



**SCIENTIFIC
UPDATE**

We've got chemistry

PRACTICAL MANAGEMENT OF IMPURITIES AND DEVELOPMENT OF EFFECTIVE AND COMPREHENSIVE CONTROL STRATEGIES

Also available ONLINE.
Check website for details.



VIRTUAL
Events Online

2 day
Course

2020

"This really was one of the best courses I have ever been on. Thanks a lot to Scientific Update for organising and to Dr Teasdale for this outstanding lectures!"

Grünenthal GmbH

PRACTICAL MANAGEMENT OF IMPURITIES AND DEVELOPMENT OF EFFECTIVE AND COMPREHENSIVE CONTROL STRATEGIES

A 2 day course

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?

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 OUTLINE

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

- > In depth examination of N-Nitrosamines, this will include an overview of regulations as well as a detailed examination of risk factors and their effective management.
- > 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.
- > El 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.

WHO SHOULD ATTEND?

Chemists, toxicologists, analysts, regulatory affairs, quality control and safety assessment professionals





SCIENTIFIC UPDATE

We've got chemistry

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 Andrew Teasdale

Andrew Teasdale PhD has over 25 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.

Dr Teasdale was the lead editor / author for the first definitive book focused on practical implementation of ICH Quality Guidelines – published September 2017 – Wiley and Sons. He is currently revising the book he wrote on Genotoxic impurities with major new chapters focusing on current issues including N Nitrosamians.



Dr Andrew Teasdale

IN-HOUSE COURSE

For 13+ people contact us to discuss holding this event In-House - sciup@scientificupdate.com

CONSULTANCY SOLUTIONS

OUR EXPERTISE

We are specialists in Industrial Organic Chemistry, solving problems and managing projects in Process Research and Development covering the following industries:

- > Pharmaceuticals
- > Fine Chemicals
- > Agrochemicals
- > Flavour & Fragrance
- > Specialty Chemicals

OUR TEAM

You will be assigned one leading consultant but you will benefit from our team with over 100 years collective industrial experience.



OUR APPROACH

We will sign a CDA and discuss your project by telecom or webinar to assess what benefits we can offer. This initial consultation (up to 4 hours) is free of charge. After which we will offer a detailed proposal with the service we can provide tailored to your individual requirements.

REGISTRATION

Use our **fast online booking system** by visiting

www.scientificupdate.com

Alternatively you can 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). A receipted invoice will be automatically generated once paid and sent via email. Should your company wish to pay by cheque or bank transfer, on booking, 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 £300.00 (or equivalent in €/€) processing fee. Unfortunately refunds are not possible after that date. Substitutions can be made at any time.

DON'T MISS OUT - REGISTER TODAY

EVENT:**DATES:****LOCATION:****No. of attendees****Price****NEW FAST ONLINE REGISTRATION**

Why not register quickly online and receive instant confirmation? Look for the **register** button on the event of your choice. www.scientificupdate.com

First attendee

Company	<input type="text"/>
Title (Dr/Prof/Mr/Mrs/Ms)	<input type="text"/>
First name	<input type="text"/>
Surname	<input type="text"/>
Job Title	<input type="text"/>
Address	<input type="text"/>
	<input type="text"/>
Post Code / Zip	<input type="text"/>
Country	<input type="text"/>
Tel	<input type="text"/>
Fax	<input type="text"/>
Email	<input type="text"/>
Mobile	<input type="text"/>
Special Diet	<input type="text"/>
I would like to subscribe to your FREE bi-monthly newsletter What's new in Process Chemistry?	<input type="checkbox"/>

Second attendee

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

Third attendee

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

Invoice Address (if different to delegate address)

Address	<input type="text"/>
	<input type="text"/>
	<input type="text"/>
Post Code / Zip	<input type="text"/>
Country	<input type="text"/>
Tel	<input type="text"/>
Fax	<input type="text"/>

 Please invoice my company

Purchase Order:	<input type="text"/>
Promotion Code:	<input type="text"/>

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.

*payments via Amex can only be made in US dollars

Currency Payments

If you select to pay in a different currency than the event is advertised in, 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