30 years of Extractables and Leachables (E&L) in Inhalation Products, a rapid(s) ride

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A review of past 30 years of E&L activity in Inhalation Products (Metered Dose Inhalers (MDIs), Dry Powder Inhalers (DPIs), Aqueous Nasal Sprays (ANS) and Nebulisers)

This five-minute presentation will highlight some of the things which have changed and some of the things which remain the same:

- 30 years ago, Nitrosamines were a key concern as leachables for MDIs, today they still represent a huge challenge for pharma, but E&L is much more than that.
- Regulatory requirements for E&L started with MDIs in asthma, those requirements are still there but have been extended covering other modalities but we still await clarity and consistency of approach
- Methods of analysis for E&L remain a challenge, UV spectra of polyaromatic hydrocarbons (PAHs) have been replaced with the state-of-the-art Mass Spectroscopy and Ion Mobility to detect, identify and quantify with more confidence than ever before.
- Safety Assessment of leachables is still a key part of the workflow, as we move from in-vivo to in-vitro and in-silico assessment much has been achieved but there are still many questions to answer in addressing the gaps in our knowledge that the risk from leachables may pose
- As always knowledge and understanding led by good science will be a cornerstone as it was 30 years ago and into the future. Much has been achieved but there is still more to do. Patients are waiting for Pharma to get this right.