REGULATORYAF

ALLIANCE • FORUM

Event Program

Conference Day 1: Monday, August 16th

7:00am **Check-in**

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

8:30am **New FDA, Who Dis?** *Where Are We Thanks to the Reorganization and COVID?*

Eriko Yoshimaru, PhD (Director of Regulatory Affairs, Hogan Lovells)

9:15am **Richer Input, Richer Investment:** *Training the Next Generation of Reg Experts*

Jim Kleinedler, PhD (Regulatory Fellow, Boston Scientific)

10:00am **Break**

10:15am **Start-Up Focus:** *Building a Regulatory Strategy into your Business Plan (Or, How to Avoid Investor Panic)*

Caroline Rhim, PhD (Vice President Medical Devices, NSF International)

Laura Gilmour, MS (Principal Consultant, Regulatory + Additive Manufacturing Strategies)

11:30am **Is your De Novo a De No-Go?** *Tips to Improve your Benefit/Risk Profile*

Allison Kumar (Principal Consultant, Arina Consulting LLC)

Allison Komiyama, PhD (Principal Consultant, AcKnowledge RS)

12:00pm **Networking Lunch**

1:30pm **How RA + Marketing can Learn to Love Each Other:** *The Difference Between Indications for Use, Intended Use, Substantiated Claims, and Implied Claims*

Stayce Beck, PhD, MPH (VP Clinical + Strategic Partnerships, Dexcom)

2:15pm **Pen Pals:** *Making the Most of Written Communication with FDA*

Sarah Leismer (Principal Regulatory Affairs Specialist, Medtronic)

3:00pm **Break**

3:15pm **Printing…NOW IN 3D!**

Laura Gilmour, MS (Principal Consultant, Regulatory + Additive Manufacturing Strategies)

3:45pm **AMAs:** *How to "Start Up" Your Relationship with FDA and not Wear Out Your Welcome*

Eriko Yoshimaru, PhD (Director of Regulatory Affairs, Hogan Lovells)

Jim Kleinedler, PhD (Regulatory Fellow, Boston Scientific)

Caroline Rhim, PhD (Vice President Medical Devices, NSF International)

Laura Gilmour, MS (Principal Consultant, Regulatory + Additive Manufacturing Strategies)

Allison Kumar (Principal Consultant, Arina Consulting LLC)

Allison Komiyama, PhD (Principal Consultant, AcKnowledge RS)

Stayce Beck, PhD, MPH (VP Clinical + Strategic Partnerships, Dexcom)

Sarah Leismer (Principal Regulatory Affairs Specialist, Medtronic)

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

5:30pm **Social Hour!**

Conference Day 2: Tuesday, August 17th

8:15am	**Recap of Day 1, Reg Chats**
8:30am	**So you got an EUA…Now What?** *Taking your Technology Through the Premarket Process* Michael Nilo, MS (Principal Consultant, Nilo Medical Consulting)
9:15am	**Appeals, Allegations and LB Flags:** *How to Throw a Regulatory Tantrum* Allison Kumar (Principal Consultant, Arina Consulting LLC)
10:00am	**Break**
10:15am	**Living in a Digital World** Nada Hanafi, MSc, MPH (Chief Strategy Officer, Experien Group)
11:00am	**Computers Aren't Pills:** *Why FDA Needs a New Regulatory Model for Cybersecurity* Seth Carmody, PhD, MS (VP Regulatory Strategy, MedCrypt)
12:00pm	**Networking Lunch**
1:30pm	**What's WUT (Well-Understood Technology)?** *Using FDA's Safety & Performance-Based Pathway to Submit that 510(k)* Alexia Haralambous, MS (Senior Staff Regulatory Affairs Specialist, Stryker)
2:15pm	**A Step Inside the Real World:** *Real-World Evidence Strategies in FDA Device Applications* Stephen Weber, MD (Senior Medical Advisor, MSquared)
3:00pm	**Break**
3:15pm	**PMAs and How to be High Class (III)** Caroline Rhim, PhD (VP Medical Device Consulting, NSF International) Sarah Leismer (Principal Regulatory Affairs Specialist, Medtronic)

3:45pm **AMAs:** *Taking Your Relationship with FDA to the Next Level*

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

Allison Kumar (Principal Consultant, Arina Consulting LLC)

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

Seth Carmody, PhD, MS (VP Regulatory Strategy, MedCrypt)

Alexia Haralambous, MS (Senior Staff Regulatory Affairs Specialist, Stryker)

Stephen Weber, MD (Senior Medical Advisor, MSquared)

Caroline Rhim, PhD (VP Medical Device Consulting, NSF International)

Sarah Leismer (Principal Regulatory Affairs Specialist, Medtronic)

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

Conference Day 3: Wednesday, August 18th

8:15am	**Recap of Day 2, Reg Chats**
8:30am	**Impact of COVID-19 and How IVD Manufacturers can Cope** Josh Levin, PhD (Director QA/RA, ASELL, LLC)
9:15am	**So you want to Market a Home Use Device?** David Pudwill (Principal Consultant, Mr. Regulatory)
10:00am	**Break**
10:15am	**Strategies to Avoid FDA Deficiencies on your Toxicology Risk Assessment** Ron Brown (Toxicologist, Risk Science Consortium)
11:00am	**Biocomp? More like Bio-WHOMP!** *Biocompatibility for Beginners* Kristy Katzenmeyer-Pleuss, PhD (Owner, KP Medical Device Consulting LLC)
11:45am	**The Future of Biocompatibility and Toxicological Risk Assessments** Ron Brown (Toxicologist, Risk Science Consortium) Kristy Katzenmeyer-Pleuss, PhD (Owner, KP Medical Device Consulting LLC)
12:00pm	**Networking Lunch**
1:30pm	**What the Heck is the Payor Task Force?** *A Brief Rundown of How to Best Use the Program* Kevin Go (Project Engineer, Regulatory and Quality Solutions LLC)
2:15pm	**Pre-Sub Process in 2021 + How to Keep FDA from Checking Email During Your Teleconference Call** Jemin Dedania, MS (Director of Regulatory Affairs, Hogan Lovells)
3:00 pm	**Break**
3:15pm	**Navigating Breakthrough and STeP Entrance Requests** Dulciana Chan, MS (Principal Consultant, AcKnowledge RS)

4:00pm **AMAs:** *Breaking Up with FDA is Hard to Do*

Josh Levin, PhD (Director QA/RA, ASELL, LLC)

David Pudwill (Principal Consultant, Mr. Regulatory)

Ron Brown (Toxicologist, Risk Science Consortium)

Kristy Katzenmeyer-Pleuss, PhD (Owner, KP Medical Device Consulting LLC)

Kevin Go (Project Engineer, Regulatory and Quality Solutions LLC)

Jemin Dedania, MS (Director of Regulatory Affairs, Hogan Lovells)

Dulciana Chan, MS (Principal Consultant, AcKnowledge RS)

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