



SCIENTIFIC UPDATE

We've got chemistry



**Toronto,
Canada**
Sheraton Centre
Toronto

MOLECULE TO MEDICINE

Managing the transition from
discovery to development

13-14 JUNE 2019

A 2 day course
presented by
Dr John Studley

"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."

Teva Pharmaceuticals



MOLECULE TO MEDICINE

Managing the transition from discovery to development

13-14 June 2019 Toronto, Canada, Sheraton Centre Toronto

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 1:

Session 1:

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

Explore the interface between discovery chemistry and development- what can we learn from each other? Key interactions between medicinal chemists and process chemists.

Discuss how rapidly we can we move a molecule into phase 1, the planning required to expedite the process and staying on top of compound supply.

Communication, working with other disciplines and managing expectations.

How to plan for the unexpected.

Contingency planning and redundancy in material supply.

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 2:

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.

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

We've got chemistry

Start 9.00am - Thursday 13 June

Finish 4.30pm - Friday 14 June

Course dinner 6.30pm - Thursday 13 June

Course Fee: \$1,899

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

Course fee: \$1,899

COURSE TUTOR

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.

John recently joined Scientific Update as Scientific Director. He is involved in running training events and advising on scientific content for the conference programme. He also supports the consultancy arm of the business and has a keen interest in scientific writing and communication.

@ johns@scientificupdate.com

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 (Mastercard or Visa). 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 two 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

These will be sent via email.

Late Applications

For late applications, please register online 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 (or equivalent in €/ \$) 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

Sheraton Centre Toronto

123 Queen St W
Toronto
ON M5H 2M9
Canada

www.sheratontoronto.com

Superbly located in the heart of downtown Toronto and close to the city's top attractions, Sheraton Centre Toronto Hotel is the perfect destination for both work and play. Settle into our recently refreshed guest rooms and suites and experience 4-star amenities like an on-site spa, several delicious restaurants, a full fitness center and a state-of-the-art indoor-outdoor

pool. The best of downtown Toronto is at your fingertips here - our hotel is a conveniently connected to both the financial and entertainment districts by way of the PATH, a 16 mile underground network of shops and services. Regardless of what brings you here, we look forward to exceeding your expectations at Sheraton Centre Toronto Hotel.





13-14 June 2019 Toronto, Canada

No. of attendees @ \$1,899

Special Offer! Register 2 delegates and receive 5% on 2nd booking
Register 3 delegates and receive 10% on 3rd booking
Register 4 or more delegates and receive a 15% discount

First attendee

Company
Title (Dr/Prof/Mr/Mrs/Ms)
First name
Surname
Job Title
Address

Post Code / Zip
Country
Tel
Fax
Email
Mobile
Special Diet
I would like to subscribe to your FREE bi-monthly newsletter
What's new in Process Chemistry?

Second attendee **SAVE 5%**

Title (Dr/Prof/Mr/Mrs/Ms)
First name
Surname
Job Title
Tel
Fax
Email
Special Diet
I would like to subscribe to your FREE bi-monthly newsletter
What's new in Process Chemistry?

Third attendee **SAVE 10%**

Title (Dr/Prof/Mr/Mrs/Ms)
First name
Surname
Job Title
Tel
Fax
Email
Special Diet
I would like to subscribe to your FREE bi-monthly newsletter
What's new in Process Chemistry?

Invoice Address (if different to delegate address)

Address

Post Code / Zip
Country
Tel
Fax

Please invoice my company

Purchase Order:

Promotion Code:

Payment Methods

Payment will be made by:

Cheque Bank Transfer Credit Card

In Currency:

Dollars GBP* or Euros*

We accept the following credit cards:

Amex* Mastercard Visa

To pay by credit card a secure link will be provided once you receive your booking confirmation email, this will then take you to a secure payment gateway.

*payments via Amex can only be made in US dollars

* Currency Payments

If you select to pay in GBP, or Euros 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.

Cancellations

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 fee less £300 (or equivalent in €/ \$) processing fee. Unfortunately refunds are not possible within 1 month of the course date. Substitutions can be made at any time.

Data Protection

Scientific Update Ltd is registered under the Data Protection Act 1998. We will store your information securely and only share your contact details with other attendees at this event. If you are happy for your details to be passed to any third parties please tick here:

For full terms of business and payment details please see our website

Please complete this form and fax to +44 (0)1435 872734

You can also download the PDF from www.scientificupdate.com, complete the form online and email back
Scientific Update, Maycroft Place, Stone Cross, Mayfield, E. Sussex TN20 6EW, UK
+44 (0)1435 873062 sciup@scientificupdate.com