



# Scaling from Milligrams to 1-2kgs: making the first GMP batch

A Two Day Course



22 & 23 February 2010

The Sheraton Fisherman's Wharf

San Francisco, CA, USA

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## A Two Day Course

22 & 23 February 2010 | The Sheraton Fisherman's Wharf Hotel, San Francisco, CA, USA

### Course Objectives

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
- The phases of development and indicative timelines with quality requirements
- The importance of physical form selection, understanding and control

During the course, 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 project management considerations?

### Fee

\$1600.00 including lunch & refreshments, course dinner on Monday 22 February and course manual.

### Course 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 glassware.

### Course Outline

The course will be given over a two-day period with the following content and structure:

#### 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.

#### Day Two

##### Session 6

Review the issues associated with the route provided at the end of Day one

##### Session 7

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

##### Session 8

A presentation about impurities, including their identification, isolation/preparation and control

##### Session 9

This session will consider process optimisation and validation, including when validation needs to be carried out and what can be done in the early phases of development to help with the later phases

##### Session 10

The final session of the course will review the development time-frame and what aspects of development have major impact. This will be an opportunity to compare and contrast indicative time-frames delegates may have suggested at the start of the course.

Case Studies and Problem sessions will also be included throughout the course.

“*Excellent course, good mix of theory and practice.*”  
Previous Delegate

## Tutor



**John Knight** gained a first class honours degree in chemistry at the University of Southampton, UK. John remained at Southampton to study for his PhD in synthetic methodology utilizing radical cyclisation and dipolar cycloaddition chemistry. After gaining his PhD, John moved to Columbia University, New York, USA where he worked as a NATO Postdoctoral Fellow with Professor Gilbert Stork. John returned to the UK in 1987 joining Glaxo Group Research (now GSK) as a medicinal chemist, where he remained for 4 years

before moving to the process research and development department at Glaxo, where he remained for a further 3½ years. During his time at Glaxo, John worked on a number of projects and gained considerable plant experience (pilot and manufacturing). In 1994 John moved to Oxford Asymmetry (later changing its name to Evotec and most recently to Aptuit) when it had just 25 staff. John's major role when first at Oxford Asymmetry was to work with a consultant project manager to design, build and commission a small pilot plant, whilst in parallel developing the chemistry PRD effort at Oxford Asymmetry. The plant was fully operational within 18 months, operating to a 24h/7d shift pattern. John continued to run the pilot plant for a further 3 years, during which time he had considerable input into the design of a second plant, which was completed and commissioned in 2000. After an 18-month period at a small pharmaceutical company, John returned to Oxford in 2000 (by now called Evotec) to head the PRD department. John remained in this position for 6.5 years, during which time he assisted in its expansion, established a team to perform polymorph and salt screening studies and established and maintained high standards of development expertise across the department. John has managed the chemical development and transfer of numerous NCE's into the plant for clients and been involved in process validations. He joined Scientific Update in January 2008 as Scientific Director. Email: [john.knight@scientificupdate.co.uk](mailto:john.knight@scientificupdate.co.uk)

## Who Should Attend?

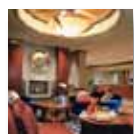
**Project managers** and those involved in technical outsourcing

**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

## Venue



The Sheraton Fisherman's Wharf Hotel  
2500 Mason Street, San Francisco, California 94133, USA  
Telephone: +001 415 362 5500 | Fax: 001 415 956 5275  
[www.sheratonatthewharf.com](http://www.sheratonatthewharf.com)

The Sheraton Fisherman's Wharf hotel is ideally situated in the heart of Fisherman's Wharf, but only two blocks from San Francisco's cable cars. It has 529 modern, well-equipped rooms. They all have individual air-conditioning and high speed internet access. There is a fully equipped business centre and fitness suite. A limited number of rooms have been reserved at the hotel for the special rate of \$149 per night (\$20 for an additional person) plus taxes until January 22nd 2010. Details about making your reservations directly with the hotel will be sent to you when you register. San Francisco Airport is 16 miles and Oakland Airport 20 miles. Please visit the hotel website for driving directions and a local map.

## General Information

The course begins with registration at 8.45am on Monday 22 February and finishes at approximately 4.30pm on Tuesday 23 February. There is a Course Dinner for all delegates on Monday 22 February.

The organisers reserve the right to change the published programme of events and course content as circumstances dictate.

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