

The Eleventh Advanced Level Workshop on

Pharmacokinetic - Pharmacodynamic Data Analysis:
A hands-on residential course using WinNonlin



**Royal
Pharmaceutical
Society**
of Great Britain

Sunday 17 - Thursday 21 May 2009 at
Maddingley Hall, Cambridge, UK

In partnership with the
Swedish Academy of Pharmaceutical Sciences



www.rpsgb.org/events

OBJECTIVES

An advanced and well-established 4 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-

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.

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”

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 relevant reference documents.
- Allow delegates to network with course tutors and other delegates from the field through a full social programme.

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 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 FDA.

VENUE



Maddingly Hall is an old country house set in the charming village of Maddingly, situated approximately three miles from the university city of Cambridge. Maddingly is easily accessible by rail, road and air. Free car parking facilities are available

PROGRAMME

Sunday 17 May

17.00	Registration
18.30	Welcome drinks reception
19.15	Course dinner

Monday 18 May

08:15	Introduction
08:30	Pharmacodynamic (Equilibrium) Review of steady-state models Steady-state models Kinetics of drug action Initial parameter estimates Design issues and case studies
09:30	Coffee/tea
09:45	Pharmacodynamic (Distributional delays) Steady-state models vs. time delay Basic concepts on distributional delays Modelling QT-data with link models Design issues and case studies
10:30	Hands-on session 1 Inst. equil. models, steady-state, log-linear, sigmoidal Incomplete datasets
12:00	Lunch
13:00 – 16:30	Hands-on session 2 Modeling EEG-data with link models Modeling QT- & MAPD data with link models Design issues and case studies
14:30	Coffee/tea
16:30	Numerical Grammar
18:00	Course dinner
19:00	Evening exercise on your own

Tuesday 19 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
09:30	Coffee/tea
09:45	Hands-on session 3 Turnover models I-IV Turnover model I of blood clotting data
12:00	Lunch
13:00	Hands-on 3 cont. Collapsing hysteresis loops Design issues and case studies
14:45	Coffee/tea
15:00	Group exercise – FTIM compound selection Compound evaluations Dose prediction, dose nomogram Assessment of safety margin
17:00	Wrap-up & project exercise
18:00	Course dinner
19:00	QTc lecture

PROGRAMME

Wednesday 20 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
09:30	Coffee/tea
09:45	Hands-on session 4 Turnover models I-IV Comparing IRP and Link Design issues and case studies
12:00	Lunch
13:00	Hands-on session 4 cont. Turnover models I-IV cont. Fitting multiple dose PD data
15:00	Coffee/tea
15:15	Introduction and Group exercises Group Exercise I Group Exercise II Group Exercise III
17:00	Wrap-up & Group exercise
18:30	Course dinner
19.45	Social programme

Thursday 21 May

08:30

Pharmacodynamics (Adaptation)

Residual questions from Day 3

Models for adaptation

Tolerance and rebound

Feed-back systems

Oscillating baselines

Initial parameter estimates

09:30 – 12.00

Hands-on session 5

Turnover models I-IV continue

Synergy

Transduction models

Irreversible response

Design issues and case studies

10:00

Coffee/tea

12:00

Lunch

13:00

Hands-on session 5 cont.

Feedback

Analyzing pd data from phase i study

14:00

Experimental design

Own datasets

Synergy

15:00

Summary

15.15

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 16 February 2009. 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.

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

RPSGB or Swedish Academy members: £2,345 ☐ **Non-members: £2,495** ☐

Registering before 16 February 2009 and claiming a complimentary textbook ☐

Title	Forename	Surname
Job Title		Post code
Company		Email
Address		Telephone
		Membership No.

☐ By giving us your details you are agreeing to be added to our electronic and postal mailing list and receive information on our events. Please note that your information will not be sold and will be handled in accordance with the Data Protection Act and the Society's Privacy Policy. Tick here if you do not wish to be added to the mailing list.

Dietary Requirements	How did you hear about this event?
----------------------	------------------------------------

METHOD OF PAYMENT

☐ 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

☐ Debit/Credit card ☐ Maestro ☐ Mastercard ☐ Visa ☐ Amex

Card No.	Security No.	Issue No.
Card holder's name and address (if different from above)		Expiry
		Signed

ONE FORM PER PERSON PLEASE – PHOTOCOPIED FORMS ARE ACCEPTED
Please return this form with your payment to: Science Programme Admin Assistant,
Royal Pharmaceutical Society of Great Britain, 1 Lambeth High Street, London SE1 7JN
Fax: 020 7572 2506 Email: events@rpsgb.org (Tel: 020 7572 2640)

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

CANCELLATION AND REFUND

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 14 days: 90% of the fee; less than 14 but over 3 working days: 50% of the fee; three or less 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. The RPSGB reserves the right to change the programme or cancel the event if necessary. RPSGB does not accept liability for any expenses incurred by delegates.