PHAGECON
PHARMACEUTICAL SERVICES AND CONSULTING

Training course on Variations

Filling Variations

23rd and 24th May 2016
Hotel HF Fénix Urban, Lisbon

- ✓ Create an effective basis for further refinement focussed on the clients exact requirements
- ✓ Understand EU requirements
- ✓ Examine the basis of regulations 1234/2008 and 7142/2012 in Europe
- ✓ Understand when grouping and worksharing is appropriate
- ✓ Learn Filing tips to submit Type IA, IB and Type II applications and how to get it right fist time
- ✓ Examine the mechanisms for variations through the Centralised Procedure, Mutual Recognition and Decentralised Procedures
- ✓ Learn special topics in variations and how to handle them as active ingredient master files
- ✓ Analyze the impact of referrals on variations and lifecycle management

OBJECTIVES

This 2-day course is designed to provide individuals with an in-depth awareness of the rules and procedures for filing variations and extensions, focusing on the legislation changes to Variations to Marketing Authorisations. This training will help you become more confident in your daily pratices after two days of intensive lectures, group work and discussion sessions, covering everything you need to know about Filing Variations

This training will allow participants to:

- Gain a comprehensive overview of filing variations
- Address new regulations governing variations to national marketing authorisations and work-sharing
- Understand and apply the rules will ensure that you can file the variations successfully and avoid rejections
- Gain highly practical skills through the use of case studies covering regulatory goals, group discussions, simulations and assessments

Who Should Attend?
This course is specifically designed for personnel in Regulatory Affairs of pharmaceutical and biotech companies who need to acquire basic knowledge or need to update their knowledge regarding filing variations, as well as to other personnel that will likely work in Regulatory Affairs, Dossier registration department, Product Information, RA compliance or in other disciplines impacting the process of filing Variations, such as manufacturing, development, clinical safety and pharmacovigilance.

You'll certainly gain the expertise to:

- Clarify the latest variations revisions
- Formulate Variations procedures that achieve faster approval
- Manage the practical hurdles of submitting your Variations on time and with the right supporting data
- Understand the impact of the CTD on your Variation dossier
- Collect and present complete information on your Variations
- Streamline your Variation procedures for international Applications
- Tackle the challenges of type II Variations under the MRP

TRAINER

Andrew Willis BSc. (Hons), MBIRA, MTOPRA – Independent Consultant to Pharmaceutical Companies at A Willis Consulting and Senior Partner at Ricanto Ltd

Andrew is a Regulatory and Development consultant with over 28 years of experience.

His management roles have seen him act as global Vice President of Regulatory Affairs and Consulting Services at Catalent Pharma Solutions, creating business and marketing strategies for complex pharmaceutical development projects.

This year he has been involved in successful registration of orphan medicinal product; Centralized approval for NCE; oversight of successful CHMP appeal and CMC lead for vaccine and biosimilar projects. Also multiple updated training course now available for advanced regulatory affairs, global CMC requirement including emerging markets, CMC requirement in Clinical stages, updated variation management courses.

He continues to provide training for all major companies in CMC and regulatory aspects and advanced regulatory affairs. Currently have extensive training courses available in Quality By Design, Global Module 3 Requirements, generic and OTC development, as well as in global development strategies and Optimizing the Life of Your Products. Specializing in Lifecycle management, creation of new line extensions and development strategies to maximize return on investment.

Experience with both EU and US applications (NDA, 505 B 2, ANDA, BLA, MAA) for NCEs, generics and line extensions. Experience covers multiple applications, scientific advice meetings, Clinical Trial applications (IND and IMPD compilation and submission), orphan drug applications.

LANGUAGE

- English

LOCATION

Hotel HF Fénix Urban Lisboa
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TRAINING PROGRAM

DAY ONE

Introduction to the Course
- Outlining the aims and objectives of the course
- Identifying individual training needs

Basis of Regulations 1234/2008 and 712/2012 in Europe
- Classification in accordance with the legislation
- Understand the differences between Type IA, Type IB and Type II variations
- Clarify foreseen and unforeseen Variations
- Sharing practical experience with European and national procedures
- Assessing how pharmaceutical companies are operating in this evolving regulatory environment
- Working with Regulators: Lessons learnt

Practical exercise: Analysing and classifying the different changes
- Analysing and classifying the different changes
- Consider the conditions and documentation requirements
- Practice classifying the changes

LUNCH

Grouping and worksharing
- Understanding when grouping is appropriate
- Clarifying what types of Variations may be grouped
- Guidance on assembling a grouped submission
- Understanding when worksharing is appropriate
- Discussion of example cases

Practical exercise: CMC case
- Identify the Variations
- Learn what to consider eligible for grouping
- Draft submission strategy
- Learn how to meet the requirements of eCTD guideline in Variation applications

Filing tips
- Submitting Type IA, IB and Type II applications
- Understand how to ensure that your dossier is complete
- Learn how to get it right first time
- Find out what to do when your application is rejected

Practical session
- Plan the timelines and project management of a Variation submission
- Differences in national EU requirements
- Identify and undertand strategic considerations

DAY TWO

Other procedures
- Article 5
- Urgent safety restrictions
- Understanding when to use extension applications

Submission Planning
- Identify and understand strategic considerations

Data requirements for Type II Variations
- Learn how to identify a Type II change
- Understand how to support Type II changes to ensure regulatory approval
- Gain an appreciation of the complexities of Type II applications

LUNCH

Special topics in Variations
- Handling active ingredient master files as Variations
- Submission of new clinical data

Practical exercise
- Data requirements for more complex changes
- Assess the data requirements for Type II Variations
- Consider extending use into a new patient population
- Integrating new safety information

Variations through National procedures and differences from Centralised Procedure
- Understand the procedures
- Languages and translations
- Explore the Linguistic review process
- Learn about the role of the EMA and EU Commission

Filling Variations Mutual Recognition and Decentralised Procedures
- Understand the procedures
- Understand the responsibilities of the MAH, RMS and CMS
- Learn how to efficiently plan for and run a MR Variation procedure

Case study exercise
- Work through an example potential changes in an MRP authorised product
- Plan the timelines for and project management of a Variation submission

Impact of referrals on Variations and lifecycle management

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REGULATION

Training policy
Phagecon Training believes that training is an asset for companies, not only by the availability of content but also by sharing experiences. Phagecon Training has the responsibility to choose the topics and the design and coordination of the programs. The invited Trainers have the responsibility of the content and documentation provided.

Attendance conditions
Only the participants that have regularized the payment of registration until 1 week before the date of the event, by check issued to Phagecon Ltd., or via bank transfer (Banco Português Investimento - Account No. 1-4404219.000.001 / IBAN PT50 0010 0000 4404 2190 0014 2 / SWIFT-BIC BBPIPTPL), stating the invoice number or the name of the participant . Phagecon Training will confirm the participant presence in the event, once payment has been received.

What is included
Participants, who have settled the payment of their registration, will receive the content and documentation provided by the trainers, coffee breaks andmeals mentioned in the program.

Cancellations
Cancellation of registration must be reported within five business days before the course date. Phagecon Training will return the amount paid, less 10%, related to administrative costs. If you cannot attend the training, you can appoint another person to replace you, but you must notify us by a written comunication, within one business day before the course.

Data protection
Pursuant to Articles 6 and 10 of the Law no. 67/98, of October 26th, Law on the Personal Data Protection, we inform you that your personal details have been deleted from a computer database to be incorporated in the file for trade promotion events, seminars and conferences organized by Phagecon Training, which is duly registered in the National Commission for Data Protection. Also in accordance with Law 97/68, and giving effect to the exercise of rights of information, access, rectification, erasure or opposition of their data by Phagecon Training, you must send a written communication to Phagecon Ltd., with the reference "data protection - Phagecon Training ", to the address Avenida José Malhoa, n.º 2, Edifício Malhoa Plaza, 3º Piso, Escritório 3.7, 1070-325 Lisboa. A photocopy of your identity card / citizen card, must be send accompanying the written communication.

TIME SCHEDULE
Day 1: 9.30h to 18.00h
Day 2: 9.30h to 18.00h

TRAINING FEE
850 € + VAT

☑ Lunch and coffee-breaks are included.

REGISTRATION FORM

Name

Company Job Title

Email Tel. Fax

Address

Inscribed in OF (Ordem dos Farmacêuticos) ☐ If Yes, Membership Number Section

PAYMENT DETAILS

☐ Bank transfer to IBAN PT50 0010 0000 4404 2190 0014 2

☐ Bank check no. Bank amount of issued to Phagecon, Lda.

Invoice must be issued to Taxpayer Id. No.

Please fill in the registration form and send it by email (training@phagecon.pt), fax or post courier to Phagecon, Lda.

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