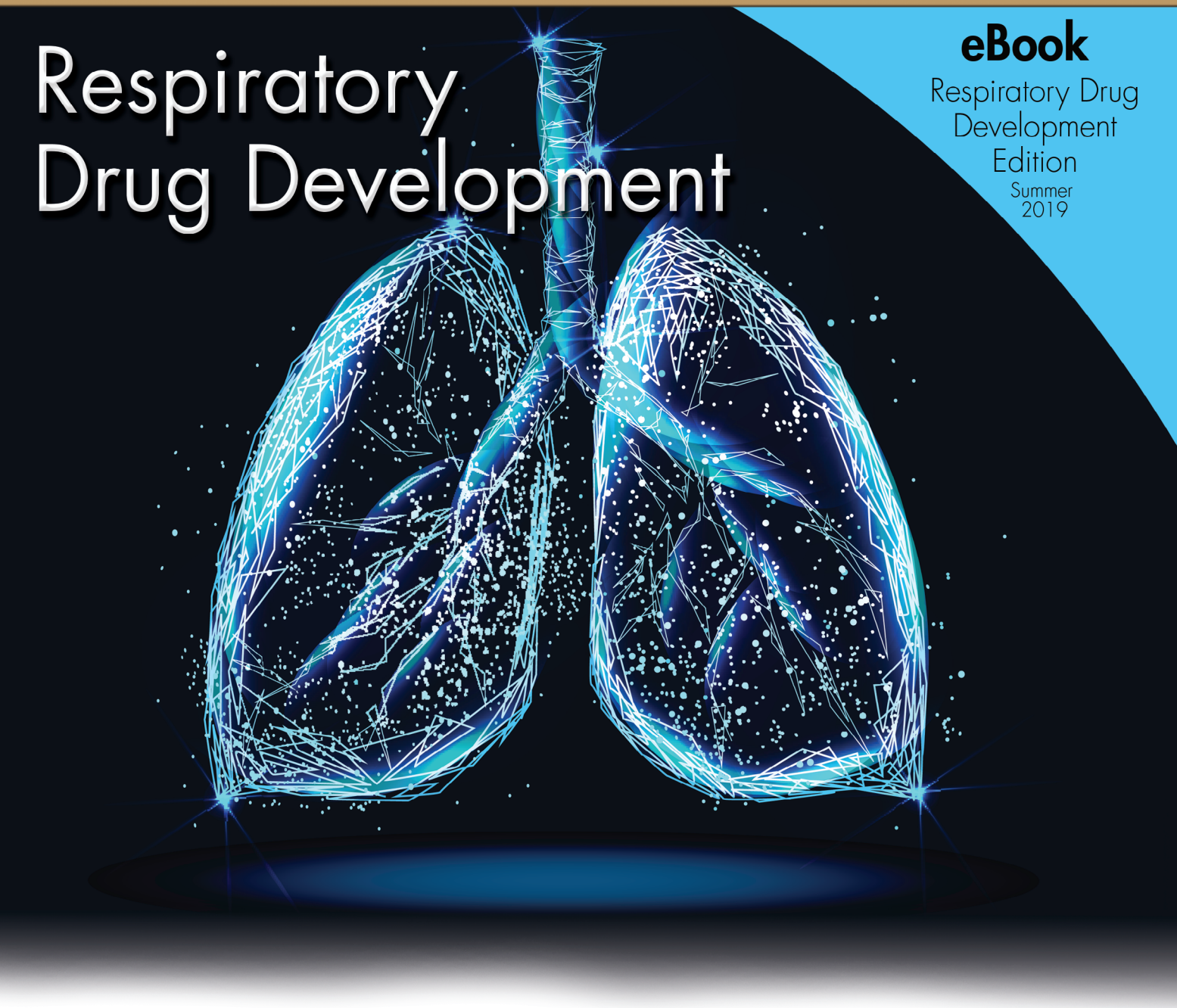
Drug Development & Delivery

Respiratory Drug Development

eBook
Respiratory Drug Development Edition
Summer 2019



Drug Development & Delivery®

Respiratory Drug Development eBook

Increased Focus on Respiratory Drug & Device Development Makes Treatment More Personal

A recent report from the Pharmaceutical Research and Manufacturers of America (PhRMA) found America's biopharmaceutical companies are developing about 130 new medicines for the millions of patients affected by respiratory diseases: chronic obstructive pulmonary disease (COPD), cystic fibrosis, pneumonia, and asthma. These medicines represent critical advancements in respiratory care and improving quality of life.[1]

In addition to the drugs, devices delivering those products are being designed to improve the quality of life for an aging population, children, and those who tend not to comply to dosing regimens because they don't know how to use the device. The global respiratory care devices market is expected to exceed more than $24 billion by 2022,[2] and could exceed $33 billion by 2023.[3]

Respiratory inhalers are often used to control respiratory conditions, whereby the patient directly inhales the drug into the respiratory tract. Manually operated inhalers account for the largest market share, 90% as of 2016, because of their widespread availability. The global dry powder inhaler (DPI) device market was $643.1 million in 2018 and could reach $912.3 million by 2026.[4] In North America, however, metered dose inhalers is the fastest growing segment. Recent advancements in customized dry powder inhalation capsule solutions provide the marketplace with optimal release performance. Industry insiders believe capsule-based DPI technology is becoming the preferred DPI drug delivery platform for pulmonary delivery because it offers stability advantages, encourages patient complaint, and is cost effective to the manufacturer because of various dosing capacity.

But the market is changing. The connected "smart" inhaler and digital inhalers segments will show a rapid growth globally after 2018. Connected inhaler technology companies have developed connected inhaler sensors, mostly as add-on solutions to existing device-drug combinations. These inhaler sensors are connectable to cloud platforms to enable remote patient monitoring. Additionally, some connected inhaler technology companies are developing new artificial intelligence-based features, which will be able to deliver more personalized and enriched services. Smart inhalers are expected to surpass $1.63 billion by 2022.[5]

While connected devices currently reign supreme, there is a market opportunity for new players offering a purely digital service. According to "The Global Digital Respiratory Solutions Market 2009-2023" report, roughly 210 million asthma and COPD patients across the globe own a smartphone, tablet or smart watch — many of whom remain untapped by digital health companies developing connected spirometers, coaching apps, software-based clinical tools, or other digital offerings.[6]

This *Drug Development & Delivery Respiratory* Drug Development eBook highlights some of the innovators and innovations in the respiratory sector, addresses the importance of end users in the device development process, and presents recent advancements in improving patient adherence.

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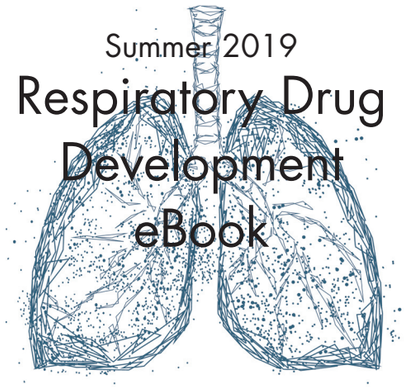

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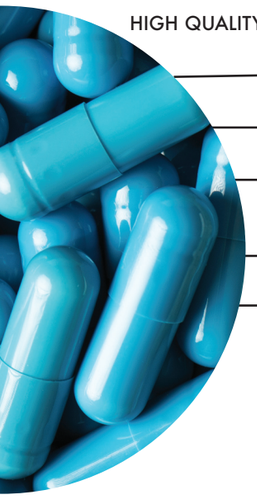

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Patient as a Team Member: Perspective of Integrating End Users in Inhaler Development

By: Audrey Chandra, Patient Media Watch Analyst, Nemera

"We put patients first" is Nemera's main purpose. As a world leader in the design, development, and manufacture of high quality drug delivery devices, Nemera is committed to improving patient quality of life. Working with the world's leading pharmaceutical, biotechnology, and generics companies, Nemera delivers leading-edge systems across different areas of application, including inhalation.

The clinical outcomes of the patients who suffer from asthma and chronic obstructive pulmonary disease (COPD) are highly dependent on treatment adherence. Patient adherence might be influenced by several factors, including disease progression and drug, as well as the device (inhaler). If patients do not perceive benefits because of drug inefficiency and side effects, they may cease taking their prescribed dose. Additionally, 70% of patients do not know how to correctly use their inhalers, which causes failure in dose administration.[1] As a result, treatment management problems may arise, leading to unfavorable clinical outcomes and prognosis. Consequently, the inhaler's ease of use is crucial to the patient's point of view.

Along with the paradigm shift to patient centricity, inhaler developers strive to innovate according to the unmet needs of the patient. The idea is to integrate the end-users – patients – into various phases of inhaler conception, as early as possible, to collect their input and better understand existing demand. A focus on obtaining valuable feedback might generate novel innovation via conducting user tests, interviewing patients, and sending questionnaires to populations in targeted disease areas. Integrating a human factors approach will help design a product that eases patients' lives on a daily basis. Most importantly, keep in mind that each patient is distinct, thus their treatment, as well as inhalers prescribed by their physicians, may vary according to their lung capacity, condition, and age group. Ultimately, adjusting inhaler design to these influencing factors is critical for improved treatment adherence and clinical outcomes.

Patients often look forward to becoming independent while living with chronic conditions. With the purpose of improving patient compliance and enhancing independent medical care, an electronic component could be integrated within the inhaler as a means of reminding patients to take their dose. Having immediate feedback features on the digital inhalers can reassure correct dose administration technique, improving treatment efficiency. Patients will find the device more interactive, which will boost their confidence and ease their life. Above all, the connected device collects data that might help patients explain their treatment management status to their physicians. Now, the healthcare providers will understand the treatment pattern, adherence, and whether or not their patient has practiced an adequate technique in dose administration. Furthermore, the summary of this collected data gives healthcare providers the most adapted therapy and improves patient-physician communication. At present, the connected devices are mainly used in the clinical trials to ensure proper adherence during trials, check inhalation technique, and for other parameters.

Nemera is aware of the challenges encountered by users in handling existing inhalers, from difficulty in coordinating a patient's breath and inhaler activation in pMDI to meticulous compliance issues that cause patients to fail to adhere to their treatment. In light of this, we identify room for improvement in developing innovative inhalers to better manage respiratory conditions. Indeed, thanks to the Internet and technology, knowledge and information are accessible by patients, which indirectly encourage them to become more critical and active stakeholders within the healthcare universe. Not only do patients' opinions matter, they offer ideas and inspiration in designing a patient-focused inhaler.

In conclusion, Nemera realizes the potential to differentiate through its expertise and competences in combining both technology advancement and human factors. This allows the improvement of device practicality, functionality, and efficiency for better adherence and clinical outcomes. Certainly, the voice of other stakeholders in the healthcare industry remains crucial, however, patients have a unique position – they are the end-users. By listening to patient feedback and understanding what patients need, Nemera acquires strategic added value, which fundamentally becomes a way to find the most adapted solution to adherence and compliance.

Reference

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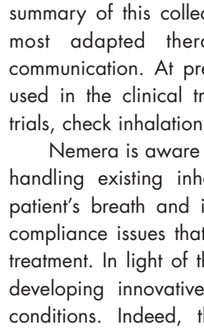
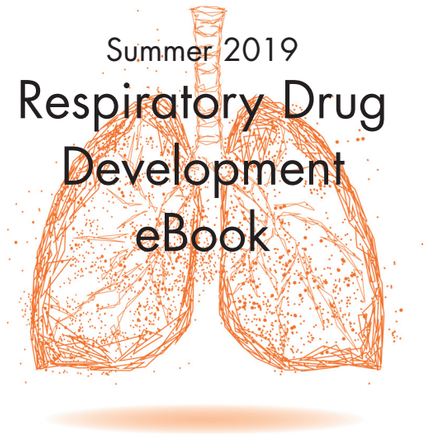


Audrey Chandra holds a Bachelor of Medicine and a Master's degree in Business Development, and is in charge of monitoring patients' insights through various media sources.



The Challenges Patients Face With Onboarding & Adherence

By: Erin Miller, Marketing Coordinator, Noble

Founded in 1994, Noble® is the global leader in medical device training solutions, patient onboarding strategies, and multisensory product development for the world's top pharmaceutical brands and biotechnology companies. Focused on driving innovation, Noble works closely with brand, device, and commercialization teams to develop turnkey solutions that improve onboarding and adherence, bringing value to clients and patients alike.

The first few months of a patient's treatment, commonly referred to as the onboarding stage, are the most important regarding patient adherence. During this process, patients are introduced to their therapies and drug delivery device by a healthcare professional who provides one-time training on proper self-administration.

After this introduction, patients are expected to self-administer using their respiratory device alone, removed from a healthcare facility and without healthcare provider supervision.

Unfortunately, there are many variables contributing to patient adherence and therapy acceptance during onboarding, including quality of in-office training, memory retention, anxiety, confidence and more.

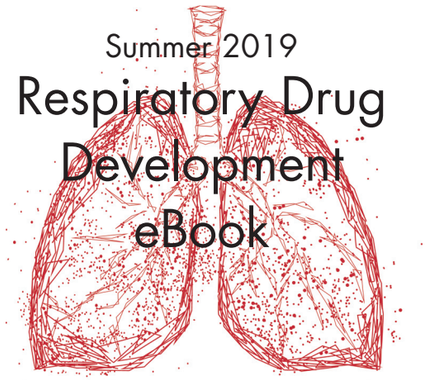
Some factors impacting patient onboarding and adherence include:

- 93% of patients make errors when using an inhaler;
- 90% of treatment information is forgotten after one week;
- 66% of patients fail to fully exhale prior to using an inhaler; and
- 50% of patients are non-adherent due to gaps/barriers in treatment experiences.

We Have The Expertise To Make A Difference For Patients & Brands

As a fully integrated product development company, Noble's in-house design, development, and manufacturing expertise enable the seamless transition of concepts from design/engineering to manufacturing. Noble's experience and platforms in these disciplines are supported by an award-winning cross-functional team of industrial, mechanical, material, manufacturing, and quality engineers who consistently develop novel solutions related to mechanical training device requirements. Such solutions result in unparalleled demonstration devices that accurately mimic the behavior of key device features, all while having the ability to be reset and function reliably over the lifetime of the product.

Our exclusive industry-leading collaborations uniquely position us to serve our clients and deliver unrivaled value and quality. Through cooperative agreements with prominent device manufacturers, Noble is provided key product specification information and insights, thereby ensuring that all training and demonstration devices not only simulate commercial drug delivery device functionality, but also provide patients a hyper-realistic simulation experience.



Beyond Noble's device manufacturer partnerships, our device agnostic technologies allow us the versatility to accommodate a variety of autoinjector, prefilled syringe, onbody, and respiratory device form factors – all while being a low-cost reusable solution to safely and effectively onboard users.

We're More Than A Product Development Company – We're Your Go-To Resource

In addition to developing innovative training platforms and holistic-based solutions, Noble also offers a variety of services designed to provide clients with comprehensive support through pre-and post-launch. We provide clients with in-depth market research, ranging from device usability and preferences and competitive analysis to training and onboarding benchmarking. We also prepare you to get the most out your launch with customized utilization and commercialization strategies, including forecasting, best practices for training devices and patient support, lifecycle management, a revolutionary Train the Trainer program, and more. Plus, Noble's reach spans the globe – with major facilities located in Orlando, Florida and Ningbo, China – so when you're ready to ship, we are well equipped to handle your global logistics management and help you navigate the nuances of shipping your patient training resources worldwide.

Experience The Noble Difference

Noble is changing the future of adherence and onboarding through research-driven insights, innovative technologies and patient-focused solutions. Our products drive innovation to make a true impact, and our advanced strategies – from development to commercialization to utilization – are purpose-built to help transform your bottom line. Find out how Noble can make a world of difference for your patients and your brand.

Erin Miller, Marketing Coordinator, Noble, is responsible for supporting marketing and advertising efforts through copywriting and editing as well as content creation for Noble's print and digital communications platforms.

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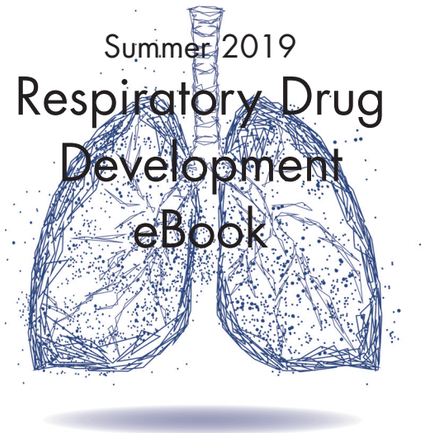
Graduate to a Respiratory Drug Delivery Conference

The Respiratory Drug Delivery (RDD®) conference aspires to be a source of learning about the latest trends in pulmonary and nasal drug delivery from pioneer-researchers, business professionals, and regulators. New thinking and product ideas stem from formal presentations as well as chance conversations, and attendance at RDD meetings continues to thrive because of sustained engagement in all the signature features of the RDD international conference series. Our curriculum includes:

- Invited speakers in thematic sessions with expert-moderated discussion of pivotal issues in pulmonary and nasal research, development, and product design;
- Focused, industry-centric workshops or Platinum Sponsor seminars for small-group, customized learning experiences;
- One-on-one information exchange and brainstorming during the Scientific Poster Session and Technology Exhibition;
- Formal and informal networking opportunities from breakfast to the gala dinner in a business-friendly environment;
- Concise exposure to new ideas and researchers during Posters on the Podium;
- Recognition of key thought leaders and distinguished researchers in aerosol delivery through the Charles G. Thiel Award;
- Encouragement of new investigators via the RDD VCU Peter R. Byron Graduate Student Award; and
- Inspiration and information from peer-reviewed conference proceedings and a searchable electronic database containing more than 2,400 focused articles.

Like collaborators at a university, whenever the opportunity arises, RDD partners with organizations that share our passion for advancing the delivery of drugs to the lung and nose for the prevention, mitigation or cure of disease. This allows meeting delegates to travel to a single, internationally accessible location and derive maximum learning and value for their time and money. An example of this 'twofer' model is our coordination with the International Pharmaceutical Aerosol Consortium on Regulation and Science (IPAC-RS) at RDD 2020.

Respiratory Drug Delivery 2020 (April 26-30) and the IPAC-RS symposium on The Global Regulatory Landscape and Advances in Digital Technology: Transforming the Patient Experience with OINDPs (April 30-May 1) will both take place at the JW Marriott Desert Springs, Palm Desert, California. Now is the time to decide how you will participate. While simply attending one or both events as a delegate is a great learning and networking opportunity, we hope you will consider nominating a speaker (it could be you) or presenting a poster. Speaker suggestions are due by August 1, 2019 while poster abstracts are due by January 13, 2020. Companies may want to consider the benefits of exhibiting, sponsoring or advertising at the conference to showcase their services and innovations. We are also actively seeking nominations for the Charles G. Thiel Award for excellence in pharmaceutical aerosol science (the deadline is November 30, 2019), and all graduate student poster presenters will be automatically eligible for the RDD VCU Peter R. Byron Graduate Student Award, which defrays the cost of attending the conference for the winning student by up to $2,000. Details are available at rddonline.com/rdd2020 or by contacting us at **info@rddonline.com** or 804-827-1490.



Conference delegates (students of respiratory drug delivery) report the pace of nasal and pulmonary research and product development is increasing and becoming ever more collaborative and international. This is reflected in the global reach of RDD conferences that now convene regularly in Europe and Asia in addition to the United States.

Having just wrapped up the largest RDD Europe conference to date in Portugal, plans are already underway for RDD Europe 2021, which will be held in Antibes, France (May 4-7, 2021). If you can't wait that long, RDD Asia 2020 will convene in Fall 2020 and is an excellent way to connect with researchers and customers in this vibrant hotspot for pulmonary and nasal drug delivery.

We hope you will join us at future RDD conferences. You can learn about all RDD programs and opportunities for participation by visiting **rddonline.com.**

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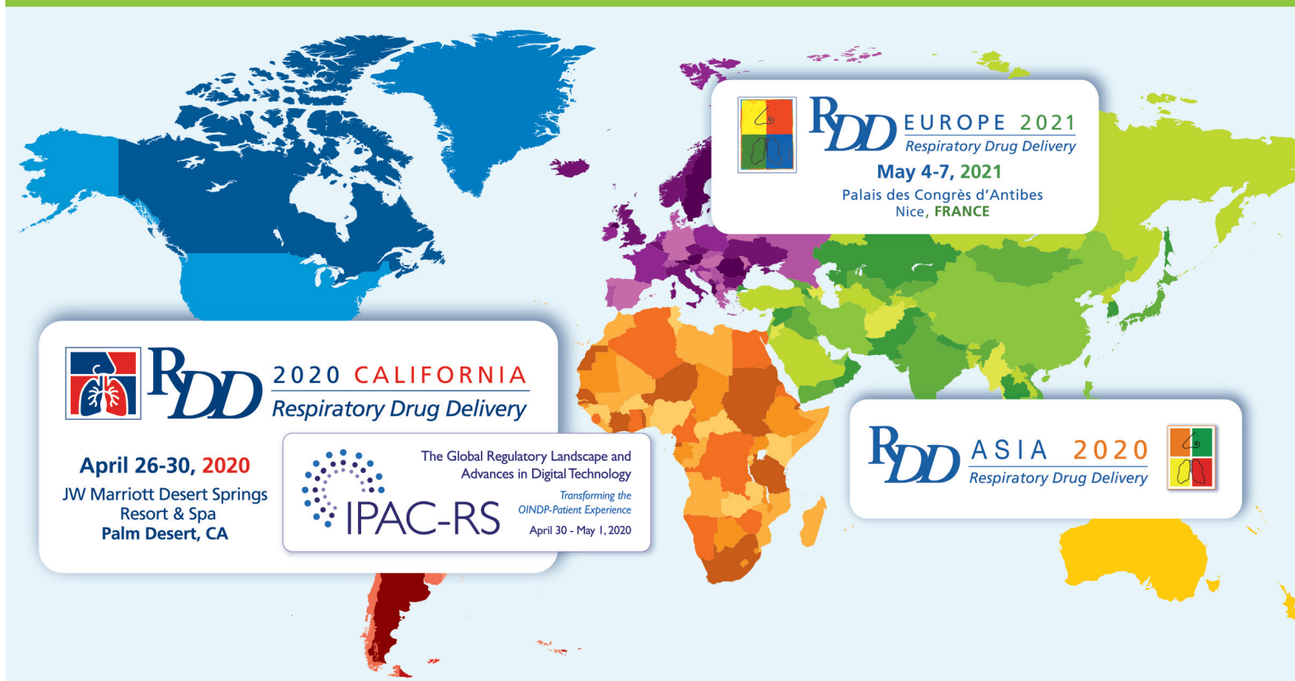

Respiratory Drug Delivery (RDD®) conferences bring representatives from the world's pharmaceutical companies active in nasal and pulmonary product development together with their suppliers, service providers, and regulators in a relaxed learning atmosphere that facilitates open communication.

Join us at RDD 2020

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