



September 18-19, 2025
Trenton Country Club, West Trenton NJ

Day 1 Recap

Presented by Carolyn Berg, Catalent

AM Recap (1)

- **Sara M. (RTI)**
 - Viability of nanovaccines for a TB vaccine -- 90% of the antigen remained using PGLA nanoparticles
 - Demonstrated efficacy in rodent models
- **Vivek G. (St. John's)**
 - Challenges and Advantages of N2B delivery
 - Liquid to Gel for N2B uptake
 - Enhanced permeation across the nasal epithelium with nanoemulgels
- **Irene R. (Harro Hofliger)**
 - Growth/pipeline of nasal vs. orals/injectables
 - Powder vs. liquid – high bioavailability of the former
 - Case study of repurposed molecule ganaxolone

AM Recap (2)

- **Reenal G. (Aptar)**
 - Formulation/ Device / Patient Trilogy – focus on patients
 - Importance of patient / role of angle in regional nasal deposition
 - Nasal casts/ quantification of regional nasal deposition in formation HF studies
- **Phil K. (Lovelace)**
 - Tools / models / casts → “all wrong but all useful”
 - Advantages & disadvantages of rodent models
 - Use of non-clinical models to evaluate changes in formulation (PK as primary)
- **Lucas S. (Nanopharm)**
 - Physiochemical properties - considerations for liquid solutions and suspensions
 - Role of formulation / impact on nasal delivery (excipients/permeation enhancers/other)
 - Case studies: mab, nuc acid/peptide encap. Liposome, peptide for N2B, antiviral

PM Recap (1)

- **Deb D. (Bayer)**
 - Enhanced nasal sprays – modified nasal gels w/use of enabling excipients
 - Mucoadhesive systems (viscosity → thinning) / preventing loss of dose
 - SNEDDS (nasal self emulsifying delivery systems) in nasal sprays and gels
- **Larry B. (Noveome)**
 - Novel biologic -- cell therapy with out the cell / derived from amniotic epithelial cells
 - ST266 (nasal) – neuroprotective efficacy, ↓ inflammation, improved cognitive effects
 - Necrotizing enterocolitis (NEC) – NICU / 5 babies to date / 2 more
- **Alan W. (Catalent)**
 - Summary of developing powder products cells / pipeline (50) and indications
 - Advantages of SD – control over particle size/morphology / alternative mnfg. Practices
 - AmorphOX® / review of devices / Zetco / characterization / formulation approaches

PM Recap (2)

- **Kay O. (Nano PharmaSolutions)**

- Nano-sizing using the Nano-CNS™ platform (freebase) / enhanced bioavailability
- Process (carrier drug < 100⁰ API < 160⁰)
- NT301 Parkinson's (3 vs. 30-45 min.) and NT401 for TBI

- **Paul S. (Aptar)**

- Acute agitation (bipolar/ schizophrenia) – hours of building up to potential violence
- Loxapine for acute agitation / benefits of outpatient administration (vs. Adasuve)
- 3 formulations / matching the 2-hour AUC / PK studies with mannitol

Common Themes

- **Benefits of nasal delivery** -- Non-invasive / Patient-friendly / Low-cost
- **Liquid vs. powder** - advantages/disadvantages / quick to clinic
- **Commercial viability** – importance of voice of the patient / understanding market viability / need for blockbusters