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Event Program

Conference Day 1: Monday, August 19th

7:00am **Check-in**

8:00am **Welcome and Kick-off Address**

8:30am **Background of Regulations and FDA Oversight**

David Pudwill (Senior Director RA/QA, ConvaTec)

9:15am **FDA Device Classification and Comparison to EU Classification**

Jemin Dedania, MS, RAC (Associate Manager Regulatory Affairs, Stryker)

Sarah Leismer (Principal Regulatory Affairs Specialist, Medtronic)

10:00am **Break**

10:15am **Regulatory Strategy 101:** *Generating a Regulatory Strategy that Fits your Company's Goals*

Nada Hanafi MSC, MPH (Chief Strategy Officer, Experien Group)

Set yourself up for success in your company's approach to effectively navigate the regulatory pathway to market and maximize your interactions with FDA. This session will focus on the critical success factors that go into a comprehensive regulatory strategy.

11:15am **Ask Me Anything:** *How Poor Classification and Regulatory Strategy Can Impact your Timeline to Market*

David Pudwill (Senior Director RA/QA, ConvaTec)

Jemin Dedania, MS, RAC (Associate Manager Regulatory Affairs, Stryker)

Sarah Leismer (Principal Regulatory Affairs Specialist, Medtronic)

Nada Hanafi MSC, MPH (Chief Strategy Officer, Experien Group)

12:00pm **Networking Lunch**

1:30pm **Pre-Sub Bootcamp:** *Different types of Pre-Subs & Figuring out which is Right for your Device*

Allison Komiyama, Ph.D. (Principal Consultant, AcKnowledge RS)

Pre-submissions can be extremely useful but can also come with some risk as many companies will botch their first impression with the agency. Submitters can request feedback from FDA and a meeting with the review team regarding their medical device. Pre-submissions are a powerful way to establish a relationship with FDA, introduce the medical device, and gain useful insight into the appropriate regulatory strategy with which to approach the premarket submission. In the session dedicated to understanding the pre-submission process, you will learn:

- *When to consider a pre-submission, including the regulatory approach.*
- *When NOT to consider a pre-submission and instead go straight with a premarket submission.*
- *The contents of a pre-submission package and how is it assembled.*
- *The various types of submissions are available (standard pre-sub, submission issue request, informational, or study risk determination), and the pros and cons of each.*
- *The kinds of feedback will be provided, and how to read between the lines of a reviewer's comments.*
- *How to ask for regulatory feedback without directly asking for a regulatory pathway.*
- *What to expect during a meeting with FDA, how to not anger the review team, and what happens afterwards.*

3:00pm **Break**

3:15pm **Pre-Sub Bootcamp:** *What comes next and How to Submit a 513(g) or Pre-Sub Supplement*

Allison Kumar (Principal Consultant, Arina Consulting)

Now that your pre-submission meeting is over, what do you do next? Should you submit a pre-sub supplement or go with FDA's suggestion on sending in a Request for Information (also known as a 513(g)? In the session dedicated to understanding what to do after your pre-submission, you will learn:

- *Whether there is such a thing as too many pre-submissions and how to submit a supplement.*
- *Content and format of a pre-sub supplement.*
- *Best practices and timing for submitting multiple pre-sub supplements.*
- *The format of a 513(g) and how to submit one to understand device classification.*
- *Knowing when to hold'em and when not to submit additional information for FDA to review.*

3:45pm **Ask Me Anything:** *Speaker panel on Best Practices for Pre-Sub Meetings*

Allison Kumar (Principal Consultant, Arina Consulting)

Allison Komiyama, Ph.D. (Principal Consultant, AcKnowledge RS)

Nada Hanafi MSC, MPH (Chief Strategy Officer, Experien Group)

4:30pm **Day 1 Wrap-Up**

5:00pm **Social Event**

Conference Day 2: Tuesday, August 20th

7:45am **Check-In**

8:00am **Recap of Day 1, Reg Chats**

8:15am **510(k)s:** *How to Write and Submit a Successful 510(k)*

Michael Nilo, MS (Principal Consultant, Nilo Medical Consulting)

By going through the 510(k) premarket process, a medical device obtains marketing authorization by demonstrating substantial equivalence to a predicate device. In the session dedicated to understanding the 510(k) submission process, you will learn:

- *When and how to submit a 510(k) for a new or modified product.*
- *The submission process and understand the FDA Pathway Guidance.*
- *The various types of 510(k) submission and when to use each.*
- *What is contained in a 510(k) submission package and how is it assembled.*
- *How to choose an appropriate predicate device, and why it matters, importance of Intended Use and Substantial Equivalence (SE).*
- *How to interact with the FDA reviewer, and how to respond to questions.*
- *How to avoid an eCopy or User Fee Hold and get through the Refusal Process.*

9:30am **510(k)s:** *"To LTF or not to LTF…" When to Submit a 510(k) for a Change to an Existing Device*

Jemin Dedania, MS, RAC (Associate Manager Regulatory Affairs, Stryker)

Congrats on your 510(k) clearance! Wait, now you want to make changes to your device? Most companies "creatively interpret" the FDA guidance document "When to submit a 510(k) for a change to an existing device." Learn how to best interpret this guidance and know the lines on when you actually should submit that new 510(k), and when a reviewer would much rather you just do a Letter to File (LTF). In the session dedicated to understanding the post-510(k) process, you will learn:

- *Best-practices when generating a Letter to File (template provided).*
- *How to avoid device creep.*
- *Keeping inspectors from being concerned about your documentation.*
- *Deciding when it's time to submit a "catch up" 510(k) to cover all your LTFs.*

10:00am **Break**

10:15am **Combination Products:** *How to Prepare a Request for Designation*

David Pudwill (Senior Director RA/QA, ConvaTec)

Combination products are therapeutic and diagnostic products that combine drugs, devices, and/or biological products. FDA expects to receive large numbers of combination products for review as technological advances continue to merge product types and blur the historical lines of separation between FDA's medical product centers. The Office of Combination Products (OCP) assigns review responsibility for combination products to a lead center (CBER, CDER, or CDRH). The agency is required to assign premarket review responsibility for combination products based on the product's "primary mode of action" or PMOA. But first, a company may submit a Request for Designation (RFD) to obtain a formal agency determination of a combination product's PMOA and center jurisdiction. In the session dedicated to understanding RFDs, you will learn about:

- *How to decide whether you should submit an RFD or Pre-RFD.*
- *The contents of a pre-RFD and how to avoid refusal.*
- *The contents of an RFD and how to avoid refusal.*
- *What happens after you receive your Designation Letter.*

10:45am **Point of Care IVD Submissions and the Routes to CLIA Waiver**

Cheng Zhang, Ph.D. (Director Regulatory Affairs, Inovio Pharmaceuticals)

Diagnostic testing has increasingly moved its way out of the central laboratory and into testing sites closer to patients. This testing modality has enabled laboratory service providers to perform testing anywhere the patient is located, referred to as point-of-care (POC) testing. However, this shift has forced manufacturers of in-vitro diagnostic (IVD) medical devices to face new questions and regulations when bringing their devices to market. In January 2000, the responsibility for categorization of commercially available IVD tests was transferred from the Centers for Disease Control and Prevention (CDC) to the FDA Center for Devices and Radiological Health (CDRH). This allowed IVD manufacturers to submit 510(k) premarket notifications or PMA applications for tests and requests for complexity categorization of these tests under CLIA to one agency. Categorization is based on their complexity—from the least to the most complex: waived tests, moderate complexity tests, and high complexity tests. In the session dedicated to understanding regulations surrounding IVDs, you will learn about:

- *Point-of-care IVD requirements and understanding the various levels of complexity based on the type of test.*
- *The CLIA Waiver process and how FDA evaluates CLIA categorization as part of the 510(k)/PMA process.*
- *How to identify the three routes to CLIA Waiver (i.e. cleared for home use, waived by regulation or waiver petition).*
- *The qualitative and quantitative data requirements used to demonstrate accuracy and precision in IVD studies.*
- *The Dual Submission process based on FDA guidance that combines the 510(k) and waiver petition in one filing.*

12:00pm **Networking Lunch**

1:30pm **Ask Me Anything:** *510(k), LTF, RFD, and IVD Horror Stories*

Michael Nilo, MS (Principal Consultant, Nilo Medical Consulting)

Jemin Dedania, MS, RAC (Associate Manager Regulatory Affairs, Stryker)

David Pudwill (Senior Director RA/QA, ConvaTec)

Cheng Zhang, Ph.D. (Director Regulatory Affairs, Inovio Pharmaceuticals)

2:00pm **De novos:** *How to Prepare your de novo Application*

Allison Kumar (Principal Consultant, Arina Consulting)

The de novo premarket review pathway is for low- to moderate-risk devices of a new type. A successful de novo application creates a new regulatory classification, which allows subsequent devices of the same type and with the same intended use to go through the FDA's 510(k) premarket process. In the session dedicated to understanding the de novo submission process, you will learn:

- *How to identify when it is appropriate to submit a de novo application.*
- *How to generate/evaluate the risk/benefit analysis for a de novo submission.*
- *Why de novo application numbers are increasing.*
- *What is included in a de novo application package, and how is it assembled.*
- *What to expect from the review process.*
- *What is the timeline associated with the de novo premarket review process.*
- *Ways to expedite assembly and increase the success of your de novo application.*
- *About the business implications associated with a successful application.*

3:00pm **Break**

3:15pm **Hot Topic***: Digital Health (SaMD, Cybersecurity, and Artificial Intelligence)*

4:00pm **Hot Topic:** *Digital Health Panel*

Allison Kumar (Principal Consultant, Arina Consulting)

Allison Komiyama, Ph.D. (Principal Consultant, AcKnowledge RS)

Jemin Dedania, MS, RAC (Associate Manager Regulatory Affairs, Stryker)

4:30pm **Day 2 Wrap-Up**

Conference Day 3: Wednesday, August 21st

7:45am **Check-In**

8:00am **Recap of Day 2, Reg Chats**

8:15am **IDEs:** *How to Prepare a Successful IDE and What to do Post-Approval*

9:15am **HDEs:** *How to Prepare a Successful HDE*

Dulciana Chan, MS (Senior Regulatory Specialist, AcKnowledge RS)

An investigational device exemption (IDE) is a regulatory submission that permits clinical investigation of a device. An approved IDE permits a device that otherwise would be required to comply with a performance standard or to have premarket approval to be shipped lawfully for the purpose of conducting investigations of that device. Also covered in this session, the humanitarian device exemption (HDE) is an approval process that allows a medical device to be marketed without requiring evidence of effectiveness. In other words, an HDE application is not required to contain the results of scientifically valid clinical investigations demonstrating that the device is effective for its intended purpose. In the session dedicated to exploring the IDE/HDE submission processes, you will learn:

- *The purpose of an IDE, the various type of IDEs.*
- *What is contained in an IDE submission and how is it assembled.*
- *What is an HDE, and when is an HDE application appropriate.*
- *What is contained in an HDE submission and how is it assembled.*

10:00am **Break**

10:15am **Hot Topic:** *Clinical Evidence (Using Real World Evidence, Expanding to Pediatric Indications, Evaluating Patient/Rx Preference)*

11:00am **Hot Topic:** *Clinical Evidence Panel*

Caroline Rhim, Ph.D. (Executive Director, NSF International)

David Pudwill (Senior Director RA/QA, ConvaTec)

Stayce Beck, Ph.D. MPH (VP Clinical, Dexcom)

12:00pm **Networking Lunch**

1:30pm **PMAs:** *How to Prepare a Successful PMA and Have Effective Meetings w. FDA*

2:15pm **PMAs:** *What to do Post-Approval*

Caroline Rhim, Ph.D. (Executive Director, NSF International)

Premarket approval (PMA) is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices, devices that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury. PMA is the most stringent type of device marketing application required by FDA, and in the session dedicated to understanding PMA submission process, you will learn:

- *When and how to submit a PMA for a new product or modified product.*
- *The submission process and understanding the relevant FDA guidance.*
- *Whether the Modular or Traditional PMA is right for your device.*
- *What is contained in a PMA submission package and how is it assembled.*
- *When advisory panels are convened and how this impacts your review.*
- *What to expect during the review process, including the timeline.*
- *What are the postmarket obligations associated with an approved PMA.*
- *The business implications associated with a successful application.*

2:45 pm **Ask Me Anything:** *How Poor PMA Management Spells Disaster for a Company*

Caroline Rhim, Ph.D. (Executive Director, NSF International)

Sarah Leismer (Principal Regulatory Affairs Specialist, Medtronic)

Stayce Beck, Ph.D. MPH (VP Clinical, Dexcom)

3:15pm **Break**

3:30pm **FDA & EU MDD/MDR Comparison***: A New Landscape for CE Marking*

4:00pm **Developing your EU MDR Technical Documentation**

Sarah Leismer (Principal Regulatory Affairs Specialist, Medtronic)

What can we expect as the EU Regulatory landscape continues to change in the next few years? How can you best prepare or at least be ready to make the leap to Medical Device Regulation (MDR)? This session will focus on major changes and key themes in the MDR. We will explore what has changed compared to the previous Medical Device Directive (MDD) and will unpack the impact these changes have/will have on a medical device manufacturers. The program will also cover how to classify your device per the new regulations, best practices on transitioning from the MDD to MDR, and how to best prepare your technical file or design dossier. In the session dedicated to exploring the EU regulatory landscape, you will learn:

- *New concepts and requirements in MDR.*
- *Key changes from the Essential Requirements to the new General Safety and Performance Requirements.*
- *What to include in your MDR Technical Documentation requirements and how it differs from Technical Files and Design Dossiers.*

4:30pm **Day 3 Wrap-Up and Farewell**