

Medical Device *and* Diagnostics Summit *on* Regulatory Approvals

Update on 510(k), PMA and Global Standards

SEPTEMBER 27, 2010 • HILTON BACK BAY • BOSTON, MA

FDA Address:

"FDA Oversight of Investigational Devices"

Michael E. Marcarelli, Pharm.D., Director, Division of
Bioresearch Monitoring, Office of Compliance, CDRH, **FDA**

Distinguished Speaking Faculty Includes:

Claudia J. Gilman, Vice President, General Counsel,
International, **Boston Scientific**

Peter C. Gonze, President, **Averion International Corp.**

James F. Kelly, Ph.D., Senior Director, Regulatory Affairs,
Roche Molecular Systems

Daniel A. Kracov, Partner, **Arnold & Porter LLP**

Irina Kulnits, Vice President, Regulatory and Clinical Affairs,
Anika Therapeutics Inc.

John McLane, Ph.D., Vice President,
Clinical and Regulatory, COO, **Clinquest, Inc.**

Susan Olinger, J.D. Corporate Vice President,
Regulatory Affairs, **B. Braun Medical, Inc.**

*The only place to receive comprehensive coverage
surrounding the latest changes and strategies to
guide you through the current regulatory process*

- Evaluate changes in the 510(k) process and the adoption of GHTF guidances
- Ensure appropriate review of investigator documents and approval of investigator regulatory packages
- Hear analysis of recent international cases impacting industry
- Hear an update surrounding FDA's new infusion pump initiative and the impact it could have on the 510(k) process for all devices
- Understand what clinical evaluation means and if the FDA can handle the extra review and inspection burdens
- Apply strategies for developing a well planned and executed IDE that positively assists with PMA or Premarket Notification 510K applications

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MAIN CONFERENCE

10:15 *Networking and Refreshment Break*

Monday, September 27, 2010

7:30 *Main Conference Registration*

8:30 *Chairman's Opening Remarks*

Peter C. Gonze, President, Averion International Corp.
Mr. Gonze oversees Averion's global operations and business development activities. He has over thirty years of healthcare industry experience. Mr. Gonze has extensive leadership experience developing and commercializing products at biotech, pharmaceutical, device and consumer healthcare companies. He has broad experience in all aspects of commercial operations having held senior level positions in general management, commercial operations and business development with pharmaceutical and biotech companies including: GlaxoSmithKline, SanofiAventis, Johnson & Johnson, Abbott Diagnostics, Medisense, AltaRex and most recently at United Therapeutics.

8:45 **Changes Ahead in the Regulatory Landscape and Their Impact on Regulatory Approvals**

As the FDA looks to improve safety and effectiveness of medical devices, the manufacturing community will likely be faced with new registration requirements. At the same time, the approaches established by the Global Harmonization Task Force are becoming the international standard for regulatory documentation. Hear about the latest developments in these areas and the impacts they will likely have on approval processes.

- Current concerns with the 510(k) process
- Adoption of GHTF Guidances
- Insights on proactive approaches to prepare for coming changes

James F. Kelly, Ph.D., Senior Director, Regulatory Affairs, Roche Molecular Systems

9:30 **Legal Issues Surrounding the Device and Diagnostic Regulatory Framework**

This presentation surveys the issues under consideration and looks at the regulatory and broader legal implications for device and diagnostic companies, including:

- Predicates in 510(k)s — “Old” predicates and predicates with sub-par performance
- Handling of incremental design changes
- Split and multiple predicates
- Indications versus Intended Use
- Rescission or modification authority for 510(k)s
- Changes in labeling post-clearance
- Authorities to control 510(k) devices postmarket — e.g., Condition of approval studies
- Potential changes to the regulation of lab-developed tests

Daniel A. Kracov, Partner, Arnold & Porter LLP

F D A A D D R E S S

10:45 **FDA Oversight of Investigational Devices**

- Overview of CDRH Bioresearch Monitoring Program (BIMO)
- Overview of the BIMO inspection process
- BIMO inspection metrics and trends
- New initiatives and areas of compliance interest

Michael E. Marcarelli, Pharm.D., Director, Division of Bioresearch Monitoring, Office of Compliance, CDRH, FDA

11:30 **Analysis of International Risk — Legal Update**

2009 saw a dramatic increase in FCPA enforcement and 2010 has continued that theme. This increase points toward a growing trend in the international enforcement landscape with heightened exposure of company executives to individual liability. In this session, hear insights surrounding the current trends and the impacts for the industry.

- Protecting against risk
- Analysis of recent cases and impacts for industry

Claudia J. Gilman, Vice President, General Counsel, International, Boston Scientific

12:15 *Luncheon*

1:30 **Emerging Healthcare Markets — Meeting Global Regulatory Needs in Latin America**

Latin America continues to be a hot market in the post economic environment. Therefore, it is prudent for companies to target this area. The challenge is that there a lot that is unknown in terms of regulatory approvals. The continent as a whole has moved from no regulatory patents to now accepting in some countries and partially accepting in others, making it very diverse and tricky to navigate through. Eight countries formed a conglomerate to develop consistency in regulations between these countries. This session provides an update on navigating through the Latin American regulatory environment.

- Highlights of regulatory processes
- Terms of different countries

Irina Kulinets, Vice President, Regulatory and Clinical Affairs, Anika Therapeutics Inc.

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2:15 **Strategies to Guide You through the Current Regulatory Process**

In this session, hear up-to-date information surrounding current regulatory guidelines. Gain insight into the current environment, impacts and strategies that can be implemented to assist in guiding you through the changing regulatory process.

- Analysis of regulatory guidelines and trends impacting device and diagnostics
- Strategies to assist in regulatory submission process
- Anticipate future requirements

Philip T. Lavin, Ph.D., Founder and Vice Chairman of the Board, Global Head, Medical Devices and Strategic Consulting, Averion International Corp.

3:00 *Networking and Refreshment Break*

3:30 **When Do You Start Preparing for Your IDE?**

Many Class II and most Class III devices under the pathway the FDA is taking may require clinical testing during the development process. One common regulatory pathway is to apply for an Investigational Device Exemption (IDE). The IDE process takes good planning and communication from the beginning with an understanding of what is needed in the application. A well planned and well executed IDE can help tremendously in the PMA or Premarket Notification 510K applications.

- Define significant and non significant risk devices
- Key parts of the IDE
- FDA and IRB communications
- Execution of the IDE study

John McLane, Ph.D. Vice President, Clinical and Regulatory Affairs, COO, Clinquest, Inc.

4:15 **Update Surrounding FDA's New Infusion Pump Initiative**

FDA has embarked on a significant new initiative for external infusion pumps. The 510(k) process will now include pre-clearance inspections, human factors simulations and clinical evaluations and assurance case reports. This promises to have a significant impact on pump manufacturers and it could impact the 510(k) process for all devices.

- The case for assurance cases
- Can FDA handle the extra review and inspection burdens?
- What does clinical evaluation mean?

Susan Olinger, J.D. Corporate Vice President, Regulatory Affairs, B. Braun Medical, Inc.

5:00 *Close of Conference*



5:00-6:00 **Networking, Wine & Cheese Reception**

Join colleagues and friends in a relaxed setting.

Photo by: Photolink / Getty Images

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Benefits of Attending:

- Latest updates surrounding changes in PMA and 510(k) applications
- FDA address surrounding new initiatives and areas of compliance interest
- Analysis of recent cases impacting *in vitro* diagnostics technology
- Strategies to guide you through the changing regulatory process

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