

## Conference Highlight

# Global Pharma Competitive Intelligence

*A Necessity in Times of Economic Uncertainty*

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**T**his year is proving to be a critical one for many industries, including the pharmaceutical industry. The results of the 2008 presidential election, the economy, and sweeping changes in the global market place all factor into how leaders in the industry will either falter or thrive. Actionable, evidence-based and global pharmaceutical competitive intelligence (CI) and general business intelligence (BI) will play an important role in the drama about to unfold.

The pressing issues facing pharma CI were addressed in-depth at the 2008 Pharmaceutical Competitive Intelligence Conference where approximately 240 attendees got to hear excellent information on the state of CI within the life sciences, and interesting suggestions as to where the discipline is headed. Some common themes across the two days were that the environments for the pharmaceutical and device industries were changing dramatically with implications for CI going forward, the importance of keeping an eye on China, and whether CI is a strategic or tactical discipline.

#### **Innovation Proven by Value**

Attendees heard two opening keynote presentations, the first of which, "New Realities for Drug/Device Development and Commercialization" by Wayne Rosenkrans, Distinguished Fellow, MIT Center for Biomedical Innovation, as well as Chairman and President, Personalized Medicine Coalition and Chief Applications Officer, SciTech Strategies, examined how we should be thinking about what now constitutes "value" within healthcare, and the importance that evidence plays (and will continue to play) within the life sciences. (See also "Value-based Pricing," PMN Reprint #76-04; <http://tinyurl.com/4chyy2>).

Rosenkrans noted that an expanded ability to demonstrate evidence will have significant repercussions for product developers as "the old hurdles of efficacy, safety, and production assurance of quality are no longer sufficient." Rosenkrans argued that new hurdles exist, namely demonstrating a product's clinical effectiveness, as well as its coverage and reimbursement by insurers.

To that end, Rosenkrans observed that innovation can no longer be tacitly accepted by stakeholders, it will increasingly need to be demonstrated. "Innovation will need to be proven in the clinic, with real patients and providers, in a cost effective manner to demonstrate what works best, for whom, and under what circumstances," said Rosenkrans.

#### **Evidence, Effectiveness, Endpoints**

Rosenkrans sees the industry moving definitively toward studies that confirm real-world, head-to-head clinical effectiveness, as well as the emerging importance of segmenting patient populations by various means including genomic, imaging, and informatics in order to increase the benefit of therapy. Additionally, he shared a new model of drug development that involves payers and regulators (early) in a trial's design, and encompasses trial simulations, surrogate endpoints that delineate benefit and risk, and continuous rather than episodic data capture with no step-function increase in patient exposure at launch

His concluding message was a call to reshape the healthcare system into one that is driven more by learning than production. "We need a learning healthcare system in which evidence emerges as a natural by-product of the care delivered [and] substantially enhanced capacity for the development of evidence and guidance for clinical decision making, stronger incentives and tools for the application of proven services, and effective communication for and between patients and providers about the nature of evidence and what it suggests."

#### **Softening of Medical Device Pipeline**

Joseph DeVivo, Global President, Reconstructive Orthopaedics, Smith & Nephew, delivered the second keynote, "A Medical Device Perspective: Healthcare in the Digital Age."

DeVivo shared with the attendees how the medical device industry was softening somewhat, with 20 initial public offerings (IPOs) withdrawn or postponed since July 2007. However, the industry still has a robust pipeline, with some 3,000 products awaiting approval and introduction to the market. The market itself, DeVivo commented, has a 62% concentration in *in vitro* diagnostics, cardiovascular and orthopedic products.

DeVivo pointed out that the industry needs trained professionals. He described a new biomedical MBA academic program that is a partnership between industry and the University of Memphis, with a curriculum concentration focusing on:

1. Global healthcare economics
2. Design and management of the supply chain within the biomedical industry
3. Healthcare administration
4. Medical device new product development

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This unique program, unlike typical consumer-products-based MBA curriculums, focuses on industry skills and knowledge for biomedical professionals, offers hands-on industry training with internships throughout the 21-month MBA program, is a company-sponsored program with several top Medical-Device companies, offers 100% tuition-paid for students, as well as guaranteed employment upon graduation for students.

DeVivo also pointed out how medical device technologies are converging within several treatment areas to bring more data into the operating room, as well as improving physicians' dexterity and visualization.

### Keeping China in Sight

Two talks with a focus on the role of China in the evolving life sciences marketplace were given by Holger Meissner, Co-Founder and President of Adler Life Sciences and Sean Freston, Managing Director of Asia/Pacific for Proactive Worldwide.

Meissner spoke of emerging markets (Central Eastern Europe, Brazil, Russia, India, China, and Mexico) and the rationale for their entry, which usually encompasses top line revenue growth, access to broader populations of patients for clinical trials, and the outsourcing of a variety of business functions to protect margins.

Meissner was, however, quick to add that there are several significant challenges and potential downsides that face those organizations seeking to expand into emerging markets (see Table 1). And, while China seems to be the current focal point for significant R&D investment according to Meissner, he tempered that comment with 2007 data from Dr Lifeng Geng that pointed to "the very high failure rate of joint ventures...currently in the neighborhood of 30%-60%."

### Global CI Role

Today's role of global CI seems focused on both business and competitive intelligence, with major projects encompassing:

1. Strategic, tactical, or operational issues
2. Global, regional, and local aspects of conducting business
3. Services provided within the country
4. Resources and budgeting
5. Communications platforms
6. Defining competitors
7. Training
8. Gap-fill analyses

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Market	Country
Less transparent data	Cultural business environment, eg, top down vs consensus driven
New local competitors	Language barriers
Different regulations	Geographical scope, eg, China, movement within country, Russia's size of 6,591,027 square miles
Different legal frameworks and views of intellectual property (IP)	Perceived local values, eg, quality of implementation
Different distribution dynamics among hospitals, clinics, retail, and domestic customers	
Finances	
Work force qualifications and labor unions	
Little historical network or infrastructure for your corporation	

Table 1: Challenges and Downsides of Emerging Markets and Countries

## Big Pharma Ranks China as Number One Destination in Asia for Pharmaceutical Outsourcing

Source: PriceWaterhouseCoopers; Full report at <http://www.pwc.com/pharma>

Big pharmaceutical companies now rank China as the best location for outsourcing in Asia, followed by India, Korea and Taiwan, respectively, according to a newly released PricewaterhouseCoopers index. The index evaluates Asian countries according to cost, risk and market opportunity for the pharmaceutical industry.

The index was published in a new PricewaterhouseCoopers report entitled "The Changing Dynamics of Pharma Outsourcing in Asia: Are You Readjusting Your Sights?" which found that Asia is emerging not just as a drug manufacturing powerhouse but a rival to the United States as a leading source of drug discovery and high-end innovation. Both clinical trial activity and investments by pharmaceutical companies to expand presence in Asia are accelerating, and the report suggests Asia outsourcing is moving up the value chain, as low-cost production is eclipsed by a broad range of factors, including market potential and R&D capacity as the drivers of growth.

"Within five to ten years, we will be moving from 'made in China' to 'discovered in China'" said one pharmaceutical industry executive interviewed for the report. "Pharmaceutical companies need to make sure they are refining their strategies to make the most of the opportunities presented in Asian countries," said Michael Keech, director, PricewaterhouseCoopers global pharmaceutical and life sciences industry group. "China and India will continue to spearhead growth in the Asian pharmaceutical sector, but, alongside those countries, Singapore will maintain its position as a center for research and innovation. While the trio of India, China and Singapore are proving to be the 'hotspots' of the Asian pharmaceutical sector, other countries, notably Korea and Taiwan, are also going to be increasingly significant. The companies that will be most successful at making pharma outsourcing and location decisions will be those that are most adept at managing and mixing a range of contractual relationships and partnerships across a number of different locations."

The report highlights three significant developments that are shaping Asian pharmaceutical outsourcing:

1. The trend towards high-end innovation -- intellectual property (IP) concerns have previously inhibited this trend in pharma but, increasingly, such concerns are being overcome and major moves are being made by big pharmaceutical companies to increase their drug discovery investment in Asia.
2. Rapid expansion of clinical trials in Asia -- the volume of clinical trials being conducted in countries outside of Europe, North America and Japan has been growing rapidly in recent years with Asian countries leading much of the growth. China has overtaken India as one of the fastest-growing locations. By June 2008, China had 428 clinical trials registered on the website Clinicaltrials.gov as under way and a cumulative total of 870 completed or ongoing trials compared with 737 in India. Cost has been a critical factor in this expansion. For example, clinical trials are estimated to be up to 50 percent cheaper in India compared to the U.S.
3. A scaling up of pharma manufacturing in Asia -- with an increased commitment to international standards, Asian contract manufacturing organizations (CMOs) are securing more outsourcing orders from big pharmaceutical companies. In India, for example, there are more than 100 FDA-approved pharmaceutical facilities -- the largest number in any country outside the U.S.

The report shows that China and India, followed by Korea and Taiwan, are now delivering a number of benefits for the pharmaceutical industry including a pool of educated and qualified scientists, intellectual property (IP) law reform and market growth. These trends are outweighing factors that had previously inhibited development, principally uncertain regulatory frameworks and enforcement.

Significant risks remain, but the report observes a growing convergence with international regulatory standards. However, the report's authors point out that such convergence is also being felt in labor markets, with the result that traditionally wide wage differentials, compared to developed country locations, are narrowing. Such convergence will continue to shrink the cost gap, prompted in part by the need for Asian countries to compete for 'high-end' skills in an international labor market. India, for example, is already finding it difficult to recruit in certain areas such as clinical research personnel.

"It proves to be a solid investment in emerging markets when applied to solving problems related to head starts in new countries (when transferring teams), establishing 'early warning' rapport, avoiding duplication of efforts and determining the best use of limited resources and expertise, ensuring global compliance, and alerting new teams of potential speed bumps and pitfalls," said Meissner.

Currently within China, BI/CI serves multiple internal customers, including:

<i>Internal customer</i>	<i>Importance</i>
<b>R&amp;D</b>	<b>&gt;25%</b>
<b>Planning</b>	<b>10% - 25%</b>
<b>Marketing</b>	
<b>Headquarters</b>	
<b>Others</b>	<b>&lt;10%</b>

Meissner predicts that there is a high likelihood that Chinese companies will intensify and expand their global BI/CI capabilities and work in the immediate future, and become significant purchasers of both BI and CI services.

#### **China's Strengths and Weaknesses**

Sean Freston echoed similar themes, especially that China was the "biology place to go," although he pointed out that there is ongoing and rabid competition for talent.

"Today," said Freston, "fluent bilingual (English/Chinese) scientists are making only 13,000 to 15,000 RMB [Renminbi or people's money; one RMB = \$0.146; 15,000 RMB = \$2,193.33] per month." With R&D costs approximating only 2%-5% of what it costs to do R&D in the US, one can see the high appeal of beginning research commitments within China.

But with those seemingly modest costs, come some significant operational headaches including infrastructure and legal barriers, as well as high employee turnover.

However Freston is fairly well sold on China from a data capture standpoint and believes it will be the location of choice for future clinical trials. The US FDA seems to be leaning that way as well, according to the agency, with a new office to be situated within the US Embassy in Beijing before year end 2008, predominantly driven by inspection issues.

"There's high quality data there, with a very low error rate," Freston commented, "But time can be an issue. For example, India allows simultaneous submissions of data in IND preparation, whereas China requires back-to-back (sequential) submissions, which can add 9-12 months to the process." There is also growing concern that portions of patient populations within Chinese trials utilize traditional Chinese medicine (TCM) without disclosing that use and thereby (potentially) threatening data integrity.

As more companies begin operations within China, Freston predicts that cost advantages will diminish as the bid for talent and operational costs escalate. "China can represent terrific new strengths for R&D, including patient recruitment, quality, and cost. But with that comes some clear current weaknesses, including lack of experience, regulatory uncertainties, and inconsistent compliance coupled with ethic concerns," warns Freston.

Freston closed with an important reminder for all those who seek to open offices in China, and that is that relationships (both public and private) are key to doing business successfully in China. "Networks (guanxi) and their growth and maintenance are crucial." Some things are universal after all.

#### **Is There a Balance between Strategic CI and Tactical CI?**

One of the more interesting panel discussions at the meeting was held among JJ Owen, Associate Director, Scientific & Competitive Analysis, Millennium Pharmaceuticals, Monika Giese, Head of Global CI, Novartis Pharma AG, and Deborah Dauber, Associate Director, Competitive Intelligence, Genentech. The panel examined how their respective organizations define and look at the competitive intelligence function, and distinctions each one makes between strategic and tactical CI.

The three agreed that the key distinction that existed between strategic and tactical CI was a time horizon, with, according to Giese, "strategic CI looking at issues 5+ years downstream that are meshed with corporate or R&D strategy."

Dauber commented that at Genentech, CI usually examines both strategic and tactical activities, and that tactical CI usually incorporates observations and recommendations that can be incorporated within a year.

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Owen reflected that most of the CI his organization undertakes is tactical, and that the key to measuring its effectiveness is whether or not a brand plan succeeds. He also cited listening and recommunication skills (the ability to reclarify and recommunicate project objectives) as key CI skills.

Giese also urged the attendees to be sure to reflect upon the following four questions when considering CI:

1. What do your clients or stakeholders know?
2. What don't they know?
3. What do they think?
4. Who influences your internal customers?

These starting points can help stakeholders frame and provide context for their CI activities, whether strategic or tactical.

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