

Practical Management of Impurities and Development of Effective and Comprehensive Control Strategies

6-7 JULY 2017



Newcastle, UK
Hilton Newcastle
Gateshead

A 2 day course given by
Dr Andrew Teasdale

NEW COURSE
for 2017

Professional Development Training

Scientific Update provides training courses for industrial chemists and chemical engineers in chemical development and scale-up and many other specialist topics in organic and process chemistry. Our short intensive training courses enable scientists to learn about highly relevant topics, to broaden their knowledge and to keep abreast of new science, new technology and new techniques.

www.scientificupdate.co.uk | info@scientificupdate.co.uk

Register for this
course by using our
fast online booking
system or form on
page 4 or call
+44 (0)1435 873062





Practical Management of Impurities and Development of Effective and Comprehensive Control Strategies

A 2 day course given by
Dr Andrew Teasdale

6 -7 July 2017 Hilton Newcastle Gateshead, Newcastle, UK

Multiple attendees discounts
UP TO 15% available

INTRODUCTION

Effective Management of Impurities within Pharmaceuticals is an integral part of the overall development process and a central core of the control strategy.

This course aims to provide an in depth examination of the key principles associated with the management of all key impurity classes and within each provide an overview of the current state of the art. It will look to examine how to apply a risk based approach to impurity identification, assessment and management and how to relate this to manufacturing processes and ultimately the overall control strategy. To ensure that not only are impurities controlled in line with regulatory requirements but also that the associated control strategy allows rather than hinders effective process optimisation.

What will attendees gain from the course?

What are the key impurity classes and how they relate to the overall manufacturing process.

A clear understanding of the pivotal role played by chemists and analysts in the impurity management process.

How to effectively relate product quality to impurity qualification ensuring that qualification studies properly align to process capability.

How to align impurity management to the over process control strategy – to optimise effective control

How to use effective impurity management to drive key process and regulatory decisions e.g. starting material definition and defence.

COURSE CONTENT

1. General Impurity management and control

- > This will examine the process of establishing appropriate limits outlining and explaining the process of Impurity qualification and what it actually means in practice.
- > Utilisation of durationally adjusted qualification thresholds.
- > How to relate this to overall impurity management including CQAs; when / where and how to control in the process.
- > How to relate management of impurities to effective selection of starting materials and how this addresses key regulatory concerns aligned to Q11.
- > Long term of control and the definition of Established Conditions.
- > Control strategy exercise including definition of starting materials.

2. ICH M7

- > The importance of control vs avoidance.
- > Interpretation of ICH M7 and practical implementation strategies.
- > How to conduct and MI risk assessment and the pivotal role played by the chemist.
- > How to maximise the use of first principles to assess risk and to minimise analytical development.
- > MI risk assessment exercise.

3. ICH Q3D

- > Key principles and concepts and key role of GMP.
- > Current areas of challenge and strategies to address.
- > Impact on API and how to establish an effective risk assessment without exhaustive testing.
- > Overview of overall scope of ICH Q3D – drug product considerations.
- > EI risk assessment exercise.

4. Extractables and Leachables

- > What are they and why the concern – illustrated by actual examples.
- > Navigating the complex framework of guidance and regulation including the potential impact of new USP general chapters.

5. Other Areas

- > Solvents – including approaches to use of non-ICH solvents.
- > Shared Facilities – Impact of Guidelines and how to handle / apply to API / Intermediates.

6. New Modalities

- > How to extend principles to new modalities e.g. Antibody drug conjugates / Oligonucleotides.
- > Effective grouping of impurities.
- > How to differentiate between process and product related impurities.
- > How to define criticality based on purge potential.
- > Potential risk assessment platform approaches.

Start 9.00am - Thursday 6 July
Finish 4.00pm - Friday 7 July
Course dinner 7.00pm - Thursday 6 July

Course Fee: £1,175 + VAT

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

Course Fee: £1,175 + VAT

COURSE TUTOR

Dr Andrew Teasdale

Andrew Teasdale PhD has over 20 years' experience in the pharmaceutical industry as an analytical chemist and within quality assurance and regulatory roles. His current role is that of chair of AstraZeneca's Impurity Advisory Board. He is a leading expert in key impurity areas, including mutagenic impurities (MIs), Elemental Impurities (EIs), Impurity qualification and Extractables and Leachables (E&Ls). As well as his role in AZ he has led many cross industry groups relating to the areas described; these include both safety and quality groups within Pharmaceutical Research and Manufacturers of America (PhRMA), European



Federation of Pharmaceutical Industries and Associations (EFPIA), Extractables and Leachables Safety Information Exchange (ELSIE) and Product Quality Research Institute (PQRI). The latter focused on the critical area of sulfonate ester formation and control. He is also the editor/author of the first book on the subject of Genotoxic Impurities: Genotoxic Impurities – Strategies for Identification and Control (Wiley). He is also the inventor of the purge factor concept now routinely used in the evaluation of the potential carryover of mutagenic impurities.

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.

IN-HOUSE COURSE

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

VENUE

**Hilton Newcastle Gateshead
Bottle Bank
NE8 2AR
T: 0191 4909700**

This stylish Newcastle hotel is situated between the famous Tyne and Swing Bridges which link Newcastle and Gateshead Quayside. Take in delightful views of the River Tyne and the city and enjoy its excellent location. A special rate of £105 bed and breakfast has been organised at the hotel and details on how to book will be sent once you register for the course.



Course:

Dates:

Location:

No. of attendees

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



NEW FAST ONLINE REGISTRATION

Look for the **register** button on the event of your choice. www.scientificupdate.com

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:

☐ Euros ☐ GBP* ☐ or Dollars*

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.

* 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.

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 Tel +44 (0)1435 873062 sciup@scientificupdate.com