



PHAGECON
PHARMACEUTICAL SERVICES AND CONSULTING

Training Course on CTD Module 3

Chemistry, Manufacturing and Controls

26th and 27th February 2018
Lisboa, Lisbon

- ✓ Compile and submit the Quality and Pharmaceutical section of your registration dossier in Europe
- ✓ Ensure suitability of data from your development and manufacturing groups
- ✓ Deal effectively with Regulators: Meeting the legal framework and guidelines for the CMC / Quality part of the dossier and links GMP

- ✓ Incorporate Quality by Design into your CTD requirements and create the optimal Module 3
- ✓ Understand the benefits of a high quality Module 3 on ensuring your products is maintained on the market
- ✓ Understand the regulatory legal framework and influences on your Module 3 style

OBJECTIVES

This 2-day course will provide you with clear understanding of the US and European regulatory requirements for Module 3 (CTD) of your application, and will show you how to compile this important part of your submission dossier. The course sessions will also examine the impact of the Common Technical Document.

This training will allow participants to:

- Compile and submit Module 3 (CTD) of your registration dossier
- Ensure that Module 3 (CTD) of your dossier contains all data needed
- Achieve the quickest turnaround of your submission
- Deal effectively with regulators

Become more confident in your daily practices after two days of intensive lectures, group work, and discussion sessions, covering everything you need to know about compiling the chemistry and pharmacy section of your dossier.

Who Should Attend?

This course is specifically designed to address the need of Regulatory Affairs Managers/Officer/Assistants, Compliance Managers, Documentation Managers, Product Registration Personnel, Qualified Persons and key contributors to the submission package.

You'll certainly gain the expertise to:

- Build Module 3 (CTD) of the dossier to meet regulatory requirements
- Know the legal framework and guidelines for the CMC/Quality part of the dossier
- Meet the legal responsibilities of the Manufacturing Authorisation Holder, and the designated qualified person
- Define the impact of the Common Technical Document on the Quality section of the dossier
- Write variation submissions for Europe and get approval first time
- Structure your submission teams to ensure compliance
- Link your dossier requirements to GMP
- Minimise delays in your submission by providing accurate documentation
- Use certificate of suitability as replacement of data



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 31 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

Lisboa, Lisbon



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TRAINING PROGRAM

DAY ONE

What is the CTD? And discovering the road map to Module 3 Understanding ICH

Preparing the drug substance section of the application

- Analysing the needs for the section
- How to submit information – Drug Master Files, Certificates of Suitability, other methods
- European Submissions, CEP and ASMF requirements
- Detailed information requirements for the section
- Q11 Explained – EU and US expectations of FMEA analysis

Case study: Essential information from API suppliers

- The case study will allow participants to identify and understand the essential data requirements from API suppliers / manufacturing section and impact on finished product

LUNCH

Examining the content of the sections concerning the drug product

Composition and development of the drug product

- Defining the formulation
- Identifying the data needs for the pharmaceutical development section, explaining QBD and FMEA requirements
- Multiple Examples of Development Report Content - practical for table of contents and creation of QBD Pyramid

Writing the section on manufacture of the drug product and process validation

- Examining the content of the section: How much information to provide
- Defining the difference between process development and validation
- Examining the content of the section
- Examine Process validation - New Paradigm Stage 1 - 3

DAY TWO

Writing the sections on control of the finished product

- Examining the content of the section
- Control of the drug product
- Examples of Specifications for Multiple Product Types
- Examples for Method Summaries

Case study: Specifications of the finished product

- The case study will allow participants to identify and understand the writing and justification of specifications

Compiling the sections for control of Excipients and Packaging

- Examining the content of these sections
- Examples of Excipient Data / Packaging Component data

LUNCH

Writing the stability section

- Examine the content of the section
- Evaluation of stability data and the impact on shelf

The function and content of the Quality Overall Summary

- Overview of the current approaches
- QOS explained
- Reviewer Questions

Whats New

- Overview of ICH Q3D and Annex 16

Best Practices

In this section participants will get to grips with recommendations to consolidate quality dossier during variations and renewals



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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 and meals mentioned in the program.

Cancellations

Cancellation of registration by the participant 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 communication, within one business day before the course.

Phagecon can proceed with the cancellation of the training within five business days before the course date once a minimum number of participants will not be fulfilled. The participants already registered will be 100% reimbursed.

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: 9.00h to 18.00h
Day 2: 9.00h to 16.30h

TRAINING FEE

850 € + VAT

☒ Lunch and coffee-breaks are included.

REGISTRATION FORM

Name	<input type="text"/>		
Company	<input type="text"/>	Job Title	<input type="text"/>
Email	<input type="text"/>	Tel.	<input type="text"/>
		Fax	<input type="text"/>
Address	<input type="text"/>		
Inscribed in OF (Ordem dos Farmacêuticos)	<input type="checkbox"/>	If Yes, Membership Number	<input type="text"/>
		Section	<input type="text"/>

PAYMENT DETAILS

<input type="checkbox"/>	Bank transfer to IBAN PT50 0010 0000 4404 2190 0014 2		
<input type="checkbox"/>	Bank check no. <input type="text"/> Bank <input type="text"/> amount of <input type="text"/> issued to Phagecon, Lda.		
Invoice must be issued to	<input type="text"/>	Taxpayer Id. No.	<input type="text"/>

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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