

Lhasa Limited & CloudScientific China Symposium

09:00 - 09:30

Registration / 注册签到



Session 1: ICH M7 Assessments **主题1: ICH M7评估**

09:30

Welcome from CloudScientific / 主办方致辞

Jack Lin, CEO, CloudScientific / 林建成 康昱盛 CEO

09:35

Developing science that helps you feel confident in your decisions /
开发提升决策信心的科学工具

Dr Chris Barber, CEO, Lhasa Limited

09:50

Overcoming challenges in ICH M7 expert review: Interactive session
with case studies /

克服ICH M7专家评审中的挑战：案例研究互动讨论

Dr Gabriela Silveira, Senior Application Scientist, Lhasa Limited



10:25 - 10:40

Break / 茶歇



10:40

The application of Derek & Sarah in impurity research and safety assessment in new drug development /

Derek & Sarah 在新药研发杂质研究和安全评估中的应用

Peng She, Director of R&D Analysis, Small Molecule Division, Porton Pharma Solutions Ltd. / 余鹏 博腾股份小分子事业部研发分析 总监

11:10

Supporting your expert nitrosamine decision /

支持您在亚硝胺方面的专家决策

Dr David Ponting, Principal Scientist, Lhasa Limited

11:35

Industrial case studies of purge to support N-nitrosamine control strategies / 工业案例研究：支持N-亚硝胺控制策略的清除方法

Dr Mike Urquhart, Scientific Director, Drug Substance Development, GSK

12:00 - 13:30

Lunch / 午餐

Session 2 : Elemental Impurities in Drug Products

主题2：药品中的元素杂质研究

13:30

ICH Q3D guidance and a data driven strategy to elemental impurities in excipients /

ICH Q3D指导原则及数据驱动的药用辅料中元素杂质策略

Grace Kocks, Senior Global Alliances Manager, Lhasa Limited



14:00

The strategies for elemental impurity control and risk assessment of pharmaceutical excipients in various pharmacopoeias /
各国药典元素杂质控制策略及药用辅料风险评估

**Dr Lirong Cai, Engineer of Pharmaceutical Excipients Key Laboratory,
Hunan Institute**

蔡立荣博士 蔡立荣 湖南省药品检验检测研究院药用辅料重点实验室工程师

14:30 - 14:50

Break / 茶歇

Session 3: Process and Degradation Impurities
主题3: 工艺及降解杂质

14:50

Using an in silico tool to solve degradation problems /
利用计算机模拟工具解决降解问题

Dr Yu Jin, Application Scientist, Lhasa Limited

15:15

Using Zeneth for degradation pathways prediction and a preliminary
real-world comparison /

使用 Zeneth 进行降解途径预测及初步的实验数据比较

Luccas Sanches, Researcher, Spektra Consulting



15:50

Closing remarks / 闭幕致辞

Dr Chris Barber, Lhasa Limited

16:00

Networking and demonstrations

交流/讨论/软件演示

