

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

New in depth focus on all aspects of management of N-NOs, seeking to address understanding of regulatory guidance both formal guidance and also regulatory intelligence and translation of this into risk assessment strategy. This will cover this from a quality and safety perspective, within each highlighting the current scientific understanding and how this shapes the area both now and in the future. This will be reinforced through practical examples and a new focused exercise.



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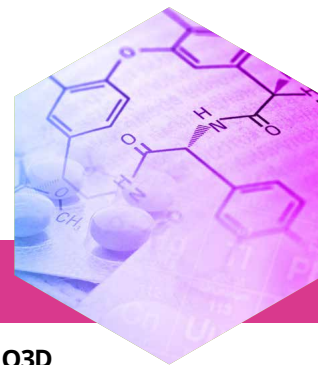
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*"This really was one of the
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Update for organising and
to Dr Teasdale for this
outstanding lectures!"*



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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.

WHO SHOULD ATTEND?

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

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.
- > 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.



ONLINE COURSE

Delivered in four sessions of 4 hours each at 1.30PM to 5.30PM UK time each day.

Fee includes: web link to watch all four session, electronic version of the manual and certificate.



FACE TO FACE COURSE

Two day course, running from 9.00AM to 5.00PM each day – local timings.

Delegate Fee includes: all refreshments, lunch, one course dinner, course manual and certificate.

COURSE TUTOR



Dr Andrew Teasdale

Andrew Teasdale PhD has 30 years' experience in the pharmaceutical industry as an analytical chemist and within quality assurance and regulatory roles. In his current role he chairs AstraZeneca's Impurity Advisory Group. Dr Teasdale has published a number of papers relating to mutagenic impurities, N Nitrosamines, extractables and leachables, and other impurity related matters. He is currently the chair of the Extractables and Leachables safety Information exchange (ELSIE) and also led a number of industry expert groups; these include both safety and quality groups within Pharmaceutical Research and Manufacturers of America (PhRMA), European

Federation of Pharmaceutical Industries and Associations (EFPIA), Product Quality Research Institute (PQRI). Andrew has also represented EFPIA in ICH Q3C, Q3D and Q3E Expert working groups. He has also advanced a number of key scientific advancements in the control of impurities as the inventor of the purge factor concept and the instigator of the development of Elemental Impurities database for excipients.

With over 50 scientific papers, he has also written 3 books:

Genotoxic Impurities – Strategies for Identification and control. Editor A Teasdale. Publisher Wiley. ISBN 978-0-470-49919-1

ICH Quality Guidelines – An Implementation Guide. Editors A Teasdale, D Elder, R W Nims. Publisher Wiley. ISBN 978-1-118-97111-6.

Mutagenic Impurities – Strategies for Identification and Control Second Edition. Editor A Teasdale. Publisher Wiley. ISBN 978-1-119-55121-8

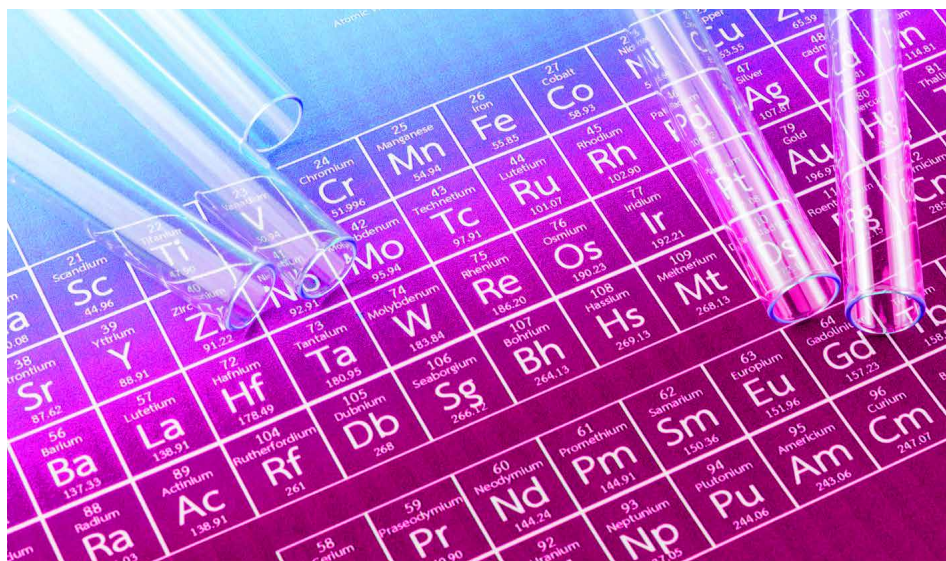


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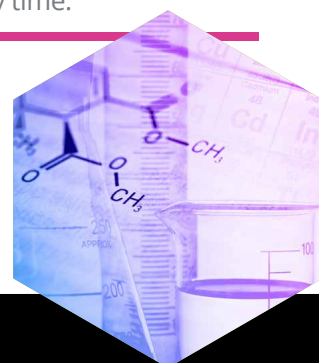
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EVENT:

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LOCATION:

No. of attendees

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