

ICH M7 Guideline for Genotoxicity Impurities, Software Evaluation Seminar

Cloud Scientific in collaboration with Lhasa Limited.

China Users & Prospects General Meeting (UGM) Agenda

Day 1 - 23rd September 2021, Thursday

Time (China)	Time (BST)	Duration	Presentation	By
15:00 - 15:05	08:00 - 08:05	5 min	Welcome and introduction	Cloud Scientific
15:05 - 15:35	08:05 - 08:35	30 min	How to assess the mutagenicity of impurities using (Q)SAR under ICH M7	Cloud Scientific
15:35 - 16:20	08:35 - 09:20	45 min	ICH M7 expert review workshop	Lhasa Limited Rob Foster, Senior Scientist
16:20 - 17:00	09:20 - 10:00	40 min	Application of (Q)SAR methodology in evaluating mutagenicity of impurities	SDIFDC Dr. Qingfen Zhu
17:00 - 17:15	10:00 - 10:15	15 min	Q&A	
17:15 - 17:20	10:15 - 10:20	5 min	Closing	
	Total	140 min		

Day 2 - 24th September 2021, Friday

Time (China)	Time (BST)	Duration	Presentation	By
15:00 – 15:05	08:00 – 08:05	5 min	Welcome and introduction	Cloud Scientific
15:05 – 15:30	08:05 – 08:30	25 min	Purge assessment and Mirabilis under ICH M7	Lhasa Limited Meekee Kok, Senior Business Development Manager
15:30 – 16:30	08:30 – 09:30	60 min	Lhasa Limited's Nitrosamine Efforts	Lhasa Limited David Ponting, Senior Scientist Rachael Tennant, Senior Scientist
15:55 – 16:40	08:55 – 09:40	45 min	Nitrosamine impurities assessment strategy and proposed solutions ~ industry perspective	Nanjing Milestone Pharma, Dr.Zifeng Zhu
17:15 – 17:25	10:10 – 10:25	10 min	Q & A	
17:25 – 17:30	10:25 – 10:30	5 min	Closing	
	Total	150 min		