



# Medical Devices

## Strategies to Help Smaller and Mid-Size Companies Develop and Maintain a Competitive Edge

September 19-20, 2005

Hilton Minneapolis/St. Paul Airport Hotel • Bloomington, MN

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Medical Center

Michael Sanchez, M.A., CCA  
Guidant



### *Special Keynote Address*

#### **New Development and Strategies for Device and Combination Product Clearances and Approvals**

Jonathan Kahan, Esq., *Partner*, Hogan and Hartson, LLP

### **Attend this conference and you will:**

- Learn how to develop a reimbursement strategy and use existing guidelines to help capture lost revenue
- Explore tools to help you plan a regulatory strategy that makes sense for your company and your product
- Hear how adaptive trial design can save you time and money in running your clinical trials
- Discuss the importance of designing a sound subject recruitment process to enhance your trial timelines

### **Attend the Co-Located Drug/Device Combination Products Conference**

As a registered attendee for Medical Devices, you may also attend the sessions and receive the documentation for IBC's Drug/Device Combination Products conference and customize your meeting experience. All social functions of the co-located meetings will be shared, allowing you to network with attendees from both events. See inside for details.

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# Medical Devices

The medical device industry and related technologies account for sales of over \$175 billion worldwide. There are a reported 90,000 approved medical devices on the market today, and more than 180,000 U.S. companies involved in developing, testing, marketing, packaging, and distributing these devices for clinical use.

With more technologies failing in early-stage development, rising costs of doing business, and increasing competition for market-share of clinical devices, **smaller and mid-size companies must think strategically to start strong, maintain their lead, and achieve their goals of bringing novel therapeutic devices to market.**

This conference brings together the thought leaders and information to enable smaller and mid-size clinical device companies to plan their strategies up-front, ensure a productive trial process, and acquire the skills necessary to work effectively with the FDA for a smooth review and approval processes.

Attend this landmark conference and hear from industry experts who can help you shape your business, operational, regulatory, and reimbursement strategies to maximize efficiency, productivity, and output.

## **PLUS! Register today and save \$300.**

Offer expires July 19, 2005.

**Medical Devices** is co-located with IBC's **Drug/Device Combination Products** conference. These two meetings provide a unique opportunity for attendees to customize their conference experience by choosing to attend presentations at either event at no additional cost. The combined keynote address, pre-conference workshop, and presentation on product liability and consumer litigation allow attendees to broaden their knowledge and learn from colleagues' best practices, and questions. For more information on **Drug/Device Combination Products**, please visit [www.ibclifesciences.com/combo](http://www.ibclifesciences.com/combo)

**An event created for executives in small to mid-size device companies, specifically:**

- Presidents/CEOs
- Executive Officers
- Chief Medical and Scientific Officers
- Vice Presidents and Directors of:

- **Clinical Operations**
- **Clinical Research**
- **Regulatory Affairs**
- **Quality Assurance**
- **Legal**
- **Finance**
- **Alliance Management**
- **Reimbursement and Outcomes Planning**
- **Business Development**



For more than 25 years, IBC has been producing conferences for the biotech/pharmaceutical industry. **Medical Devices** is one of many events that comprise the IBC Life Sciences Pharmaceutical Development Series, which covers clinical trials, trial design, therapeutics, and drug delivery from Phase I to IV, including business and outsourcing strategy, and regulatory affairs.

### **Cardiac Safety**

*From QT and COX-2s to the Future of Clinical Medicine*

July 18-20, 2005 • Reston, VA • [www.IBCLifeSciences.com/3129](http://www.IBCLifeSciences.com/3129)

### **How US Companies are Conducting Global Clinical Trials**

July 25-26, 2005 • Phoenix, AZ • [www.IBCLifeSciences.com/3132](http://www.IBCLifeSciences.com/3132)

### **Biopharma Outsourcing for Clinical Trials**

September 12-14, 2005 • Boston, MA • [www.IBCLifeSciences.com/3138](http://www.IBCLifeSciences.com/3138)

### **Drug/Device Combination Products**

*Overcoming Development, Regulatory and Legal Hurdles to Gain Approval*

September 19-20, 2005 • Bloomington, MN • [www.IBCLifeSciences.com/combo](http://www.IBCLifeSciences.com/combo)

## **Call for Poster Submissions**

The organizers of **Medical Devices** recognize the significant educational value in poster presentations. Any registered conference attendee may sign up to present a poster. **The deadline to submit your abstract online at [www.IBCLifeSciences.com/devices](http://www.IBCLifeSciences.com/devices) is August 29, 2005 to be included in the conference handbook (see registration page for poster fee).** Poster abstracts and registrations received after August 29, 2005 will be subject to availability for on-site poster board and will not be included in the handbook. Full payment of conference registration and poster fees must also be received by August 29, 2005 for the abstract to be included in the handbook, and for poster board assignment to be made.

The size of the conference poster board is 4'h x 8'w. Please note: poster presentations may not be used as exhibit displays or for marketing purposes. All posters are subject to approval by conference organizers and are available strictly on a first-come, first-served basis.

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## EU Regulatory Update for Drug/Device and Biologic Products

**Thierry Chignon**, *Principal Consultant Europe, Quintiles Consulting Europe*

This workshop allows companies to find their way through the European regulatory maze, which currently has poorly-defined borders between some medicinal products and hTEPs, and assists companies to develop a relevant strategy to market their bioproducts in the EU. In addition, the speaker highlights the current opportunities for marketing combination products today in some European countries, taking advantage of the lack of European harmonized regulation.

7:30 *Pre-Conference Workshop Registration and Coffee*

### 8:00 Part One - Update on the European Regulation for Biological Combination Products

This session describes the current European regulations that exist for the vast range of products utilizing animal or human materials including:

- The medical device regulation (Directive 93/42/EC) with latest TSE requirements (Commission Directive 2003/32/EC) and viral safety utilizing the harmonized EN 12442 series
- The regime for medical devices utilizing human plasma derivatives regulated under Directive 2000/70/EC
- The medicinal regime for some cell therapy products with Directive 2003/63/EC
- The new human tissue/cell Directive 2004/23/EC, which was initially intended to be used for procurement, but will now affect products utilizing human tissue/cells

**Thierry Chignon, MSC, M.B.A, RAC**, has more than 15 years of experience as Regulatory Affairs and Quality Assurance Director of pharmaceutical and medical device companies (Head Pharmacist). As a Principal Consultant working for Quintiles Consulting Europe, he combines technical, regulatory, quality and business expertise with practical know-how for European health care regulations. He has particular knowledge of medical devices, biologics and drug/device combination products. In addition, he has been working for more than 5 years as an expert of the CEC (Commission of the European Communities – DG Enterprises G4) on the above mentioned topics and may provide the latest available information.

- The draft human Tissue Engineered Products (hTEPs) Regulation that is under preparation at the Commission level but should regulate marketing of most (if not all) products made of human engineered tissues/cells

9:45 *Networking Refreshment Break*

### 10:15 Part Two - Update on the European Regulation for Drug/Device Combination Products

This session highlights the most updated requirements for CE marking for combination products. It takes into account the newly published Medicinal Directive 2004/27/EC and the guidance MEDDEV 2.1/3 Rev.2. It describes the implementation of Directive 2000/70/EC for combination products utilizing human blood derivatives.

12:00 *Pre-Conference Workshop Concludes  
Lunch on your Own*

12:00 *Main Conference Registration*

### Reimbursement Strategy and Process

#### 1:00 Chairperson's Opening Remarks

**Michael Sanchez, M.A., CCA**, *Senior Reimbursement Analyst, Guidant*

#### 1:10 Evidence-Based Assessments of Novel Technologies

This presentation describes how the Blue Cross and Blue Shield Association Technology Evaluation Center (TEC) evaluates devices and diagnostics and provides feedback on the ways in which these technologies may improve net health outcomes. The presentation discusses TEC's process for developing assessments, with an emphasis on quality of evidence. Frequently asked questions are answered, including selection of technologies for assessment, how to communicate with TEC, and how Blue Cross and Blue Shield Plans use TEC assessments.

**Naomi Aronson, Ph.D.**, *Executive Director, Technology Evaluation Center, Blue Cross Blue Shield Association*


#### 1:50 Is Your Investigational Device Reimbursable?

Implementation of third-party reimbursement strategies is vital for medical device companies. This presentation explores third-party reimbursement opportunities available, specifically, Medicare policy under the 1995 FDA/HCFA Interagency Agreement (i.e., CMS Category A & B) for Investigational Device Exemptions (IDEs) and the 2000 National Coverage Determination (NCD) for Qualifying Clinical Trials. These distinct policies are compared and contrasted to facilitate

better understanding of which affects a specific investigational device. Medicare claims requirements for hospital and physician providers, Medicare's position on payments for trial complications, best practices in dealing with non-Medicare payers, and integrating third-party payer compliance into clinical trial contracting are also addressed.

**Michael Sanchez, M.A., CCA**, *Senior Reimbursement Analyst, Guidant*

2:30 *Networking Refreshment Break*

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#### 3:15 Fiscal Management of IDEs: The Site Perspective

This presentation provides a comprehensive review of regulations and requirements pertaining to reimbursement in clinical trials involving medical devices, from the site perspective. Expertly designed and run trials have become increasingly important for successful product launches in the device and diagnostic industries. Developing a winning strategy for conducting these trials is critical and requires an understanding of changing regulations both in the United States and internationally. A firm understanding of billing codes and reimbursement challenges associated with trials involving devices is also a necessity. Insufficient understanding of the intricacies involved in Medicare coverage regulations regarding devices can hinder the process and can result in a lack of reimbursement at the site level and lost revenue to the sponsor.

**Debbie Rosenfelder, BSN, CCRC**, *Clinical Research Coordinator, University of Pittsburgh Medical Center*

### 3:55 **Planning to Get Your Device Paid for in Canada**

This presentation covers new medical device technology diffusion in the Canadian public health care system, and preparation for this market access. Device companies looking to commercialize emerging technologies should consider not only strategies for intellectual property protection and regulatory approval, but also for technology diffusion. Planning can help accelerate growth of sales, economies of scale, and brand recognition, and should start early, ideally at the stage of clinical data collection, which can help health care providers evaluate and ultimately accept adoption of new technology.

**Jackie Csonka-Peeren, MASC, P.Eng, M.B.A.,** *President, BioAlliance Consulting Inc.*

### 4:35 **Panel Discussion: Lessons Learned and Challenges Met: The Device Reimbursement Process**

Bringing together experiences from sponsor, site, and service provider perspectives, panelists will discuss practical examples of how they have met reimbursement challenges, and how they view the evolution of medical device reimbursement for the industry.

*Moderator: Michael Sanchez, M.A., CCA, Senior Reimbursement Analyst, Guidant*

*Panelists:*

**Jackie Csonka-Peeren, MASC, P.Eng, M.B.A.,** *President, BioAlliance Consulting Inc.*

**Debbie Rosenfelder, BSN, CCRC,** *Clinical Research Coordinator, University of Pittsburgh Medical Center*

5:15 *Conclusion of Day One*

## Tuesday, September 20, 2005

## Main Conference

7:30 *Coffee*

### Shared Session with IBC's Drug/Device Combination Products Conference

#### 8:00 **Keynote Chairperson's Opening Remarks**

**David M. Fox, J.D.,** *Partner, Hogan & Hartson LLP*

#### 8:10 **Keynote Address**

##### **New Development and Strategies for Device and Combination Product Clearances and Approvals**

This presentation addresses current critical issues now facing CDRH, with special emphasis on the present and future regulation of combination products, and includes strategies for dealing with the Office of Combination Products (OCP) and the centers on novel new combinations of drugs, devices, biologics, and human tissues. Specific examples are provided detailing how FDA has handled some of the more complicated and controversial combination product questions. The presentation analyzes all aspects of determining the primary mode of action of a new combination and explains how best to present primary mode of action arguments in Requests for Designation and in meetings with OCP and the centers. User fees and the appropriate manufacturing regulatory scheme are also addressed. In addition to combination products, the keynote explores several of the most important regulatory issues facing the device industry, including the impact of MDUFMA on clearances and approvals, new initiatives within the Office of Device Evaluation, post-market studies, and current issues in humanitarian devices.

**Jonathan S. Kahan, J.D.,** *Partner, Hogan & Hartson LLP*

#### 8:55 **Stemming the Tide: An Update on Product Liability and Consumer Litigation Against Medical Device and Combination Product Manufacturers**


This talk provides a timely update on the most important product liability and consumer litigation issues facing medical device and combination product manufacturers today. The presentation focuses on current developments in two topics of concern to manufacturers:

- Federal preemption of state law tort claims
- Increasing focus on litigation against manufacturers on sales and marketing

The presentation provides tools and practical tips to help minimize liability risks.

**John P. Lavelle, Jr., Esq.,** *Partner-In-Charge, Product Liability and Mass Tort Practice Group, Ballard Spahr Andrews & Ingersoll, LLP*

9:35 *Networking Refreshment Break*

Sponsored by:  **Sterne Kessler Goldstein Fox**  
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### Regulatory Strategy and Legal Challenges

#### 10:20 **Chairperson's Opening Remarks**

**Mark Macedo, BSN, RN,** *Manager, Clinical Affairs, Organogenesis Inc.*

#### 10:30 **Placing a Medical Device in the EEA (European Economic Area)**

The purpose of the EU's product directives is to ensure safety and performance of the devices and at the same time enable free trade. For certain devices, it is necessary that a conformity assessment is carried out by a third party, a Notified Body. The manufacturer's internal control documentation in combination with a technical file, the use of harmonised standards, and a declaration of conformity assuring that the device complies with the requirements form the basis for the CE-marking.

**Marie Lindahl, B Pharm Sc.,** *Quality Assurance Advisor, TFS Trial Form Support AB, Sweden*

#### 11:10 **Early and Expanded Access to Significant-Risk Medical Devices**

Significant-risk medical devices must undergo clinical studies to evaluate safety and efficacy before being approved by the Food and Drug Administration (FDA) for general use. Certain patients may have access to significant-risk devices prior to the FDA approval and outside the auspices of clinical studies. This presentation discusses such early and expanded access to these devices.

**Mark Macedo, BSN, RN,** *Manager, Clinical Affairs, Organogenesis Inc.*

#### 11:50 **Strategic Intellectual Property Management for Medical Device Companies**

A well-developed intellectual property (IP) strategy goes beyond patent portfolio development and focuses on freedom-to-operate issues. Medical device companies face unique issues in a hostile legal environment. A systematic IP strategy enhances company value and becomes a valuable asset in fund-raising. Such a strategy forces early consideration of evolution in product design, indicated uses, and possible competitive responses.

**Timothy R. Conrad, J.D.,** *Partner, Merchant & Gould, P.A.*

## Operational Strategy: Planning for a Competitive Future

### 1:45 How to Prevent a Strategic Alliance from Turning into a Nasty Divorce

The medical device industry is populated with both well-established innovative companies and smaller specialized companies. As research dollars become scarce and the development of new products demands divergent scientific expertise, it becomes incumbent on all companies to form strategic partnerships. How rights and responsibilities are allocated and how fruits are divided are paramount to the success of the alliance. For the uninitiated, sorting out ownership of trade secrets, patents, and designs is replete with pitfalls. Intellectual property is often an afterthought in negotiating strategic alliance agreements. This presentation identifies and discusses several intellectual property issues that parties to a strategic alliance should consider prior to entering into such an agreement.

**David K.S. Cornwell, J.D., Director, Stern, Kessler, Goldstein & Fox LLP**

### 2:25 Avoiding Study Delays and Minimizing Burn Rate Due to Lagging Study Enrollment

Fewer than 20 percent of medical device companies complete their clinical plans either on time or ahead of time. As a result, many device companies incur a higher-than-expected capital burn rate. In the evolution of a new device, the clinical trial process represents the single most expensive and lengthy period; taking steps to minimize financial impact is critical. This presentation focuses on the planning process to ensure that companies achieve their goals. The presentation details recruitment and retention planning, and how to optimize recruitment investment.

**Elizabeth Moench, President, MediciGroup, Inc.**

### 3:05 Networking Refreshment Break

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### 3:50 Planning Ahead: Positioning Your Company for Sale

All too often, companies only think of an exit when need forces them or they are approached by someone else. At this point, it is usually too late to package the company to maximize value to stockholders. Positioning your company for sale requires proactive management and planning well ahead of the time an exit is either needed or desired. This presentation highlights key factors to consider in the years prior to any exit, with trends and case studies taken from the medical device community.

**David Q. Anderson, Ph.D., Vice President, Healthcare Investment Banking, Covington Associates LLC**

### 4:30 Customized IVR Systems Incorporating Adaptive Randomization for Clinical Trials

This presentation addresses adaptive randomization which supports the statistical methodology of a clinical trial by maintaining balance among treatment groups for the analysis population and for subgroups. With this technology, response information about each subject is maximized. This is especially important for studies involving rare conditions, terminally ill patient populations, or when it is anticipated that a trial may be terminated before completion.

**Eva R. Miller, Ph.D., Manager, Biostatistics, Interactive Clinical Technologies Inc. (ICTI)**

### 5:10 Conference Concludes

## Venue & Travel Information

**Hilton Minneapolis/St. Paul Airport Hotel**  
**3800 American Blvd. East**  
**Bloomington, MN 55425-1658**  
**Tel: 952-854-2100 • Fax: 952-854-8002**

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**DISCOUNTED HOTEL RESERVATIONS:** Please call the hotel directly at 952-854-2100 before August 29, 2005 to be included in IBC's dedicated room block for this conference. Please be certain to mention IBC along with the conference title and date of the conference.

## Registration Information

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**SPECIAL NEEDS:** If you have a handicap or have special needs, please let us know in order that we may address your special needs for your attendance at this conference.



For security precautions, a photo identification will be required of ALL attendees at check-in.



# Medical Devices

*Strategies to Help Smaller and  
Mid-Size Companies Develop and  
Maintain a Competitive Edge*

September 19-20, 2005

Hilton Minneapolis/St. Paul Airport Hotel • Bloomington, MN

## Medical Devices

Product Code: 3133 FAX

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Title \_\_\_\_\_ E-mail \_\_\_\_\_

Company \_\_\_\_\_ Department \_\_\_\_\_

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|   | Early Bird Commercial<br>(Until July 19)  | Commercial<br>(After July 19)   | Early Bird Academic/Govt.<br>(Until July 19)        | Academic/Govt.<br>(After July 19) |
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