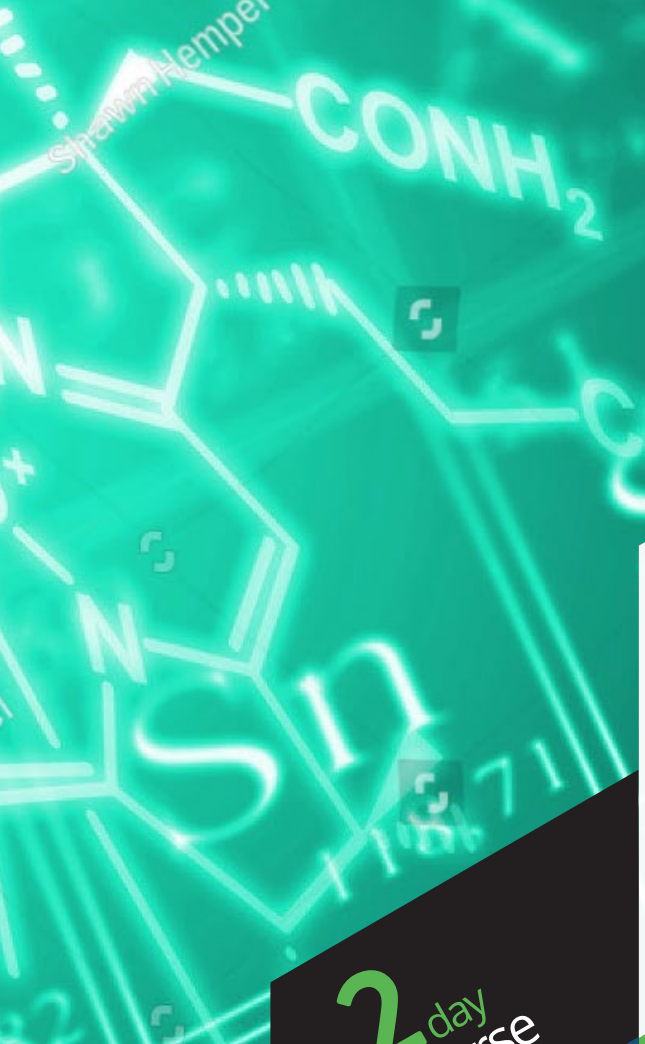

SCIENTIFIC UPDATE

We've got chemistry

2 day Course

2020

MOLECULE TO MEDICINE

Managing the transition from discovery to development

"The course was so relevant to my current challenges. John answered all of my questions and I now have many new suggestions to try when I get back in the lab."

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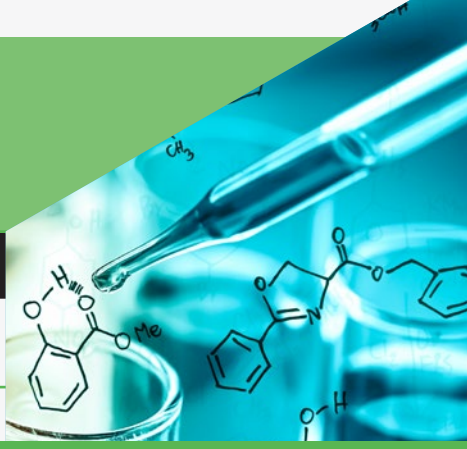
MOLECULE TO MEDICINE

MANAGING THE TRANSITION FROM DISCOVERY TO DEVELOPMENT

A 2 day 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 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 1:

Session 1:
Introduction - Where do the development candidates come from?

An overview of pharmaceutical discovery and development.

Exploring the interface between discovery and development- where, when and how process chemistry should get involved.

Rapidly moving a molecule into phase 1- planning, compound supply and managing expectations.

Session 2:
Transitioning from research to development: compound route selection and preparing the first toxicology batches.

Making the first GLP toxicology batches.

Starting materials, chromatography, specifications.

Managing with limited resources and stage appropriate development.

Session 3:
Solid form.

Establishing physical form in early development. Solid form, polymorphism and crystallization. Salt selection.

Session 4:
Preparing the first cGMP batch and accelerating the progression of a molecule into phase 1.

An introduction to GMP's and how they impact on the first scaling exercise.

Session 5:
Process safety and raw material supply- how these might impact on route selection.

Introduction to process safety and testing.

Raw materials- sourcing and maintaining supply of intermediates.

Review of the day and questions.

Day 2:

Section 6:
Technology transfer and outsourcing- communication, planning and dealing with the unexpected

Successful outsourcing strategies.
The importance of communicating critical information.

Section 7:
Scaling into fixed vessels: heat transfer, mixing and scalability.

Operations that transfer well and those that typically do not.

Section 8:
Impurities: detection, Isolation, identification and control.

Setting specifications and regulatory requirements.

Section 9:
Introduction to genotoxic impurities- what they are, where they come from and how we control them.

Reactive functional groups and classification

Regulatory requirements.

Section 10:
Towards a green future- new technologies and sustainable chemistry.

Green processes and waste minimization
Continuous processing.
Future technologies in process chemistry.

Review of the day, questions and final thoughts.

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

SCIENTIFIC UPDATE
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Registration 8.45
Course commences 9.00 Day 1
Course adjourns 4.30 on Day 2

Course fees include a comprehensive course manual, refreshments throughout each day, lunches and one course dinner on the first evening

For all prices and dates please refer to our website

IT'S EASY TO REGISTER ONLINE

COURSE TUTORS

Dr John Studley

Dr John Studley
Scientific Director,
Scientific Update

John started his industrial career at Rhone-Poulenc (formerly RTZ chemicals) in Avonmouth- Bristol, working on fluorination technology, before gaining a chemistry degree and organic chemistry PhD at the University of Bath in 1995. He then did postdoctoral research at the University of Sheffield before joining the process chemistry group at Oxford Asymmetry working on route development and optimization, scale-up and custom synthesis.

In 1999 John joined Vertex Pharmaceuticals (Europe) in the discovery chemistry department, spending a number of years working in oncology and inflammation therapeutic areas. He then formed a scale-up group to support synthesis of pre-clinical candidate molecules and intermediates and in 2010 oversaw construction and commissioning of a new kilo lab facility. In 2012 John was appointed to head of process chemistry for Vertex (Europe), overseeing synthesis of compounds for preclinical toxicology assessment, designing safe, scalable synthetic routes and working with external vendors and global CRO's to deliver key intermediates and develop new enabling technologies. He was also responsible for developing chemistry for cGMP synthesis of early phase clinical material.

johns@scientificupdate.com

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?

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EVENT:

DATES: **LOCATION:**

No. of attendees **Price**

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