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INTRODUCTION TO PHARMACOKINETICS FOR THE NON-SPECIALIST

LIVE Online Academy

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Grow your knowledge and confidence in PK/PD to fully understand the data and decisions made

COURSE OVERVIEW

Pharmacokinetics (PK) and pharmacodynamics (PD) play a key role in drug development, and a good understanding of the implications of PK/PD data is crucial when designing clinical trials or preparing a drug submission dossier. As a professional working with PK/PD data on a regular basis you must have a solid understanding of the topic to communicate effectively with the development teams - a daunting and challenging task, due to the breadth and complexity of the topic area.

This course assumes no prior PK knowledge, and aims to give you a broad understanding of this fascinating subject, using multiple case studies and relevant examples. You will learn what pharmacokinetics involves, what data is collected and its impact on the drug development process. By learning these skills you will be able to understand, communicate and challenge the data presented to you.

Dr. Stefano Persiani

Dr. Stefano Persiani is currently Director of Translational Sciences and Pharmacokinetics at Rottapharm Biotech, Italy. After years working in academia, Dr. Persiani moved to the pharmaceutical industry and CRO sector holding different positions in R&D at Farmitalia Carlo Erba, Pharmacia, Upjon, and Zambon Group.

His experience within pharmaceutical companies and CROs ranges from drug discovery and lead optimization to early preclinical and full clinical development in different therapeutic areas including oncology, respiratory, CNS, anti-infective, cardiovascular, gastrointestinal, and rheumatology.

MODULE ONE

The Role of PK in Drug Development

- What is PK?Understand the PK/PD model of therapeutics
- The importance of PK throughout the phases of drug development
- The increasing importance of PK in the go/no go decision
- Interdisciplinary interaction in the pharmaceutical industry – let’s all speak the same language
- PK as a tool in strategic decision making
- How PK knowledge is used to reduce time and cost
- What do we measure and how do we measure it?

MODULE TWO

Fundamentals of Pharmacokinetics 1

- Absorption
- Distribution
- Metabolism
- Excretion
- Elimination
- Disposition
- PK in drug candidate selection

MODULE TWO

Fundamentals of Pharmacokinetics 2

- Essential drug concentrations such as in blood, plasma and excretions
- Basic terminology such as half-life, clearance and volume of distribution
- Essential measurements: end points such as Cmax, Tmax, and AUC
- Other essentials, drug metabolism, drug transporters and the blood/brain barrier
- Key features and misconceptions

MODULE THREE

Pharmacokinetic Analysis

- Examine different types of PK/PD analysis
- Compartmental vs non-compartmental analysis: Jargon explained

Drug-Drug Interactions

- Cytochrome P450 - What are they? What do they do? What do they tell us?
- In-vitro and in-vivo measurements
- Species differences- extrapolation to man
- Dangers and pitfalls

Pre-clinical Pharmacokinetics

- Studies with radiolabelled drugs
- Toxicokinetics

MODULE FOUR

Pharmacokinetic and Pharmacodynamic Studies

- Different routes of administration
- Single dose vs multi dose PK
- Bioavailability and bioequivalence
- Effects of food, gender, race, age, medical conditions
- Use of biomarkers in PD analysis
- Human radiolabelled studies

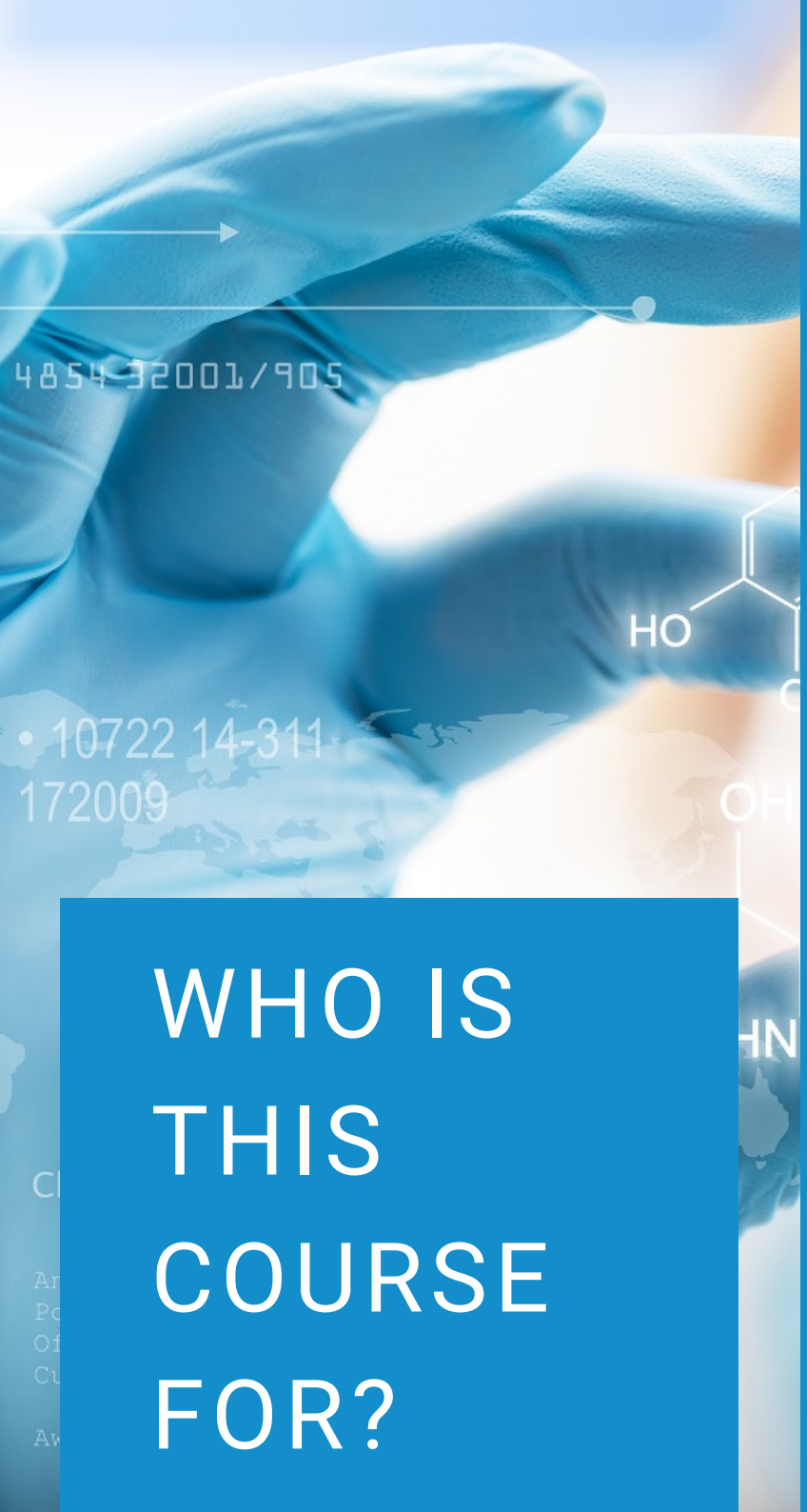
MODULE FIVE

Pharmacokinetics and Regulatory Guidelines

- What do the Regulators say?
- The impact of the EU Directive
- EMA guidelines: Paediatric, hepatically impaired, renally impaired
- Differences between FDA and EMA requirements

Reporting of Pharmacokinetic Data

- How do we report data?
- What are we trying to demonstrate?
- Common pitfalls



WHO IS THIS COURSE FOR?

This course is aimed at anyone who comes into contact with PK/PD data but does not require specialist knowledge in the field. No previous knowledge of PK/ PD is assumed.

The course is designed to give an overview of the field without the equations. It will be of particular benefit to professionals working in:

- Development
- Preclinical
- Phase I
- Licensing
- Clinical Operations
- Regulatory Affairs
- Data Management
- Drug Safety
- Clinical Pharmacology
- Registration

For information contact our training consultants

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