



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

# Welcome and Forum Introduction

Presented by Carolyn Berg, Catalent

# Background to Forum

- Nasal drug delivery is rapidly transforming modern therapeutics, offering a non-invasive and efficient route for both local and systemic treatments. Whether designed for emergency use, chronic conditions, vaccine administration, or novel brain delivery, nasal formulations are at the forefront of pharmaceutical innovation. However, significant regulatory and technical challenges remain, making it critical for drug developers to adopt best practices to ensure product success
- Following the expert presentations and discussions, the Forum Organizing Committee will meet after the Forum to consider options and plan for future Forums in 2026 and 2027

# What to Expect

With growing regulatory scrutiny and high failure rates in product development, the Forum will focus on the key challenges and solutions in nasal drug delivery, including:

- Device selection and performance considerations – Understand how delivery systems impact dose uniformity and therapeutic success
- Advancements in analytical methods – Explore strategies for ensuring reproducibility, accuracy, and regulatory compliance in testing
- Optimizing formulations for enhanced bioavailability – Discover best practices for improving drug absorption and efficacy
- Bridging preclinical and clinical development – Learn how translational strategies can enhance the success of nasal drug products
- Manufacturing, stability, and characterization – Address the critical factors that influence product quality and long-term viability
- Navigating regulatory expectations – Learn how to meet evolving global requirements and avoid common pitfalls in the approval process

# Forum Objectives

- This Forum will bring together industry leaders, regulatory experts, and scientific pioneers to explore the complexities of nasal drug development. This forum provides a unique opportunity to engage in thought-provoking discussions, gain insights from expert speakers, and participate in collaborative roundtable sessions.
- Day 1 will focus on Scientific Understanding and Marrying Formulation and Device & the Role of Clinical Models.
- Day 2 will focus on Good Practices for Manufacturing and Commercialization and Regulatory Perspective.
- Through podium presentations from expert speakers and roundtable discussions, attendees will learn from academia and pharma companies what is on the horizon for nasal delivery

# Day 1 Agenda

## **Session 1: Scientific Understanding** (Moderator: Laleh Golshahi, VCU)

- **Intranasal Nanovaccines for Tuberculosis Prevention: Novel Strategies in Formulation and Delivery**
  - Sara Maloney Norcross, RTI International
- **Brain Bound! Nose-to-Brain Delivery with In-situ Intranasal Gels**
  - Vivek Gupta, St. John's University
- **Current and Future Nasal Pipeline: Benefits and Challenges in Drug Repurposing**
  - Irene Rossi, Harro Höfliger

## **Session 2: Marrying Formulation and Device & the Role of Preclinical Models** (Moderator: Sana Hosseini, Aptar Pharma)

- **Delivering for Patients: Navigating Nasal Routes for Optimal Impact**
  - Reenal Gandhi, Aptar Pharma
- **How to Use Non-clinical Models in Intranasal Drug Development**
  - Philip Kuehl, Lovelace Biomedical
- **Strategic Product Design for Liquid Nasal Formulations: A Target Profile Perspective**
  - Lucas Silva, Nanopharm, An Aptar Pharma Company

## **Lunch Break**

# Day 1 Agenda (Cont.)

## Session 2: Marrying Formulation and Device & the Role of Preclinical Models (Continued)

- **A Novel Modified-Release Nasal Self-Nanoemulsifying Drug Delivery System (n-SNEDDS) for Enhanced Solubility, Retention, and Brain Targeting**
  - Deb Das, Bayer Healthcare LLC
- **Intranasal Nose-to-Brain Delivery of ST266 Cell Secretome: From Non-Human Primate to Clinical Translation**
  - Larry Brown, Noveome Biotherapeutics, Inc.
- **Developing Nasal Powder Products: Formulation, Delivery and Characterization**
  - Alan Watts, Catalent Pharma Solutions
- **Nano-CNSTM: Patient-centric CNS Medicines**
  - Kay Olmstead, Nano PharmaSolutions, Inc.
- **Development of a Loxapine Nasal Powder: Leveraging a 505(b)(2) Regulatory Pathway and PK Bridging to Enable At-Home Prevention of Acute Agitation**
  - Paul Shields, Aptar Pharma
- **Panel Discussion: The Future of Nasal Drug Delivery: Trends and Innovations**

Happy Hour and Networking

# Day 2 Agenda

## **Session 3: Good Practices for Manufacturing and Commercialization** (Moderator: Eric Uffman, Proveris)

- **Sniffing Out the Standards: Making Sense of Evolving Nasal Spray Testing**
  - Maria Smith, Proveris Scientific Corporation
- **Commercializing Nasal Sprays: Overcoming Challenges in Manufacturing & Tech Transfer for Sterile and Non-Sterile Products**
  - Mark Ignaczak, Catalent Pharma Solutions
- **Development and NDA Approval of STS101 (Dihydroergotamine Nasal Powder)**
  - Robert Schultz, Satsuma Pharmaceuticals, Inc.

## **Session 4: Regulatory Perspective** (Moderator: Julie Suman, Aptar Pharma)

- **Recommendations for Demonstrating Bioequivalence of Complex Nasal Sprays: Scientific Thinking and Regulatory Research (Pre-recorded)**
  - Susan Boc, US Food & Drug Administration (Invited)
- **Navigating Regulatory Bridging Strategies for Nasal Product Development**
  - Rachel Ward, Kymanox
- **Post Approval Change Strategy**
  - S. Prasad Peri, Eli Lilly and Company
- **Panel Discussion: Regulatory Roundtable**

## **Closing**

# Key Points

This Forum is **your** opportunity to:

- share experiences,
- raise questions,
- learn from each other,
- shape future collaborative initiatives

Therefore, **GET INVOLVED** in the discussions!

Or, as we say, it's not a meeting, **it's a collaboration!**



# 60+ Years of Nasal Innovation

## 1938-1962

- ✓ 60-day approval window - safety
- ✓ Any identical, related, or similar drug products approved in this time could be marketed without independent approvals
- ✓ Scarce data for nasal products prior to this date
- ✓ phenylpropanolamine (1930s?)
- ✓ phenylephrine (<1960s)
- ✓ pseudoephedrine (1940/50s?)



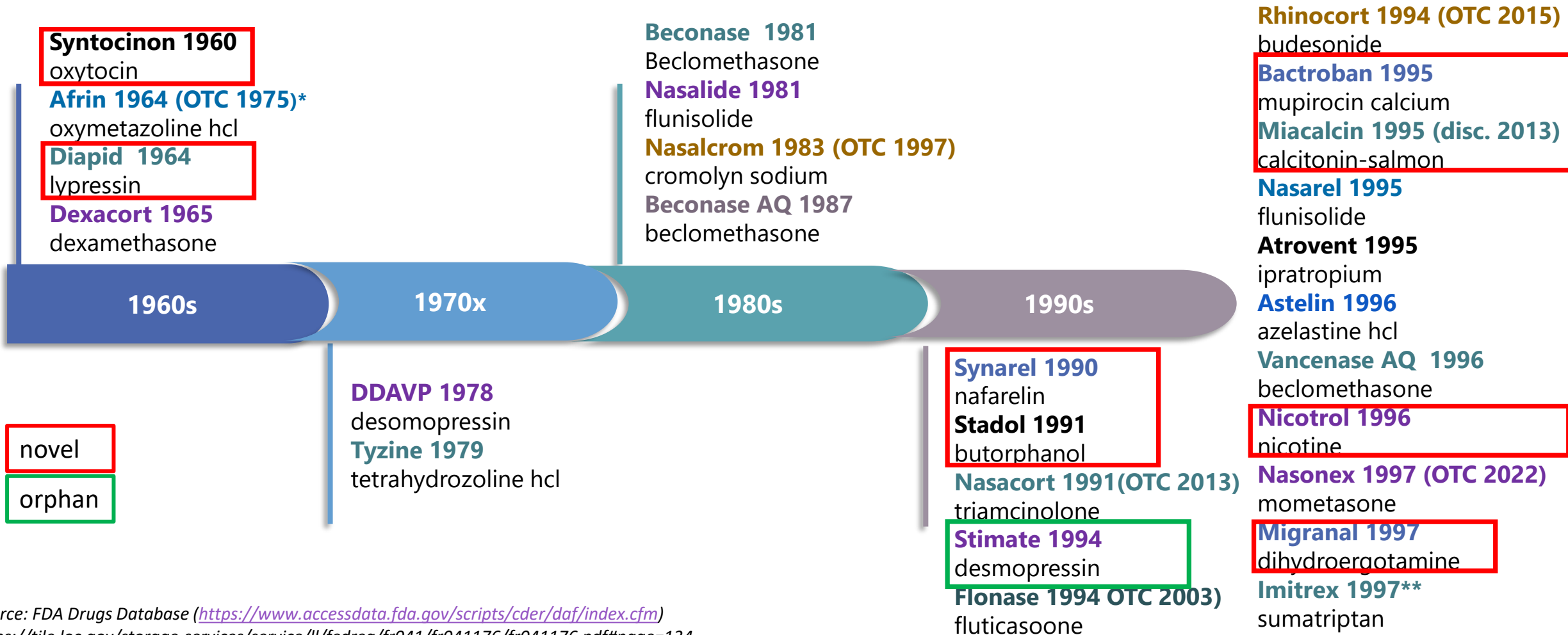
## 1962

- ✓ Kefauver-Harris Drug Amendments (to the FD&C Act) mandated new drug products show efficacy for approval
- ✓ Drug Efficacy Study Implementation (DESI) for approved products (1938-1962)
- ✓ Required supplement to update the application and revisions to the product labeling
- ✓ Identical/related/similar products needed to submit applications

## 1960-2025

- ✓ 195 Nasal NDAs and ANDAs approvals since 1960
  - ✓ 40 NDAs
  - ✓ 3 combination products
  - ✓ Rest are ANDAs
- ✓ Molecules discontinued:
  - ✓ phenylpropanolamine (<1965) - disc. 2005
  - ✓ lypressin – late 90s
  - ✓ mupirocin calcium -- 1997
  - ✓ oxytocin (Rx) - 1997
  - ✓ fentanyl 2024

# Nasal Launches: 1960-1990



Source: FDA Drugs Database (<https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm>)  
<https://tile.loc.gov/storage-services/service/ll/fedreg/fr041/fr041176/fr041176.pdf#page=134>

# Nasal Launches: 2000s-2025

## Qnasl 2002

beclomethasone

## Ryaltris 2002

mometasone/ olopatadine

## FluMist Quadrivalent 2003\*\*

influenza vaccine

## Nascobal 2005

cyanocobalamin

## Sprix 2010

ketorolac tromethamine

## Lanzanda 2011 (disc. 2022)

fentanyl

## Dymista 2012

azelastine/fluticasone

## Zetonna 2012

ciclesonide

## Xhance 2017

fluticasone

## Noctiva 2017

desmopressin

## Narcan 2017 (OTC 2023)

naloxone (AGs/generics)

## Goprelto 2017

cocaine hcl

## Valtoco 2020

diazepam

## Gimoti 2020

metoclopramide

## Numbrino 2020

cocaine hcl

## Tyrvaya 2021

varenicline

## Rextovy 2023

naloxone

## Neffy 2024

epinephrine

## Atzumi 2025\*\*/\*\*

dihydroergotamine

2000s

2010s

2020s

## Fortical 2005

calcitonin-salmon

## Omnaris 2006

ciclesonide

## Calomist 2007

cyanocobalamin

## Patanase 2008

olopatadine hcl

## Zomig 2013

zolmitriptan

## Natesto 2014

testosterone gel

## Onzetra Xsail 2016

sumatriptan

## Kovanaze 2016

tetracaine/  
oxymetazoline

## Tosmyra 2019

sumatriptan

## Spravato 2019

esketamine

## Baqsimi 2019\*\*\*

glucagon

## Nayzilam 2019

midazolam

## Trudhesa 2021\*\*

dihydroergotamine

## Kloxxado 2021

naloxone 8 mg

## Opvee 2023

nalmefene

## Rivive 2023

naloxone 3 mg

## Zavzpret 2023

zavegepant