



# **Medical Device Transactions: Conducting Effective Due Diligence and Mitigating Risk**

Offices of Arnold and Porter  
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## **Wednesday, December 9<sup>th</sup>**

**8:30 – 8:55**                      **REGISTRATION AND CONTINENTAL BREAKFAST**

**8:55**                                **Welcome**  
*Thomas Maeder, Executive Director, MTLI, AdvaMed*

### **The Role of Diligence in Transactions** *Steve Parker, Partner, Arnold and Porter*

- Purpose
- Structure
- Resources
- Diligence Logistics
  - Time frames
  - Project and information management
  - Staff and team development
  - Use of experts
- The role of privilege in due diligence

### **Evaluating Corporate and Financial Due Diligence** *Richard Baltz, Partner, Arnold & Porter*

- Public company issues
- Corporate formalities and framework
- Board/audit committee activities
- Key financial indicators and controls

### **BREAK**

### **Evaluating Medical Device Technologies** *Karen Becker, President and CEO, Becker & Associates (invited)*

- The clinical value of a new technology

- The competitive landscape
- Practice of medicine and potential obstacles to new technology adoption

### **The Role of Compliance Programs in Due Diligence**

*Keith Korenchuk, Partner, Arnold and Porter*

- Compliance as a control framework
- Compliance risk assessments
- Using compliance as a framework for other diligence activities
- Identifying key relationships and transactions
- Isolating specific risk activities
- FCPA risk assessments

### **LUNCH**

### **Evaluating Litigation and Ongoing Government Investigations**

*James Cooper, Partner, Arnold and Porter*

- Identifying key risk areas
- Evaluating the merits and exposure presented by litigation and investigations
- Assessing future costs/opportunities

### **Evaluating Intellectual Property**

*David Marsh, Partner, Arnold and Porter*

- Portfolio review
- Evaluating offensive and defensive context
- Litigation potential

### **BREAK**

### **Evaluating Employment and Benefits Issues**

*Edward Bintz, Partner, Arnold and Porter*

- Reviewing compensation and benefits issues
- Evaluating benefit plan structure, costs and future workforce related issues
- Workforce consolidation

### **Evaluating Regulatory Clearances, Approvals and General Compliance Status**

*Dan Kracov, Partner, Arnold and Porter*

- FDA clearances/approvals and related regulatory framework
- FDA enforcement actions
- Promotional Review

### **Evaluating Quality Systems Compliance**

*Elaine Messa, Becker and Associates*

- Developing a plan for assessing quality systems compliance
- Key issues to address in document requests

- Conducting audits

### **Evaluating Coverage, Reimbursement and Healthcare Compliance Status**

*Allison Shuren, Partner, Arnold and Porter*

- Evaluating coverage, coding and payment status
- Examining fraud and abuse risks

### **Products Liability Issues**

*Tom Konopka, Senior Vice President, Business Development and Marketing, Medmarc*

### **Using Diligence Generated Information**

*Steve Parker, Partner, Arnold and Porter*

- Pre and post closing clean up
- Financial and deal restructuring
- Potential self disclosure issues

### **Final Questions/Discussion**

### **ADJOURNMENT**

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