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June 19 – 21, 2018 | Boston, USA

www.combinationproducts-lifecycle.com

Combination Products Lifecycle Management Summit 2018

Maximize Your Combo Products' Competitive Advantage & Extend Market Life through Excellent Quality & Innovations

Chairman:

Mike Stelmah
Director, Regulatory Affairs CMC & Combination Products
Alnylam Pharmaceuticals

16+ Keynote Speakers Include:

Mathias Romacker
Senior Director, Device Strategy
Pfizer

James Dishong
Global Head of Medical Device Development Operations
Sanofi

Matthew James Clemente
CTO, Connected Product Solutions
Eli Lilly

John Schalago
Global Regulatory Affairs TA Head Devices
EMD Serono

Steve Bowman
Device Program Lead
Shire

James Wabby
Executive Director, Regulatory Affairs
Allergan

"Although you have been in this industry for decades, you will still learn a lot from this conference!"
Shire, Hanson Wade Event Past Attendee

Media Partner

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Welcome to Combination Products Lifecycle Management Summit

With increasing competition, costs and patent cliffs, developers of combination products must innovate and continue to improve product features to drive commercial competitiveness, while maintaining a quality drug-device for patient safety and adherence.

Building on 7 years of experience and success in the injectable community, the **Combination Products Lifecycle Management Summit** will offer a unique platform for industry leaders in the space to exchange ideas and insights on how to:

- **Increase speed to market** and ensure smooth approval process – from pre-launch to post-market safety reporting
- **Mitigate your risks and investment costs**, and refine your quality risk management approach throughout end-to-end LCM
- **Extend product longevity** with the latest innovations in connected technologies

This must attend summit forum will give you access to **practical case studies providing actionable insights** which you can implement immediately to keep up with the rapidly changing landscape of combination products!

What Previous Hanson Wade Event Attendees Have Said:

"I found this conference enjoyable and learned a lot. Several of the speakers shared their own experiences and lessons learned, which I will be able to directly apply in my job"
Pfizer

"This conference exceeded all of my expectations. The topics, speakers and suppliers were very relevant to my interests. I was able to walk away with many ideas and contacts to benchmark with!"
GSK

5 Spotlight Talks for Actionable Insights

1. **Shire** reveals how to define LCM roadmap with user research to maximize device lifespan

2. **Biogen** guides you on tactics to handle change management, quality events and post-market safety reporting

3. **Eli Lilly** showcases how connected platforms can leverage commercial competitiveness of combination products

4. **Merck** shares tips on maximizing combination products' shelf life through better quality risk management

5. **Sanofi** discusses lessons learned from speed to market at launch vs. speed to market of next generation products to help you increase efficiency

Your Expert Speakers

Mike Stelmah
Director, Regulatory Affairs CMC & Combination Products
Alnylam Pharmaceuticals

Mathias Romacker
Senior Director, Device Strategy
Pfizer

James Dishong
Global Head of Medical Device Development Operations
Sanofi

James Wabby
Executive Director, Regulatory Affairs
Allergan

Matthew James Clemente
CTO, Connected Product Solutions
Eli Lilly

Laura Polin
Global Commercial Director, Inflammation & Immunology
Pfizer

Michael Doyle
Director of Medical Device Regulatory & CMC
Pfizer

Ning Yu
Principal Engineer, Technical Development
Biogen

Steven Holcroft
Head of Regultaory Compliance, Enterprise Combination Products
Johnson & Johnson

John Schalago
Global Regulatory Affairs TA Head Devices
EMD Serono

Steve Bowman
Device Program Lead
Shire

Leonel Vanegas
Medical Device & Combination Product Quality Director
Merck

Jonathan Amaya-Hodges
Senior Manager, Regulatory Affairs CMC Combination Products & Medical Devices
Biogen

Michael Song
Snr Manager R&D, Drug Delivery & Device Development
MedImmune

Nan Yung Lin
Associate Director, Product Development
Dermira

Jeffrey Schacherl
Project Manager, Advanced Device Technology & Innovation
Amgen

Steven Badelt
Founder & Managing Partner
Suttons Creek, Inc.

Dirk Kreder
Founder & CEO
anteris medical GmbH

Christian Marc Schmidt
Founder & Principal
Schema Design

"Really focused and practical discussions. Engaging and informative!"
Astellas

Pre-Conference Workshop Day | Tuesday, June 19

Workshop A

Lifecycle Management of Combination Products – Regulatory & Development Timelines

08:00 – 11:00

Combination products, as the term implies, draw from the pharmaceutical and the medical device industries, and force developers and regulators into a complex and challenging evaluation of opportunities and risks. From a commercial perspective, market players act to prolong the commercial life of a product, counter a competitor's move, increase the products value by offering additional value to the patient, or simply bring a product up to the standard of care. Whatever the change to the product, a series of regulatory, commercial, or supply chain consequences have to be considered to make the effort successful.

The workshop is intended to develop a comprehensive and actionable framework for decision makers or development teams in an interactive fashion, allowing participants to

- Gain an **overview of market trends** and ongoing changes in the combination product market
- **Assess the expected regulatory consequences of LCM** changes to a combination product
- **Evaluate commercial strategies** regarding their likelihood of achieving the intended goal and their competitive value

Workshop Leader
Dirk Kreder, Founder & CEO,
anteris medical GmbH

Dirk founded anteris medical GmbH in 2014, supporting companies to develop medical devices, such as autoinjectors, biosimilar drug/device combination products, with a particular focus on shortening development timelines and registration pathways.

Prior to this, Dirk was the Global Program Leader at Sandoz Pharmaceuticals, leading lifecycle management efforts for the development of complex generics and biosimilars (generic Copaxone®, Omnitrope®, the first biosimilar in regulated markets, and a biosimilar monoclonal antibody).

Dr. Dirk Kreder holds a Ph.D. from University of Stuttgart, and an International Executive MBA. He has worked for several Biotech and Pharma companies in the US, Switzerland, and Germany.

> "This was one of the best conferences I've been to in years. Specific to the business needs, applicable to current situations facing pharma"
> **Sanofi**

Workshop B

Design Thinking for Product Innovation

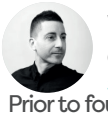
11:30 – 14:30

Product innovation plays a pivotal role for combination products – not only from a commercial life-cycle management standpoint but also through incorporation of a patient centricity approach.

You will hear how Amgen applied Design Thinking to develop an innovative application to manage knowledge of the drug delivery technology landscape and pipeline.

This focused and interactive workshop will help you:

- Understand how to turn pain points into design opportunities
- Learn methods for concept ideation and envisioning
- Translate concepts into actionable solutions
- Validate designs as you go by involving the end-user in the design process



Workshop Leader

Christian Marc Schmidt, Founder & Principal, **Schema Design**

Prior to founding Schema in 2012, Christian worked at the design firms IDEO and Pentagram, and was an interaction designer at Microsoft. His experience spans the fields of information design, interaction design, and media installation. He holds a BFA from Parsons School of Design in New York, and an MFA from Yale University. His work has received recognition from organizations such as D&AD, the American Institute of Graphic Arts (AIGA), the Society for Environmental Graphic Design (SEGD), Communication Arts, Print Magazine, and the Industrial Designers Society of America (IDSA). Christian has taught in the Interactive Telecommunications Program (ITP) at New York University and the Visual Communication Design program at the University of Washington.

Workshop Leader

Jeffrey Schacherl, Project Manager, Advanced Device Technology & Innovation, **Amgen**

Jeffrey joined Amgen in 2016 as a founding member of Amgen's Device Technologies Innovation Center in Cambridge, Massachusetts. Jeffrey's responsibilities focus on technology strategy, guiding evaluation and development of innovative drug delivery and device technologies to advance Amgen's mission to serve patients. Jeffrey holds several patents and has over 6 years of experience in early technology development, medical device design and combination product development through commercialization. Prior to joining Amgen, Jeffrey completed his research fellowship through MIT with Sanofi in Frankfurt, Germany, and earlier worked as a Mechanical Design Engineer for Plexus Corporation in Neenah, Wisconsin and Darmstadt, Germany. Jeffrey earned a Master's degree in Mechanical Engineering and MBA from the Massachusetts Institute of Technology and Bachelor's degree in Mechanical Engineering from the University of Wisconsin-Madison.

Workshop C

Integrating Connectivity Into Your Devices & Your Company

15:00 – 18:00

Digital add-ons have become extremely popular amongst combination products developers. Recent evidence demonstrates significant return on investment for connected health in pharma.

This workshop will inform your decisions about integrating digital health into the pharmaceutical domain. By the end of this session, you should be able to:

- Assess the quality, lifecycle, and regulatory impacts of digital health across your organization
- Recognize common execution risks and how to mitigate them
- Evaluate technology platforms and business models

Workshop Leader

Steven Badelt, Founder & Managing Partner, **Suttons Creek, Inc.**

Steven W. Badelt, PhD. is a seasoned expert in product development, engineering management, business development, and systems engineering. He has over 20 years of experience in the design and launch of combination products and medical devices, including auto injectors, insulin-pumps, implantable defibrillators, wireless plaforms, and patient management software. Steve is the Founder & Managing Partner of the biotech consulting firm Suttons Creek, Inc., which serves as the device team for pharma.

Conference Day One | Wednesday June 20, 2018

8.00 Welcome Coffee & Registration

Mike Stelmah
Director, Regulatory Affairs CMC & Combination Products
Alnylam Pharmaceuticals

9.00 Chair's Opening Remarks

Combination Products – Global Opportunities & Challenges

James Dishong
Global Head of Medical Device Development Operations
Sanofi

9.10 Keynote Address: Be the Influencer – Optimizing the Value of Your Combo Product

- Balancing risk vs. reward of the launch configuration
- Facing competitive realities of the drug and device attributes
- Looking for value bending opportunities in the combo product's lifecycle

Steven Holcroft
Head of Regultaory Compliance, Enterprise Combination Products
Johnson & Johnson

9.40 A Makeover – Reviving Your Existing Combo Products

CASE STUDY

- Late stage lifecycle of combo products (20+ years) – what can you do to maximize shelf life?
- How to handle regulatory compliance and inspections?
- Case study: lessons learnt and best tips

10.10 Morning Refreshments & Speed Networking

James Wabby
Executive Director, Regulatory Affairs
Allergan

CASE STUDY

11.40 The Coupling Effects – How to Handle the Lifecycle of Combination Products from a Risk & Regulatory Compliance Perspective?

Combination products are a hot topic in healthcare. These products combine two areas of medicine: medical devices and drugs/biologics. While these products open doors to exciting new possibilities in the medical world, they also bring new challenges.

This session will discuss the importance of promoting a culture of compliance to build a compliant lifecycle management infrastructure around combination products to ensure appropriate cGXPs and Quality System regulations are enforced throughout the franchise. Open discussions, case studies and dialogue will be included.

- From clinical trial to launch: Addressing regulatory expectations and differences for devices and drugs, how to manage parallel development programs and minimize risks?
- Outlining best practice of handling adverse effects and complaints throughout drug/device lifecycle
- Establishing an on-going and rigorous post-market surveillance strategy to identify product, design, and process improvement
- Developing effective regulatory inspection strategies at launch and post-launch at multi-sites to ensure compliance
- Discussing challenges and opportunities

From Product Development Pathways to Program Management

Mike Stelmah
Director, Regulatory Affairs CMC & Combination Products
Alnylam Pharmaceuticals

12.10 When Change is Constant – How Best to Manage?

- Setting requirements, design controls and managing changes
- Considerations before making a change: rational and testing
- Update on FDA Design Control and ISO 13485 requirements
- What is the best way to submit and file your change to regulatory agencies?
- Full assessment and validation of consequences of 'change' – from technical to quality perspectives

12.40 Lunch & Networking

Nan Yung Lin
Associate Director, Product Development
Dermira

13.40 A QbD Approach to the Characterization of a 2mL PFS for a Biologics Combination Product
- Addressing challenges of defining and concerting two or more products' development timelines
- Evaluating strategic product and program planning from resources' perspectives
- Ensuring speed-to-market and developing a winning USP from commercial considerations – case study of launching a smaller needle delivery platform for both PFS and autoinjectors

Ning Yu
Principal Engineer, Technical Development
Biogen

14.10 Improve Usability & Manufacturability through Second Generation Design
- Define LCM needs based on functionality, usability and manufacturability
- Prioritize and strategize needs and design solutions
- Prototype and optimize design
- Verification/validation and implementation

14.40 Afternoon Refreshments & Networking

Maximizing Your Combo Products' Commercial Opportunities

15.10 Roundtable Discussion
Audience can choose a specific topic to discuss and share their challenges with colleagues. Through open dialogues, we hope to facilitate knowledge exchange and spark inspiration to help you find solutions to your daily problems.

Track 1:
Tackling challenges with quality control of combination products during design change: Defining best practice

Track 2:
Analyzing regulatory pathways and re-approvals for combination products throughout lifecycle

Track 3:
Discussing product development and continuous improvement approach – how do you deal with suppliers' change requests?

Moderated by:

Mike Stelmah
Director, Regulatory Affairs CMC & Combination Products
Alnylam Pharmaceuticals

CASE STUDY

Steve Bowman
Device Program Lead
Shire

16.00 Roadmap of Lifecycle Management for a Rare Disease Designated Combination Product
- Reviewing product life cycle management from vial to PFS and beyond
- Addressing specific requirements and considerations for combination product development
- When connectivity becomes part of lifecycle management
- Understanding the importance of user research to maximize device lifespan

Mike Stelmah
Director, Regulatory Affairs CMC & Combination Products
Alnylam Pharmaceuticals

16.30 Chair's Closing Remarks

16.35 Close of Day One

Conference Day Two | Thursday June 21, 2018

8.00 Coffee & Registration

Mike Stelmah
Director, Regulatory Affairs CMC & Combination Products
Alnylam Pharmaceuticals

9.00 Chair's Opening Remarks

Looking Ahead – Next Generation Combination Products

John Schalago
Global Regulatory Affairs TA Head Devices
EMD Serono

9.10 The Regulatory Future of Connected Combination Products

CASE STUDY

- Digitalization: electronic-enabled combination products to enhance disease management – regulatory perspective
- Tackling hurdles of connectivity for combination products: technology, regulatory and time-to-market considerations
- Looking ahead - impact of MDR changes for Combination Products and implementation in 2020

Michael Song
Snr Manager R&D, Drug Delivery & Device Development
MedImmune

9.40 Technology Innovations to Leverage Your Patient Adherence & Drive Commercial Success

- Analyzing digital connectivity technology development
- Evaluating challenges and lessons learned so far – can this give you a commercial advantage?
- Exploring the most value-adding options for your intended users and combo products

Matthew James Clemente
CTO, Connected Product Solutions
Eli Lilly

10.10 The Digital World – How Much Longer Can Your Device Live?

- Is this a hype? Product life extension with digital platform
- When should you start embedding digital platforms into your products?
- Addressing the regulatory uncertainties – what do regulatory agencies think?

10.40 Morning Refreshments & Networking

Excellent Quality & Risk Management Systems

11.10 Master Mind: The Winning Team – Embed Creative Product Development & Portfolio Management in Your Combination Product Lifecycle Management

Combination product development requires multiple departments' input throughout the timeframe, especially during life extension and re-design.

This roundtable session will split the audience into groups for a discussion to re-define the best roadmap and LCM team structure. Each group will also have to identify one common pitfall and share one tip with peers at the end of this session to facilitate knowledge exchange and help you find solutions to your daily problems.

Combination Products Supporting Functions	Different Stages of Lifecycle
• Marketing & Commercial • Project Director/ Combo Product Lead • Regulatory Affairs/ CMC • QA • Engineers/ Scientists • Manufacturing	• Clinical Ph.3 – Pre-Launch • Launch • Yr 1- 3 post-launch • Yr 5+ post-launch

Led by:

Mathias Romacker
Senior Director, Device Strategy
Pfizer

 **Leonel Vanegas** Medical Device & Combination Product Quality Director **Merck**	**12.00 Ensuring the Quality of Drug-Device Combination Products Post-Launch** • Reviewing ICH Q9 risk management approach • Evaluating quality risk management system to ensure quality throughout the entire product lifecycle • Outlining unique challenges for combination products' post-launch changes • Ensuring clear documentation and considerations to be audit-ready
	12.30 Lunch & Networking
Session reserved for Expertise Partner	**13.30 Strategic Customer Engagements to Increase Life Span of Combination Products** • Investigating the most cost-effective and risk-free option to maximize lifecycle and fence off competition • Be the only choice of your customers – why patient engagement post-launch can be key to success • Acquiring a deep understanding of your customer behavior and experience to match your product design and brand strategy
 **Jonathan Amaya-Hodges** Senior Manager, Regulatory Affairs CMC Combination Products & Medical Devices **Biogen**	**14.00 Quality & Regulatory Affairs Best Practices for External Partnerships in Combination Product Development** • Reviewing current combination product regulations, guidance, standards, and expectations, particularly those relevant to partnerships • Moving beyond minimum compliance for combination product partnerships • Discussing best practices for combination product development from a quality and regulatory perspective • How to handle life cycle management, including change management, quality events, and post-market safety reporting
 **Mathias Romacker** Senior Director, Device Strategy **Pfizer**  **Laura Polin** Global Commercial Director, Inflammation & Immunology **Pfizer**  **Michael Doyle** Director of Medical Device Regulatory & CMC **Pfizer**	**14.30 The Worldwide Market Opportunities of Combination Products & What Does It Take Internally?** PANEL DISCUSSION • Trends of combination products – comparison between US and EU • Cost/benefits analysis of developing a combination product with effective lifecycle management • Market access and launch strategy to maximize commercial opportunities *We've invited 3 experts from different functions within Pfizer to share how to collaborate and align internal strategy throughout LCM, which will also drive strategic partnerships with external suppliers.* *Audience will also have the opportunity to ask panellists questions at the end of the session*
 **Mike Stelmah** Director, Regulatory Affairs CMC & Combination Products **Alnylam Pharmaceuticals**	**15.15 Chair's Closing Remarks**
	15.20 Close of Conference

"I appreciated that the conference covered broad spectrum of topics. This is a great forum to learn about combination products for folks who are new to it!"

Momenta

Partnership Opportunities

WHY PARTNER?

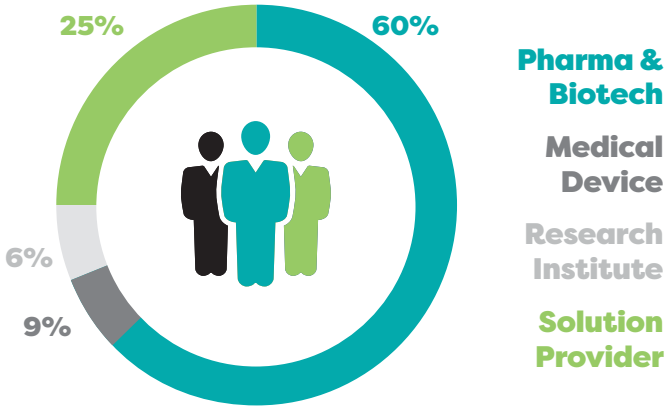
The last 12 months have been marked with significant milestones for pharma and device manufacturers.

With the latest focus on combination products and regulatory guideline updates, our audience is urgently seeking solutions in the following areas:

- **Lifecycle Management Solutions** to optimize end-to-end LCM of combination products development
- **Quality Risk Management and Design Control Solutions** to document and manage change, offering thorough quality assurance and risk dashboard to be audit-ready
- **Digital and Connectivity Platforms** to provide value-added features of the combination products, driving patient adherence
- **Combination Product Design** to enhance usability and commercial features
- **Regulatory and Project Management Advisory** to ensure on-time and on-budget delivery with the best coordination of multiple stakeholders, and smoothing out regulatory approval process

If you have a solution or product to help our community, please get in touch to discover bespoke partnership opportunities that will connect you with them.

TYPES OF COMPANIES ATTENDING*



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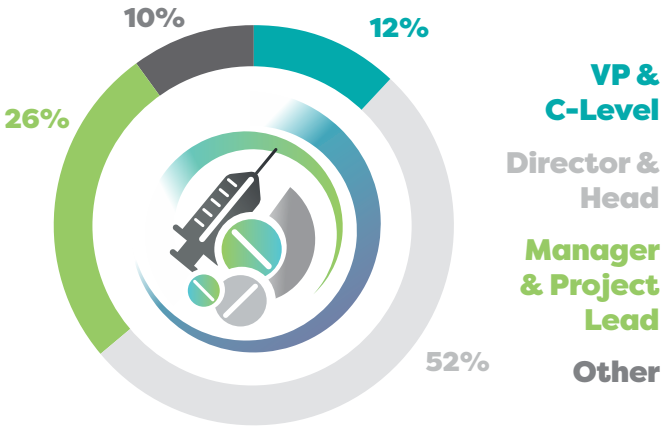

*Based on 2017 Injectables Series attendees' profile

WHO WILL YOU MEET?

60+ VPs, Directors, Heads, Leads and Managers of:

- Combination Products
- Device Strategy
- Device/ Combination Products Commercial/ Marketing/ Franchise/ Development
- Connected/ Digital/ Technology Platforms
- Regulatory Affairs & CMC
- Quality & Risk

From pharmaceutical, biotechs and medical device companies.

BECOME A PARTNER

Peter Trebelev
Partnerships Director
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READY TO REGISTER?

3 EASY WAYS TO BOOK

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> It was a very well prepared conference and where participants were very engaged and brought good energy and engagement into the conference and the discussions!
>
> **Novo Nordisk**

Team Discounts*

10% discount – 3 delegates
15% discount – 4 delegates
20% discount – 5 or more delegates

Please note that discounts are only valid when three or more delegates from one company book and pay at the same time.
Contact: register@hansonwade.com

*Special rate for academics at 40% discount available upon request

SECURE YOUR PLACE

Pharma & Biotech Pricing	Register & Pay before Friday April 6, 2018	Standard Prices
Conference & 3 workshops	$4196 **(save $700)**	$4596 **(save $300)**
Conference & 2 workshops	$3597 **(save $600)**	$3997 **(save $200)**
Conference & 1 workshop	$2998 **(save $500)**	$3398 **(save $100)**
Conference only	$2399 **(save $400)**	$2799
Workshop - Individual	$699	

Solution Provider Pricing	Register & Pay before Friday April 6, 2018	Standard Prices
Conference & 3 workshops	$4896 **(save $700)**	$5296 **(save $300)**
Conference & 2 workshops	$4197 **(save $600)**	$4597 **(save $200)**
Conference & 1 workshop	$3498 **(save $500)**	$3898 **(save $100)**
Conference only	$2799 **(save $400)**	$3199
Workshop - Individual	$799	

VENUE

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