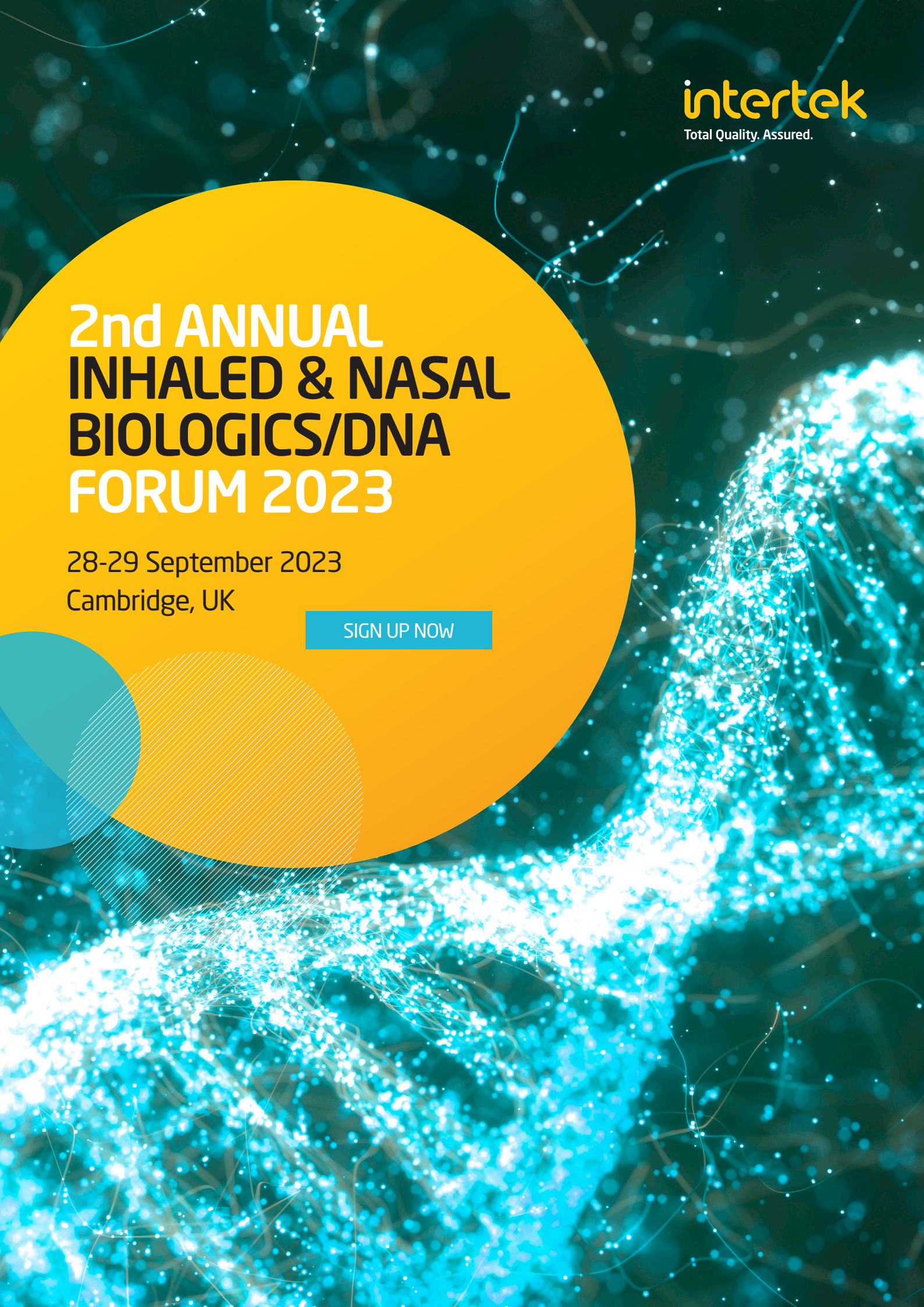
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2nd ANNUAL
INHALED & NASAL
BIOLOGICS/DNA
FORUM 2023
28-29 September 2023
Cambridge, UK
SIGN UP NOW

Welcome

As drug discovery programs place greater emphasis on biologic drug substances for both local respiratory and systemic targets, the need to develop effective solutions for nasal and inhaled biologics delivery is becoming increasingly important for the industry.

Respiratory administration of biologics and DNA modalities poses distinct obstacles. Developers must carefully balance various factors when designing a product, including product performance, manufacturability, regulatory risk, and commercial considerations.

This year's conference features world-renowned industry leaders who will share the latest insights in the field of inhaled or nasal biologics and vaccine development with real-world case studies to stimulate discussion.

We look forward to welcoming you to the second annual event in this series - Join industry leading experts for two days of conference and networking.

KEYNOTE SPEAKER

Igor Gonda, Founder and CEO, Respidex LLC

KEYNOTE: Inhaled biologics: What can we learn from Pulmozyme success 30 years later?

Pulmozyme was the first and so far the only approved inhaled recombinant human protein. It was launched in record time of 4 years from cloning the molecule, despite no prior regulatory precedents. Many believed that this success heralded entry of many new inhaled biologics both for treatment of respiratory diseases as well as a non-invasive route of administration of macromolecules.

The debacle of inhaled insulin brought the field to a screeching halt. This talk will discuss the lessons learned that include the key criteria for the choice of the target product profile for inhaled biologics and the tools needed to develop successfully such products.

FORUM AGENDA

Wednesday Sept 27th - Networking and Optional Lab Tour

- Laboratory tour hosted by Intertek at their laboratory in Melbourn, Cambridgeshire, 2pm (optional)
- Networking drinks reception, Hinxton Hall, 5:30pm (optional)

Thursday Sept 28th - Day 1 of Conference

- Keynote Speaker: Igor Gonda, Founder and CEO, Respidex LLC
- Session 1: Learnings from Real World Case Studies
- Session 2: Choosing the Right Drug Delivery Device
- Panel Discussion
- Networking Drinks 5:30pm
  Evening: Conference Dinner

Friday Sept 29th - Day 2 of Conference

- Session 3: Designing An Appropriate Formulation
- Session 4: Regulatory Driven Test Requirements
- Panel Discussion
- Conference Close

Day 1 Thurs 28th Sept 2023	AGENDA
Keynote and Session 1: Learnings from Real World Case Studies	**Inhaled biologics: What can we learn from Pulmozyme success 30 years later?** Keynote Speaker: Igor Gonda, Founder and CEO, Respidex LLC **Development of mRNA Formulations for Inhaled Drug Delivery** Professor Ben Forbes, Professor of Pharmaceutics, King's College London **Inhaled Oxytocin, Bringing Safer Childbirth to Women in Need** Jacob Harker, Director, BnL Pharma Solutions Pete Lambert, Director, Program Management, Monash Institute of Pharmaceutical Sciences
Choosing The Right Drug Delivery Device	**Mesh Devices Beyond Small Molecules – Challenges and Opportunities** Gunilla Petersson, Ph.D., Chief Scientific Officer (CSO), HCmed Innovations Co., Ltd. **Aerosolization of biologics by different soft mist and nebulizer technologies** Prof. Cees Van Rijn, University of Amsterdam **Nasal Device Optimization: Balancing Formulation and Patient Needs** Kaoutar Kristou, Aptar Pharma Rx, Northern EU
Day 2 Fri 29th Sept 2023	
Designing An Appropriate Formulation	**Challenges and opportunities of a mucosal platform for nasal vaccination** Mathieu Epardaud, PhD, Co-founder and Scientific Consultant LoValTech **The role of excipients in the future of pulmonary drug delivery** Ross Blezard, Product and Application Specialist, DFE Pharma
Regulatory Driven Test Requirements	**Non-clinical development of inhaled biopharmaceuticals and newer classes of compounds compared to inhaled NCEs** Bruce Hamilton, Drug Development Leader, Early Phase Development Solutions, Labcorp David Coleman, Drug Development Leader, Inhaled Drug Development, Labcorp **DNA Medicine Testing for Inhaled and Nasal Oligonucleotide and mRNA Products** Ashleigh Wake, Intertek Pharmaceutical Services

LOCATION

VENUE: Hinxton Hall, Cambridge, UK

Set within a one-hundred-acre estate bordering the River Cam, Hinxton Hall Conference Centre is located on the Wellcome Genome Campus, alongside research institutions that are at the forefront of the genomics revolution.

Hinxton Hall is 25minutes from the centre of Cambridge, and a mere 60 minutes from London and accessible from Heathrow, Luton and Gatwick airports and is only 20minutes from London Stansted Airport. The hall is easily accessible from the M11. For GPS please use: CB10 1SA.

The Intertek team will book accommodation on your behalf if you indicate that you require a room during registration. The cost for two nights' accommodation is included in your registration fee. Please note that there are limited double rooms available at the venue and these will be allocated on a first-come, first-served basis.

REGISTRATION

Save your spot as a key stakeholder in this growing industry community. Places are limited and so please register now.

Registration packages are available including accommodation. Please make your selection during registration.

Rate	Incl. 2 nights' accommodation	Incl. 1 night accommodation	No accommodation required
Standard Rate (from 1 June 23)	£449	£399	£349

Please follow this link to register your interest in attending the event >

Meet our speakers

This year's conference features world-renowned industry leaders sharing the latest learnings on inhaled & nasal biologics and DNA medicine development with real-world case studies to stimulate discussion.

Igor Gonda, Founder & CEO, Respidex LLC

Igor Gonda is the founder of Respidex LLC – a consulting firm assisting pharmaceutical companies in corporate strategy, including R&D program design, collaborations with patient advocacy groups, regulatory process, intellectual property management, financing and business development. He is a Principal Consultant for Scendea - a product development and regulatory consulting practice.

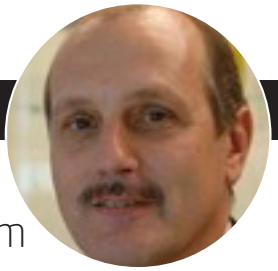
He was previously in various executive roles (Chief Scientific Officer, CEO and President) at Aradigm Corporation – a US company developing inhalation therapies for the prevention and treatment of serious respiratory and systemic diseases.

Igor conducted health-related aerosol research and product development at Genentech Inc. (USA) and at universities in the UK, USA and Australia. He was also the CEO and Managing Director of the transdermal company Acrux Ltd in Australia. His current research interests include cancer prevention and treatment using inhaled small molecules and biologics. He has both past and current company Board experience in USA and Australia. Igor has over 120 US patents and patent applications. He published over a hundred papers. He received the British Pharmaceutical Society Astra-Zeneca Industrial Achievement Award and the Thomas T. Mercer Joint Prize of the International Society for Aerosols in Medicine and the American Association for Aerosol Research, for Excellence in Pharmaceutical Aerosols and Inhalable Materials.

Igor graduated in Chemistry and received PhD in Physical Chemistry from the University of Leeds, England.

Gunilla Petersson, Ph.D., Chief Scientific Officer (CSO), HCmed Innovations Co., Ltd.

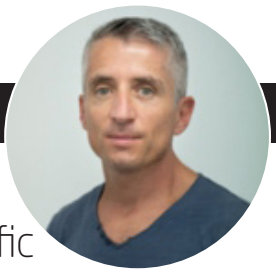
Former Science and Innovation Director of Inhaled Drug Delivery at AstraZeneca, Dr. Petersson has more than 29 years of experience in the pharmaceutical industry. Affiliated to the Innovation Strategies and External Liaison segment, in most recent years, she dedicated herself to novel technology scouting, due diligence activities, and scientific marketing. During her extended and successful professional career, Dr. Petersson has also focused on inhaled medicines, medical devices (inhalers), pharmaceutical research, quality by design, and regulatory documentation, accumulating a vast number of connections with global pharmaceutical companies and renowned experts in the field.



Prof. Cees van Rijn, University of Amsterdam

Van Rijn has been working as senior researcher and director of Intellectual Property Rights (IPR) at Medspray B.V. since 2012. As IPR Director, he is responsible for the company's innovation policy. From 2007 to 2017, he was professor by special appointment of MicroSystem and Nano Technology at Wageningen University & Research (WUR). He has set up several nanotechnology companies, including Nanomi and Vycap, and has initiated a range of public-private research projects with the business community. He studied Physics at Vrije Universiteit Amsterdam and obtained his doctorate at Leiden University.

Van Rijn has published a large number of academic articles in peer-reviewed journals. The work he recently conducted into aerosols – with several collaborators, including UvA physicist Daniel Bonn – made world news. It was partly on the basis of their publication in The Lancet Respiratory Medicine that the World Health Organization (WHO), among others, pointed to the possible role played by aerosols in the transmission of the coronavirus and the importance of good ventilation in public spaces.



Mathieu Epardaud, PhD Co-founder and Scientific Consultant at LoValTech

An immunologist specialized in immunotherapies and vaccinology, Mathieu Epardaud joined the BioMAP team of the joined Unit UMR ISP 1282 (Tours University – INRAE) in 2018 to contribute to the development of anti-cancer immunotherapies and to develop strategies for mucosal vaccine platforms.

He previously contributed to research on (1) preclinical model for studying the immunopathology of tuberculosis in the same UMR (Tours, France), (2) cancer immunotherapy at the Dana Farber Cancer Institute & Harvard Medical School (Boston, USA) and (3) systemic vs mucosal immune response within another INRAe unit (Jouy en Josas, France).

Mathieu Epardaud participates in the intranasal vaccine development platform project and is one of the founders in January 2022 of the start-up LoValTech, for which he holds a position of scientific consultant, in particular for the preclinical studies and the development of the intranasal delivery system.

Ross Blezard, Product and Application Specialist, DFE Pharma

Ross Blezard is a Product and Application Specialist at DFE Pharma, specializing in Inhalation and Biopharma. With a physics background, he began his career as a formulator in inhalation and transdermal delivery. As the former head of formulation development at a prominent UK-based CDMO, Ross possesses expertise in size and solid-state characterization techniques. Since joining DFE Pharma in 2019, he has provided valuable support to inhalation and biopharmaceutical clients, tackling their technical challenges.

Bruce Hamilton, Drug Development Leader, Early Phase Development Solutions, Labcorp

Bruce has more than 25 years of pharmaceutical research and development experience working within large pharma and biotechs. His current role is managing a team of Drug Development Leaders who provide Labcorps' clients with scientific and regulatory advice and who work across the range of pharmaceutical products including biological therapies (mAbs, cells, genes), oligonucleotides, vaccines and NCEs.

Before joining Labcorp, Bruce was Director New Product Development at Abcam and has also held previous positions with Medimmune, Bicycle Therapeutics, GlaxoSmithKline, and Astex Therapeutics. He has been responsible for end-to-end delivery (from compound selection to completion of IND enabling studies/ initiation of clinical testing) of three compounds as well as assisting many progress through intermediate milestones.

He is adept at managing risk and timelines to accelerate drug development, prioritize resources and maximize the potential for commercial value. During his time with Labcorp he has been the assigned DDL responsible for one inhaled protein therapy as well as producing strategies for the development of multiple others.

Ben Forbes, Professor of Pharmaceutics, King's College London

Ben Forbes is Professor of Pharmaceutics at King's College London. He has a BPharm from King's College London (1987) and a PhD in Drug Delivery from Strathclyde University (1996). Before doctoral studies, he worked as a hospital pharmacist in London and Sydney, and for Inveresk Clinical Research in Edinburgh. He was appointed to the academic staff of King's College London in 1997 and is a registered pharmacist in the UK. The term 'Inhalation Biopharmaceutics' was coined by Professor Forbes in the dying embers of the last Millennium to describe the scientific field that considers the factors that influence respiratory and systemic exposure to inhaled drugs [Ehrhardt C, Pharm Res 34: 2451–2453, 2017]. Professor Forbes has authored many publications in this area, in the fields of: (1) inhaled medicine formulation, (2) the development and application of techniques to study respiratory drug transport and metabolism, (3) inhalation toxicology.

David Coleman, Associate Director, Drug Development and Regulatory Strategy, Early Phase Development Solutions, Labcorp

David Coleman has over 20 years of experience conducting toxicology studies and is an expert in all aspects of nonclinical safety testing required to support locally or systemically administered pharmaceuticals (NCEs and large molecule biotherapeutics). As part of Labcorp's Early Phase Development Solutions team, he provides scientific advice and oversight for clients' preclinical programs. His professional highlights include four years of experience in drug development strategy in a CRO environment, dealing with a broad range of modalities. He has also overseen several first-in-human enabling programs that have been reviewed by regulatory agencies and proceeded to phase I trials. David presents regularly on the regulations and strategies essential for nonclinical development, addressing both external and internal audiences.

Pete Lambert, Director, Program Management, Monash Institute of Pharmaceutical Sciences

Originally trained as a pharmacist in the UK, Pete Lambert has 20 years experience in drug development in the pharma industry, primarily focusing on inhaled and intranasal delivery systems. In 2010 he transitioned to working in global public health, completing his Masters in HIV Management at Stellenbosch University, South Africa, and joining Monash Institute of Pharmaceutical Sciences (MIPS) in Melbourne, Australia in 2012. He currently leads the Inhaled Oxytocin project, is the founder and director of the Monash Quality of Medicines Initiative and co-coordinates the Global Health Therapeutic Program Area at MIPS.

QUESTIONS?

Please contact our event team:
Email: inhaled.biologics@intertek.com
Tel: +44 (0)1763 261 648

Ashleigh Wake, Business Development Director, Intertek

Following graduation, Ashleigh joined Zeneca as Biotransformation Chemist followed by technical and operational management roles with AstraZeneca and Syngenta before joining Intertek.

She has a background in mass spectrometry and a career of over two decades as an operational/technical team leader and study director for projects spanning the drug development process (including metabolism, PK studies and API/product characterisation, CMC support analytics and ICH stability studies). Ashleigh has specialized in the design and delivery of regulatory (GXP) studies relating to the physiochemical and biological activity of biomolecules including oligonucleotides, proteins, mAbs and vaccines and is currently responsible for strategic growth and business development at Intertek's GMP compliant centre of excellence for biologics characterisation in Manchester, UK

Jacob Harker, Director, BnL Pharma Solutions

Jacob is a consultant and formulator, with some 20 years' experience in developing drug device combination products. He has a passion for novel formulation technologies and developing dry powder oral and nasal inhalers. During his career as formulation chemist and product development specialist, Jacob worked at Pfizer, AsteraZeneca and Circassia, before starting his own consultancy in 2018. He now works with a variety of companies to help develop their respiratory assets.

Kaoutar Kristou, Area Sales Manager Northern EU Rx, Aptar Pharma

Kaoutar Kristou is the Sales Area Manager UK & Northern Europe within Aptar Pharma's Prescription division, where she is responsible for driving a portfolio of nasal and pulmonary drug combination product opportunities, with a specific focus on new nasal delivery technologies. Kaoutar is a scientist by training. driven by innovation and science, she has been active in drug developments and bioanalytical activities related to vaccines and biologics. Her interest lies in supporting the development of innovative combination product treatments with Aptar drug delivery devices, balancing formulation, technology, and commercial potential.

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