# FORMULATION & DELIVERY

SERIES UK 2020

**Pre-Event Newsletter April 2020**

INCLUDING...



ILEC CONFERENCE CENTRE

*08 - 09 JULY 2020 | LONDON, UK*

OXFORD GLOBAL CONFERENCES

# Contents

This is an Interactive Newsletter. You can click on elements such as website links or the contents below.



# Meet The Team

**Hayley Watson**
Portfolio and Client Engagement Director

**Rimsha Raza**
Senior Operations & Events Executive

**Charlotte Catley**
Portfolio Manager

**Emma Richardson**
Conference Producer

**Ryan Leahy**
Associate Senior Producer & Digital Media Coordinator

**Emily Hawkings**
Marketing Executive

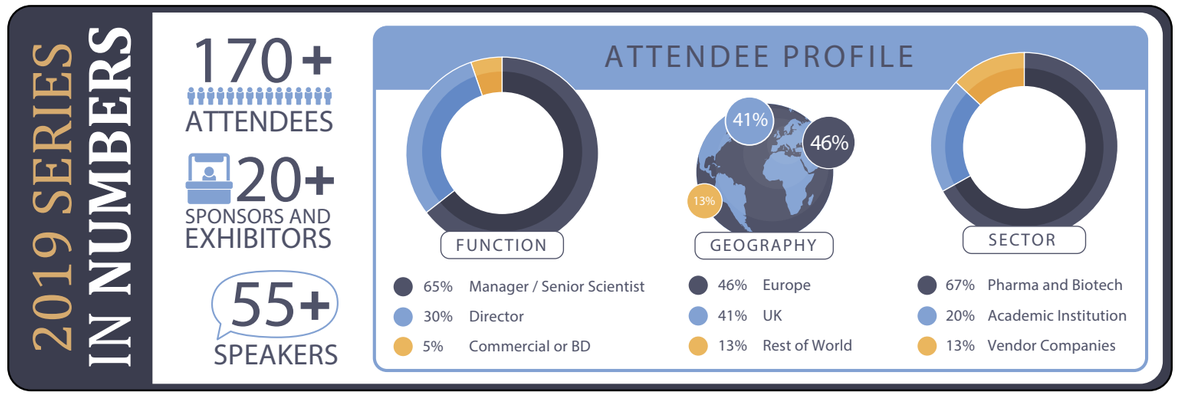
**Betsy Lewin-Leigh**
Assistant Team Leader

**Marc Long**
Business Development Executive

**Bota Godwin**
Delegate Sales Executive








# WELCOME TO OXFORD GLOBAL'S FORMULATION & DELIVERY SERIES UK PRE-EVENT NEWSLETTER!

In light of the ongoing COVID-19 pandemic causing significant disruption to a number of everyday activities and the deployment of travel restrictions throughout Europe and the United States; Oxford Global has taken the decision to reschedule **6th Annual Formulation & Drug Delivery Congress** to ensure safety to all our delegates and staff and maximise networking opportunities. **The dates have been confirmed at the same venue for the 8 – 9 July 2020.** Ahead of the event, I am delighted to share with you an overview of the key features of the congress, as well as exclusive content from our industry-leading speakers.

**As we take a look back at the 2019 event, I am delighted to provide you with some exciting details on a few of the key features from last year & some further new additions for the 2020 congress.**

Featuring over 70 presentations from leading figures within the industry and key sponsors offering relevant solutions & services, the 2019 event brought together over 250 attendees to discuss small and large molecule drug formulation and delivery. It also examined the development & formulation of inhaled therapies as well as novel inhalation devices and analytics. 2019 saw the addition of two new featured streams focusing on continuous manufacturing and processing, and the delivery for RNA therapies and Nanoparticle-mediated formulation and delivery. As expected, these proved to be a hit amongst our audience, welcoming comments made by the attendees on the number of interesting and high-level senior scientific presentations on the programme.

New for 2020 is the expansion of the event, introducing the eagerly anticipated Biomanufacturing congress which will host four streams discussing topics on cell & gene therapy biomanufacturing, upstream & downstream processing, and advances in biologics manufacturing, CMC & continuous manufacturing. The 6th Formulation & Drug Delivery 2020 Congress will again ensure delegates gain invaluable insights into both small and large molecule formulation development as well as drug delivery. At the 5th Inhalation & Respiratory Drug Delivery Congress, alongside the popular 2019 topics in novel inhalation and devices, in line with current industry trends, our 2020 event will have case studies on alternative therapeutic fields and in-depth presentations on pioneering technological advancements in digital health. We look forward to welcoming over 300 attendees from leading European based pharma & biotech companies for high-level discussions on the latest innovations for biopharmaceutical development. After a full day of learning, knowledge sharing and meeting new people, what better way to unwind after the first day of the congress than with a glass of wine (or two) at Oxford Global's networking drinks. We hope you can join us this year and look forward to welcoming you next month at the 2020 congress. See you then!

**- Hayley Watson,**
**Portfolio and Client Engagement Director**

# ILEC CONFERENCE CENTRE

*08 - 09 JULY 2020 | LONDON, UK*

6TH ANNUAL
**FORMULATION & DRUG DELIVERY**
CONGRESS

5TH ANNUAL
**INHALATION & RESPIRATORY DRUG DELIVERY**
CONGRESS

**BIOMANUFACTURING**
CONGRESS

## WHO IS ATTENDING?

For the full attendee list please contact
marketing@oxfordglobal.co.uk

- **300+ senior level attendees** from leading pharmaceutical, biopharmaceutical, biotechnology, diagnostics, CRO and solution provider companies.
- **Professors, Directors and Heads** of formulation development and drug delivery, biologics developments, inhalation drug delivery, respiratory pharmacology, inhalation process development, inhaled dosage forms, pulmonary disease, respiratory therapeutics.
- **Highly esteemed members** of academic and government institutions.

**These companies and many more:**

gsk GlaxoSmithKline · Boehringer Ingelheim · AstraZeneca · Takeda · teva · NOVARTIS · MERCK · SANOFI · Roche · FERRING PHARMACEUTICALS · IMMUNOCORE targeting T cell receptors





GOLD

evotec · Recipharm · SCIEX

SILVER

WYATT TECHNOLOGY

BRONZE

MACS Miltenyi Biotec · ADVANCED INSTRUMENTS · Lonza Pharma & Biotech · MERCK · Celanese The chemistry inside innovation · EMERGO a UL company · Aptar CSP Technologies · MedPharm Breaking through boundaries · CAS A DIVISION OF THE AMERICAN CHEMICAL SOCIETY · Pfanstiehl · UNCHAINED LABS

NETWORK AND PROGRAMME

ZERION · Cambrex · leon NANODRUGS · Quotient Sciences · Harro Höfliger · MUNIT WE ARE MICRONIZATION · Upperton Pharma Solutions · Telstar · INTEC PHARMA · MG2 Keeping ahead for you · ARCINOVA · OCCLUGEL Innovative Solutions

Oxford Global understands that there is a lot of uncertainty regarding the COVID-19 situation. The Event is still going ahead as planned on 8 – 9 July 2020 in London, UK, but rest assured we will continue to monitor all developments in the coming months and follow advice from authorities. Our primary objective is to protect all attendees of our events. If you are unable to commit to attending in person, we are offering you an option to attend the event virtually for £350 +VAT.

*If you would like to secure your place or know more about our virtual passes, please contact Betsy Lewin-Leigh at* ***b.lewin-leigh@oxfordglobal.co.uk***

# OCULAR DRUG DELIVERY - MAKING GREAT DRUGS BETTER

## DR. RAJ THAKUR

Diseases that originate in the back of the eye can cause permanent loss of vision if left untreated and account for the majority of blindness, such as in age-related macular degeneration (AMD). For example, worldwide estimates approximated that 30–50 million people are affected by AMD.

Current therapies for treating these diseases require frequent intravitreal injections, which have shown to prevent further vision loss and gain visual acuity, in some cases. However, frequent intravitreal injections increase the risk of infection, retinal detachment, hemorrhage, pain, discomfort, and rise in intraocular pressure. On the other hand, diseases of the front of the eye such as glaucoma can cause serious blindness. For example, glaucoma is the considered to be the second leading cause of blindness that affects more than 60 million worldwide. However, frequent application of high drug doses (e.g. topical eye drops), due to poor ocular bioavailability, leads to other long-term side effects (e.g. darkening of eyelid skin color caused by latanoprost), have negative effects on patient compliance, which leads to disease progression from suboptimal to poor medical management. Importantly, less than 5% of the drug penetration occurs following topical administration that too for only small molecules, resulting in excessive waste of costly drugs, exposure to high drug levels yet poor efficacy/compliance and minimal benefit to the patient. Additionally, adherence to treatment is also of a significant concern with increasing frequency of administration such as seen in patients with glaucoma. Non-adherence with topical treatments often leads to more invasive surgical treatments, and ultimately can cause permanent vision damage. All of these issues further escalate the costs and creates a significant burden on patients, carers, and physicians. Therefore, the largest problem plaguing the development of ocular therapeutics is maintaining an effective concentration of the drug at its target site of action, to achieve the expected pharmacological response.

*"Proof of concept data of our proprietary photocrosslinked-based sustained drug release systems have shown the ability to provide release of small and large molecules for a markedly extended time period (4-12 months) to treat both front and back of the eye diseases such as AMD, and glaucoma."*

### Re-Vana's Technology

Re-Vana's proprietary sustained drug release technologies, OcuLief™ and EyeLief™, offers delivery of both small and large molecules with wide range of physicochemical properties. Its technologies are comprised of photosensitive polymeric materials that are selectively photocrosslinked to provide tailored release profiles of wide range of ocular therapeutics in the treatment of a range of ocular diseases. The polymer-based photocrosslinked platforms are both biodegradable and biocompatible in nature.

The photosensitive injectable gel-based platform, OcuLief™, is injected in the eye through intravitreal route – using conventional hypodermic needles, followed by a short-term application of UV light to induce in situ photocrosslinking resulting in a photocrosslinked implant formation. Its preformed photocrosslinked implant, EyeLief™, is engineered to allow intraocular administration to achieve sustained delivery of both small and large therapeutics.

Proof of concept data of our proprietary photocrosslinked-based sustained drug release systems have shown the ability to provide release of small and large molecules for a markedly extended time period (4-12 months) to treat both front and back of the eye diseases such as AMD, and glaucoma.

### Summary

- Proprietary photocrosslinked drug delivery platforms providing sustained drug delivery for 4-12 months
- Proved delivery of a range of small and large therapeutic molecules
- Proved preclinical safety, tolerability and biocompatibility of the drug delivery platforms
- Ability to achieve tailored release profiles and biodegradation – with controlled burst release
- To address both front and back of the eye diseases by delivering using different routes

*Raj will be presenting on 'Ocular Drug Delivery' on Day One, Stream 2: Biologics Drug Delivery.*

**Dr. Raj Thakur**
**Reader in Pharmaceutics, Queens Univeristy Belfast**
**Co-Founder and CTO Re-Vana Therapeutics**

Dr Raj Thakur is a Reader in Pharmaceutics at the School of Pharmacy (SoP), QUB and is the Co-founder, CTO and Director of Re-Vana Therapeutics. His research interest is in the design and physicochemical characterisation of advanced long-acting biodegradable drug delivery systems including minimally invasive medical devices for localised drug delivery. He is the Chair for Ocular Drug Delivery (OcDD) Focus Group supported by the mission of Controlled Release Society (CRS). He has authored over 160 scientific publications, including 60 full papers, 10 book chapters, four text books, several invited talks in national and international conferences and patents. To date, he has secured research funding of approximately £5 million.

# THE FUTURE OF CELL THERAPY MANUFACTURING

## JOSEPH LANING

**What is your view on the overall outlook of Biomanufacturing in 2019?**

Overall I'm quite optimistic about the outlook for Biomanufacturing for 2019. The interest in cell-based therapeutics has never been higher and between the increased investment in technology and infrastructure, the improved dialog with regulators about path and process, and the interest in regenerative medicine through industry and advocacy groups like ARM and PhRMA, the momentum continues.

**What are the major restraints hindering progress in Regenerative Medicine Biomanufacturing?**

Certainly, manufacturing capacity for both drug substance and drug product will be a challenge for both independent manufacturing entities and CMOs as more and more products move into trials and toward commercialization. Another factor that may hinder progress would be a lack of clear regulatory guidance on biomanufactured products of all types, biologics to cell therapies. Some of these guidance requirements or lack thereof may seem like esoteric topics but areas such as foreign matter contaminant limits (beyond USP or other guidances) or product/process comparability requirements at different stages of a product lifecycle are always lively topics at industry group meetings and conferences. One other significant potential restraint, which has been gaining some traction of late, is the availability and potential customization capability for single use culture ware and feeding systems. In particular, products that actually fit your process and development path. These systems are often geared narrowly toward scale-up of standard culture ware or jumping straight to bioreactors that do not fit your process. Scale-up can be a very time-consuming developmental trek and is related to patient dosing, supply chain requirements, and a host of other parameters. Ultimately, your process needs to deliver lot sizes that are enabling, whatever that size may be, and planning carefully can add downstream value.

**What are the critical success factors for successful commercialisation?**

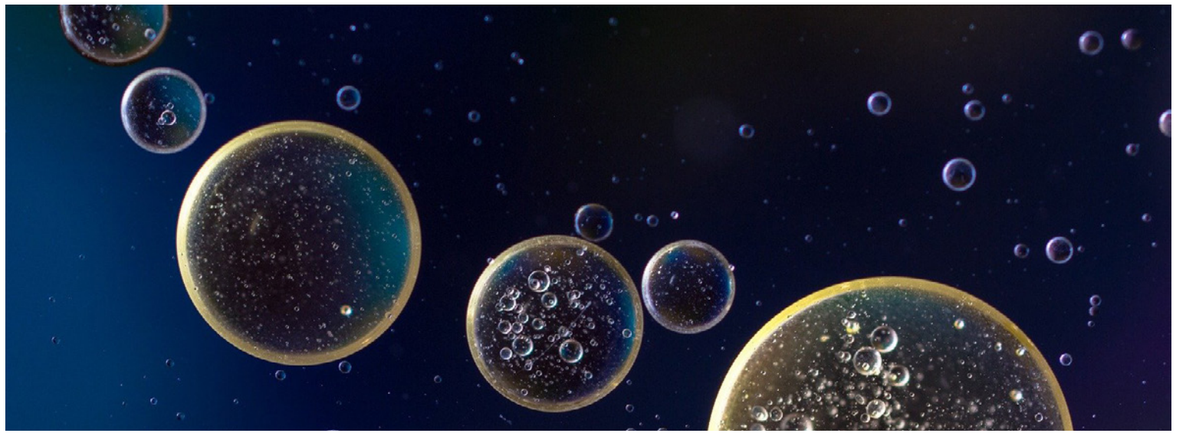
I think primarily the importance of knowing your intended indication and understanding your product profile to the greatest extent possible should not be underestimated. The flipside of this is understanding your process and the ability to deliver on forecasted success is crucial. In understanding these pieces, you develop a product that will meet requirements. The strategy to move an ostensibly manual cell culture process forward and expect it to meet commercialization demands is likely unrealistic without automation. In addition interjecting automation technologies at the right stage and in the right place when it may be impossible to fully automate your process, brings value and ROI into sharp focus. Doing this, as you are moving through clinical trials adds to the enormity of the task.

The second piece is to consider is the thorough evaluation of your process materials and reagents early and often. This includes the manufacturers you procure from in order to head off shortages, regulatory uncertainties, and developmental improvements. Materials quality can be a downstream regulatory stop sign that you want to avoid. A clear path and some forethought can save time, expense, and pain in the future lifecycle of your product.

**What are the biggest developments necessary for Cell Therapy Manufacturing for the future?**

Many cellular therapeutics are multistage, complex processes that may take weeks or months to complete a single run, which may not be conducive to immediate full automation but could benefit from flexible, staged automation platforms for particularly labor intensive or tedious process steps. Robotics systems and automation vendors are beginning to fill some of these gaps but more can be done in this regard. Another area where progress might have a significant impact is in the field of testing technologies for product quality. Often times it seems that lot sizes for cellular products are often at odds with quality testing methods. This would pertain to product-specific testing for purity and potency for instance as well as the more well known quality parameters. Working towards testing technologies and regulatory requirements that maximize safety with an eye towards advances that minimize sampling burden seems like a win-win with the benefit being maximal information recovery the most frugal sampling profile possible.

In line with this last point, a more global perspective on regulatory requirements with EMA, PMDA, CFDA, and FDA working more closely to align requirements wherever possible will make product development and product lifecycle planning more cohesive and definitive. This could not be more true than for cellular therapeutics and regenerative medicine where seemingly subtle differences in regulatory guidances can lead to disruptive detours.



**Joseph Laning,**
**Director Cell Manufacturing Operations,** astella

Dr. Laning is currently the Director of Cell Manufacturing Operations at the Astellas Institute for Regenerative Medicine (AIRM). He received his BA degree in Biology from Boston University and his PhD in Immunology from Harvard University. He is a member of the International Society Cell Therapy and is the ISCT voting delegate to the USP. Dr. Laning has spent the past 24 years seeking to translate concepts into products in the fields of wound care, regenerative medicine, and stem cell therapies. He began his post-doctoral career at Organogenesis, Inc. where he developed and implemented pre-clinical investigations and subsequently managed all patient immunology safety testing leading to the approval of the PMA of Apligraf™ with the FDA. In 2002, he joined ViaCell, Inc. where he served as Director of Therapeutic Development and subsequently Senior Director of Analytical Biology. In these roles he oversaw strategic and operational scientific plans leading to successful approval of both IND and IDE filings and completion of the company's first clinical trial using allogeneic expanded cord blood stem cells. In 2010, he became Senior Director of the Massachusetts Stem Cell Bank and Registry and Research Associate Professor of Molecular Medicine at the University of Massachusetts Medical School. He served as Chief Technology Officer at Provia Laboratories leading strategic implementation of their cGMP cell and tissue banking operations. Current interests include developing and enhancing human iPS and ES manufacturing methods for delivery of drug substance and drug product for AIRM clinical programs and the scale up and automation of hPSC and derivative cultures to deliver commercial scale cell therapeutics.

# INNOVATION IN CONNECTED INHALERS

## MARK MILTON-EDWARDS

**Could you describe the current focus of your work in connected inhalers?**

I defined and wrote the specification for our FDA approved digital inhaler. I remain responsible for further product definition and market development. New technology offers different, and in many ways faster innovation cycles and the goal is to make improvements for key stakeholders.

**What are the key benefits of optimising digital devices? What makes technological advances in this area so exciting?**

Multiple benefits for the three key stakeholders being patients, clinicians and Society – direct and more real-world engagement with patients, in-situ and in the moment of relevance. Good, i.e. high fidelity and highly usable, technology should be able to live with patients and therefore tell us totally new things and test known beliefs and hypotheses.

**What have been the biggest challenges that you have faced when developing inhalation devices?**

Going in a different direction from competitors and researchers meant winning internal support, or working out acceptable ways to 'skunk'. Secondly, regulatory approval while standards and approval paths were yet to be fully defined.

**What are some priorities for your work on developing connected inhalers over the next year?**

I believe my priority over the next year will be delivering topquality total experience considering at least three elements of hardware, software and humanware across the US, EU and the rest of the world.

**How are current regulations on inhaled therapies and devices impacting your research?**

They are our daily work and represent a shifting and developing landscape that in some cases we need to co-define with stakeholders. They represent a 'limitation' and also a welcome high standard to ensure mainly seriously committed companies enter and succeed.

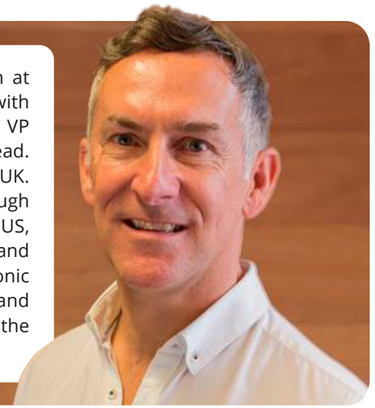
**Why is improving patient adherence and technique such a key focus within the inhalation industry?**

They are 'surrogates' or 'lead indicators' towards real improve in outcomes. As such they appear important but only for the outcomes that sit behind them. Despite >40years we've not shifted outcomes such as disease control enough and for enough people. There is still much to do and these two factors may lead to true change.

**How do you see the inhalation field developing in the future?**

I see greater segmentation and differentiation overall. The ability to personalise will become increasingly real. Greater technology advances will be introduced, but unless they are based on true patient/stakeholder needs and mainly passive collection, they will fail to make a meaningful impact. Prices will reduce for 'standard' inhalers through loss of exclusivity and general pricing pressures to release resource and budget towards true value-based innovation. The total inhaled market will continue to grow in accordance with population and urbanisation. Microelectronics and new analysis techniques like machine learning and artificial intelligence will sit at the heart of what we can learn about a patients every-day, and therefore what we can do to make it better.

Mark is responsible for the Product & Health Solutions within Digital Health at TEVA Pharmaceuticals.Over ten years with TEVA and prior to that sixteen with AstraZeneca. Mark has held various positions including R&D Project Leader, VP Sales & Marketing, Strategic Planning & Business Development, and Global Brand Lead. Graduated in Aeronautical Sciences and completed his MBA at Durham University, UK. During his career he has led technology & especially inhaler development teams through engineering, CMC characterisation, clinical evidence generation, registration within US, EU and International Markets and ultimately to successful global launch. Total Brand Leadership value >$2.5bn. Mark has numerous patents granted and pending in electronic communications, sports technologies, inhaled pharmaceutical development, and respiratory physiological function & predictive AI. Mark is the inventor of Digihaler®, the first FDA approved digital inhaler with built-in sensors.







# STABILIZATION OF POOR GLASS-FORMING APIs WITH MESOPOROUS SILICA

## FINN BAUER

FINN BAUER, Head of Solid Formulations R&D, **Merck**

Dr. Finn Bauer is Director for Solid Formulations R&D, recently launching two PVA-based excipients for sustained release and solubility enhancement through hot melt extrusion. He is a biochemist by education and holds a Doctoral degree from the University of Bayreuth, Germany. In 2016, in addition, Finn completed a Master of Business Administration at Ashridge Executive Education, Hult Internarial Business School, UK. With broad experience in managing product and application development projects, Finn has guided many programs in his 13-year career with Merck Life Sciences. During this time, Finn held positions from Quality Control to R&D and Site Manager across various countries. Most recently, Finn has assumed additional responsibility for Merck's Global Actives & Formulations Application Labs network including locations in Europe, India and China.

**What is your current role – and what drew you to work for Merck?**

I'm currently Director of Solid Formulation R&D with Merck Life Science. More than 10 years ago I was drawn to Merck as the world's oldest pharmaceutical and chemical company. In the past 13 years that I'm now with the organization (moving through different roles in quality control and research and development in Germany, US and Switzerland), I have been fortunate to witness and shape how we at Merck constantly re-focusses our activities to ensure that our products meet current and future customer needs. Today I'm excited to make Merck a vibrant science and technology company and expanding our solid formulation excipient portfolio especially for applications like solubility enhancement and controlled release of APIs.

**What are you working on at the moment?**

At this moment our focus is on new product developments of polymer-based excipients. This includes new solutions for solubility enhancement of small molecule APIs and sustained release from matrix tables. At the same time, we're still very much committed to our previous product innovations. Specifically, I would like to highlight our silica microcarrier for solubility enhancement. We introduced this carrier material back in 2013. Nevertheless, we're constantly optimize our technical support and service offering around this product – e.g. by scaling up the API loading process of this microcarrier material to commercial manufacturing scale (up to 150 kg loading scale).

**What are the biggest challenges working with Solid Oral Dosage Form?**

Solid oral dosage forms are the gold standard in patient centric drug delivery formats. However, solubility enhancement technologies, continuous manufacturing approaches and the potential of additive manufacturing techniques are about to disrupt the solid oral dosage manufacturing footprint of the future. As more and more specialized treatment approaches immerge, the need for efficient and increasingly flexible fabrication processes rises. As an excipient manufacturer we strive to support our customers to mitigate these challenges. The before mentioned drug product manufacturing scale-up know-how is just one example on how we support our customers in minimizing development risks.

**There have been significant developments in targeted therapeutics – how do you see this progressing?**

There have been numerous extremely interesting targeted drug delivery approaches recently – manly in the area of parenteral applications with special emphasis on implants and nanoparticle. That being said, most of these approaches, however, still must prove their economic feasibility and relevance. Therefore, one of our mail efforts is to further innovate in the area of "classical" solid oral dosage forms to further optimize solubility enhancement and controlled release of APIs.

**What would you like to get out of the Formulation & Drug Delivery event?**

I'm looking forward to Formulation & Drug Delivery as a platform for excellent scientific presentations and discussions along with a great networking opportunity.

*Finn will be presenting on 'Stabilization of Poor Glass-Forming APIs with Mesoporous Silica' on Day One, Stream 1: Small Molecule Formulation.*

# SYNTHETIC "STEMNESS" NANOPARTICLES FOR DEGENERATIVE DISEASES

**SU METCALFE**

There is immense societal and economic need to treat degenerative and autoimmune diseases that are predicted to reach global annual costs of trillions of dollars and already costing $250 billion for Alzheimers alone. Tragically the young also suffer, including autoimmune attack against the brain in Multiple Sclerosis costing $100 billion. Yet still today there is no cure despite huge investment in drugs and more recently stem cell approaches - here costs may soar to $1 million per patient.

LIFNano Therapeutics has invented a nanomedicine to heal and repair the brain. In effect we take the "stemness" out of Stem Cells - a growth factor called "LIF" - and formulate it as a nanoparticle using FDA-approved biocompatible, biodegradable gel to create nanoparticles with the properties of stem cells: these are named "LIFNano™".

LIFNano™ is a game changer - a cell-free synthetic stem cell for low cost, high gain. The particles are designed to hitch a ride on immune cells - T lymphocytes - that act as a Trojan Horse, carrying LIFNano™ to where disease is active - even behind the blood-brain-barrier (BBB) to treat the CNS. LIFNano™ also acts on endogenous stem cells and precursor cells to increase the natural regenerative capacity of targeted tissues and organs, including the eye where LIF is known to support health of the retina's photoreceptors. Natural homeostasis is supported by LIF, and it is interesting to note how the immune system exploits LIF to maintain immune quiescence via Treg-derived LIF. In autoimmunity, Treg may become switched to aggressive TH17 cells: LIFNano™ is able to flip the switch back to Treg and self-tolerance. The CNS has a natural requirement for LIF to be transported across the BBB, using a receptor-mediated mechanism. Since peripheral inflammation suppresses this natural LIF-transporter - an effect that over time becomes a risk to brain health - LIFNano™ may reset CNS homeostasis following intravenous delivery where LIFNano™ reaches the brain's parenchyma within a few hours.


Being synthetic, industrial scale production has the potential to provide global access to patients suffering degenerative diseases. Millions of years of evolution of stem cells has been captured at nanoscale - quantum biology with immense power to treat the body without drugs. Preclinical Proof is compelling - including some reversal of paralysis in gold-standard models of MS. With successful tech transfer to a cGMP facility for scale-up, LIFNano™ is now primed for First in Human trials in MS with an expert team to deliver the healing power of LIFNano™ to patients following Regulatory approval.

*Su is the Founder and CEO of LIFNano Therapeutics Cambridge UK & will be presenting on 'Exploiting The Therapeutic Value Of LIF Using NanoTechnology' on Day One, Stream 3.2: Formulation & Delivery for Nano & RNA Therapies.*

# Q&A WITH RECIPHARM'S LEI MAO

Lei Mao, Director of Inhalation Science and Product Development at Recipharm Laboratories

Lei Mao is the Director of Inhalation Science and Product Development at Recipharm Laboratories. With over twenty years of experience, Lei has a wealth of knowledge in formulation and inhalation product development within the pharmaceutical industry. He started a career working as a senior scientist, where he developed particulate formulations for inhalation applications and has since held managerial positions for big pharma companies. He also holds a Ph.D. in Pharmaceutical Sciences and a degree in pharmacy.

**Describe your current focus within inhalation science.**

As a leading contract development and manufacturing organisation (CDMO), our goal at Recipharm is to support pharma companies with the development and manufacturing of inhaled products, including metered dose inhalers (MDIs), dry powder inhalers (DPIs) and nasal sprays, in line with regulatory requirements. It is well known that inhalation dosage forms are unique and technically more challenging compared to other dosage forms. Inhalable products require specialist expertise from development through to manufacturing, meaning our core focus is utilising our development team's expertise and scientific knowledge to fully support the needs of our clients' projects. The majority of our customers come to us for an end-to-end service. At the beginning of 2019, we launched Recipharm Inhalation Solutions™ which provides an integrated service from development, scale-up and clinical supply to commercial manufacturing to meet this demand.

**What are your main priorities within the inhalation field and how do these compare to the priorities of the industry as a whole?**

Advances in science and technology mean that a key area for growth is trying to deliver medicines for unmet patient needs. In order to cater for evolving patient needs, it is important that CDMOs deliver high quality products that can progress to market as quickly as possible. CDMOs offering integrated services are able to better expedite the process and achieve this goal, as they facilitate projects from development to commercial manufacturing. In recent years, we have been continuously investing in our inhalation business in terms of both capabilities and capacities. For example, the acquisition of Sanofi's former inhalation product manufacturing facility at Holmes Chapel provided us with specialist technologies for MDIs and nasal sprays. It also afforded the team with equipment for the development, scale up and commercial manufacture of inhalation products. In acquiring access to specialist development suites at the facility, Recipharm can contribute to the advances in inhalation science and launch new patient-centric products that can improve the lives of people living with conditions like asthma and other prevalent respiratory diseases. To better satisfy customer needs, we continue our investment in building new MDI and nasal spray production lines as well as expanding dry powder filling capability at our manufacturing site.

**What has been the biggest recent advancement for Recipharm within inhalation?**

In a bid to continue to expand our development and manufacturing offering for inhalation and nasal dosage forms including MDIs, DPIs, soft mist inhalers, nebulizers, nasal sprays and nasal powders, we are continuing our M&A strategy. As part of this, we are looking at different capabilities to add to our offering, including the onboarding of medical devices, to support our growth in the inhalation market.

From a technical perspective, we invested in a SprayVIEW system at our Research Triangle Park (RTP), US facility along with a newly built aerosol collection lab and modified development process lab. This strengthens our capability in supporting both inhalation and nasal product development and we expect more investment to take place in the coming months/years.

**Outline the current challenges that Recipharm is working to overcome in the development of inhalation products?**

At Recipharm, we are actively seeking to develop dual and triple API inhalation products. Although the development of these products is highly complex, they present pharma companies with an opportunity to deliver more patient centric medicines and gain a competitive edge, as they will remain patent protected for a long-term period.

Selecting the best dosage form is also a challenge that we work with our customers to overcome. For example, in the early phase development of new chemical entities for inhalation, providing a quality clinical supply is critical to reduce the development cycle. Recipharm supports and recommends selection of dosage forms and the delivery platform for first in human studies. This can include DPIs or nebulised solutions based on the desired dose, physicochemical properties including solubility and stability of the compounds.

> *"Technology in the inhalation space has significantly evolved"*

Also, helping customers to understand drug development and clinical costs associated with inhalation drug products is also a key challenge. Due to their complexity, these products often involve a costly development process which is not fully recognised by customers. As an example, we have seen an increase in requests for drug products involving cannabidiol (CBD) and minimising costs for these types of projects is a key focus.

**What future innovations within inhaled formulations and devices do you expect to see over the next year? What impact will these advancements have upon the inhalation industry?**

While inhalation therapy has a long history, it has been adopted more since the launch of the first nebuliser during the nineteenth century. Following the invention of the first MDI and DPI in the midst of the twentieth century, technology in the inhalation space has significantly evolved. Each advancement in inhalation sciences and technology has generated a large volume of products to patients. For example, the introduction of hydrofluoroalkane (HFA) propellants delivered numerous MDI products to patients in the early 1990s. In addition, the invention of the soft mist inhaler device has enabled the launch of four inhaler products since the beginning of the 21st century.

More recently, successful development of the Ellipta DPI device and application of PulmoSphere™ particles made triple combination products accessible to patients with respiratory diseases.

Looking to the year ahead, we expect to see continuous advances in technologies and applications in the inhalation field. These include, but are not limited to, the following areas:

- New user and environment-friendly formulation and devices. For example, new DPIs make formulations more compatible for multiple compound products. We have seen more portable nebulizers under development and vaporised inhalers, which could offer potential advantages.
- Application of new particle technology in DPIs following the launch of MDIs based on the same technology will bring more products to the market.
- Smart inhalers will continue to grow.
- There is a potential need to explore more environment-friendly propellants for MDIs.
- New molecules, especially biologicals for inhalation, will start to appear which will require specific formulation technologies and delivery platforms.
- Dual or multiple compound inhalers for controlling chronic obstructive pulmonary disease (COPD) and severe asthma are in increasing demand.
- Inhaled drugs for new applications or the same application via inhalation or nasal routes through 505(b)2 regulatory path will bring more products to the market

In addition, developing generic inhalation products will continue to be a keen interest to reduce the burden of healthcare costs.

All these advances require scientists to take initiative and shorten the development cycle, whilst not compromising on product quality. The employment of new approaches, such as understanding in vitro and in vivo correlation of inhaled products, quality by design (QbD) throughout development, subsequent product life cycle management and working closely with regulatory agents will likely become routine in the inhalation industry, ultimately bringing more quality products to patients.

OXFORD GLOBAL CONFERENCES

# FORTHCOMING EVENTS

OXFORD GLOBAL CONFERENCES

## Biologics Series

**UK**

**13th Annual Proteins & Antibodies Congress**
26 - 28 August 2020 | London, UK

**7th Annual Peptides & Oligonucleotides Congress**
26 - 28 August 2020 | London, UK

**2nd Annual Bispecifics in Discovery & Development Congress**
26 - 28 August 2020 | London, UK

Co-located Events

## Biomarkers Series

**UK**

**16th Annual Biomarkers Congress**
February 2021 | Manchester, UK

**2nd Annual Genomic Markers Congress**
February 2021 | Manchester, UK

**Digital Biomarkers & Pathology Congress**
February 2021 | Manchester, UK

Co-located Events

**US**

**5th Annual Biomarkers & Precision Medicine USA Congress**
15 - 16 October 2020 | San Diego, USA

## Cell Series

**UK**

**9th Annual Cell Culture & Bioprocessing Congress**
06 - 07 October 2020 | London, UK

**7th Annual Regenerative Medicine & Advanced Therapy Development Congress**
06 - 07 October 2020 | London, UK

**6th Annual Cell & Gene Therapy Manufacturing Congress**
06 - 07 October 2020 | London, UK

Co-located Events

## Formulation & Delivery Series

**UK**

**6th Annual Formulation & Drug Delivery Congress**
08 - 09 July 2020 | London, UK

**5th Annual Inhalation & Respiratory Drug Delivery Congress**
08 - 09 July 2020 | London, UK

**Biomanufacturing Congress**
08 - 09 July 2020 | London, UK

Co-located Events

**US**

**3rd Annual Formulation & Drug Delivery USA Congress**
29 - 30 September | San Diego, USA

**3rd Annual Inhalation & Respiratory Drug Delivery USA Congress**
29 - 30 September | San Diego, USA

Co-located Events

## Immuno Series

**UK**

**5th Annual Advances in Immuno-Oncology Congress**
24 - 25 August 2020 | London, UK

**Autoimmunity & Immunology Congress**
24 - 25 August 2020 | London, UK

Co-located Events

**US**

**3rd Annual Advances in Immuno-Oncology USA Congress**
15 - 16 October 2020 | San Diego, USA

## PharmaTec Series

**UK**

**18th Annual Pharmaceutical IT & Data Congress**
24 - 25 September 2020 | London, UK

**4th Annual Artificial Intelligence in Drug Development Congress**
24 - 25 September 2020 | London, UK

**2nd Annual SmartLabs & Laboratory Informatics Congress**
24 - 25 September 2020 | London, UK

Co-located Events

## R&D Series

**EU**

**21st Annual Drug Discovery Summit**
11 - 12 August 2020 | Berlin, Germany

**8th Annual Drug Design and Medicinal Chemistry Congress**
11 - 12 August 2020 | Berlin, Germany

**2nd Annual Neuroscience Drug Discovery Congress**
11 - 12 August 2020 | Berlin, Germany

Co-located Events

## NextGen Omics Series

**UK**

**12th Annual Next Generation Sequencing & Clinical Diagnostics Congress**
05 - 06 November 2020 | London, UK

**8th Annual Single Cell Analysis Congress**
05 - 06 November 2020 | London, UK

**6th Annual Genome Editing Congress**
05 - 06 November 2020 | London, UK

**2nd Annual Digital PCR Congress**
05 - 06 November 2020 | London, UK

Co-located Events

**US**

**6th Annual Next Generation Sequencing USA Congress**
07 - 08 April 2020 | Delivered Digitally

**6th Annual Single Cell Analysis USA Congress**
07 - 08 April 2020 | Delivered Digitally

**4th Annual Genome Editing USA Congress**
07 - 08 April 2020 | Delivered Digitally

Co-located Events

Register your interest, e-mail us:
info@oxfordglobal.co.uk