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2nd Annual

CPLM Summit

Combination Products Lifecycle Management

June 25 - 27, 2019 | Boston, MA

www.combinationproducts-lifecycle.com

"Great speakers and case studies which brought great discussions to current challenges and opportunities"

James Wabby, Executive Director, Regulatory Affairs, Allergan

Boosting Your Combination Products' Life Span through Refining Your LCM Strategy

Your Expert Speaker Panel Include:

Suzette Roan
Senior Director, Global Regulatory Affairs
Sanofi

Michael Roe
Director – Device Development & Industrialization
Kaleo

John Schalago
Head, Global Regulatory Affairs, Devices & Applications
EMD Serono

Stephen Fournier
Director – Device Platform Management
Alnylam Pharmaceuticals

Kristina Lauritsen
Combination Products Regulatory Advisor
FDA

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WELCOME TO THE 2ND CPLM SUMMIT

Uniting Industry Pioneers to Transform the Success of Your Combination Products

ABOUT US

Lifecycle management in drug-device combination products has gained the spotlight in recent years. Drug-device developers have realized the long-term benefits of embedding an LCM mind-set at the R&D concept stage, as opposed to only applying such a program to legacy products. This will ultimately benefit our patients with **faster access to better quality and more affordable therapeutics** globally.

As the only industry-led community focusing on LCM, the inaugural meeting in 2018 was a huge success - gathering industry leaders from Combination Products Lead, Product Strategy & Commercial, Quality and Regulatory Affairs to share their challenges and discuss a common lifecycle framework.

The 2nd annual meeting will delve further into the trending topics by incorporating first-hand insights from the likes of **Teva, Novartis AG, Allergan** and **Sanofi,** such as: how to navigate in the **unknown regulatory framework** and **its implications to your combination products' launch** and **market access; best practices in design change control** and enhancing quality validation; exploring the **next innovative** and **commercially competitive combination products** for your patients - and **streamline the device development program** to be the first in market.

With plenty of fresh content and experts from diverse disciplines, you will not only learn but be inspired with unparalleled stories to succeed in this space!

SPOTLIGHT CASE STUDIES

1. **FDA** shares with you their combination products regulatory framework to drive quality products for patients
2. **Sanofi** reveals how they work with the FDA to ensure a smooth approval process
3. Be smart about platforming: **Alnylam** discusses how they optimized development time and costs and reduced risks through platform selection
4. **kaleo** - reveals how they can be the rising star by creating a unique combination products and embed LCM from the get go
5. Can you integrate drug-device product design and control for a seamless and collaborative program? **Novartis AG** shows you how it's done.
6. Focused workshop day to help you embed a UX-culture and LCM-mindset at the start of your combination products R&D design, and devise a fit-for-purpose QRMS throughout product lifecycle

"It was a great opportunity to meet our pharma colleagues, and better understand the trends and challenges of combination products lifecycle management!"

Director of Product, Sorrel Medical

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EXPERT SPEAKER PANEL

Suzette Roan
Senior Director,
Global Regulatory Affairs
Sanofi

Michael Roe
Director – Device Development & Industrialization
kaleo

Kristina Lauritsen
Combination Products Regulatory Advisor
FDA

Raihan Hossain
Associate Director of CH I&D Medical Device Quality
Bayer

John Schalago
Head, Global Regulatory Affairs, Devices & Applications
EMD Serono

Stephen Fournier
Director – Device Platform Management
Alnylam Pharmaceuticals

Helen Kim
Associate Director
RA, Device & Combination Products
Allergan

Prasad Peri
Senior Director
Regulatory Affairs
CMC
Teva

Leonel Vanegas
Quality Assurance Director
Medical Devices & Combination Products
Merck & Co.

H.E. Sengoku
Director, GRL Medical Devices/ Combination Products
UCB, Inc.

Margaret Kelly
Device Manager
Device Development & Commercialization
Novartis

Will Sutton
VP Engineering & Technology
Minnetronix Medical

Alastair Clarke
Managing Principal
Weaver Technical Solutions

Naveen Agarwal
Principal & Founder
Creative Analytics Solutions

John McMichael
Associate Director
AstraZeneca

Winifred Wu
President & Principal
Regulatory Strategy Partners, LLC

Jonathan Amaya-Hodges
Associate Director, Regulatory Affairs CMC Combination Products & Medical Devices
Biogen

"An informative, collaborative and great expertise speaker faculty!"

Head of GRA Devices, EMD Serono

PRE-CONFERENCE WORKSHOP DAY
TUESDAY, JUNE 25

08.30 – 11.30 **Workshop A**

How Regulatory Affairs Can Drive a Robust Combination Product with Business Continuity and Smooth Approval?

The fast-evolving regulatory environments in combination products can be challenging for drug-device developers. Gaining a thorough understanding is step one, but being able to leverage this will help ensure smooth approval, speed-to-market and maximize your product's commercial competitiveness.

This workshop will be separated into 2 mini sessions to give you a 360° view of managing your combination products from start to finish:

Session 1: How to Manage Post-Approval Change Details?

Change is inevitable during combination product's lifecycle. Being able to anticipate change and mitigate risks can ensure business continuity and maintain a quality product for patients. This session will look at the various types of specific changes using an example of PFS to auto injector for discussion.

- Prospective LCM changes from PFS to AI: design control and clinical bridging requirements
- Reactive LCM changes: supplier change for device constituent supplier: material/ component change, and device design change for enhanced safety features

Session 2: TPLC/ Line Extension Consideration for Your Next Gen Combination Products

- This session will explore the regulatory pathway and general data requirement to support a new presentation of existing combination product, and how RA can provide support during design control process.
- We will use a hypothetical line extension case for participants to discuss the data requirements of providing an additional presentation of a combination product for different intended users and use environments.

WORKSHOP LEADERS:

Winifred Wu
President & Principal
Regulatory Strategy Partners, LLC

Jonathan Amaya-Hodges
Associate Director, Regulatory Affairs CMC Combination Products & Medical Devices, **Biogen**

12.00 – 15.00 **Workshop B**

Turning Risks into Opportunities in Your Combination Product Development

Quality and risk management are no longer separate functions in a drug-device program. They should be heavily involved and integrated into the LCM from the beginning of the product design journey.

This session will help you understand:

- What a good QMRS framework looks like
- Why you should involve your risk management team early on
- Thinking outside the box – turning risks into an opportunity, how can you improve your product based on risk profile?
- Post-launch management in both changes and risks
- Why and how a good QMRS can increase your product's patient adherence

This will be a hands-on and interactive session with built-in exercises which we encourage you and fellow colleagues to get involved with for the best learning results.

WORKSHOP LEADER:

Naveen Agarwal
Principal & Founder
Creative Analytics Solutions

15.30 – 18.30 **Workshop C**

It All Starts from R&D – Product Design to Extend Lifecycle

This is obviously easier said than done, and this workshop will be a deep dive session , utilizing classic and successful case studies to benchmark on:

- How to embed a UX-culture and LCM-mindset at the start of your product design
- What are the parameters and considerations? Planning your next generation product early on
- Combination product progression – an incremental change can make a huge difference
- Who should you collaborate with? Market access and launch planning
- Case studies of successful product evolutions to capture patients' hearts

WORKSHOP LEADERS:

Alastair Clarke
Managing Principal
Weaver Technical Solutions

Prasad Peri
Senior Director, Regulatory Affairs, CMC, **Teva**

CONFERENCE DAY ONE WEDNESDAY, JUNE 26

08.00 **Breakfast & Registration**

09.00 **Chair's Opening Remarks**

Combination Products – The Fast Evolving Landscape

09.10 **Keynote Address: Who is in Charge? Securing Early Support from the FDA**

Suzette Roan
Senior Director, Global Regulatory Affairs
Sanofi

- Who should you engage within the FDA for your CP approval? The establishment of combination products office
- The challenges with drug-device combinations and different regulatory approval pathways
- What data should you provide? Human factors to clinical evidence

09.40 **Panel Discussion: How to Handle Regulatory Uncertainty and What Does It Mean to Your Combination Products' LCM?**

The changing requirements of EU MDR and post-marketing reporting have created a lot of concerns amongst drug and device manufacturers. We'll be asking panelists for their thoughts and experiences in handling this:

- FDA's current guidelines on combination products and post-market surveillance?
- Collaboration between RA and commercial and drug-device teams – ensuring a smooth transition and compliant combination product
- Are you ready for 2020? Handling the drastic change of EU MDR and its implications on combination products
- Where to start? Expectations from EMA for filing and securing your CE mark
- Impacts beyond EU – reference approval for APAC and Japan markets

Joined by:

Helen Kim
Associate Director, RA, Device & Combination Products, **Allergan**

Kristina Lauritsen
Combination Products Regulatory Advisor
FDA

Suzette Roan
Senior Director, Global Regulatory Affairs
Sanofi

10.20 **Morning Refreshments & Speed Networking**

From Product Development Pathways to Program Management

11.30 **Innovation Talk: Leveraging Medical Device Expertise to Develop Combination Therapies**

Will Sutton
VP Engineering & Technology
Minnetronix Medical

- Critical attributes of a drug delivery system / medical device development partner
  - Medical device quality and regulatory expertise
  - Proven design controls from requirements through verification
  - Usability – improving delivery accuracy, simplicity and compliance while reducing risk
  - User interface and human factors design
  - System architecture and integration of complex systems
  - Embedded software, electronics and electromechanical design
  - Scalability from prototype to trial to delivery system manufacturing
  - DFx – design for manufacturing, test, safety, usability, etc.
- State-of-the-art med device technologies beneficial to the pharmaceutical industry
  - Sensors, connectivity, wireless power, miniaturization, complex software/ hardware integration, batteries, data analysis, human factors, etc.

CONFERENCE DAY ONE WEDNESDAY, JUNE 26

11.45 **Embedding Lifecycle Management Early On – but How Early?**

- Why you should think about LCM at R&D stage?
- Balancing speed-to-clinic, commercial and quality aspects for a unique product
- Addressing the differences between drug and device development plans
- Pre- vs. post-launch considerations and risk mitigation strategy
- Having a clear roadmap to drive next generation products in a cost-effective and timely manner

Leonel Vanegas
Quality Assurance Director, Medical Devices & Combination Products
Merck & Co.

12.15 **Lunch & Networking**

13.15 **Excellent Integration of Design Control Throughout LCM**

- Can you integrate drug and device product design and design control for a seamless and collaborative program?
- Design control is not just documentation – it is a tool to help you develop and differentiate your product!
- How to manage change to minimize risks, costs and disruptions?
- From verification to validation – communication with your project teams and external suppliers to be audit-ready

Margaret Kelly
Device Manager, Device Development & Commercialization
Novartis

13.45 **From ICH Q12 to ISO Assessments – Delivering a Quality Drug-Device Combination Product with Continuous Improvements Post-Commercialization**

- Update on ICH Q12 and its impacts on product LCM post-launch
- The roles of CMC and QA: Establishing a robust quality management system to capture feedback for continuous improvements
- Challenges with change and multi-site operations – what's your best practice?

Session reserved for Program Partner

14.15 **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 inspirations to help you find solutions to your daily problems.

This is your opportunity to have direct and candid dialogue with your combination products colleagues. We will split the audience into mini groups of 10. Each group will be nominating a leader to kick off of a 30 minute high-paced discussion.

The objective is to offer 1 top tip for the rest of the delegation.

Track 1: Pharma needs to catch up on LCM – but who should be in charge?
Track 2: How should CMC and Regulatory Affairs engage with other functional teams to plan for PMS and EU MDR?

15.30 **Afternoon Refreshments & Networking**

16.00 **kaleo's Successful Injectable Story – From Concept to Product Commercialization**

- A winning product starts from early concept and engaging with the right stakeholders – from the FDA to ISO
- Ensuring a unique differentiator in your combination product design
- Is connectivity the answer?

Michael Roe
Director – Device Development & Industrialization
kaleo

16.30 **Be Smart – Strategic Platforming for Your Combination Products**

- Optimizing development time, costs and reducing risks through platforming
- How do you select your platform device and what are the important considerations during your LCM?
- It's not a one size fits all solution and due diligence is required

Stephen Fournier
Director – Device Platform Management
Alnylam Pharmaceuticals

17.00 **Chair's Closing Remarks**

17.10 **Close of Day 1**

CONFERENCE DAY TWO THURSDAY, JUNE 27

08.00 **Breakfast & Refreshments**

09.00 **Chair's Opening Remarks**

The Winning Partnerships to Develop a Winning Combination Product

09.10 **Keynote Address: Building the Engagement and Dialogue with the FDA**

- CDER vs Combination Products – who should you talk to?
- Current framework from the FDA and when you should start engaging?
- What does the regulatory agency expect?
- Q&A

Kristina Lauritsen
Combination Products Regulatory Advisor
FDA

09.40 **Case Study: How Can Quality Contribute to a Winning Product and LCM?**

- Change is constant – how should you handle that pre- and post-launch?
- Can you simplify your process without compromising on quality?
- Creating a process that help you mitigate risks – a case study of employing these techniques to manage change and CAPA

Raihan Hossain
Associate Director of CH I&D Medical Device Quality
Bayer

10.10 **Panel Discussion: What Does a Good Control Strategy Look Like and Its Importance to Drive a Sustainable Lifecycle?**

- From start to finish – is there an end-to-end change control for your combination products?
- Defining the processes and understanding what the FDA expects for quality control and assurance
- It's not a check-box exercise – developing a robust control framework to drive a sustainable LCM for your combination products to optimize your development timeline, costs and quality of products

John McMichael
Associate Director, Combination Products
AstraZeneca

Raihan Hossain
Associate Director of CH I&D Medical Device Quality
Bayer

10.40 **Morning Refreshments & Networking**

11.10 **Catching Up on the Digitalization Trend?**

- Are you all connected? Understanding the rapidly evolving regulatory framework
- What does it mean for your go-to-market strategy? The different scenarios for legacy products and candidates in the pipeline
- What are your considerations and how should you handle post-market surveillance reporting with the boom of connectivity?

John Schalago
Head, Global Regulatory Affairs, Devices & Applications
EMD Serono

11.40 **What Innovations Do You Need to Extend Your Combination Product Lifespan?**

- Device design matching tomorrow's patients' needs
- From concept to R&D to commercialization: how should engineering team collaborate with other functions
- It doesn't need to be revolutionary – incorporating UX to drive product development

Session reserved for Program Partner

12.10 **Lunch & Networking**

13.10 **Master Mind: How to Transition from a Mechanical to Electro-Mechanical Drug-Device Product?**

Connectivity is definitely the trending buzzword in 2018. While we have seen a surge of projects and activities across drug and device manufacturers, the transition from a pure mechanical to electro-mechanical drug-device isn't easy. In this mastermind session we will explore the following themes and seek solutions:

Who Should be Involved?

- Regulatory Affairs/ CM
- Engineers
- Software & hardware development
- IT, Infosec & cybersecurity
- Risk & quality management

Different Areas of Consideration

- Commerciality
- Usability
- Cybersecurity
- Patient data security
- Battery and device management

The audience will be split into a group of 10. During the 30 minute exercise and discussion, each group will have the opportunity to re-work the organization and process flow chart, and share your recommendation with the rest of the audience at the end of this session for comparison.

13.45 **Is Connectivity the Answer?**

- Is 'app' everything patient need?
- The overwhelming support from the FDA for connected devices
- Opportunities and risks in connected device
- From a single product entity to building an ecosystem to realize the full potential of digital combination products for best patient insights
- How to deploy and apply digital in clinical trials to accelerate timeline?

H.E. Sengoku
Director, GRL Medical Devices/ Combination Products
UCB, Inc.

14.15 **Chair's Closing Remarks**

14.45 **Close of Conference**

"This conference provides a unique opportunity to collaborate on key roadmap requirements set forth by the pharma & biotech companies and device manufacturers."

Director of Device Development, Genentech

WHO WILL YOU MEET?

100+
ATTENDEES

12+
HOURS OF DEDICATED NETWORKING

3
INTERACTIVE WORKSHOPS

SENIORITY

- **16%** VP/C-Level
- **30%** Director
- **16%** Head
- **13%** Manager
- **25%** Other

COMPANIES BY TYPE

Pharma & Biotech	**60%**
CMO	**10%**
Equipment & Device Component Manufacturers	**13%**
Consultancy & Research Institution	**17%**

*Figures based on CPLM 2018 attendees' profiles

2018 ATTENDING ORGANIZATIONS INCLUDE:

abbvie · ALEXION · Allergan · Alnylam · AMGEN · antares pharma · Biogen · Bristol-Myers Squibb · Boston Biomedical · Dermira · Lilly · EMD Serono · Fresenius Kabi · Genentech · gsk · kaléo · MedImmune · MERCK · novo nordisk · Pfizer · REGENERON · SANOFI · Takeda · West

"The networking opportunity was fantastic. The meeting had a broad range of topics which interested a diverse panel of participants".

Associate Director - Commercial Development, Safety & Systems-Self Administration Injection Systems

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PARTNER WITH US

The combination products community is eager to stay ahead of the curve through refining their lifecycle management approach. If your company offers services and solutions that would benefit our audience, we'd love to hear from you.

Combination Products Lifecycle Management Summit is dedicated to the community and serves as a unique platform for 100+ **VPs, Directors, Heads of Combination Product (CP) Commercial Leads, Quality & Risk, Regulatory Affairs and CMC** to share their LCM journeys so far and ideas and views towards best practices and innovations in this field.

Our community is actively seeking solutions in the following areas:

- Lifecycle and QRM systems
- Digital combination products platform
- Compatible and innovative combination products platform solutions
- Regulatory and project management advisory

This is your go-to community in 2019.

I'm looking for the right partners who can add value to our community and demonstrate thought leadership.

If you and your team are the trailblazers in combination products LCM, please drop me a line to have you involved!

LET'S TALK

Sam Berrill
Partnerships Director
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Innovation Partner

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Package Details	**Register by April 26**	**Standard Price**
Conference & 3 Workshops	$3796 (save $800)	$3996 (save $600)
Conference & 2 Workshops	$3397 (save $500)	$3597 (save $300)
Conference & 1 Workshop	$2898 (save $300)	$3098 (save $100)
Conference Only	$2299 (save $200)	$2499
Workshop Only	$699	

Solution Provider		
Package Details	**Register by April 26**	**Standard Price**
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