

Scaling from Milligrams to 1-2kg: Making the first GMP Batch

9-10 OCTOBER 2017



Lisbon, Portugal
Sana Malhoa Hotel

A 2 day course presented by
Dr John Knight, JKonsult Ltd

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Scaling from Milligrams to 1-2kg: Making the first GMP Batch

A 2 day course presented by Dr John Knight

9-10 October 2017 Sana Malhoa Hotel, Lisbon, Portugal

Multiple attendees discounts
UP TO 15% available

INTRODUCTION

The aim of the course is to provide attendees with a good basis to work from when involved in taking development candidates to the first in human trials with a view also on some longer-term requirements.

The course content will therefore focus on the necessary early phases of chemical development as would typically be required to support production of up to about 2kg using laboratory-based 20L equipment and pilot plant equipment. The course will introduce and discuss the following:

- Requirements in order to move from small (<1g) supplies to the first 100g or so for preclinical work
- Further scaling to 1-2kgs non-cGMP
- Requirements to make material for use in clinical trial – an introduction to cGMP coupled with the scaling issues
- An overview of the requirements to move processes to fixed vessels, assuming cGMP is required – what operations can readily be transferred and those that should ideally be developed out
- The importance of physical form selection, understanding and control
- Impurities and their control, with specific discussion on genotoxic impurities and developing the specification for the API as it moves from preclinical batch preparation to cGMP batches for clinical trials

COURSE OUTLINE

Day One:

Session 1:

Introduction to typical pharmaceutical development activities and timeframes for toxicological studies.

Session 2:

Making the first 100g non-GMP batch for GLP toxicological studies; discussion of topics such as setting the specification, the use of chromatography, accessing starting materials, identifying how much development to do.

Session 3:

Non-GMP vs GMP preparation. A brief introduction to GMPs and how they impact on the initial chemistry scaling exercise.

Session 4:

Physical version and form, spending time on the importance of salt selection, especially in the early phases of development with form/polymorph considerations also being discussed. There will be a brief introduction of polymorphism and which aspects of physical form should ideally be established at the early phase of development.

Session 5:

Process safety and raw materials supply issues and how these might impact on the chosen route.

Session 6:

Review of the day and questions.

Day Two:

Session 7:

Scaling into fixed vessels with discussions about those operations that transfer well and those which typically do not.

Session 8:

Technology transfer and a discussion of the issues and suggestions to mitigate against them.

Session 9:

A presentation about genotoxic impurities – what are they, what are the suggested control levels, how well do chemists identify them?

Session 10:

A presentation about impurities, including their identification, isolation/preparation and control with discussions about setting specifications.

Session 11:

The final session of the course will review the two days and follow-up on any questions.

Case Studies and Problem sessions will also be included and audience participation is encouraged throughout the course.

IN-HOUSE COURSE

For 8+ people contact us to discuss holding this event In-House - sciup@scientificupdate.co.uk

Target audience/attendees

- Project managers and those involved in technical outsourcing
- Project leaders and bench chemists involved in preparation of material
- New starters to the area
- Medicinal Chemistry support teams involved in making the first batches for toxicological evaluation

Start 8.45am - Monday 9 October
Finish 4.30pm - Tuesday 10 October
Course dinner 7.30pm - Monday 9 October

Course Fee: €1,725

Which includes comprehensive course manual, refreshments throughout the day, lunch and one course dinner.

Course Fee: €1,725

COURSE TUTOR

Dr John Knight

Consultant,
JKonsult Ltd



John first started his industrial career at the age of 16 as a technician with ICI. Following several years' laboratory experience he went on to study at the University of Southampton for a degree in chemistry, staying on to complete his PhD with Phil Parsons. John then took up a NATO-funded post-doctoral position with Gilbert Stork before returning to the UK to work for Glaxo, initially in medicinal chemistry before transferring to chemical development. John then moved to work for a small contract research organisation which, after significant growth, is now part of Aptuit. John left Aptuit at the end of 2007, following 14

years in the CRO arena, to join Scientific Update LLP where he provided training and consultancy services. In January 2015 John established his own consultancy business while continuing to work very closely with Scientific Update.

John's main professional focus is in working with early stage chemical development projects and transfer to plant, often working with small pharma companies where he helps with CMC issues and securing material supplies to toxicological studies and Phase I and II clinical trials.

 john@jkonsult.co.uk

REGISTRATION

You can either use our fast online booking system or mail or fax the attached registration form to:

Scientific Update
Maycroft Place, Stone Cross, Mayfield,
East Sussex, TN20 6EW, UK
Fax Number +44 1435 872734

How to Pay

When you register online, you can have the option to pay via credit card (Amex, Mastercard or Visa) For email payments please include course title, card number, expiry date and security code. A receipted invoice will be automatically generated once paid and sent via email. Should your company wish to pay by cheque or bank transfer bank details will be supplied with an invoice.

Bank Transfer or Cheque

Should your company wish to pay by cheque or bank transfer, on booking you can choose between paying in either £ or €. All bank details will be supplied with an invoice.

Group Discounts

Group discounts are available on multiples of 2 or more attendees – see registration form. This offer only applies if bookings are made simultaneously and from the same billing address.

Confirmation of your registration

Confirmation and your invoice will be sent via email.

Late Applications

For late applications, please register on-line or fax the completed registration form, including credit card payment information.

Cancellations/Refunds

Should you be unable to attend and cancel in writing no later than 1 month before the start of the course, Scientific Update will refund your registration less £300 processing fee. Unfortunately refunds are not possible after that date. Substitutions can be made at any time.

The lessons and the key learning opportunities are considered to be:

- How long does it take to get from milligrams to 1-2kgs suitable for human clinical trials?
- What are the main hurdles?
- What can be left out and what must be included?
- What are the key and strategic project management considerations?

VENUE

Sana Malhoa Hotel Av Jose Malhoa
1099 – 089
LISBON Portugal
P. +351 21 006 1803
www.sanahotels.com

Located in a main financial district, this glass-fronted business hotel is a 7-minute walk from a metro stop and 5 km from Praça do Comércio's trendy shops and nightlife.

The modern rooms come with free Wi-Fi, flat-screen TVs and minibars. Suites add verandas and sitting areas with sofas. There's 24-hour room service.

Breakfast is included and served in a Mediterranean restaurant with an atrium dining room. Other amenities include a lobby bar/piano lounge, plus a health club with a fitness area, a sauna, and a whirlpool tub. Parking is complimentary.

A limited number of rooms have been reserved at the hotel for the special rate of €80.00 per night including breakfast and VAT. A hotel booking form will be sent when you register.

Course:

Dates:

Location:

No. of attendees

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* Currency Payments

If you select to pay in GBP or Dollars, the amount charged will be based on the exchange rate at the time of preparing the invoice.

Discounts

Complete the details for either two or three delegates and your discount will automatically be applied. This offer only applies where all delegates are booked simultaneously and at the same billing address.

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