Training Course Brochure

Revised March 2023

DMDG Training Course Brochure

Foreword

Training and continued development of the membership is a core philosophy of the DMDG. DMDG is recognised for its long standing history of delivering training courses across the breadth of DMPK with content focussed on theory and application to drug discovery and development in the pharmaceutical industry. Our portfolio of courses is continuously evolving with content regularly reviewed to ensure it remains current and industry relevant.

DMDG is also committed to ensuring connectivity between members and interaction across the community and our training courses are all designed with interaction in mind. All courses are delivered using lectures, tutorials and interactive elements focussed on the application of DMPK science in 'real life' scenarios with ample opportunity also for social engagement.

Training courses are delivered by tutors who are both experienced and passionate about the subject matter and from diverse backgrounds. All tutors provide their time voluntarily and DMDG thanks all those involved, past and present, for the enormous contributions made to training scientists and in development of the course material. If you wish to get involved in being a tutor please contact us at info@dmdg.org.

Our training course hub is at Burleigh Court in Loughborough, UK. However the geographical diversity of our membership is recognised and we have begun delivering some courses from mainland Europe venues also. All training course materials are now predominantly electronic.

All courses are designed to support scientists & leaders seeking a deeper insight in to the different aspects of DMPK, those seeking a change or extension of role or scientists from other related disciplines wishing to develop a wider appreciation of the role of DMPK in drug discovery & development. Each course is standalone but the entire programme may also be approached in a progressive manner. Our current portfolio is shown below. Additional courses under development include a course focussed on prediction of clinical drug interactions.

Course Title	Course leader
Fundamentals of DMPK	Graeme Scarfe (Sosei Heptares)
Methods for Bioanalysis and Drug Metabolism	Gordon Dear (GSK)
In vitro Technology	Peter Kilford (Certara)
Pharmacokinetics in Drug Discovery	Pablo Morentin-Gutierrez (AZ)
Introduction to Pharmacokinetic-Pharmacodynamic Concepts	James Yates (GSK)
Large Molecules	Robert Nelson – Co-leader (Labcorp) Rob Wilson – Co-leader (Healx)
Tissue Distribution and Imaging	Claire Henson (Pharmaron, UK)
Chemistry Essentials for DMPK Scientists	Scott Summerfield (GSK)
Drug Interaction Course (under development)	Filipe Lopes (Roche)

Simon Taylor,
Training Officer 2020-2022

Course title: Fundamentals of DMPK

Course Synopsis:

The Fundamentals of DMPK Course was previously known as the Basic Training Course and has been supporting the industry for nearly 40 years! Always up to date, this course covers a range of topics highlighting the pivotal role played by DMPK throughout the drug discovery and development process. Specific consideration is given to topics as diverse as, in vitro metabolism, pharmacokinetics, quantitative analytical techniques, qualitative detection methodology and isotopic techniques. In addition, consideration is also given to topics which have taken on a greater prevalence in recent years, for example, modelling & simulation techniques and an introduction to the DMPK aspects of large molecules.

The course format includes focussed lectures backed-up by small group tutorials/ interactive workshops, allowing delegates the opportunity to discuss each topic in greater depth. Electronic lecture materials, tutorial questions and model answers will be provided to each delegate. It is hoped that this course will provide an introduction to all aspects of DMPK science, upon which delegates will be able to build through attendance at the DMDG's other focussed training courses.

Course content includes:

- Introduction to physicochemical techniques
- Absorption theory
- Metabolism fundamentals
- In vitro techniques
- Quantitative analytical techniques of extraction, chromatography and detection
- Introduction to pharmacokinetics
- Isotopic techniques
- Development ADME
- Qualitative detection
- Introduction to modelling & simulation
- Introduction to biologics

Intended audience:

This course is intended for new DMPK scientists, or those from other scientific disciplines, who would like a broad introduction to DMPK science.

Schedule:

The course is usually delivered in a face to face format over 3 days (2 night stay). Designed as an interactive course, content is delivered using a combination of lectures and tutorials/ interactive group sessions. Delegates join together as smaller virtual project teams for the tutorials/ interactive workshops. There are 8.5 hours of lectures and 4 hours of tutorials/ interactive workshops.

Consistent with the DMDG core principles, the interactions and networking between delegates and with tutors is encouraged at all times including opportunities to connect at coffee breaks and at dinner each evening.

Logistics:

The course runs every 2 years for a maximum of 45 delegates. More frequent courses may operate according to delegate interest and tutor availability.

Location:

The course is usually run from our DMDG training base at Burleigh Court, Loughborough, UK.

Tutors:

- Graeme Scarfe, Sosei Heptares (Course Leader)
- Melanie Golding, UCB
- Lee Boyling, Quotient Sciences
- Mira Wenker, Charles River
- Lee Goodwin, Labcorp
- Simon Wood, Cyprotex
- Matthew Barfield, Roche

For more information info@dmdg.org

Course title: Methods for Bioanalysis and Drug Metabolism

Course Synopsis:

The Methods for Bioanalysis and Drug Metabolism course is an interactive course focussing on the core principles of bioanalytical methods and the application to both drug bioanalysis and metabolite identification. The course includes both fundamental concepts and more in-depth bioanalytical application to support drug discovery and development, with a strong focus on small molecules but also with an introduction to these principles for large molecules.

The course starts by examining how the structure of a drug molecule influences its physicochemical properties and how these properties can be used to develop good extraction, separation and detection strategies. This provides a platform to learn in more detail the fundamental aspects of mass spectrometry, with a focus on modern techniques, together with HPLC theory and practice, with associated sample treatment and extraction procedures. Basic principles of chromatographic process with some practical tips and help with common problems, are also presented; including how to get the best from your HPLC system - focusing on resolution, efficiency and performance. Real world application is then explored in quantitative mass spectrometry, with the challenges of ion suppression a core topic. Optimisation of HPLC methods for LC/MS/MS, the effect of mobile phase on ionisation, and automated MS method development are also examined. This is integrated into strategies for method development, including initial considerations and experiments, chromatographic options, optimisation, validation and application of the final method. Quantitative bioanalysis is complemented with a series of lectures on qualitative methods, to support metabolite identification with detailed discussions on the use of MS/MS for structural elucidation (concepts, instrumentation and experimentation), accurate mass measurements, on-line radiochemical detection and integration with NMR spectroscopy. This section of the course also describes sample selection criteria and experiment types (*in vivo*, *in vitro*, *in situ*) for successful metabolite identification.

Several lectures are now devoted to the analysis of larger biopharmaceutical molecules, as a prelude to the DMDG “Large Molecule” training course. Introduction to this topic includes peptides, oligonucleotides and large intact proteins, comparing both LC/MS and ligand binding approaches.

Course content includes:

- Physicochemical Properties of Drugs
- Fundamental Aspects of Mass Spectrometry (MS) – focus on atmospheric pressure ionisation (API) techniques
- Sample Preparation & Retention Mechanisms – protein precipitation, liquid/liquid extraction and solid phase extraction
- HPLC & UHPLC Theory and Practice – reverse-phase, normal phase, ion-pair, ion-exchange, chiral HPLC and HILIC chromatography
- Quantitative Mass Spectrometry
- An introduction to Biopharmaceutical Analysis
- Qualitative Mass Spectrometry (Metabolite Identification)

- Strategies for Bioanalytical Method Development
- Strategies for Metabolite Isolation

Intended audience:

This course is intended for DMPK scientists wanting to further develop their bioanalytical practice to support drug discovery and development. It is recommended that delegates have some industrial experience. Although the course is designed to develop bioanalytical understanding for DMPK applications, and is applicable to scientists entering this discipline, it is also suitable to other scientists within the wider DMPK field, medicinal chemistry, biology, pharmacology, toxicology, who may want to gain insight into how bioanalysis supports their project work.

Schedule:

The course is usually delivered in a face to face format over 4 days (3-night stay). Designed as an interactive course, content is delivered using a combination of lectures and tutorials. The tutorials aim to reinforce lecture material, but in a more practical form, including a tutorial on "method development", which will describe *real* examples from lecturers to illustrate some of the more (or less) common problems encountered in the bioanalytical process. There are 15 hours of lectures, 6 hours of tutorials.

Consistent with the DMDG core principles, the interactions and networking between delegates and with tutors is encouraged at all times including opportunities to connect at coffee breaks and at dinner each evening.

Note that in 2021 due to the COVID-19 pandemic, a reduced course was using our online platform over 5 half days with non-core content available as online supplementary materials.

Logistics:

The course runs every 2 years for a maximum of 48 delegates. More frequent courses may operate according to delegate interest and tutor availability.

Location:

The course is usually run from our DMDG training base at Burleigh Court, Loughborough, UK.

An online course operated in 2021 due to the COVID-19 pandemic. We hope to resume face to face training next time.

Tutors:

- Gordon Dear, GlaxoSmithKline (Course Leader)
- Angus Nedderman, Unilabs
- John Allanson, BioAppSolutions
- Mohammed Abrar, BioAppSolutions
- Benno Ingelse, Byondis
- David Berry, GSK

For more information info@dmdg.org

Course title: *In Vitro* Technology Course

Course Synopsis:

The *In Vitro* Technology training course is an interactive courses which focusses on the design and implementation of *in vitro* assays to support drug discovery and development. The course introduces the concepts of the different enzyme systems that are important for drug metabolism and discusses the appropriate methodologies and design for conducting in vitro experiments. The interpretation of the data from enzyme kinetics, inhibition and induction assays is covered before moving on to drug transporter assay design and interpretation. All of the learning is reinforced by tutorials structured around the key learning content where delegates get to work in a small team to complete the work. The course finishes with drug discovery scenario whereby the project team has to interpret in vitro data to select lead candidates to move in to further development.

Course content includes:

- Enzymology of drug metabolism
- Enzyme kinetics
- Inhibition and induction of ADME targets,
- Use of different *in vitro* systems for DMPK assays
- Drug transporters

Intended audience:

This course is intended for DMPK scientists wanting to understand the best practices for designing and conducting *in vitro* assays to support drug development. Delegates will learn how to interpret in vitro data to support drug discovery and development projects. It is recommended that delegates have some industrial experience and appreciation of DMPK as a broad discipline and of the discovery-development pathway. The course is also suitable for scientists from other disciplines (eg medicinal chemistry, biology, pharmacology, toxicology) wanting to learn more about the role of *in vitro* assays in the wider discovery project environment to enhance overall project leadership skills and decision making.

Schedule:

The course is usually delivered in a face to face format over 4 days (3 night stay). Designed as an interactive course, content is delivered using a combination of lectures, tutorials and interactive group sessions. Delegates also join together as smaller virtual project teams for the interactive workshops. There are 11 hours of lectures, and 10.5 hours of interactive workshops.

Consistent with the DMDG core principles, the interactions and networking between delegates and with tutors is encouraged at all times including opportunities to connect at coffee breaks and at dinner each evening.

Logistics:

The course runs every 2 years for a maximum of 48 delegates. More frequent courses may operate according to delegate interest and tutor availability.

Location:

The course is usually run from our DMDG training base at Burleigh Court, Loughborough, UK.

An online course operated in 2021 due to the COVID-19 pandemic. We hope to resume face to face training next time.

Tutors:

- Peter Kilford, Labcorp, UK (Course Leader)
- Sandy Baldwin, GSK
- Rob Elsby, Cyprotex, An Evotec Company
- Mark Wenlock, Cyprotex, An Evotec Company
- Louise Wray, GW Pharmaceuticals
- Roz Southall, Certara, UK

For more information info@dmdg.org

Course title: Pharmacokinetics in Drug Discovery

Course Synopsis:

The PK in drug discovery course is an interactive course focussing on the concepts and applications of drug metabolism and pharmacokinetics to molecule design, selection and decision making in the pre-IND phase. The course is currently focussed around small molecules but many of the principles and content can be applied more widely.

The course covers PK in detail but with content extended to cover factors that influence PK properties in molecule design and how PK integrates and drives decisions with other aspects of DMPK, ADME and related disciplines. A core concept running throughout the course is on the role of the DMPK scientist as a discipline expert but also as a data integrator. The importance of molecule quality in the design and optimisation phase is enforced. This is followed by teaching the theory and the tactics for forecasting human PK and dose as a way of contextualising molecule properties and clinical potential. To ensure the discovery scientist has an appreciation of the later clinical and development requirements content includes a review of clinical pharmacology and PK in regulatory applications.

Delegates get to experience real life decisions in a virtual project team. Exercises in the selection of a lead series followed by a candidate molecule are experienced. Following prediction of the human PK and dose teams then assess the risk – benefit potential of the molecule to make a recommendation to proceed to Phase 1.

Course content includes:

- Physicochemical properties and their influence on PK
- Basic pharmacokinetic principles required in compound evaluation: theory and calculations
- Theories and strategies for the application of PK in drug discovery projects
- Principles and application of PKPD in drug discovery
- Predicting human pharmacokinetics
- ADME and toxicokinetics: principles and measurement
- Pharmacokinetics of metabolites: theory and important considerations
- Pharmacokinetics of biologics: theory and implications for PK and PKPD
- Clinical Pharmacology: importance and impact in drug development
- PK requirements for regulatory applications

Intended audience:

This course is intended for DMPK scientists wanting to gain further insight in to the role of DMPK in discovery projects and/or step up to become a DMPK Discovery project leader. It is recommended that delegates have some industrial experience and appreciation of DMPK as a broad discipline and of the discovery-development pathway. The course is also suitable for scientists from other disciplines (eg medicinal chemistry, biology, pharmacology, toxicology) wanting to learn more about the role of DMPK in the wider discovery project environment to enhance overall project leadership skills and decision making.

Schedule:

The course is usually delivered in a face to face format over 4 days (3 night stay). Designed as an interactive course, content is delivered using a combination of lectures, tutorials and interactive group sessions. Delegates also join together as smaller virtual project teams for the interactive workshops. There are 10 hours of lectures, 4.5 hours of tutorials and 7.5 hours of interactive workshops.

Consistent with the DMDG core principles, the interactions and networking between delegates and with tutors is encouraged at all times including opportunities to connect at coffee breaks and at dinner each evening.

Logistics:

The course runs every 2 years for a maximum of 48 delegates. More frequent courses may operate according to delegate interest and tutor availability.

Location:

The course is usually run from our DMDG training base at Burleigh Court, Loughborough, UK.

Tutors:

- Pablo Morentin-Gutierrez, AstraZeneca (Course Leader)
- Simon Taylor, Pharmaron UK
- Ruth Lock. Consultant, AUCuba Sciences
- Carl Petersson, Merck KGaA
- Paolo Vicini, Confo Therapeutics
- Ludy van Beijsterveldt, Johnson and Johnson
- Essam Kerwash, MHRA

For more information info@dmdg.org

Course title: Introduction to Pharmacokinetic-Pharmacodynamic Concepts

Course Synopsis:

Increasingly DMPK departments are involved in the design and analysis of in vivo pharmacology (PKPD) experiments. This course aims to cover the basic concepts of PKPD that will allow scientists to start practising PKPD interpretation. Prior mathematical experience is not required and the objective is not to teach hands on modelling but understanding and interpretation: "what does it mean?". The course covers a range of topics of linkages between plasma/blood PK and PD, reasons for observing a delay between PK and PD, and the effects of drug tolerance. PKPD knowledge specific to antibodies is also taught. Special emphasis is placed on good design of in vivo PKPD experiments and a systematic approach to understanding trends observed in the data.

Course content includes:

- Direct effects
- Effects with time delay
- PKPD of therapeutic proteins
- Tolerance & feedback models
- Best practice for in vivo experimental design

Intended audience:

The course is for DMPK scientists, and their biology and pharmacology colleagues, who want to learn more about the PKPD and its uses for drug discovery and development.

Schedule:

The course is usually delivered in a face to face format over 3 days (2 night stay).

The course format is a lecture followed by hands-on exercises in small tutor groups. Further discussion of the exercises will be as a whole course group. The hands-on exercises will use example data sets to illustrate the concepts taught in the lectures.

Consistent with the DMDG core principles, the socialising and networking between delegates and with tutors is encouraged at all times including opportunities to connect at coffee breaks and at dinner each evening.

Logistics:

The course runs every 2 years for a maximum of 36 delegates. More frequent courses may operate according to delegate interest and tutor availability.

Location:

The course is usually run from our DMDG training base at Burleigh Court, Loughborough, UK.

Tutors:

- James Yates (GSK)
- Dave Fairman (GSK)
- Steffi Harlfinger (AstraZeneca)
- Ben-Fillippo Krippendorff (Roche)

For more information info@dmdg.org

Course title: Large Molecules

Course Synopsis:

This course serves as an introduction of DMPK-PD/Bioanalytical/Immunogenicity aspects of "large molecules" to attendees. Molecules to be discussed in the course include oligonucleotides, antibodies, antibody fragments and proteins.

The following topics are covered:

LC-MS/MS

Most of the techniques that bioanalysts are familiar with for small molecule analysis may also be applied to allow quantification of larger biomolecules. Larger molecules however pose their own unique problems for LC-MS/MS analysis, spanning from their extraction from biological fluids through to the chromatography and MS/MS ionisation. These talks will present the many challenges and commonly used strategies to allow quantification of therapeutic peptides and oligonucleotides by LC-MS/MS, as well as proteolytic digestion based strategies for proteins which are too large to analyse intact.

Immunoassays

An introduction to immunoassays is provided covering assay formats, technologies and with supporting examples using case studies. Topics will include: Principle of mass action and how it affects all immunoassays; assay formats – how to run free, total and complex assays including the pros and cons of various formats and how best to analyse the data; critical reagents and technologies including MSD, Gyrolab, DELFIA and Luminex.

Immunogenicity

This section introduces the concept of immunogenicity, the importance in preclinical and clinical studies and discusses strategies to determine an immune response. Assay formats, examples of various technologies and the regulatory requirements will also be covered.

ADME and PK/PD

These sections detail typical ADME properties of large molecules, why we do or do not conduct certain studies, and how best to evaluate PK/PD relationships for large molecules. Particular attention will be given to restrictive distribution, functional aspects of large molecules and target behaviours influencing disposition.

Intended audience:

This course is intended for DMPK-PD/Bioanalytical scientists (as well as others involved in non-clinical or early clinical development) who wish to learn more about the key aspects influencing large molecule drug development.

Schedule:

The course is usually delivered in a face to face, residential style format over 3 days. Designed as an interactive course, content is delivered using a combination of lectures and interactive tutorials.

Consistent with the DMDG core principles, the interactions and networking between

delegates and with tutors is encouraged at all times including opportunities to connect at coffee breaks and at dinner each evening.

Logistics:

The course runs every 2 years for a maximum of 40 delegates.

Location:

The course is usually run from our DMDG training base at Burleigh Court, Loughborough, UK.

Tutors:

- Robert Nelson – *Co-leader* (Labcorp)
- Rob Wilson – *Co-leader* (Healx)
- Jo Goodman (Astra Zeneca)
- Richard Kay (Cambridge University)
- Mark Penney (UCB)
- Rob Wheller (LGC)
- Graeme Clark (Concept Life Sciences)

For more information info@dmdg.org

Course title: Tissue Distribution and Imaging

Course Synopsis:

Tissue distribution studies, particularly those utilising autoradiography, can provide a wealth of information concerning tissue targeting, distribution within target tissues, distribution across natural barriers (e.g. blood brain barrier, placenta) and sites of potential toxicity. In addition, quantitative whole body autoradiography (QWBA) data can be used in support of ARSAC submissions prior to human clinical studies performed to meet MIST guidelines. When combined with the detailed information that can be obtained using microautoradiography (mARG) for target tissue analysis at the light microscope level, or with mass spectrometry imaging (MSI) which can be utilised to confirm the presence of parent drug and metabolites, distribution studies are a powerful tool for the DMPK scientist. It is critical then that the design, conduct and interpretation of these highly specialised studies are fully understood by study monitors, study directors and technicians alike.

This course has been designed to give delegates a broad understanding of whole body autoradiography and microautoradiography, from experimental design through to interpretation of results, including regulatory requirements, human dosimetry calculations, methodology and instrumentation. The added value that MSI techniques can provide will also be discussed.

Course content includes:

- Experimental design – lectures and tutorials in both QWBA and mARG
- Methodology
- Animal/tissue anatomy and histology
- Quantification
- Human dosimetry assessments
- Result interpretation
- Mass Spectrometry Imaging
- Practical day with hands-on experience

Intended audience:

This course aims to provide a solid foundation in autoradiography techniques to study monitors/managers/directors and technicians wishing to improve their understanding of the theoretical background. Delegates may wish to expand this theoretical knowledge by adding in an optional 'practical' element at a member company's laboratory. Here, practical demonstrations of the methods and instrumentation utilised for autoradiography studies will be given, and delegates can try/practice some of the techniques first-hand. This additional content is perfect for those new to autoradiography or for those whose involvement has been purely theoretical and who would like to gain a deeper understanding of the methods involved.

Schedule:

The course is usually delivered in a face-to-face format over 2 days (theoretical option only) or 3 days (including 'practical' day). The first 2 days of the course are primarily lecture based, with practical sessions covering both QWBA and mARG techniques running on day 3. There

are 10 hours of lectures, 3 hours of tutorials and 6 hours of practical demonstration/ experience.

Due to the specialised nature of the techniques discussed, the delegate group is generally smaller than with other DMDG courses, resulting in an extremely inclusive and interactive environment. Consistent with the DMDG core principles, the interactions and networking between delegates and with tutors is encouraged at all times including opportunities to connect at coffee breaks and at dinner each evening.

Logistics:

The course runs every 2 years for a maximum of 30 delegates (2-day option), with places for the additional practical day limited to a maximum of 14. Courses may operate more frequently according to delegate interest and tutor availability.

Location:

The course is usually run from a venue close to a member company's facility to enable use of laboratories for the practical day.

Tutors:

- Claire Henson, Pharmaron UK (Course Leader)
- Lee Crossman, Labcorp Drug Development
- Karen Stephenson, Charles River UK
- Phil Fernyhough, Labcorp Drug Development

For more information info@dmdg.org

Course title: Chemistry Essentials for DMPK Scientists

Course Synopsis:

For small molecules, Chemistry governs both 'what the drug does to the body' and 'what the body does to the drug'. This course brings your chemistry knowledge to life in the context of small molecule drug design, how organic and physical chemistry influence molecular interactions and what considerations are applied to chemical structure in order to optimise potency, selectivity and ADME. Course content includes:

- Molecular Structure
- Molecular Interactions
- Physical Chemistry
- Drug Reactivity and Metabolism
- Molecular interactions with ADME
- Molecular Interactions with Pharmacological Targets
- Hit ID strategies
- Hit to Lead strategies

Intended audience:

This course is intended for DMPK scientists who interface with drug discovery projects and wish to learn more about the essential chemistry concepts influencing small molecule drug design. An prior understanding of core chemistry concepts is preferable (e.g., types of chemical bonding, chirality, valency (for bonding), basic thermodynamic properties such as enthalpy and entropy).

Schedule:

The course is delivered in a face to face, residential style format over 3 days. Designed as an interactive course, content is delivered using a combination of lectures and interactive tutorials.

Consistent with the DMDG core principles, the interactions and networking between delegates and with tutors is encouraged at all times including opportunities to connect at coffee breaks and at dinner each evening.

Logistics:

The course runs every 2 years for a maximum of 45 delegates.

Location:

The course is usually run from our DMDG training base at Burleigh Court, Loughborough, UK.

Tutors:

- Sharan Bagal (AstraZeneca)
- Tim Barrett (GSK)
- Kevin Beaumont (AstraZeneca)
- Steve Clifton (Charles River)
- Iain Martin (Relay Therapeutics)
- Scott Summerfield – Course Leader (Pharmaron)
- Beth Williamson (UCB)

For more information info@dmdg.org

For further information on any of our courses please contact info@dmdg.org