

# The thirteenth advanced level workshop on

Pharmacokinetic - Pharmacodynamic data analysis:  
A hands-on residential course using Phoneix WinNonlin V6



ROYAL  
PHARMACEUTICAL  
SOCIETY

Sunday 15 - Thursday 19 May 2011  
Moller Centre, Cambridge

In partnership with the  
Swedish Academy of Pharmaceutical Sciences



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# OBJECTIVES

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An advanced and well-established four-day residential course designed to:

- Provide an interface between the computer analysis of PK and PD data and physiological concepts.
- Equip delegates, through lecture sessions, with an advanced understanding of all aspects of the subject, including pharmacodynamic theory, interpretation of computer output, practical experimental design, discrimination between rival models and combining data of different sources.
- Give delegates the unique opportunity of access to the WinNonlin modeling package to undertake hands-on exercises on real-life case studies - allowing delegates to apply the concepts learnt in- lecture sessions to an extensive number of real-life problems and data-sets. Users of software other than WinNonlin will also benefit from the methods discussed in the lectures and hands-on sessions.
- Allow delegates one-to-one time with the expert course tutors in problem-solving sessions.
- Participants are encouraged to bring their own kinetic/dynamic data.
- Provide reference material for use after the course through a full resource pack and textbook relevant to predictive science.
- Allow delegates to network with course tutors and other delegates from the field through a full social programme.

### Terms and Conditions

Should you find that you are not able to attend the event after booking a place, please advise us in writing as soon as possible. If a colleague is able to attend in your place and you notify us in writing, we are pleased to accept the substitution at no charge. In the event that it is necessary to cancel a registration, please notify us in writing. A processing fee is payable. For cancellations, the following refunds will apply: Over 30 working days before the event: 50% of the fee; 30 or less than 30 working days: nil. The time of notification is taken at the date of receipt of fax or letter. Substitution is permitted at any time if notified in writing. We reserve the right to amend the programme. In the unlikely event of cancellation of the event, delegates will receive a full refund of fees but we cannot be held liable for other expense incurred by delegates.



## WHO SHOULD ATTEND

- Advanced level research scientists in the pharmaceutical industry, academia, regulatory agencies and contract research firms who have a minimum of 3-5 years of experience in PK/PD analysis and modelling.
- Participants who attended the earlier introductory workshop.
- Researchers with a working knowledge of WinNonlin who want to learn more about the advanced features of the programme.
- Primary and safety pharmacologists engaged in PKPD studies

## WHAT PREVIOUS DELEGATES HAVE SAID

“I would like to thank the teachers for their patient, encouraging and often painstaking focus on our comprehension”

“The lecturers were really helpful and were ready for any type of question”

“This is certainly the best course that I have attended for several years”

## LEARN FROM A TEAM OF EXPERTS



**Dr Johan Gabrielsson** is a Senior Principal Scientist at AstraZeneca R&D Mölndal. He is author of the book ‘Pharmacokinetic and Pharmacodynamic Data Analysis: Concepts and Applications’ 4th ed. (2006). He is academically affiliated with the Department of Pharmacology, Gothenburg University, Sweden. He has conducted numerous workshops on biological (PK/PD) data analysis within and outside the pharmaceutical industry.



**Dr Daniel Weiner** is a Senior Vice President and CTO at Pharsight Corporation. He is co-author of the book ‘Pharmacokinetic and Pharmacodynamic Data Analysis: Concepts and Applications’ 4th ed. (2006). He has conducted numerous workshops on biological (PK/PD) data analysis and has served as an expert consultant to the FDA.



## VENUE

The Moller Centre in Cambridge is a modern and comfortable purpose-built conference and training venue in the grounds of Churchill College - easily accessible by road, train and air. Car park facilities are available.



# PROGRAMME

## Sunday 15 May

17.00 Registration  
18.30 Welcome drinks reception  
19.15 Course dinner

## Monday 16 May

08:15 **Introduction**

08:30 **Pharmacodynamics (Equilibrium)**

Review of steady-state models  
Steady-state models  
Kinetics of drug action  
Initial parameter estimates  
Design issues and case studies

09:45 Coffee/tea

10:00 **Pharmacodynamics (Distributional delays)**

Steady-state models vs. time delay  
Basic concepts on distributional delays  
Modelling QT-data with link models  
Design issues and case studies

10:45 **Hands-on session 1**

Inst. equil. models, steady-state, log-linear, sigmoidal  
Incomplete datasets

12:15 Lunch

13:15 – 16:45 **Hands-on session 2**

Modeling EEG-data with link models  
Modeling QT- & MAPD data with link models  
Design issues and case studies

14:45 Coffee/tea

16:45 **Numerical grammar**

18:15 Course dinner

19:15 **Evening exercise on your own**



## Tuesday 17 May

08:30

### Pharmacodynamics (Turnover A)

Residual questions from day 1  
Turnover concepts I - 'The gang of four'  
Constant and variable baseline  
Comparing link- and turnover models  
Initial estimates  
Design issues and case studies

09:45

Coffee/tea

10:00

### Hands-on session 3

Turnover models I-IV  
Turnover model I of blood clotting data

12:15

Lunch

13:15

### Hands-on 3 cont.

Collapsing hysteresis loops  
Design issues and case studies

15:00

Coffee/tea

15:15

### Group exercise – FTIM compound selection

Compound evaluations  
Dose prediction, dose nomogram  
Assessment of safety margin

17:15

### Wrap-up & project exercise

18:15

Course dinner

19:15

### Optional Phoneix NLME demonstration

# PROGRAMME

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## Wednesday 18 May

08:30

### Pharmacodynamics (Turnover B)

Residual questions from Day 2  
The thought process  
Peak shifts  
Limited production and loss  
Synergy by means of turnover models  
Transduction models  
Irreversible response  
Initial parameter estimates

09:45

Coffee/tea

10:00

### Hands-on session 4

Turnover models I-IV  
Comparing IRP and Link  
Design issues and case studies

12:15

Lunch

13:15

### Hands-on session 4 cont.

Turnover models I-IV cont.  
Fitting multiple dose PD data

15:15

Coffee/tea

15:30

### Introduction and group exercises

Group Exercise I  
Group Exercise II  
Group Exercise III

17:15

### Wrap-up & group exercise

18:45

Course dinner

20.00

Social programme



# PROGRAMME

## Thursday 19 May

- 08:30                    **Pharmacodynamics (Adaptation)**  
Residual questions from Day 3  
Models for adaptation  
Tolerance and rebound  
Feed-back systems  
Oscillating baselines  
Initial parameter estimates
- 09:45 – 12.15        **Hands-on session 5**  
Turnover models I-IV continue  
Synergy  
Transduction models  
Irreversible response  
Design issues and case studies
- 10:15                    Coffee/tea
- 12:15                    Lunch
- 13:15                    **Hands-on session 5 cont.**  
Feedback  
Analyzing pd data from phase i study
- 14:15                    **Experimental design**  
Own datasets  
Synergy
- 15:15                    **Summary**
- 15.30                    Close of course

**Please note: all delegates will require a copy of the 4th edition of “Pharmacokinetic/ Pharmacodynamic Data Analysis: Concepts and Applications” (Swedish Pharmaceutical Press 2006, 1250 pages). A complimentary copy of this textbook will be given to delegates who register before Monday 14 February 2011. Delegates registering after this date must order and pay for a copy of the book in advance of the course.**

### IMPORTANT INFORMATION

Delegates **MUST** bring their own laptops to the course. Instructions on downloading WinNonlin will be provided in advance of the course.



## PKPD DATA ANALYSIS – 15-19 MAY 2011 REGISTRATION FORM

Delegates will be registered upon receipt of the completed form and will liable to pay the fees. Payment must be made before the start of the course. Fees inclusive of 4 nights' accommodation, meals and refreshments, a welcome reception, social programme, and a resource pack with full course documentation.

MEMBERS OF RPSGB OR SWEDISH ACADEMY	£2,415	<input type="checkbox"/>
NON-MEMBER	£2,565	<input type="checkbox"/>
MEMBER (NO ACCOMMODATION OR EVENING MEAL)	£1,995	<input type="checkbox"/>
NON MEMBER (NO ACCOMMODATION OR EVENING MEAL)	£2,150	<input type="checkbox"/>
COMPLIMENTARY TEXTBOOK (BEFORE 11/02/11)		<input type="checkbox"/>

Title	Forename	Surname
Job Title	Post code	
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The contact details you have provided may be used to keep you informed about future RPSGB events, products and services. If you do not wish to receive such information by any of the methods listed below please indicate by ticking the corresponding box:

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Dietary Requirements	How did you hear about this event?
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### METHOD OF PAYMENT

- Debit/Credit Card  
Someone will contact you to obtain card details.
- Bank transfer (Sort Code 60 60 04 Account Number: 70378193. National Westminster Bank, 91 Westminster Bridge Road, London SE1 7ZB) Quoting ref: **MMS EVT 401**

ONE FORM PER PERSON PLEASE – PHOTOCOPIED FORMS ARE ACCEPTED

Please return this form to: Events Coordinator, Royal Pharmaceutical Society,  
1 Lambeth High Street, London SE1 7JN

Fax: 020 7572 2506    Email: [events@rpharms.com](mailto:events@rpharms.com)  
Tel: 020 7572 2640    Web: [www.rpharms.com/events](http://www.rpharms.com/events)

**NB. IF YOU DO NOT RECEIVE A CONFIRMATION OF YOUR PLACE VIA EMAIL WITHIN 5 WORKING DAYS OF SUBMITTING YOUR REGISTRATION FORM PLEASE LET US KNOW**