Pediatric Device Consortia Grant Program

FDA OOPD Pediatric Medical Devices Workshop

THE GREAT ROOM
WHITE OAK CAMPUS

10903 New Hampshire Avenue
Silver Spring, Maryland 20993

Agenda

Background/Vision: The Pediatric Devices Workshop is intended to address perceived challenges to pediatric device development—namely, how to successfully attract investors, businesses, and industry sponsors to invest in pediatric device development projects AND how to effectively interact with the regulatory agency in the course of device development.

The target audience for the meeting includes both leaders and members from the various FDA-sponsored pediatric device consortia, other innovators who are interested in issues related to pediatric device development, and interested participants from industry and the financial community.

The meeting is intended to be engaging, interactive, and thought-provoking. It is also intended to facilitate interactions between the consortia leaders and industry/business participants.

8:30 A.M. **Introduction: Welcome and explanation of mock device to be used in the day's discussion**

Gayatri Rao, M.D., J.D.—Director, Office of Orphan Products Development (OOPD), Food and Drug Administration (FDA)

Linda Ulrich, M.D. — Director, Pediatric Device Consortia Grant Program, OOPD, FDA

Welcome

Judith Cope, M.D., M.P.H. — Office of Pediatric Therapeutics, FDA

8:45 A.M. **Pediatric Devices Patient and Family Member Experience**

Devin Alvarez — VEPTR Patient and *Rixys Alfonso* — Devin's mother

9:10 A.M. **Market Approaches and Considerations**

Moderator: *Linda Ulrich, M.D.* — FDA

- Entrepreneurs' perspectives
  - *David Ku, M.D., Ph.D.* — Professor of Engineering Entrepreneurship, Georgia Tech
  - *Nick Deeter* — OrthoPediatrics
  - *David Melnik* — PediaVision
  - *Tim Moran* – Pediaworks and Pediacath

10:20 **Perspectives on Pediatric Device Development**

Stephen Spielberg, M.D., Ph.D. — Deputy Commissioner for Medical Products and Tobacco, FDA

10:35 A.M. **Break**

10:45 A.M. **Considerations in early stage device development: A Medical device consultant's perspective**
Schulyer Ritter, M.B.A. — Beaufort LLC

10:55 A.M. **Audience Participation**

11:00 A.M. **"Show me the Money" — Addressing Funding Issues and Concerns**

Moderator: Eric Chen, M.S.

Overview of potential funding sources
Scott Merz, Ph.D. — Michigan Critical Care Consultants (MC3)

- Angel Investor Perspective
  - Do's and Don'ts of the pitch
  - How an Angel decides where to invest

  Ed Berger, Ph.D. — Larchmont Strategic Advisers
- Venture Capitalist Perspective
  - Do's and Don'ts of the pitch
  - How a VC decides where to invest

  Brian Duncan, M.D. — Arboretum Ventures
- Reimbursement strategies
  Ed Berger, Ph.D. — Larchmont Strategic Advisers

12:00 NOON **LUNCH BREAK (ON YOUR OWN)**

1:00 P.M. **Afternoon Introduction**
Jacqueline Francis, M.D. — Chief Pediatric Medical Officer, CDRH, FDA

1:10 P.M. **Clinical Trials Overview and Pediatric Issues**
Laura Thompson, B.Sc. — Statistician, General Surgical Devices Branch, CDRH, FDA

1:40 P.M. **Regulatory Overview**
Moderator: Francesca Joseph, M.D.

- IDE/HUD/HDE
  Lynn Henley, M.B.A. — Investigational Device Exemption Section, CDRH, FDA
- 510K Pathway
  Marjorie Shulman, M.B.A. — Premarket Notification Section, CDRH, FDA
- PMA
  Nicole Wolanski — Premarket Approval Section, CDRH, FDA
- Audience Participation

2:40 P.M. **BREAK**

2:55 P.M. **MOCK Pre-Submission Meeting…**
Participants from the Cardiovascular Review Division, CDRH
Andy Muelanaer, M.D. — Virginia Tech Carilion School of Medicine and *Al Wicks, Ph.D.* — Virginia Tech as "Sponsors"

4:00 P.M. **Audience Commentary/Debrief from Mock Pre-Submission Meeting**

4:15 P.M. **Lessons Learned by a sponsor-investigator**
Richard Ringel, M.D. — Johns Hopkins Children's Center

4:35 P.M. **Marketing Considerations: "I've got my clearance or approval—now what?"**
Schulyer Ritter, M.B.A. — Beaufort LLC

4:55 P.M. **Needs-assessment model (IPI)**
Don Lombardi, M.S. — Institute for Pediatric Innovation

5:15P.M. **Audience Participation**

5:20 P.M. **Closing Remarks**
Linda Ulrich, M.D. — FDA

5:30 P.M. **ADJOURN**