Drugs are from Mars, Devices from Venus: Understanding the Value of Opposite Perspectives

Thursday March 23, 2017
Drugs are from Mars, Devices from Venus: Understanding the Value of Opposite Perspectives

Today’s Forum is Hosted by MassBio’s Medical Device Forum Working Group

Co-Chairs:

- **Omar Amirana**, MD, Senior Vice President, Allied Minds LLC
- **Jeremy Bond**, MSc, JD, Senior Counsel, Device Patents, Sanofi
- **Dale Larson**, MS, Director of Commercial Initiatives, Charles Stark Draper Laboratory
- **Barry Sands**, MBA, President & Founder, RQMIS, Inc.
- **Evan Sherr**, MS, VP Operations, Windgap Medical, Inc.
DRUGS ARE FROM MARS,
Devices Are from Venus

A Practical Guide for Improving Communication and Getting What You Want in Your Relationships

MASS BIO
Drug Device Combinations!!
Combination Types

• Examples of combination products where the components are physically, chemically or otherwise combined:
  – Monoclonal antibody combined with a therapeutic drug
  – Device coated or impregnated with a drug or biologic
    • Drug-eluting stent; pacing lead with steroid-coated tip; catheter with antimicrobial coating; condom with spermicide
    • Skin substitutes with cellular components; orthopedic implant with growth factors
  – Prefilled syringes, insulin injector pens, metered dose inhalers, transdermal patches

• Examples of combination products where the components are packaged together:
  – Drug or biological product packaged with a delivery device
  – Surgical tray with surgical instruments, drapes, and lidocaine or alcohol swabs

• Examples of combination products where the components are separately provided but labeled for use together:
  – Photosensitizing drug and activating laser/light source
  – Iontophoretic drug delivery patch and controller
  – Companion diagnostics
Impacts on Regulatory Strategy

- Center for Devices and Radiological Health (CDRH)
- Center for Drug Evaluation and Research (CDER)
- Center for Biologics Evaluation and Research (CBER)
  - Office for Combination Products (OCP)

Who Has Jurisdiction?

- Governed by Primary Mode of Action (PMOA)
  - 21 CFR 3.2m
    - Primary mode of action is the therapeutic action that is expected to make the greatest contribution to the overall intended therapeutic effect of the combination product.
    - Whichever product has the greatest therapeutic effect, the center that the product is regulated in will have jurisdiction.

- Drug eluting stent - CDRH - PMOA is the stent opening the artery
- Drug eluting disks - CDER - PMOA is the cancer chemotherapy
- Bone graft substitutes – CDRH and CDER
  - CDRH lead – PMOA is spinal or fracture stabilization
  - CDER lead – device component acts as drug delivery system
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 Speakers:

• **Maria Palasis**, PhD, President and Chief Executive Officer, 480 Biomedical

• **Veena Rao**, PhD, MBA, Sr. Director, Search and Evaluation, Delivery and Devices, Eli Lilly and Company

• **Carol Ryerson**, PhD, Senior Regulatory Principal Advisor, RCRI, Inc.

• **Howard Wolpert**, MD, VP for Medical Innovation, Lilly Cambridge Innovation Center, Eli Lilly and Company

Moderator:

• **Stuart Pollard**, PhD, Associate Vice President and Principal, Sanofi-Sunrise
THE CONVERGENCE OF MEDICAL DEVICES & DRUGS: The Future of Combination Products

Presented By:

MassBio

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May 12, 2017; 12:00pm – 6:00pm
The Westin - Waltham, MA

Registration is now open