants gain?

* Increased confidence to discuss PK issues within their drug projects * Understanding of the common PK terms and their importance * Understanding of how PK data influences the clinical development Programme * An understanding of the factors that contribute to variability in PK * The role of PK/PD modelling in drug development * An appreciation of how regulatory guidances influence PK

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Email: info@pharma-training-courses.com Website: www.pharma-training-courses.com

Pharmaceutical Dissolution Testing – a Hands-on Course

Dates: ***21, 22, 23 & 24 May, 8, 9, 10 & 11 October 2019, London UK*** **Expert Speaker:** Dr Mark Powell
Fee: £1850.00 (+VAT if applicable) **Early-bird fee:** £1665.00 (+VAT if applicable) *If paid prior to course*

Dissolution and drug release tests are directly relevant to the safety and efficacy of many common pharmaceutical dosage forms. To achieve reliable and reproducible results, it is important that analysts understand the importance of correctly setting up and sampling from the chosen apparatus. In addition to use of dissolution testers, this course will also cover equipment qualification, development and validation of dissolution procedures, and the use of dissolution testing in the assessment of bioavailability and bioequivalence.

After completing this course, trainees will be familiar with the different types of pharmaceutical dissolution testing equipment, understand the factors that must be considered when developing a test, and be able to perform a dissolution test.

Programme

Day 1 - Why do we perform dissolution testing? Dissolution theory, sink conditions and intrinsic dissolution rate Dissolution and drug release testing apparatus **Practical session:** setting up a dissolution tester with basket and paddle apparatus **Day 2 - Requirements for different dosage form types (including data interpretation)** ▪ Immediate release ▪ Extended release ▪ Delayed release ▪ Transdermal delivery systems Dissolution equipment qualification **Practical session:** delegates will perform a dissolution test on an immediate release drug product **Day 3 - Dissolution method development** ▪ General requirements · Selection of dissolution medium ▪ Apparatus and agitation · Sampling (time points & filtration) ▪ Assay requirements **Dissolution method validation** ▪ Setting acceptance criteria with reference to drug product specifications ▪ Specificity ▪ Linearity/range ▪ Accuracy/recovery · Precision ▪ Robustness ▪ Solution stability D**ay 4(half-day - optional)** Dissolution and the assessment of bioavailability/bioequivalence · Bioavailability and bioequivalence - definitions and *in vivo* evaluation · *In vitro* biowaivers · *In vitro-in vivo* correlation

Hands-on Tablet Development, including Pre-Formulation, Formulation and Process Development

Dates: ***10, 11 & 12 April, 26, 27 & 28 June, 4, 5 & 6 December 2019, Croydon Greater London UK***
Expert Speaker: Dr Michael Gamlen **Fee:** £1770.00 (+VAT if applicable) **Early-bird fee:** £1593.00 available

This unique 3 day course is designed to integrate the key elements of tablet development with hands-on, practical experience in a small scale, lab scale test facility. Each day will consist of lectures on aspects of tablet development, followed by linked sessions in which participants take part in related experimental work. The course enables attendees to apply the theory learnt in the taught sessions, and also to directly observe the effect of formulation on product properties, and relate the theory to the practice of Quality by Design (QbD).

Who Should Attend?

- Newcomers to tablet formulation development and manufacturing
- Production operators who need a better understanding of their products and how they have been developed
- Analytical and QC staff who would benefit from understanding the tablet development and production process
- Experienced personnel in one area of product development who need a broader overview
- Project team members needing a broader insight into formulation development including preclinical, clinical, and project management representatives
- Regulatory staff who would benefit from brief practical experience of the processes for which they are compiling dossiers
- Regulatory agency staff requiring practical experience *Numbers are restricted for maximum benefit to participants*

Powder Technology for Pharmaceutical Development and Manufacturing

Dates: ***25, 26 & 27 September 2019, London UK*** **Expert Speaker:** Dr Michael Gamlen
Fee: £1770.00 (+VAT if applicable) **Early-bird fee:** £1593.00 (+VAT if applicable) if booked and paid by 31 July
Powder properties have a major impact on formulation, development and manufacturing of Oral Solid Dosage forms. They also play an important role in meeting the requirements of Quality by Design for OSDs.

In this course we examine powder properties and their role in these important processes, so that attendees can understand:

- The influence of drug substance properties on formulation development how and why particular tablet components are selected and what impact they have on powder properties and tablet behaviour
- Manufacturing method selection and the importance of powder flow Mechanisms of powder mixing and segregation
- Powder properties, Critical Quality and Material Attributes, and the Product Control Strategy
- Effects of blending behaviour and scale on Critical Process Parameters
- The relationship between input material properties and tablet properties

Proper integration of these elements is essential to achieve "Quality by Design" because data from each phase is used to control the next step in the development process. By achieving proper integration based on sound scientific principles based on powder technology, many development and production problems can be avoided, and formulation robustness can be improved. The course includes case studies of tablet formulation development and a detailed step by step analysis of all elements of the tablet manufacturing process.

By the end of the course the attendees will be able to recognise key powder properties which affect process performance, and make improved judgements about how to improve processes.

Pharmaceutical Granulation and Compression

Dates: ***11, 12 & 13 November 2019, London UK*** **Course Director:** Dr Mike Rubinstein
Fee: £1770.00 (+VAT if applicable) **Early-bird fee:** £1593.00 (+VAT if applicable) if booked and paid by 20 September

Course Objectives

The aims of the Course are to provide a comprehensive and sound understanding of the theory and practice of tablet granulation and compression and to appreciate the various processes batch or continuous, that are available. The importance of the granulation process in producing good quality tablets will be emphasised. The modern techniques of extrusion, spheronisation, powder layering, roller compaction, fluid-bed processing, spray drying, melt extrusion, oral dispersion technology and tablet compression will be covered. The Course will be taught primarily by industrial scientists who have been closely involved with investigating these granulation and compression processes and thus a pragmatic approach will be adopted throughout.

Summary of Key Benefits of Attending At the end of the Course participants will have: * An understanding of the fundamental principles of granulation and the advantages, disadvantages and potential of the various granulation, layering, spray drying, oral dispersion, extrusion and spheronisation methods * An understanding of the techniques and processes available for granulation in relation to controlled release products * Detailed knowledge on current ideas and thoughts on Scale-Up, Transfer Technology and SUPAC * An appreciation of some of the compression problems that can arise and how they can be overcome * A knowledge of the factors that should be taken into consideration when selecting granulation and compression equipment * Specialist knowledge on fluid-bed granulation, roller compaction, layering, spray drying, oral dispersion technology and melt extrusion * Detailed knowledge on compression machinery * An appreciation of the techniques available and their limitations for end-point granulation control * A knowledge of the reasons why problems arise in the granulation and compression processes and how these problems can be avoided