MINISTRY OF FOREIGN AFFAIRS OF DENMARK
The Trade Council

LÆGEMIDDELSTYRELSEN
DANISH MEDICINES AGENCY

FDA-EMA
4-part Virtual Seminar Series

Regulatory developments & trends in medical products regulation

The Embassy of Denmark in Washington, DC and The Danish Medicines Agency are proud to present a 4-part virtual seminar series in collaboration with the **U.S. Food and Drug Administration (FDA)** and the **European Medicines Agency (EMA**). Each session will focus on a specific theme addressing related topics and incorporate recent examples and relevant cases. Sessions will be interactive with a Q&A period following each presentation. Session titles are shown below with detailed descriptions of each in the following pages.

Session 1	**Transatlantic Cooperation in Medical Products Regulation**	**March 22**
Session 2	**What's new in Oncology?**	**April 19**
Session 3	**Patients in Drug Development & Regulatory Processes**	**May 17**
Session 4	**Innovations in Therapy & Digital Transformations**	**June 14**

Why attend?
- Hear the latest developments in regulatory science directly from FDA & EMA
- Follow current trends in adapting regulations in the development and innovation of drugs and medical technologies
- Understand critical changes underway to create successful strategies in the USA & Europe.
- Benchmark your regulatory strategies against agency requirements
- Reserve a brief private one-on-one meeting with FDA & EMA officials

Who should attend?
Professionals in Research & Development, Regulatory Affairs, Medical Affairs, Corporate Strategy & Business Development, Market Access & Policy, Health Technology and Patient Advocacy

This announcement includes:
- Session Descriptions
- Session 1 - Program & Speakers
- Background on the 4-part series & Practical information
- Registration Form & Reservation for 1-1 meeting with speakers

Registration deadline March 18, 2021

FDA U.S. FOOD & DRUG ADMINISTRATION

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Session Descriptions

Session 1 **Transatlantic Cooperation in Medical Products Regulation** **March 22, 2021**

This introductory seminar will present global trends and challenges facing regulatory bodies in Europe and USA, and how these agencies cooperate to address innovation, advancements, and approvals of new medical products from drugs to vaccines and beyond. In this first session, participants will learn about the scope of FDA's engagement in Europe as well as the FDA and EMA collaboration. Regulatory experts will present examples from pediatrics, rare diseases, advanced therapy challenges and recent developments of counter-measures to COVID-19. This session will provide the foundation upon which the future sessions on oncology, patient engagement, and digital transformations are built.

Session 2 **What's New in Oncology?** **April 19, 2021**

Drug development for treating cancer is one of the fastest growing areas of regulatory science, and one that has had long had strong collaborations across the European Medicines Agency and the US Food and Drug Administration. Experts from the two agencies have been meeting monthly to discuss applications and challenging issues in cancer every month for a decade. In this session, FDA and EMA experts will share perspectives on novel approaches in oncology from both regions, showcasing their work together as well as sharing how perspectives are similar and not. Precision medicine, tissue independent cancer treatments, the challenges of advanced therapies, development and use of master protocols, and transforming activities like FDA's Oncology Center of Excellence and other programs in Europe, including Denmark, and how programs complement each other will be covered.

Session 3 **Focus on Patients in Drug Development and Regulatory Processes** **May 17, 2021**

Patient focus in drug development has been a long needed and major force in recent years, and regulatory agencies have led the charge for change, offering a variety of different approaches that serve to complement each other. In the United States, legislation like the 21st Century Cures Act has ensured that FDA develops strong programs to ensure robust programs included in a framework for Patient Focused Drug Development, focusing first on the experience of living with a disease as a way to guide clinical trial design and even product development. In Europe, patients, consumers, and their organizations have long been active participants in EMA's activities, including as members of scientific committees (orphan diseases, pharmacovigilance and others), being consulted during medicines life cycle, reviewing labelling and safety communications, and most recently as part of the EMA COVID-19 Task Force. In this session, the agencies will share their approaches, learnings and continuing challenges, including how they are learning from each other though the FDA-EMA Patient Engagement Cluster. In Denmark, a Citizens' Council within the DKMA remit has been established in order for citizens to provide the agency with their input, perspectives and experiences. Focus will be centered around tasks with a direct interest for citizens, such as side effects, PILs, compassionate use and the shift from biologicals to biosimilar medicines. How the agencies are advising companies and patient advocacy groups on how to optimize their work in this critical area, including the challenges, will be discussed.

Session 4 **Innovations in Therapy & Digital Transformations** **June 14, 2021**

Transformational research in biomedical science is bringing new treatment opportunities and innovation across the lifecycle of medicines. Examples include the explosion of advances in cell and gene therapies, biomarkers and novel manufacturing technologies. These are increasingly coupled with innovations in clinical trial design, conduct and analysis that strive to streamline ascertaining the safety and efficacy of new products. Such advancements and innovations pose new regulatory and scientific challenges, calling for Agencies to be nimble and actively engage with innovators to ensure advances in product development are met with equally innovative regulatory science. This session will offer insight to how these programs work with examples of how companies can prepare to take advantage of them.

Amplifying advances in biology and methodology, digital transformation in healthcare and research has catalyzed clinical trials operations, endpoint measurement and data assessment. Here, too, it is essential for regulatory agencies to think strategically about how to adapt and respond rapidly and collectively, especially sharing learnings globally. In this session, you will hear how the Danish Medicines Agency, EMA and FDA are seizing opportunities offered by digital transformation and collaborating to not only support innovative approaches in therapy, but build new tools for doing so, such as through the EMA's Digital Business Transformation Task Force, the DKMA Data Analytic Center and FDA's Digital Health Center of Excellence.

Session 1*

Transatlantic Cooperation in Medical Products Regulation

14:00 – 14:10 **Welcome**
Dr. Thomas Senderovitz, Director General,
Danish Medicines Agency

14:10 – 14:25 **Bird's eye view: The Why and How of the FDA Europe Office**
Rita Nalubola, PhD, Director, Europe Office,
US Food and Drug Administration

This session will focus on the FDA's role in outreach and connectivity across a variety of product types, including how FDA bridges activities across the spectrum of trade matters, health policy, public health and mutual recognition

14:25 – 15:00 **Focus on Medicines:**
The FDA & EMA Collaborations in Action –
Connecting Regulatory Science Experts.
Dr. Sandra L. Kweder, Deputy Director, Europe Office, FDA Liaison to EMA,
US Food and Drug Administration

Anabela Marcal, EMA Liaison Official to FDA, International Affairs,
European Medicines Agency

FDA and EMA officials will describe in more detail how the Agencies connect regulatory science experts. They will highlight the various types of interaction and collaboration, including how their system of expert clusters works and the kinds of topics discussed. Examples of their collaborative work covering a wide range of areas from pediatrics to rare diseases and advanced therapy product challenges will be discussed.

15:00 – 15:15 **Break**

15:15 – 16:30 **Case Study**

How FDA-EMA partnership paves the way for global collaboration in COVID-19 and what that means for industry and the public health. Examples likely to cover clinical data, drug development advice, inspections, real world evidence and its role

Dr. Sandra L. Kweder, Deputy Director, Europe Office, FDA Liaison to EMA,
US Food and Drug Administration

Dr. Agnes Saint-Raymond, Head of Division of International Affairs,
European Medicines Agency

16:30 – 17:00 **Q&A / Adjourn**

17:00 – 18:00 Separate One-on-One sessions (10-15 min each)
FDA and EMA (all speakers, potentially others as case warrants)

*** Final program can be subject to changes**

Speakers

Ritu Nalubola, Ph.D., Director of the Europe Office, FDA Office of Global Policy and Strategy. Before assuming this role in July 2018, she served as a Senior Policy Advisor in the FDA's Office of Policy in the Office of the Commissioner. She advised senior leadership at the FDA, the Department of Health and Human Services, and other U.S. government agencies on complex and cross-cutting policy issues, including those related to biotechnology, nanotechnology, food safety, nutrition, and trade-related matters. Most recently, Dr. Nalubola served as the primary lead for FDA's efforts, working in conjunction with the broader U.S. government, in modernizing the federal regulatory system for biotechnology products. She has been the agency's voice on this subject in numerous domestic and international fora.

Dr Agnès Saint-Raymond, **Head of International Affairs and Head of Portfolio Board at EMA.** Dr Saint-Raymond is an MD and qualified Paediatrician and joined the European Medicines Agency (EMA) in 2000 and was responsible for Orphan Medicines, Scientific Advice, the Small & Medium-sized Enterprises Office, and Paediatric Medicines Sector, implementing the EU Regulation on paediatric medicines. In 2013, she became Head of the Portfolio Board Division, providing oversight of projects for EMA. Since November 2016, she is also the EMA Head of the International Affairs Division

Dr. Thomas Senderovitz , Director General of the Danish Medicines Agency. Dr. Senderovitz holds several posts in the EU Medicines Regulatory Network, e.g. chair of the Heads of Medicines Agencies Management Group and member of the European Medicines Agency's Management Board. In Denmark, he is member of the Reference Group for the Center of Public Leadership, University of Aarhus, of the Board of the Danish Strategy for Personalized Medicine and of the newly- established Data Ethics Council.

Sandra L. Kweder, M.D., Deputy Director of the Europe Office, FDA Liaison to EMA, FDA Office of Global Policy and Strategy . Before joining OGPS, Dr. Kweder was Deputy Director, Office of New Drugs in FDA's Center for Drug Evaluation & Research (CDER). In CDER, she actively led several initiatives including improvements in the drug review process, modernizing non-prescription drug review, building a systematic drug shortage prevention and management program, patient-focused drug development and clinical outcomes assessment, and the growth and development of pediatrics and maternal health as standard aspects of drug development.

Anabela Marçal, EMA Liaison Official to FDA since July 2020. Previously Ms. Marçal had an active role in activities for the implementation of the new EU Clinical Trials Regulation, becoming Head of Clinical Trials in 2020. She was also Head of Committees and Inspections Department and was closely involved in international collaboration initiatives, including work on Mutual Recognition Agreements. Ms Marçal joined the EMA in 1999 where she held positions in pharmacovigilance, post-authorisation regulatory procedures, compliance and GXP inspections, clinical trials and management of EMA's Scientific Committees.

About the FDA-EMA Virtual Seminar Series

Due to the pandemic, the Danish Embassy in Washington, DC has not been able to host the annual FDA Seminar in Denmark. Instead, we are pleased to offer a exciting series of seminars led by FDA and EMA officials addressing regulatory developments and trends in the USA and Europe.

During the 4-part series of focused seminars, FDA and EMA officials will present how they work together and where they are different in addressing innovation, advancements and approval of new medical products.

This is a unique opportunity to hear directly from FDA and EMA officials and one you do not want to miss!

Practical Information

Registration fee

The registration fee of DKK 1500 per person includes participation in all sessions, materials, a certificate of participation, session recordings, and the opportunity for a brief 1:1 consultation with FDA/EMA officials. Registration for single sessions is not allowed. **Deadline for registration is March 18, 2021**

Format

Each session will run from 14:00-17:00 cet. The program will be interactive with Q&As following each presentation with regulatory officials. A break will be held in the middle of the program. Microphones will be muted but questions can be submitted in the ”chat” function. The 1-1 sessions will run from 17:00-18:00 cet in separate pre-assigned virtual rooms.

Upon Registration

Participants will receive a confirmation email acknowledging registration. A separate mail will be sent providing access to and technical information about the series and links for participation. Updates will be sent over the length of the seminar series with relevant information such as; upcoming program agenda and speakers, reminders, request to complete a short exit survey after each session, etc.

Contact

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Registration is for the entire series of virtual FDA-EMA seminars

REGISTRATION FORM

The registration fee covers the entire 4-part series of seminars. Registration includes seminar participation, materials, certificate of participation, recording of the sessions, and the opportunity for a brief consultation with FDA/EMA officials (first come basis). Registration is binding and considered agreement to pay, unless cancellation received by March 18, 2021

_____ I want to participate in the FDA-EMA 4-part Virtual Seminar Series (mark required).
_____ I agree to pay the registration fee of DKK 1500 per person (mark required)

Name: _____

Title/Department: _____

Purchase Order (PO) Number (if applicable in your company): _____

Company Name & EAN Number: _____

Address: _____

Your Phone: _____

Your Email: _____

Name/Initials of person to be sent invoice:_____

Email address: _____

1-1 Consultations
I would like to reserve a consultation of 10-15 minutes with the speaker(s). Participants from the same company may reserve as group. Please identify the speaker and the general topic(s) you wish to address here:

Briefly describe topic (below) & select agency for session (right)	FDA	EMA	FDA & EMA

Consultations assigned on a first-come basis

_____
Signature Date

Registration Deadline – March 18, 2021

Return completed registration form to Hans Magnussen hanmag@um.dk