

<p>LHASA AND IPEC-EUROPE COLLABERATIVE MEETING Thursday 21st March 2024</p>
<p>8:45-9:00 WELCOME AND REGISTRATION</p>
<p>9:00-9:15 INTRODUCTIONS</p>
<ul style="list-style-type: none"> • Nitrosamines in substances and medicinal products – current Ph. Eur. requirements and EDQM responses <i>Anne Garnier, EDQM</i> • Nitrites in Excipients – USP Perspective <i>Christan Zeine, USP</i> • The Nitrite Database - what do we know so far about the risk of excipients? <i>Grace Kocks, Lhasa Limited</i> <p><i>Q&A session</i></p>
<p>10:30-10:50 COFFEE BREAK</p>
<ul style="list-style-type: none"> • Excipients Under Scrutiny: Technical Challenges and Strategies for Nitrosamine Reduction <i>Krizia M. Karry, BASF</i> • Challenges to Determine Trace Levels of Nitrite in Lactose <i>Ricarda Leister, MEGGLE GmbH & Co. KG</i> • Best practice sharing for nitrite testing – lessons learned within the consortium. <i>Sebastian Hickert, Merck KGaA</i> • Nitrite consortium comparative testing studies and our learnings <i>Giorgio Blom, AstraZeneca</i> <p><i>Q&A session</i></p>

<p>12:20-13:10 LUNCH BREAK</p>
<ul style="list-style-type: none">• Managing nitrite impurities – view of an excipient manufacturer <i>Ulrich Reichert, Merck KGaA</i>• Key excipients and validation challenges <i>Tamas Balogh, GSK</i>• Parts per Billion of Nitrite in Microcrystalline Cellulose by Ion Chromatography Mass Spectrometry with Isotope Labeled Internal Standard <i>Markus Mintert, IFF</i>• DFE Pharma’s road to advanced Nitrite level testing in Excipients <i>Pauline Janssen, DFE Pharma</i> <p><i>Q&A session</i></p>
<p>14:40-14:55 COFFEE BREAK</p>
<ul style="list-style-type: none">• Nitrite analysis in Hypromellose: Literature overview and validation of an HPLC method <i>Vanessa Havenith and Andreas Sauer, SE Tylose</i>• Challenges in Chromatographic Analysis of Nitrite in PVP-based Polymers <i>Volker Neu, BASF</i>• Sample Preparation – Consortium Survey Results and Best Practices <i>James Sabatowski, Eli Lilly</i> <p><i>Q&A session</i></p>
<p>16:10 - 16:15 CLOSE MEETING</p>