

Opening International Opportunities Market Development

**How Medical Device/Biotech Companies Develop an
International Presence**

**Lise N. Halpern
FocusOn Strategies**

The Challenge

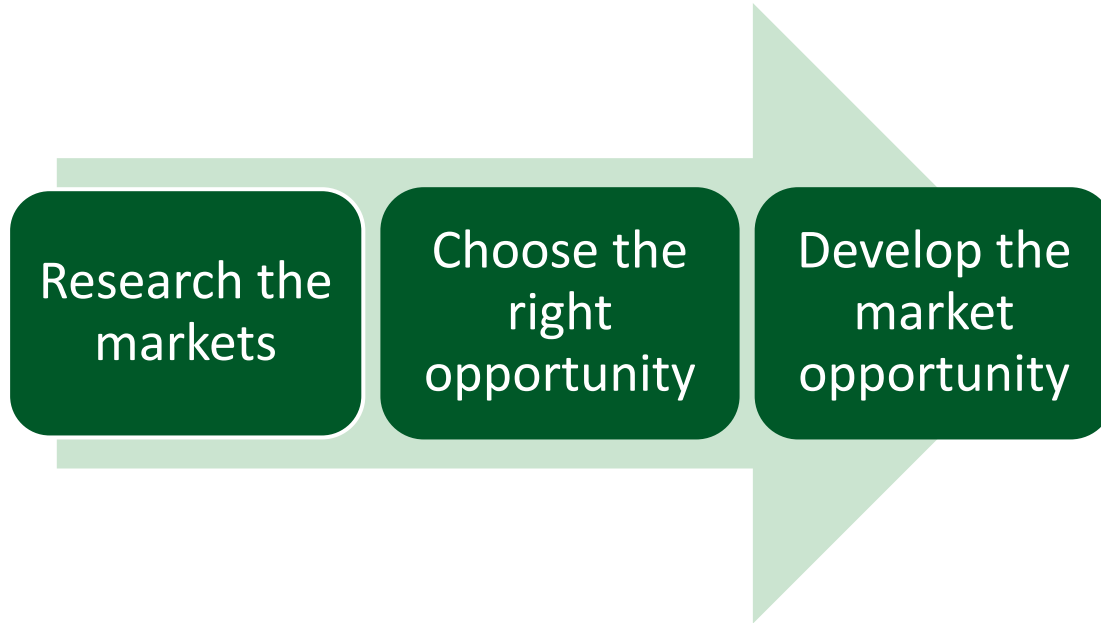


- Opening international medical device markets is a marathon not a sprint
- Requires a significant investment of time and money
 - ▶ Opportunity cost



- Start when the timing is right
 - ▶ Fits with corporate strategic goals
- Start from a position of strength
 - ▶ Product stability
 - ▶ Financial resources

Key Steps



Keys to Success

- Recognize biases and assumptions
- Focus on the few best opportunities
- Be willing to make and fix mistakes

Qualitative Market Research



- Identify thought leaders
 - ▶ Publications, societies, referrals, leading institutions
- Arrange face to face interviews
 - ▶ Sessions at shows, visits to hospital sites
 - ▶ Leverage sneak peek at innovation to get in the door



Collect Quality Qualitative Data



- Ask open-ended questions
- Observe the clinical environment and talk to support staff
- Listen and document carefully
 - ▶ Don't try to analyze while you interview
- Use a data collection process (eg Voice of the Customer)
- **Beware of Assumptions!!!**



Evaluate Market Opportunities



Use a robust process to compare opportunities and evaluate risks

Key Questions	Rating
Sufficient size market opportunity	
Product fits into clinical practice	
Product offers a significant clinical benefit	
Offers an economic benefit	
No competitive roadblocks	
Few significant barriers to entry	
Strategic importance to other markets	
Clear point of entry	
Potential sales channels	

Low Impact High Likelihood	High Impact High Likelihood
Low Impact Low Likelihood	High Impact Low Likelihood

Short-term Success AND Long-term Results



- Choose markets that will bring sustainable business
 - ▶ Scalable sales process
 - ▶ Point of Entry to larger markets
- Yet can bring short-term success
 - ▶ Interested customers
 - ▶ Low barriers to entry
 - ▶ High value application

Bad reasons to pick a market

They speak English

The distributor will buy a demo unit

The distributor said they already have POs

**Dr. X saw it at the last trade show and
really, really wants one**

It is the largest opportunity

Getting Started

- Localize product and labeling
- Obtain regulatory/reimbursement approvals
- Demonstrate clinical utility
- Localize promotional materials
- Build a local presence
 - ▶ Strategic partner
- Promote – Get noticed



Localize Product and Labeling



- Observe and understand the clinical environment
- Preview product to potential customers
 - ▶ Ask form, fit and function questions
 - ▶ Ask clinical use questions
 - ▶ Preview labeling and instructions
- Localizing labeling
 - ▶ Minimize text in official (regulatory approved) documentation
 - ▶ Supplement with localized materials as necessary



Demonstrate Clinical Utility



- The US is not enough
- Not just about regulatory approval or reimbursement
- Local clinical trials and references
 - ▶ Thought leaders & leading institutions
 - ▶ Address clinical use issues
 - ▶ Choose endpoints carefully
 - ▶ Collect data on economic impact
- Publish in local journals and at local meetings



Localize Sales Approach



- Promotional Materials
 - ▶ Language
 - ▶ Target audience
 - ▶ Cultural preferences
 - ▶ Meet the needs of sales process

- Sales Process
 - ▶ Target selection
 - ▶ Customer call points
 - ▶ Hospital/ Clinic administration
 - ▶ Government agency requirements



Build a Local Presence



- Identify partners/distributors
- Never abdicate your sales responsibility
 - ▶ Know your key customers personally



- Make it easy to business
 - ▶ Communication channels
 - ▶ Web site
 - ▶ Technical and customer support
 - ▶ Contracts and agreements

Promote – Get Noticed

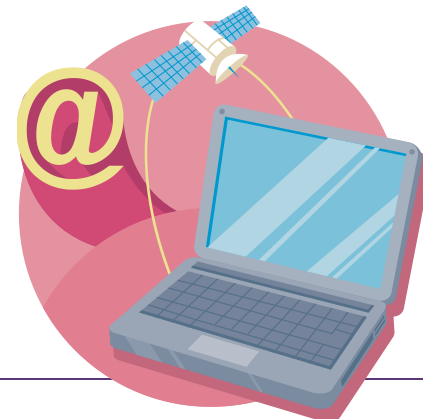


- Maintain Key thought leader relationships



- Participate in trade shows/meetings
 - ▶ Publish
 - ▶ Preview new technology
 - ▶ Booth presence
 - ▶ Seminars and symposiums

- Find innovative ways to “touch” customers
 - ▶ Web casts
 - ▶ Leverage US reference sites
 - ▶ eNewsletters
 - ▶ User groups



Putting it All Together



■ The Steps

- ▶ Understand market
- ▶ Select starting point
- ▶ Localize product
- ▶ Prove clinical efficacy
- ▶ Localize sales approach
- ▶ Build a local presence
- ▶ Get noticed

■ Keys to success

- ▶ Recognize biases and assumptions
- ▶ Focus on the few best opportunities
- ▶ Be willing to make and fix mistakes

