COMBINATION PRODUCT REGULATION

FEBRUARY 28 - MARCH 1, 2019 | ARLINGTON, VA

Defining the Primary Mode of Action as a Drug or Device to Determine FDA Jurisdiction, Ensuring Optimized Human Factors Study Design to Prove Safe Patient Use, while Maintaining Compliance With Post Market Reporting Requirements

DISTINGUISHED PRESENTERS INCLUDE:

LIFE SCIENCE INDUSTRY EXPERTS:

Darin Oppenheimer, PhD
Executive Director, Head Drug Device Center of Excellence
MERCK

Ruby Gulati
Head Combination Product Quality
GENENTECH

Diane Radcliffe
Associate Director, Device Quality
MERCK

Michael Song
Sr. Manager, Drug Delivery and Device Development
MEDIMMUNE

Edward Halpern, PhD
Principal Human Factors Research Engineer
ABBVIE

Steven Bruun
Regulatory Affairs Leader – Peripheral and Combination Products
WL GORE

Suzette Roan
Senior Director, Global Regulatory Affairs
SANOFI

Andrea Redd
Senior Director, Regulatory Affairs
FRESENIUS KABI

Ana Ladino
Director of Regulatory Affairs
WEST PHARMACEUTICAL SERVICES

Suchitra Basu, PhD
Global Strategy Manager, Regulatory Affairs
DEPUY SYNTHES

Jennifer Recknor, PhD
Product/Technology Specialist, Combination Products Platform - Medical Product Division
WL GORE

Waiss Faissal
Certification Project Manager
GMED NORTH AMERICA

Gary Hartman
Head of Device, Combination Product, and SaMD Quality
ASTRAZENECA

Kirsten Paulson
Sr. Director, Global CMC-Medical Device Lead
PFIZER

Bob Laughner
Regulatory Director, Combination Products and Medical Devices
ASTRAZENECA

Anoop Padival, PhD
Manager, Global Labeling Strategy, Regulatory Affairs
ABBVIE

Allison Kumar
Executive Regulatory Affairs Advisor
THERANOVA

LEGAL EXPERTS:

Jeff Gibbs
Director
HYMAN, PHELPS, & MCNAMARA

Lina Kontos
Counsel
HOGAN LOVELLS

James A. Boiani
Member of the Firm
EPSTEIN BECKER GREEN

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COMBINATION PRODUCT REGULATION

Day One Agenda | Thursday, February 28

7:45 REGISTRATION & WELCOME COFFEE

8:20 CHAIRPERSON'S OPENING REMARKS

8:30 OPENING ICE-BREAKER: INSIGHTS INTO REGULATORY INTELLIGENCE COLLECTION STRATEGIES

With continuously evolving requirements and standards released from health au¬thorities in the USA and internationally, regulatory affairs teams face the ongoing challenge of remaining abreast of changes impacting combination products. As various methods are applied throughout the industry to ensure timely awareness of new rules, the opening ice-breaker will kick off the conference with the chance for all participants to meet new attendees and connect through short, engaging discussions. In this interactive session, participants are encouraged to share perspectives on key insights into regulatory collection intelligence best practices. In addition, participants have the opportunity to immediately build contacts with industry peers, kicking off the event networking platform.

9:00 CO-PRESENTATION: HUMAN FACTORS DESIGN AND USABILITY FOR OPTIMIZING INSTRUCTIONS FOR USE

- Design criteria for human factors & usability studies
- Assessing differing patient needs & environmental factors
- Merging human factors findings with regulatory requirements
- Team collaboration to target content for intended patient population

Anoop Padival, PhD, *Manager, Global Labeling Strategy, Regulatory Affairs*
ABBVIE

Edward Halpern, PhD, *Principal Human Factors Research Engineer*
ABBVIE

10:00 COFFEE & NETWORKING BREAK

10:30 OVERCOMING CHALLENGES IN CLINICAL STUDY DESIGN & DRUG-DEVICE EVIDENCE BRIDGING

With two constituents in a combination product, clinical studies must be constructed to simultaneously test both components and yield data proving that the drug and device perform as intended, and are safe for patient use. Clinical and regulatory affairs executives are often challenged with the study design as the clinical hypothesis is complex to define for both parts together, and must put in relation the dependency of one component on the other. Additionally, combination product teams therefore seek effective methods to bridge evidence for both the drug and device elements for regulatory submission documents.

- Formulating the hypothesis & both parts' interdependence
- Study design to evaluate both components simultaneously
- Bridging drug & device evidence for regulatory submission

Bob Laughner, *Regulatory Director, Combination Products and Medical Devices,* **ASTRAZENECA**

11:15 EARLY & EFFECTIVE COMMUNICATION WITH RELEVANT FDA CENTERS TO DEVELOP FLAWLESS SUBMISSIONS

Once the primary mode of action is established, determining which FDA center will oversee regulation of the combination product, regulatory teams face the challenge of compiling accurate data sets for both the device and pharmaceutical components to be submitted conjointly in a timely manner. With both the CDER and CDRH evaluating the submission, either in a consultative or collaborative approach, organizations must acquire a deep understanding of the review process and develop the file in a manner to avoid repetitive and contradictory feedback from FDA divisions. As a proactive step towards securing compliance and providing the expected type of product insight, many companies request early communication with the FDA to align the specified requirements and to avoid common mistakes later on in the review process.

- OCP, CDER, & CDRH roles in the regulatory review process
- Defining robust and comment-proof regulatory submissions
- Necessary information for both constituents in submission file

Allison Kumar, *Executive Regulatory Affairs Advisor*
THERANOVA

12:00 LUNCHEON FOR ALL PARTICIPANTS

1:00 EXCHANGE GROUPS: REGULATORY SUBMISSION CHALLENGES SPECIFIC TO DEVICE & PHARMACEUTICAL COMPONENTS

Many regulatory executives have developed expert knowledge on either medical device or pharmaceutical regulations, based on work experience in the industry, and now require education on the field they may be less familiar with in order to ensure a holistic approach to combination product regulatory requirements. This peer-to-peer learning session allows device experts to join together in a group led by a pharmaceutical executive, and discuss challenges to acquire enhanced knowledge about the pharmaceutical regulatory landscape. Additionally, pharmaceutical teams will discuss with a device expert in the small group format to pose concerns and understand device specific regulations.

DEVICE GROUP: Ana Ladino, WEST PHARMACEUTICAL SERVICES
PHARMA GROUP: Steven Bruun, WL GORE

1:45 PANEL: OPTIMIZING PRIMARY MODE OF ACTION DETERMINATION & PROCESS TO APPEAL FDA DECISIONS

One of the most prominent areas of challenge is for combination product teams lies in classifying the product as a drug or a device through establishing the primary mode of action, which affects regulatory pathways, the lead FDA center, and the organization's overall strategy. In order to maximize chances for the company's perspective of the PMAO to also be adopted by the FDA, combination professionals aim towards securing the best understanding possible of the Agency's analysis process regardless of ongoing grey areas and lack of transparency. In addition, with the risk of having the FDA disagree with the PMOA, executives must also be familiar with the appeal process should they wish to pursue the regulatory team's initial determination.

- Methods of determining an unclear primary mode of action
- Regulatory strategy shift in the case of opposite FDA determination
- Practices to effectively navigate the jurisdiction appeal process

PANELISTS: Jeff Gibbs, HYMAN, PHELPS, & MCNAMARA
Darin Oppenheimer, MERCK
Suchitra Basu, DEPUY SYNTHES

2:30 EUROPEAN MDR 2017/745: NEW PROVISIONS & EFFECT ON COMBINATION PRODUCTS

The EU MDR 2017/745 introduces a completely new approach to combination product regulatory compliance within the territory, spanning all operations from product development to testing and CE mark approval. With the transition period ending in May 2020, regulatory affairs teams are prompted to revise and update strategies accordingly, demanding for a robust understanding of new provisions. Although both devices and pharmaceutical experts notice an increase in the workload due to the impending deadline, pharmaceutical organizations are more heavily impacted and face the challenge of entering a completely new regulatory framework.

- Comparison of EU MDD & EU MDR for combination products
- Regulatory organizations involved in products assessment
- Changes to assessment & approval process for both constituents
- Defining the impacts of Article 117 of EU MDR 2017/745

Waiss Faissal, *Certification Project Manager*
GMED NORTH AMERICA

3:15 COFFEE & NETWORKING BREAK

3:45 MANEUVERING AN UNCERTAIN REGULATORY LANDSCAPE IN ASIAN MARKETS

Part 1: Focus On Regulatory Requirements In China & Japan

- Regulatory updates affecting combination products
- Specific areas of consideration for submissions
- Comparison of requirements with US FDA demands

Suchitra Basu, PhD, *Global Strategy Manager, Regulatory Affairs*
DEPUY SYNTHES

Part 2: Updated Compliance In Malaysia & Taiwan

- Combination product requirement challenges in Malaysia & Taiwan
- Update on new registration rules for products in Malaysia
- Combination product submissions & pathways in Taiwan

Darin Oppenheimer, PhD, *Executive Director, Head Drug Device Center of Excellence*
MERCK

4:35 REGULATORY UPDATE & CLARIFICATION ON THE DEVICES REFERENCING DRUGS PATHWAY

In the absence of a viable regulatory process for medical devices meant to be used in conjunction with a legacy or generic pharmaceutical product without needing to change the drug component's initial label, or file a new NDA, the FDA is exploring the development of a new product category. The considered Devices Referencing Drugs (DRDs) regulatory pathway could potentially enable medical device manufacturers to proceed without becoming a drug sponsor, and obtain approval solely for the device intended to be used with the pharmaceutical component. While promising, the new category is still unclear as the frontier with combination products remains confusing for both the pharmaceutical and device industries alike, demanding for an in-depth interpretation of the new pathway.

- Reasoning behind FDA's newly proposed category
- Comment period extension & challenges raised
- Industry action to conform to DRD requirements
- Implications for device & pharmaceutical companies

Lina Kontos, *Counsel*
HOGAN LOVELLS

5:20 CLOSING REMARKS & DAY 1 CONCLUSION

6:30 CONTINUED NETWORKING: FACILITATED GROUP DINNERS

** With the immense value in peer-to-peer interaction and experience sharing, we wish to provide attendees with an opportunity to continue networking after the first day of the conference. Q1 Productions will arrange dinner reservations at local restaurants close to the conference hotel for those interested in joining a group of fellow participants for dinner on February 28th. Please note that dinner expenses must be covered by each participant individually.*

COMBINATION PRODUCT REGULATION

Day Two Agenda | Friday, March 1

8:00 REGISTRATION & WELCOME COFFEE

8:20 CHAIRPERSON'S OPENING REMARKS

8:30 CASE STUDY: CONDUCTING GAP ANALYSES TO PRODUCE DESIGN HISTORY FILES FOR LEGACY PRODUCTS

Regulatory teams must ensure legacy products remain compliant with new and updated guidance, including the recently released FDA final ruling for cGMP. The new manufacturing practice rules include provisions pertinent to design history files, posing difficulties for the industry due to lack of sufficient records at the time of legacy products release. It is therefore critical to promptly conduct in-depth gap analysis in the effort of shedding light onto outdated manufacturing strategies and properly document practices from the past in order to achieve compliance.

- Review of cGMP final ruling on design history files
- Performing a gap analysis towards legacy product compliance
- Coordinating appropriate & up to date design history files

Ruby Gulati, *Head Combination Product Quality*
GENENTECH

9:15 UPDATE ON FDA'S POSTMARKETING REPORTING GUIDANCE & COMBINATION PRODUCT REQUIREMENTS

FDA's release of the draft guidance, "Postmarketing Safety Reporting for Combination Products", has created concern as regulatory affairs professionals attempt to interpret the information and educate quality teams on compliance requirements prior to the 2019 implementation date. As the reporting processes and timelines for the pharmaceutical and device components of the product differ, regulatory executives aim to effectively manage both procedures. Additionally, as combination products face split jurisdiction, many organizations work to determine whether to inform CDER, CDRH or both, of adverse events and product failures to ensure compliance at all times.

- Updates to FDA draft guidance & implementation
- Key differences in reporting for drugs vs. devices
- Reporting adverse events to either CDER or CDRH
- Articulating a comprehensive post-market strategy

Ana Ladino, *Director of Regulatory Affairs*
WEST PHARMACEUTICAL SERVICES

10:00 COFFEE & NETWORKING BREAK

10:30 EXCHANGE GROUPS: FDA FINAL GUIDANCE ON cGMP REQUIREMENTS FOR COMBINATION PRODUCTS

Once the primary mode of action is determined and the combination product is assigned to CDER or CDRH, quality & regulatory executives must prepare the organization's manufacturing infrastructure to comply with either cGMP regulations for pharmaceuticals, specifically 21 CFR parts 210 and 211, or the device quality system regulation, 21 CFR part 820. This peer-to-peer learning session allows regulatory executives to discuss areas of concerns pertinent to compliant manufacturing practices, as well as the FDA final guidance with quality assurance experts. Delegates will have the choice to join the pharmaceutical or device group to discuss cGMP specific challenges.

MODERATORS:
Andrea Redd, FRESENIUS KABI
Bob Laughner, ASTRAZENECA
Gary Hartman, ASTRAZENECA
Diane Radcliffe, MERCK

11:15 CONTROL STRATEGY DEVELOPMENT CONSIDERATIONS: FOCUS ON DRUG-DELIVERY SYSTEMS

- Review of current control strategy regulatory expectations
- Defining important attributes such as essential performance
- Methods to control the most critical characteristics
- Comparing drug vs. device approaches for control strategy development
- Submission strategies for combination product control strategies

Suzette Roan, *Senior Director, Global Regulatory Affairs*
SANOFI

12:00 LUNCHEON FOR ALL PARTICIPANTS

1:00 UPDATED ISO 10993-1 AFFECTING COMBINATION PRODUCT BIOCOMPATABILITY & MATERIAL ASSESSMENT

- Review of changes to updated 2018 ISO 10993-1 Standard
- Process & material changes impact on biocompatibility
- Resolutions to last minutes vendor mitigated changes
- Design platform & semi-platform biocompatibility studies

Michael Song, *Sr. Manager, Drug Delivery and Device Development*
MEDIMMUNE

1:45 PANEL: MULTI-TEAM COOPERATION TO EFFICIENTLY BRING COMBINATION PRODUCTS TO MARKET

It takes the effort of various teams, such as product development, regulatory affairs, and quality engineering to achieve the overall goal of compliantly manufacturing and testing an innovative combination product before market release. Each function plays a distinct role, requiring organizations to create a step by step process outlining the overall collaboration timeline and necessary flow of communication. Companies must specify how the work of each function impacts the following activities and compiles throughout the life cycle to create the finished product.

- Designing a plan & timing for multi-team collaboration
- Outlining & understanding each team's distinct needs
- Impact of each function on the following team's activities
- Team interaction differences in drug & device companies

PANELISTS:
Jennifer Recknor, PhD, WL GORE
Diane Radcliffe, MERCK
Kirsten Paulson, PFIZER

2:30 COFFEE & NETWORKING BREAK

3:00 DETERMINING WHEN THE USE OF SOFTWARE ALONGSIDE A DRUG WILL RESULT IN A COMBINATION PRODUCT

- Defining software as a device based on intended use & clinical testing
- Analyzing regulatory implications prior to development & trial design
- Clarification of FDA requirements & guidance for software components

James A. Boiani, *Member of the Firm*
EPSTEIN BECKER GREEN

3:45 REGULATORY UPDATE ON COMPARATIVE ANALYSES & REQUIREMENTS FOR GENERIC COMBINATION PRODUCTS

- Defining generic & reference product similarity targets
- Use of threshold analysis in practice & FDA expectations
- Critical design attributes & focus on safe user experience
- Confirming equivalent generic & reference product use error rate
- Industry best practices to meet large statistical requirements

Andrea Redd, *Senior Director, Regulatory Affairs*
FRESENIUS KABI

4:30 CLOSING REMARKS & CONFERENCE CONCLUSION

ABOUT THE ORGANIZERS:

Q1 Productions designs and develops webinars, training courses, conference programs and forums aimed at specifically targeted audiences in order to provide strategic and timely information. Through a rigid production process focused on end-user research and design, our team is able to understand the immediate business concerns of today's leading executives. Whether focusing on new or pending legislative issues, enhanced business processes or technologies that will drive efficiency and customer service, our programs provide solutions to the urgent needs of our attendees.

COMBINATION PRODUCT REGULATION

Day Two Agenda | Friday, March 1

KEY SPEAKER HIGHLIGHT:

Darin Oppenheimer, PhD
Executive Director, Head Drug Device Center of Excellence
MERCK

Dr. Darin S. Oppenheimer is an Executive Director of the Drug Device Center of Excellence focusing on Medical Devices and Combination products at Merck based in Upper Gwynedd, PA. Darin is involved in many facets of the Product Development Lifecycle including regulatory submissions, due diligence, and active participation on industry trade organizations and standards committees over the past 15 years. His prior background as a Research and Development Scientist focused on pharmaceuticals and medical device diagnostic applications for biomarker and drug discovery. Darin's undergraduate degree is in Molecular Biology from the University of Tampa. He also holds two Masters Degrees from Johns Hopkins University in Biotechnology and Regulatory Science as well as a graduate Certificate in Biotechnology Enterprise. Recently Darin has completed his Doctorate degree in Regulatory Science from the university of Southern California. Darin is also a 2017 Regulatory Affairs Professional Society Fellow.

Waiss Faissal
Certification Project Manager
GMED NORTH AMERICA

Waïss Faissal is a Certification Project Manager and the Drug Usefulness subject matter Expert at GMED North America. He is a Doctor of Pharmacy (and graduated from the University of Paris Sud where he also completed a Biomedical Engineering Master Degree at the Engineering School of l' Ecole Normale Supérieure des Arts et Métiers (Paris, France). Prior to joining GMED North America, Waïss was working as Regulatory Affairs and Clinical Studies Manager in the Medical Device Industry, for a company specialized in orthopedic implant devices. His responsibilities involved but were not limited to the maintenance and monitoring of Post Market Surveillance (PMS) activities, the Clinical Evaluation and Clinical Investigations data collection and reporting, the evaluation of the new Medical Device Regulation (745/2017) requirements on the company's activities.

ATTENDEE PROFILE:

Executives from the combination product industry that will find this program of greatest application are those involved in leveraging regulatory requirements to ensure up-to-date knowledge and to impact product clearance approval and strategic implementation of policies. With a blend of aligning submissions, maintaining US and global policy knowledge, as well as internal communication and education, the role of today's combination product regulatory affairs executive combines a tremendous number of skills. Recognizing the industry growth and regulatory complexity of the combination product industry, the Q1 Combination Product Regulatory Affairs Conference attracts a range of executives with job titles including:

- Regulatory Affairs Combination Products
- Regulatory Affairs, Devices (within pharmaceutical organizations)
- Regulatory Affairs, Pharmaceuticals/Biologics (within medical device organizations)

SPONSORSHIP OPPORTUNITIES:

At this time, there are a variety of sponsorship and exhibition opportunities available for companies wishing to increase their visibility and participation in the program, ranging from keynote speaking opportunities through to exhibitor and documentation sponsors. Organizations most suitable for this type of exposure provide services and solutions including:

- Regulatory Consultants
- Quality Assurance Consultants
- Clinical Research Organizations
- cGMP Service Providers
- Device/Pharmaceutical Expert Consultants

KEY SPEAKER HIGHLIGHT:

International Reg Affairs & Quality Compliance Leader, **3M**
Director, Product Development, **ABBOTT**
Director Quality Assurance Medical Device, **ABBVIE**
Sr. Labeling Specialist, **ALCON**
Former Global Head EU MDR Compliance, **ALCON**
Sr. Manager, Regulatory Affairs Device, **AMGEN**
Manager, Regulatory Affairs, **ARTHREX**
Assoc. Dir., Reg Chemistry, Manuf. & Controls, **ASTRAZENECA**
Senior Director Global Regulatory Affairs, **BAUSCH HEALTH**
Assoc. Dir., Regulatory Affairs, **BAUSCH HEALTH COMPANIES**
Director, Regulatory Intelligence, **BAXTER**
Head, Reg. Intelligence; Dir., Reg. Policy & Intelligence, **BAYER**
Head, Global Regulatory Affairs Operational Excellence, **BAYER**
Director, Regulatory Affairs, **BD**
EU MDR Project Manager, **BD**
Sr. Dir. of Global Regulatory Operations, **BECTON DICKINSON**
VP of Global Regulatory Operations, **BECTON DICKINSON**
VP, Global Regulatory Policy, **BIOGEN**
Regulatory Intelligence Lead, **BIOGEN**
Associate Director, Regulatory Affairs, **BIOGEN**
Associate Director, Regulatory Affairs, **C.R. BARD**
Director, Regulatory Affairs, **CARDINAL HEALTH**
SVP, QRA, **CARDINAL HEALTH**
Director, Regulatory Science, **COOK MEDICAL**
Principal Certification Manager, **DEKRA CERTIFICATION B.V.**
Director RA International Markets, **EDWARDS LIFESCIENCES**
Dir., Corporate Reg. Affairs, Systems & Standards, **HOLOGIC**
Sr. Regulatory Intelligence Specialist, **IMPAX LABORATORIES**
Director, Regulatory Policy & Intelligence, **LEO PHARMA**
Principal Compliance Specialist, **MEDTRONIC**
Director, Global Regulatory Policy, **MERCK**
Associate Director, Drug-Device Center of Excellence, **MERCK**
Director, Regulatory CMC & Combination Products, **MERCK**
Exec. Dir., Global Regulatory & Development Policy, **NOVARTIS**
Senor Director, Regulatory Policy, **NOVO NORDISK**
Regulatory Intelligence, **NOVO NORDISK**
Associate Director & Regulatory Intelligence Lead, **OTSUKA**
Sr. Regulatory Affairs Specialist, **PHILIPS HEALTHCARE**
Director Regulatory Affairs, **PRENUMBRA**
Regulatory Affairs, **STRYKER**
Senior Regulatory Specialist, **STRYKER**
Senior Director Regulatory Affairs Corporate, **STRYKER**
VP Quality Assurance & Regulatory Affairs, **STRYKER**
Associate Director, Regulatory Affairs, **SUNOVION PHARMA**
Senior Director Regulatory Intelligence & Policy, **TAKEDA**
Clinical Reviewer, Clinical Center of Excellence, **TUV SUD**
Global Director Sales & Strategic Marketing MHS, **TUV SUD**
Head of Notified Body, **UL INTERNATIONAL**
VP, Reg. Policy & Operations, **VERTEX PHARMACEUTICALS**
Dir. of Regulatory Affairs, **WEST PHARMACEUTICAL SERVICES**
Associate Director, Regulatory Affairs, **ZOLL MEDICAL**
& MANY MORE...