



NASAL INNOVATION FORUM 2026



September 16-17, 2026

Speaker/Moderator Bios

Molly Adam, M.S.

Group Lead, Respiratory Delivery
Engineering
Lonza

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Molly Adam is a Group Lead at Lonza with eight years of experience spanning research, product development, and advanced drug delivery technologies. She holds a Bachelor of Science in Chemical and Biological Engineering from the University of Wisconsin–Madison and a Master of Science in Computer Science from DePaul University, bringing a unique combination of engineering and computational expertise to her work.

During her tenure at Lonza, Molly has contributed across multiple functional areas, including the internal research group and product development. She has developed broad technical expertise across a range of pharmaceutical manufacturing and formulation platforms, including spray drying for bioavailability enhancement, spray-dried powders for respiratory delivery, immediate- and controlled-release tableting, and hot melt extrusion.

In her current role, Molly leads a team of engineers supporting client programs focused on respiratory delivery technologies.

Ashlee Brunaugh, Ph.D., Pharm.D.

Assistant Professor, Department of
Pharmaceutical Sciences
University of Michigan College of
Pharmacy

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Dr. Ashlee Brunaugh is an Assistant Professor of Pharmaceutical Sciences at the University of Michigan College of Pharmacy. Her laboratory studies how formulation and local physicochemical environments govern drug and biologic transport in the respiratory tract. Her work integrates aerosol engineering, solid-state formulation, mucus biophysics, and transport modeling to develop inhaled and intranasal therapies, including strategies to extend nasal residence of antiviral proteins while preserving mucociliary function. Dr. Brunaugh is a clinically trained pharmacist and pharmaceutical scientist whose translational research spans biologic stability, complex inhaled products, antimicrobial delivery, and airway disease. Her interdisciplinary work has been supported by the NIH, FDA, Cystic Fibrosis Foundation, PhRMA Foundation, industry partners, and the University of Michigan.

Kiran Chaudhari, Ph.D.

Associate Director - R&D, Formulation
Development

Hikma Pharmaceuticals

kchaudhari@hikma.com



Dr. Kirankumar Chaudhari is Associate Director in R&D, Formulation Development at Hikma Pharmaceuticals, with more than 17 years of experience developing nasal, Respiratory, Injectable and Topical products.

He specializes in 505(b)(2) dosage form as value added formulation design, taking programs from concept through CMC, device selection, and preclinical and clinical strategy, including pre-IND interactions with U.S. FDA.

He has filed 40+ regulated-market dossiers and broad regulatory/CMC experience with US FDA, MHRA, EMA and Health Canada authorities. He holds a Ph.D. in Pharmacy from The Maharaja Sayajirao University of Baroda and the University of Eastern Finland, with eight patents and eleven research publications.

Christophe Demaison, Ph.D.

CEO

ENA Respiratory Pty Ltd

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Dr. Christophe Demaison is the Managing Director and CEO of ENA Respiratory, a clinical-stage biopharmaceutical company developing novel antiviral host defence enhancers to protect at-risk populations from respiratory viral infections. Under his leadership, ENA Respiratory has advanced its lead asset, INNA-051, through to a 1,100-participant US Phase 2 trial, while raising over USD 45M in equity financing and securing over USD 15M in US Government contracts. Christophe holds a PhD in Immunology from the University of Paris VII/Pasteur Institute and has 20+ years of experience building venture-backed life sciences companies.

Reenal Gandhi

Global BD Director

Aptar Pharma

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Reenal Gandhi is Global Business Development Director within Aptar Pharma's Prescription division, where she is responsible for driving the assessment of potential new opportunities, with a specific focus on new technologies.

Reenal has over 15 years' experience in both the drug delivery device and pharma industries, developing and commercializing drug delivery solutions for biotech, vaccines and pharma. Throughout her career, Reenal has been active in business development activities related to nasal devices and injectable devices such as pre-filled syringes and autoinjectors. Her interest lies in developing combination products with drug delivery devices, balancing formulation, technology, and commercial potential.

Before joining Aptar Pharma in 2020, Reenal worked for drug delivery device company and global pharma/Gx company with a focus on licensing and acquisition of innovative and generic products.

Rick Geoffrion
President & CEO
Cyrano Therapeutics, Inc.
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Laleh Golshahi, Ph.D.
Associate Professor and Engineering
Foundation Professor
Virginia Commonwealth University
Founder and CEO, 3DInhale
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Dr. Laleh Golshahi is a Tenured Professor and the Founding Director of the Respiratory Aerosol Research and Education ([RARE](#)) Laboratory at Virginia Commonwealth University (VCU). Her research develops anatomically informed, variability-driven models of nasal and respiratory drug deposition that help drug product developers de-risk dose selection and build more efficient nasal drug development programs, with a special interest in pediatric populations.

She led the creation of the VCU Adult and Pediatric Nasal Models through a five-year collaboration with the U.S. FDA and ongoing industry partners, and leads a research group with over 50 peer-reviewed [publications](#) and three book chapters spanning respiratory and nasal drug delivery. She earned her Ph.D. in Mechanical Engineering from the University of Alberta in 2012, joined VCU as a postdoctoral fellow in Pharmaceutics (2012–2014), and was appointed to her first independent investigator position in Mechanical and Nuclear Engineering in 2014. She was promoted to Associate Professor with tenure in 2021 and awarded an Engineering Foundation Professorship in 2022.

Dr. Golshahi has served as an Associate Editor of the Journal of Aerosol Science (2022–2026) and holds several national honors, including Canada's NSERC PGS doctoral award and Alberta Innovates recognition for developing the Alberta Idealized Child Throat (AICT) and Idealized Infant Nasal Model — both commercialized by Copley Scientific — as well as the International Society of Aerosol Medicine (ISAM) 2019 Young Investigator award.

Most recently, she founded [3DInhale](#), an anatomically informed nasal airway platform for intranasal and nose-to-brain drug delivery. By accounting for intersubject variability in nasal anatomy, 3DInhale gives drug product developers a data-driven way to reduce regulatory risk and support the development of safer, more effective nasal drug delivery products.

Nil Gural, Ph.D.
Principal
Polaris Partners
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Nil joined Polaris in 2022 and is a principal in the firm's New York office. She is focused on biotech and healthcare investments. Prior to joining Polaris, Nil was a manager at Bain & Company's healthcare practice with a focus on pharma and medical devices. Before Bain, she was a part of the initial team at Glympse Bio where she helped develop their platform technology. She currently serves on the Board of Directors of Tavo Biotherapeutics, and as a Board Observer to EpiBiologics and August Bio. She also works with other Polaris portfolio companies including Crossbow Therapeutics, FIRE1, and Satellite Bio. Nil holds a PhD from the HST program of Harvard & MIT where she was an HHMI fellow and a BS in Biomedical Engineering from Washington University in St. Louis.

Steve Hoare
Head of Standards and Regulatory
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Medicines and Healthcare products
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Steve Hoare is Head of Standards and Regulatory Governance at the Medicines and Healthcare products Regulatory Agency (MHRA) and is supporting the Agency's Strategy Group in the development of its Sustainability Policy.

Steve is the Scientific Director and Secretary for the British Pharmacopoeia, which sets the minimum standards for Quality for medicines marketed in the UK (and recognised in over 100 countries).

With over 25 years spanning technical, quality, and policy roles, Steve brings extensive expertise in regulatory affairs, change management, and science communication. Prior to joining the Agency in 2023, Steve was a policy director for the UK biopharmaceutical trade association, ABPI, leading on both regulation and sustainability policy. Steve is active in the development of international approaches to sustainability in standards setting.

Sana Hosseini, Ph.D.
Principal Engineer
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Dr. Sana Hosseini is a Principal Engineer at Aptar Pharma's clinical manufacturing facility in New Jersey, where she leads CMC programs from development through clinical manufacturing for a diverse portfolio of clients. She earned her Ph.D. in Mechanical and Nuclear Engineering from Virginia Commonwealth University in 2021, where her graduate research received several academic awards. In her current role, Dr. Hosseini collaborates closely with cross-functional teams to identify technical risks early, develop integrated strategies, and drive programs efficiently toward clinical milestones. She also leads R&D initiatives to advance scalable product development capabilities and particle engineering platforms.

Prior to joining Aptar, Dr. Hosseini held senior technical roles at global pharmaceutical CDMOs, where she led development programs for inhaled therapeutics across multiple modalities. Her experience spans early feasibility, formulation and process development, scale-up, and clinical manufacturing. Dr. Hosseini has been a member of IPAC-RS since 2022 and contributes to cross-company collaboration within the OINDP community. She is also engaged in mentorship, talent development, and peer review for scientific journals, including Int. J. Pharmaceutics and J. Aerosol Sci.

James P. Kelly, MA, MD, FAAN, FANA
Chief Medical Officer
Oragenics, Inc.
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Dr. James Kelly is Chief Medical Officer of Oragenics, Inc., a biotechnology company focused on revolutionizing neurological care through its proprietary technology providing intranasal delivery of medications aimed at treating brain-related conditions. He is an academic behavioral neurologist with a career focus on traumatic brain injury (TBI) including clinical care, research, education and administration.

Dr. Kelly is Emeritus Professor of Neurology and Physical Medicine and Rehabilitation at the University of Colorado Anschutz Medical Campus in Aurora, CO. His immediate past position was Executive Director of the Marcus Institute for Brain Health (MIBH), a specialized treatment program funded by the Marcus Foundation to care for US military Veterans and First Responders with persistent symptoms of TBI. He was also National Director of the Avalon Network TBI Medical Programs for which the MIBH served as the clinical coordinating center.

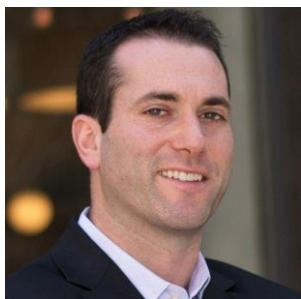
Prior to founding the MIBH, he was Director of the National Intrepid Center of Excellence (NICoE) at Walter Reed National Military Medical Center in Bethesda, MD. As its founding Director, he led the creation of an innovative interdisciplinary team of healthcare professionals who blended high-tech diagnosis and treatment with complementary and alternative medical interventions in a holistic, integrative approach to the care of U.S. military personnel with the complex combination of TBI and psychological conditions such as post-traumatic stress, depression, and anxiety. In this role, Dr. Kelly was frequently called upon by leaders of the Military Health System in the Pentagon, the U.S. Congress, the Department of Veterans Affairs, and numerous military facilities in the continental U.S. and abroad. He twice traveled to Afghanistan to advise and assist at military hospital programs and forward operating base medical units.

Dr. Kelly is President of Kelly Neuroscience Consulting, LLC and co-owner of Valor Industries which manufactures hockey helmets. He is the Chief Medical Scientist of the Chicago-based Invisible Wounds Foundation. He holds US patents on helmet liners and the transmission of signals from helmet motion sensors.

Ryan Kole, MBA

CEO

Beyond Barriers Therapeutics

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Ryan Kole, MBA is a serial entrepreneur and operator with over 20 years of experience building and leading start-up organizations. He is a Co-Founder and CEO of Beyond Barriers Therapeutics which is a clinical stage startup developing a repurposed therapeutic for disorders of the CNS, with a focus on concussions. He is a Partner at VCapital Management Co., LLC, where he is responsible for deal sourcing, diligence, and investment and working directly with portfolio companies. Ryan co-founded and was the Director of the Midwest Venture Capital Consortium (which was comprised of 55 venture capital firms and \$12b of dry powder) which he then merged with VentureNext (175 venture capital firms and \$55b in AUM), where Ryan now sits on the executive team. Ryan also co-founded RK Inventions, LLC, which has six issued patents and a licensing deal for a consumer product sold worldwide. He is a co-author on a study and poster presentation titled Reduced Pathogen Transmission via Modified Sink Lever Design at CRFHC presented to the New Hampshire Public Health Association (NHPHA). He has received his BS from the University of Illinois at Urbana-Champaign and his MBA from the University of Chicago Booth School of Business.

Philip Kuehl, Ph.D.

Director of Science & Technology

Aptar Pharma

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Philip Kuehl is the Director of Science and Technology at Aptar Pharma. He holds a bachelor's degree in biochemistry from Hamline University in St. Paul, MN and a PhD in Pharmaceutical Sciences from The University of Arizona, College of Pharmacy in Tucson Arizona. Dr. Kuehl is an Adjunct Professor at the University of New Mexico College of Pharmacy. Dr. Kuehl is responsible for science and innovation within Aptar Pharma including intranasal, pulmonary and dermal applications. Philip has over 20 years of experience in drug development from early proof of concept to NDA. He has supported five approved inhalation products over 20 IND's and one DMF. Dr. Kuehl's research interests are in the area of inhalation formulation and its effects on deposition, pharmacokinetics and pharmacodynamics. Philip is the author/co-author on over 90 peer reviewed manuscripts, over 150 abstracts, two book chapters and three patents.

Howard L. Levine, MD, FACS, FARS
Director
Cleveland Nasal Sinus & Sleep Center
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Howard L. Levine, MD, is the physician Director of the Cleveland Nasal-Sinus & Sleep Center. He is the former head of the Section of Nasal and Sinus Disorders of the Cleveland Clinic Foundation, Cleveland, Ohio. He also founded and directed The Mount Sinai Center for Nasal and Sinus Disorders, Cleveland, Ohio.

After graduating from the University of Pennsylvania, Dr. Levine attended Northwestern University School of Medicine, trained in general surgery at University Hospitals of Cleveland Ohio and in otolaryngology at Northwestern University Medical Center. He is a member of the American Medical Association, fellow in the American Academy of Otolaryngology-Head and Neck Surgery, the American Rhinologic Society and was its President (2006-2007).

Dr. Levine has lectured, taught and performed surgery throughout the world. He has authored over 100 peer reviewed articles and textbooks. Dr. Levine has been a pioneer in medical devices and procedures such as Balloon Sinuplasty and office procedures to manage nasal and sinus disorders, snoring and sleep apnea. Dr. Levine has had interest in non-invasive and non-surgical management to preserve function and structure and return patients to normal lifestyle as quickly as possible.

Dr. Levine serves as a consultant across the world to several companies that specialize in innovative technologies for nasal and sinus problems. Among those companies are Aerin Medical (Menlo Park California) and Dianosis (Paris and Strasbourg France). He serves as a quality and safety officer for several medical device companies. Presently, Dr. Levine is the Medical Director for RhinoSystems who manufacture Naväge, the world's foremost handheld powered suction irrigating device for the nose.

Dr. Levine served as the Vice-President of Medical Affairs for Acclarent, an Ethicon, Johnson & Johnson Company from 2010-2016.

Dr. Levine has been consistently named in "Best Doctors in America" from 1992 to the present, "Top Doctors in Cleveland", and "America's Top Doctors".

Dr. Levine is a lifelong serious amateur photographer with interests in landscape and street photography. Through his personal and professional ventures, he has had the opportunity to travel and photograph unique sites and people around the world. Dr. Levine not only continues independently to study these disciplines, but also personally studies with several noted landscape and street photographers. His photography is shared with friends and those he photographs on Instagram at HowardsPix. He has had showings at the University of Pennsylvania Alumni Competition and community based photographic salons.

Michael M. Lipp, Ph.D.
Chief Technology Officer
Decoy Therapeutics Inc.
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Michael Lipp co-founded Decoy Therapeutics and serves as Chief Technology Officer. He has more than two decades of experience in pharmaceutical development and drug delivery, with roles at Nocion Therapeutics, Acorda Therapeutics, Civitas Therapeutics, Pulmatrix, and Alkermes, much of it focused on inhaled and pulmonary delivery of therapeutics. He was previously a post-doctoral associate and research affiliate in the Langer Laboratory at MIT.

Michael Lusty, Ph.D.
Industry Consultant
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Michael Lusty has 25+ years experience in the development, approval, launch and post approval support of nasal and inhalation products, including the nasal steroid Nasonex® and the dry powder inhaler Asmanex® while working at Schering-Plough, Azmacort® metered dose inhaler at Kos Pharmaceuticals/ Abbott and nasal midazolam, Nayzilam® for the treatment of seizure while at Ikano Therapeutics prior to the products acquisition and launch by UCB. For the past 15 years, Michael has been a consultant known for his deep subject matter expertise coupled with a deep pragmatism for moving programs from one phase of development to the next. Michael holds a BSc in Combined Sciences from the University of Ulster and a MSc and PhD in Applied Physics from the University of St. Andrews, Scotland.

Justin Lygrisse
Director, Research & Development
Kindeva
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Justin Lygrisse is the Director of R&D at Kindeva, bringing over 20 years of pharmaceutical industry experience to advanced intranasal product development. Since 2019, he has focused exclusively on nasal spray drug products and combination devices across the full product lifecycle from concept through commercialization. He has successfully driven spray performance characterization, device-formulation optimization, scale-up strategies and regulatory filing sections for multiple NDA and ANDA submissions. Justin is recognized for building collaborative laboratory cultures that optimize analytical validation timelines and integrate a quality-first mindset into R&D.

Silvia Matiz, MSc
 Formulation Specialist
 Nanopharm, an Aptar Pharma company
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Silvia holds a MSc in Pharmaceutical Chemistry and Technology from the University of Trieste, Italy, complemented by an international exchange experience at University College London, UK. She joined Nanopharm in 2025 as a Formulation Specialist.

With over eight years of experience in preclinical research and development of biologics, Silvia specialises in formulation development and characterisation, drug delivery technologies and preclinical in vivo studies to support the advancement of innovative therapeutics across a range of biologic modalities. Throughout her career, she has contributed to peer-reviewed publications and has presented her research at various international conferences.

Elizabeth B. Norton, Ph.D.
 Associate Professor
 Tulane University
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Elizabeth “Betzi” Norton, MPH, PhD is an immunologist with 20 years of experience in evaluating immunity, vaccines, and microbial infections. Dr. Norton began her training at the Centers for Disease Control (CDC) prior to completing a Masters in Public Health and PhD in Biomedical Sciences at Tulane University. She is currently an Associate Professor in the Department of Microbiology & Immunology at Tulane University with a research lab supported through NIH grants and contracts and Gates Foundation. Her research spans basic science to translational applications with a focus on evaluation of immunity in special human populations and design of novel vaccines or therapeutics. A specific area of expertise is use of mucosal delivery (nasal, sublingual, oral) by adjuvanted formulations to help generate protection from diseases such as lung or intestinal infections and fentanyl intoxication.

Kay Olmstead, Ph.D.
 Chief Executive Officer
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Dr. Kay Olmstead is the Founder and CEO of TransformaBio, Inc. (formerly Nano PharmaSolutions), bringing over 30 years of pharmaceutical industry expertise in CMC, Quality Systems Management, and regulatory strategy. A specialist in poorly soluble small-molecule drugs, she played a lead role in developing five FDA-approved therapeutics for San Diego biotechs, including Santarus, Inc. (\$2.6B acquisition by Salix) and Intercept Pharmaceuticals. Dr. Olmstead holds 16 issued patents, 9 pending applications, and over 14 publications. She completed her Ph.D. in Organic Chemistry at Johns Hopkins University and an NIH Postdoctoral Fellowship at Stanford University.

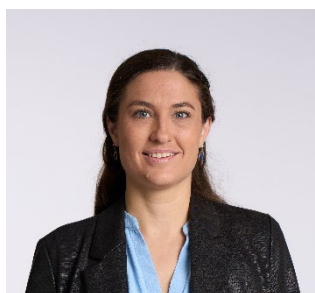
Måns Österberg Widerstrand, M.Sc.
 Director Business Development and
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 Iconovo AB
Mans.Osterberg@iconovo.se



Måns Österberg Widerstrand is Director of Business Development and Alliance Management at Iconovo, where he leads global business development, partnering and commercialization activities for innovative dry powder inhalation technologies. He has over 25 years of experience in the pharmaceutical and healthcare industries, spanning R&D, cGMP manufacturing, medical and scientific affairs, business development and commercialization. His background includes extensive experience in allergy and asthma, as well as inhalation product development and drug delivery devices. Today, his work focuses on bringing innovative inhalation and nasal drug delivery technologies from development into global partnerships and commercial applications. Måns holds an M.Sc. in Chemical Engineering and an Executive Master of Medical Business Strategy.

Christopher Potts
 Chief Business Officer
 Persephoni BioSciences
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Danielle P.
 Neurelis Inc.
 Patient Ambassador



Danielle is a strong advocate for herself and has a passion for making the world a better place for others with epilepsy. Danielle will talk about her journey with epilepsy and share a message of empowerment.

M. Alain Regard, MSc
 Technology Product Manager
 Nemera
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Alain Regard is a Technology Product Manager at Nemera a device development and manufacturing company. He holds an MSc in Polymer Engineering and Processing from Ecole Supérieure de Plasturgie (ESP) in Yonnax, France.

After 15 years in the automotive industry, Alain joined Nemera in 2010 as a Product Development Leader working on multiple projects related to pumps, sprays and pMDIs. Alain, today at the position of Technology Product Manager leads the innovation and early-stage concepts research in the fields of nasal drug delivery. Alain has a track record of 15 published patent families in the field of drug delivery. His main fields of expertise are design of nasal drug dispensing devices, atomization, spray generation and characterization as well as Ear Nose and Throat (ENT) anatomy and physiology.

Selena Roberts, B.Sc., PMP®
 Medical Device Program Leader
 Rocket Science Health
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Selena Roberts is a medical device program leader with extensive experience guiding complex product development programs from design through commercialization. She has led multidisciplinary engineering and product development teams, managed strategic client programs and portfolios, and helped organizations navigate the competing demands of scope, schedule, cost, risk, regulatory requirements, and business objectives.

A certified Project Management Professional (PMP®), Selena brings a practical and collaborative approach to medical device development, with a particular focus on connecting strategy with effective execution. She is now with Rocket Science Health, successfully bringing innovative medical technologies through development toward commercialization.

Irene Rossi, Ph.D.
 Respiratory Science Expert
 Harro Höfliger
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As Harro Höfliger's Expert in Respiratory Science, Irene supports the team and her clients on product development and respiratory drug delivery matters. She is also part of the INTO technical team together with experts from DFE Pharma and Sterling.

Irene obtained a MSc in 2014 and a PhD in Drugs, Biomolecules and Health Products at the University of Parma (Italy) in 2019. In the same year she joined Nanopharm, An Aptar Pharma Company (UK) where she covered different roles. Most recently, she was leading a group focused on the development and characterization of new formulation technologies for OINDP products comprising both small and large molecules.

Irene has published her work in several original papers and filed 4 patent applications. She presented her work at more than 50 international conferences.

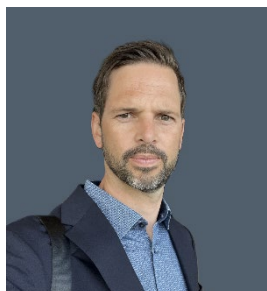
She also serves on the Drug Delivery to the Lungs Scientific Advisory Board and as co-chair of the ISAM Formulation Networking Group.

Ronak Savla, Ph.D., Pharm.D., MBA
 Blavatnik Fellow
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Ronak Savla is currently a Blavatnik Fellow at Yale Ventures where he works with faculty members to accelerate their academic research into biotech spinouts. Prior to joining as a Blavatnik fellow, Ronak was the Senior Director of Strategic Ventures at Catalent Pharma Solutions, where he managed the company's strategic limited partnerships, and worked closely with leading life science investment firms, biotech incubators, universities, and other organizations that support early-stage biotech companies. Ronak led several corporate initiatives that enhanced Catalent's approach and offerings for early-stage biotech companies. Previously, he led Medical Affairs and New Product Planning at Innate Pharma, supporting the commercial launch of a novel rare leukemia therapy and multiple clinical stage assets. He has spent his career at the intersection of science, capital, and execution. Ronak Savla holds a PharmD and PhD from Rutgers University and an MBA from Johns Hopkins University – Carey Business School.

Jonas Sävmarker, Ph.D., R.Ph.
 Scientific Director
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Jonas Sävmarker is Scientific Director at Orexo AB, with a strong track record in translational drug development and pharmaceutical innovation. At Orexo, he has played a key role in advancing the company's proprietary AmorphOX® platform, a powder-based drug delivery technology designed to improve the stability and bioavailability of sensitive molecules. He earned his PhD in medicinal chemistry from Uppsala University and subsequently held a research position at the Beijer Laboratory, focusing on early drug discovery. Since joining Orexo in 2017, he has contributed to the development of spray-dried powders for nasal administration, spanning preclinical development, clinical studies, manufacturing scale-up, and device filling and assembly. Jonas is one of the inventors of Orexo's nasal powder technology, including Izipry (naloxone) and OX640 (epinephrine) rescue products currently under development.

Manu Sharma
 Project Manager
 Rocket Science Health
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Manu Sharma is a Program Manager at Rocket Science Health with four years of industry experience in medical device and drug-delivery development. His work focuses on intranasal and nose-to-brain delivery technologies, spanning device engineering, bench testing, human factors, preclinical research, and clinical study preparation. He defines development strategies, coordinates technical teams and external partners, plans and executes preclinical studies with CROs and research institutions, and supports device readiness for clinical studies.

Trained in mechanical engineering with a background in marketing, Manu brings both technical and business perspectives to product development. He believes successful drug-delivery development starts with the patient: device technology and route-of-administration decisions should be considered early so that treatments are designed around patient needs from the outset.

Paul Shields, Ph.D.
 Site Director
 Aptar Pharma
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Paul Shields, Ph.D. is Site Director of Aptar Pharma Services in Boonton, New Jersey, where he leads pharmaceutical development and manufacturing operations supporting both innovator and generic drug programs. A chemical engineer by training with a Ph.D. in Biochemistry, Paul has more than 38 years of experience in the pharmaceutical industry, with a primary focus on Chemistry, Manufacturing, and Controls (CMC) development and commercialization.

Prior to joining Aptar Pharma Services, Paul held leadership positions at Unigene Laboratories and served as Chief Executive Officer of both Enteris BioPharma and Mod3 Pharma, where he led product development, regulatory strategy, and business growth initiatives. Throughout his career, Paul has contributed to the development of numerous pharmaceutical products across multiple stages of the product lifecycle, with particular expertise in formulation development, process development, manufacturing, regulatory submissions, and CMC strategy.

At Aptar Pharma Services, Paul works closely with pharmaceutical and biotechnology companies to advance complex drug products from early development through clinical and commercial manufacturing.

Maria L. Smith, MS

Director, Applications and Business Development

Proveris Laboratories

msmith@proveris.com



Maria Smith is Director of Applications and Business Development at Proveris Laboratories, bringing over 20 years of expertise in the contract development and manufacturing of orally inhaled and nasal drug products. A recognized authority in spray characterization, she specializes in method development and performance evaluation.

Throughout her career, Maria has collaborated with industry experts and key opinion leaders on a wide range of nasal and oral spray devices and methods. Her deep technical knowledge has contributed to the successful submission of more than fifteen combination NDA/ANDA products. Maria has applied her knowledge and understanding in both the R&D and QC spaces.

Maria has co-authored more than 10 publications on spray characterization and is widely respected across the industry. As head of Proveris Laboratories, she champions a weight-of-evidence approach to OINDP development and testing, uniting regulatory rigor with innovative thinking to deliver new possibilities for customers.

Eric Sorscher, M.D.

Professor

Emory University

esorscher@emory.edu



Dr. Sorscher has maintained a research focus on cystic fibrosis (CF) related science and clinical intervention for more than 25 years. He has contributed to studies of cellular and molecular biology describing aminoglycoside suppression of CFTR truncation alleles, clinical significance of mild CFTR mutations and the bioelectric phenotype, acquired loss of CFTR function in vivo, and mechanisms underlying activation of CFTR by potentiator and corrector compounds. In this manner, he has participated in recent advances with regard to CF molecular pathogenesis and experimental therapeutics. Studies of other orphan conditions are also pursued by Sorscher and colleagues using “lessons learned” from CF. For example, a major interest involves characterization of a mechanism for tumor sensitization using the E. coli PNP gene. In this approach, tumors are rendered hundreds or thousands of times more sensitive to conventional chemotherapy by expression of a prokaryotic enzyme that cleaves nontoxic nucleoside prodrugs to a very active form. The research involves analysis of the crystal structure of E. coli PNP, and structure-based drug design of new compounds that are effectively cleaved in vivo.

Julie D. Suman, R.Ph, Ph.D.
Principal
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Dr. Julie D. Suman is the Principal of Suman Pharma Solutions, LLC. She previously served as Vice President of Scientific Affairs for Aptar Pharma co-founder of Next Breath. She holds a B.S. in Pharmacy from Duquesne University and a Ph.D. in Pharmaceutical Sciences from the University of Maryland, Baltimore. Dr. Suman provides scientific support as an Expert Advisor on USP Expert Committee Panel. In addition, she is a co-editor for Respiratory Drug Delivery Proceedings, an international symposium, and an Affiliate Assistant Professor in the Department of Pharmaceutics, School of Pharmacy, Virginia Commonwealth University. She is a licensed Maryland pharmacist. Dr. Suman has published her research in peer-reviewed journals and has been presented during podium sessions at international meetings, the FDA Topics in Bioequivalence Seminar Series and has been an invited speaker at ANVISA in Brazil. Dr. Suman's doctoral research, which focused on the relationship between in vitro tests for nasal sprays and in vivo deposition, has been recognized for excellence by a research award presented at the International Society for Aerosols in Medicine, 2001. In 2008, Dr. Suman received an award from the Greater Baltimore Committee for Entrepreneurial Spirit.

Frank Verhoeven
Manager-Business Development
Resyca B.V.
frank@resyca.com



Frank Verhoeven is Manager Business Development at Resyca, where he partners with pharmaceutical and biotechnology companies to advance next-generation soft mist inhalation and nasal drug delivery technologies. His expertise spans business development, regulatory strategy, and drug-device combination products.

Prior to joining Resyca, Frank held aerosol testing, product management, and business development roles at Medspray, contributing to the development and commercialization of innovative soft mist delivery platforms, including nasal drug delivery systems.

Frank has authored and co-authored multiple scientific publications and conference presentations in aerosol science, nasal drug delivery, and respiratory medicine, and is passionate about building strategic partnerships that bring innovative therapies to patients.

Claudia Vincenzi, Ph.D.
Senior Quality Specialist
European Medicines Agency (EMA)
Claudia.Vincenzi@ema.europa.eu



Claudia Vincenzi, PhD, is a Senior Quality Specialist at the European Medicines Agency (EMA) in Amsterdam. A pharmacist by training, she holds a PhD in Pharmaceutical Technology from the University of Bradford, UK. Her experience spans both regulatory authorities (MHRA and EMA) and industry, including a role as Regulatory CMC Director for inhalation products.

At EMA, Claudia provides scientific peer review of pharmaceutical quality data across the lifecycle of medicinal products and supports scientific advice, regulatory procedures, and guideline development. Her areas of expertise include inhalation and nasal drug products, digital health technologies, container closure systems, pharmaceutical packaging, and extractables and leachables. She is also actively involved in sustainability and environmental initiatives for pharmaceuticals, supporting interactions and collaborative activities with the European Commission, sister agencies, and international organisations, including the World Health Organization (WHO) and United Nations (UN), to advance environmental sustainability within the pharmaceutical sector.

David Wilcox, B.S.

Director, Technical Operations
Catalent

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David Wilcox is Director, Technical Operations at Catalent and has over 25 years of pharmaceutical industry experience, with substantial expertise in the formulation, development, and manufacturing of orally inhaled and nasal drug products. In his current role, he is responsible for providing operational, scientific, and technical leadership for the Product Development and Manufacturing Science and Technology (MS&T) functions at the Catalent Morrisville, NC site. He holds a Bachelor of Science in Chemistry from Wofford College.

Maria Wilson, MSc

Scientific Projects Lead
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Maria Wilson is a Scientific Projects Lead at Therakind Limited, a London-based pharmaceutical company dedicated to advancing innovative therapeutics. She holds a BSc. in Biochemistry and Biology from the University of the West Indies, Trinidad, and an MSc. in Pharmaceutics from University College London, where her master's thesis focused on the effect of aging on vaccine efficacy. Her outstanding research contributions led to her co-authorship of book chapter Tailoring Vaccines for Older Individuals: Aging of the Immune System and the Impact on Vaccine Efficacy, in the book Pharmaceutical Formulations for Older Patients, published in 2023.

She joined Therakind in 2021 and has been actively involved in various aspects of drug development including nonclinical project administration and management. She has experience with coordinating cross-functional teams, aligning early-stage planning with regulatory standards including ISO and supporting the advancement of preclinical programs. Maria has contributed to the advancement of DriDose®, an innovative intranasal dry powder delivery device platform, and manages device quality systems and risk management activities.

She is also involved in business development activities, researching and identifying new projects and collaborative opportunities, and remains committed to supporting innovation and enhancing the effectiveness and accessibility of emerging pharmaceutical technologies.

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For Information on IPAC-RS, please contact the IPAC-RS Secretariat:

Mary Devlin Capizzi, MB, JD

Partner

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Mary Devlin Capizzi is a Partner at Faegre Drinker where she advises individual corporations and consortia clients on complex regulatory compliance, legislative, scientific and policy issues. She is highly valued for her facilitation of cross-industry and industry-wide initiatives focused on collaborative technology development and data sharing. For the past 30 years, Mary has worked with industry leaders to establish several special-purpose consortia, including the International Pharmaceutical Aerosol Consortium on Regulation and Science (IPAC-RS), the International Pharmaceutical and Medical Device Privacy Consortium (IPMPC) and the International Consortium for Innovation & Quality in Pharmaceutical Development (IQ Consortium). Further, she has facilitated numerous cross-industry and industry-specific roundtables and events focused on best practices and identifying pathways for optimal collaboration. A long-time firm leader, Mary served as an executive partner, a firm board member for 15 years, and recently finished a six-year term as co-leader of the firm's health & life sciences industry group.

Svetlana (Lana) Lyapustina, Ph.D.

Principal

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Dr. Svetlana (Lana) Lyapustina is a Principal at Faegre Drinker where she applies her rigorous scientific training to help health and life sciences stakeholders address regulatory and technical challenges. She advises individual companies and industry consortia on scientific innovation, patient safety, and product and device regulatory approaches. Her experience includes consulting on medical product development (pharmaceuticals, medical devices, biologics and combination products), quality control, development and manufacturing, regulatory compliance, patient adherence, and regulatory expectations. Lana works with companies and industry consortia composed of industry, government and academia representatives to proactively address regulatory hurdles and policy mandates throughout the medical product development lifecycle. She has represented clients in interactions with regulatory, governmental and scientific agencies in the U.S. and other world regions, including: U.S. Food and Drug Administration (FDA), European Medicines Agency (EMA), Health Canada, Medicines and Healthcare Products Regulatory Agency (MHRA), U.S., British, Japanese and European Pharmacopoeias (USP, BP, JP and EP), and International Organization for Standardization (ISO).

Lee Nagao, Ph.D.

Principal

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Dr. Lee Nagao is a Principal at Faegre Drinker where she partners with pharmaceutical innovators to identify and overcome regulatory and product-development obstacles as they shepherd their products from the lab to the marketplace. Driven by her own background as a scientist, Lee is passionate about helping clients maximize efficiency in the product development lifecycle so that high-quality, life-saving products reach patients quickly and clients have more time to focus on new innovations. She advises domestic and international clients on current and emerging regulatory oversight of biologics and pharmaceutical drug development and manufacturing, including drug-device combination products. She works with clients to address complex issues related to pharmaceutical packaging, drug-device combination products, supply chains, nonclinical toxicology and clinical pharmacology. Lee is skilled in providing strategic counsel on aspects of chemistry, manufacturing and controls (CMC), risk assessment and management strategies, lifecycle management, current

	good manufacturing practices (CGMPs), and regulatory frameworks for drug master files and other regulatory submissions. Lee represents industry groups before regulatory agencies and industry and scientific organizations throughout the world, including: FDA, Health Canada, EMA, MHRA, China National Medical Products Administration, Brazilian Health Regulatory Agency (ANVISA), Japan Pharmaceuticals and Medical Devices Agency (PMDA) and United States Pharmacopeia (USP).
Dede Godstrey Senior Project Coordinator Faegre Drinker Dede.godstrey@faegredrinker.com info@ipacrs.org 	Dede Godstrey, Senior Project Coordinator at Faegre Drinker, has over 30 years of experience in project management. She is responsible for the daily activities and support of several life science industry collaborations, including IPAC-RS. Dede has organized numerous international workshops, conferences, webinars and meetings involving industry thought leaders and global health regulatory agencies. She is an experienced event planner who oversees all aspects of executing an exceptional event. She also manages financial matters, such as budget preparation and management, for large events as well as for industry collaborations. Further, Dede is a seasoned communications professional with extensive experience creating and maintaining client websites, developing newsletters, and overseeing communication and outreach strategies.