SCIENTIFIC UPDATE

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

8-9 MARCH 2018

Clearwater, USA
Sheraton Sand Key Resort

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A 2 day course given by
Dr Andrew Teasdale

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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?

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

> 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.

SCIENTIFIC UPDATE

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Start 9.00am - Thursday 8 March
Finish 4.30pm - Friday 9 March
Course dinner 7.00pm - Thursday 8 March

Course Fee: $1,925
Which includes comprehensive course manual, refreshments throughout the day, lunch and one course dinner.

Course Fee: $1,925

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.

IN-HOUSE COURSE

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

VENUE

Sheraton Sand Key Resort
1160 Gulf Boulevard
Clearwater Beach
Florida 33767, USA

sheratonsandkey.com

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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.

PRACTICAL MANAGEMENT OF IMPURITIES

8-9 March 2018 Clearwater, USA

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