What's Your Opinion?

2005 — A LOOK AHEAD

What are the most significant business challenges you believe the industry will face in 2005?

Higher development costs and deceleration of drugs to market

I believe technologies can become a reality, however, the resultant reduction in drug-development costs by 75% and cuts in lead time by nine years, as reported in a recent study, are way overestimated. With sustained FDA oversight (not altogether a bad thing), the need for continuous quality reviews, and the diminishing supply of successful drug candidates the tendency will be higher development costs and a deceleration of the number of drugs to market.

Judy Klein, B.S., MBA
Manager, Clinical Services Procurement
Amgen

In a global market, trade compliance becomes every bit as important as regulatory compliance. The ability to cross borders with precision and speed are keys to being successful in the international marketplace.

SCOTT SZWAST
UPS Supply Chain Solutions

AARON GRAHAM
Purdue Pharma L.P.

New technology is now available that can help ensure the integrity of the pharmaceutical supply chain by tracking medicines electronically from production plant to pharmacy through the inclusion of RFID (radio frequency identification) "license plates" on each bottle.

sion is a key area of competitive differentiation and indeed profitability. It is not enough to source and distribute pharmaceuticals quickly; the tasks must also be done precisely. While meeting regulatory compliance (FDA, DEA, individual state pharmaceutical licensing regulations) has long been a core competency of successful pharmaceutical corporations, being compliant is a constantly moving and evolving target that requires continuous process improvement. Further, the ongoing migration of many products into the retail-sales channel drives the need for customer compliance in addition to adherence to regulatory requirements such as voluntary intra-industry compliance standards. The ability to meet the aforementioned challenges is a key demarcation between leaders and laggards in this industry.

GRAHAM. From my perspective, having worked for the FDA, DEA, and Pfizer before joining Purdue Pharma, the counterfeiting of prescription drugs is a growing patient-safety issue. New technology is now available that can help ensure the integrity of the pharmaceutical supply chain by tracking medicines electronically from production plant to pharmacy through the inclusion of RFID (radio frequency identification) "license plates" on each bottle. The FDA is encouraging all companies to incorporate this technology by 2007. Purdue began using this technology in November 2004 when it launched the industry's first integrated, anticounterfeiting, track-and-trace packaging for a scheduled pharmaceutical product. Each 100-tablet bottle of OxyContin Tablets provided to two of our largest wholesale customers now includes a RFID tag that can be scanned by special sensors. This will make it possible for our products to be tracked and validated along every step of the supply chain. We also are adding a special variable-effect, color-shifting ink to our labels to thwart would-be counterfeiters. We expect this to become the industry standard in a few years.

TECHNOLOGY

CAUWENBERGH. Ideally, predictive tools, including assays, computer modeling techniques, and biomarkers could shorten development time, reduce the cost of development,

and increase the accuracy of diagnosis, making sure that the right patient gets the right drug because of proper diagnostic tools rather than improper sales and marketing tools. Realistically, these technologies will add a layer of complexity to development resulting in no change in development requirements except for the addition of the cost of using the tools on top of what is already done today. In medicine, progress has come with increased quality of life, increased life expectancy, and increased cost to corporations, physicians, and patients.

WILHELM. The timeframe for identification and initial qualification of new product candidates can potentially be decreased, particularly in the setting of new technologies coming from the academic research centers. Some universities have technology-transfer centers

BIG CHANGES AHEAD FOR TECHNOLOGY-BASED PHARMACEUTICAL DETAILING

E-detailing, the practice of providing pharmaceutical information and promotional material to physicians using technology, continues its rapid evolution. A new study from Manhattan Research LLC finds that using technology to support the interaction between the physician, pharmaceutical company, and detail representative, which itself is just a few years old, has already broken the boundaries of its traditional definition.

"Electronic detailing has rapidly moved beyond physicians using a static Website for product information," says Mark Bard, president of Manhattan Research. "It is now more accurately described as technology-supported detailing — a way to engage, educate, and incorporate physician preferences, including how and when they want to learn over time."

The study, the Technology-Supported Detailing Research Module, is based on an analysis of data collected from two nationally representative physician research studies, ePharma Physician v4.0 and Taking the Pulse v4.0. It explores all aspects of physician adoption of e-detailing, including use, satisfaction, relevance, relative channel mix, response rates, and the pharma and vendor competitive landscape.

"With its flexibility and convenience, technology-supported detailing continues to be an effective and highly economical way to communicate with physicians," says Ashley Wendus, senior analyst, at Manhattan Research. "It offers a supplemental channel to build on existing relationships with high-prescribing physicians and a primary channel to connect with hard-to-reach physicians."

At the same time, despite top-line growth in users, physicians are becoming more selective about when and where they will participate in technology-based detailing when invited. They are seeking to optimize their information mix, including reallocating where they pull information.

Today's options for physicians include accessing a self-service information site, participating in Web-based seminars, interacting with a remote rep by video stream, and meeting with sales reps who use mobile-device detail aids. On the horizon are more choices based on different lengths of details, interactive learning that enables physicians to proceed at their own speed and pace, and close-loop analytics that can monitor physician users over time tailoring new offerings based on historical trends.

As physicians continue to spend less time with pharma detail reps and seek alternative information channels, pharmaceutical sales executives must rethink their approach, the study concludes. Pharma companies can take one of two paths: fight market trends and risk alienating a growing segment of their physician audience or embrace these new technologies with new strategies that foster enhanced relationships with the physician community.

Source: Manhattan Research LLC, New York.
For more information, visit manhattanresearch.com.

STUDY RESULTS

- Of the physicians invited to participate in e-detailing, an estimated **THREE-QUARTERS ARE PARTICIPATING TODAY**. Additionally, about half of all physicians not currently participating indicate future interest in doing so.
- Physicians, on average, spend less than 10% of their overall time accessing pharmaceutical information through e-detailing. To achieve an optimal channel mix, physicians **EXPECT THEIR TIME SPENT ACCESSING E-DETAILING TO INCREASE BY ALMOST 66%** in the near future.
- The types of e-detailing sessions with the **HIGHEST RESPONSE RATES ARE A FLASH ANIMATION DETAIL AND A SELF-SERVICE WEBSITE**
- In rank order, the top seven pharma companies in reaching physicians with e-detailing are: **PFIZER, ASTRAZENECA, NOVARTIS, GLAXOSMITHKLINE, AVENTIS, MERCK, AND LILLY**.
- Vendor platforms analyzed in this research include: **PHYSICIANS INTERACTIVE, MEDSCAPE, LATHIAN (A.K.A. MY DRUG REP), MARKETRX, MEDSITE, APTILON, IQLEARNING, AND DOTCOM ADVISORS**.

ALLIED HEALTH PROFESSIONALS ARE PRIMED FOR E-DETAILS

NURSE PRACTITIONERS (NPS) AND PHYSICIAN ASSISTANTS (PAS) ARE A READY AUDIENCE FOR E-DETAILS because they haven't been overwhelmed by promotional attention, and they welcome new information about meds but don't write the volume of prescriptions that would warrant the cost of an in-person detail. Although NPs and PAs are only responsible for 3.5% of the total prescriptions in the United States, pressure from health plans will increase the amount of primary care delivered by these allied health professionals, including scripts for pain management, birth control, depression and anxiety, infection, and hypertension. Pharma firms — not just brands — should build long-term relationships with NPs and PAs now to influence prescribing and build momentum for compliance programs.

Source: Forrester Research Inc., Cambridge, Mass.
For more information, visit forrester.com.

What's Your Opinion?

2005 — A LOOK AHEAD

What are the most significant business challenges you believe the industry will face in 2005?

E-Technologies

In the clinical-trial industry, CROs, pharmaceutical, and medical-device companies have begun to recognize the value of e-clinical technologies and we see these tools becoming an everyday component of clinical-trial research. The next challenge will be to investigate ways to spur even greater efficiencies, competitive advantages, and cost savings. One such example of this shift is the increase of in-licensing agreements that enable companies to have easy access to valuable research tools.

Standards also have come to the forefront as a business challenge for the clinical-trial industry. The next few years will lay the foundation for progressing industry-wide standards that result in sponsors, vendors, and regulators sharing data more effectively and with even more impact on the drug-development life cycle.

John Cline
CEO
ETRIALS WORLDWIDE INC.

that help out-license potential therapies, but transfer practices are not standardized, and there is room for improvement to help increase the efficiency of this process. Many novel and effective therapeutic drugs are just sitting in the lab doing nothing for their intended markets. Many individuals will continue to suffer from their ailments if we cannot find a way to expedite drug discovery and commercialization.

BABISS. I believe some of these technologies currently, and will continue to, have a major impact on our ability to mitigate portfolio risk by progressing the highest quality clinical leads. But, while performance standards are very important, I believe that the time has come to move away from discussing the potential of emerging technologies to their actual use. The only way that researchers can determine whether a single technology or multiple technologies used in parallel (coupled to a foundational informatics platform) will enhance quality is to generate the right hypotheses and do the actual experiments. As the industry is at the early stages of validation of the concepts, we must set realistic timelines so that we can select those technologies

12-MONTH SPENDING OUTLOOK POSITIVE; CLINICAL-TRIALS AREA LEADS IN OPTIMISM

The life-sciences industry is moderately bullish regarding IT spending growth over the next 12 months, with the average IT budget expected to increase by 5%, according to a report from Life Science Insights.

Across all segments, spending on information infrastructure emerged as a priority, with performance-related and security-related concerns being key drivers behind these anticipated investments. Study results reflect growing industry concerns that existing storage systems are not up to the capacity or performance levels required to meet the growing demands of information-intensive life-sciences environments.

Many metrics, including the migration of e-submissions to regulators, indicate industry momentum toward a greater reliance on technology.

Clinical trials was the only segment in which IT spending was anticipated to be higher this quarter than last quarter. The clinical portion of the value chain is under increasing pressure to reduce the time and cost of trials, and the only way to achieve that objective is by overhauling existing processes and increasing automation, with IT playing a central role. Many metrics investigated, including the redesign of clinical-trial processes, the migration of clinical trials to electronic formats, e-submissions to regulatory agencies, and the standardization of clinical-trial platforms, all indicate industry momentum toward a greater reliance on technology.

Similar to the clinical-trials area, research results suggest fundamental shifts are under way in the use of IT in the basic research and drug-development segments as well, with laboratories expected to become more automated and laboratory information management systems (LIMS) more centralized in the next 12 months.

"The industry drive toward increased efficiency, quicker time to market, and earlier risk evaluation as enabled by technology presents a substantial opportunity for IT providers," says Melissa Utter, research analyst. "But, because of the complex nature of this market, commercial offerings still do not meet the needs of a significant portion of the life sciences, especially in the industry specific areas of research, development, and clinical trials. The market landscape will shift significantly over the next year as the race to garner market share in this lucrative segment continues to intensify."

Source: Life Science Insights, an IDC company, Framingham, Mass.
For more information, visit life-science-insights.com.

IBM believes the following technologies will be key to pharma: petaflop and grid computing, predictive biosimulation, advanced storage solutions, and Web-scale mining and advanced text analytics.

CAROL KOVAC
IBM Healthcare and Life Sciences

The only way that we can determine whether a single technology or multiple technologies used in parallel will enhance quality is to generate the right hypotheses and do the actual experiments.

DR. LEE BABISS
Roche

that provide outcomes that drive good decision making.

ERICKSON. These technologies could have a huge impact and help us develop, and ultimately prescribe, highly targeted therapeutics for a host of diseases, particularly cancer. But, if the regulatory framework does not adapt to the scientific and business realities of new technologies, they will never become products. One way to improve the value proposition for patients is to have diagnostic tools and drugs that work together to raise response rates from 15% to 20% to response rates of 70% to 80%. This will cause pharmaceutical companies to focus on more target-specific therapeutics versus shotgun blockbuster drugs, but only if the target-specific therapies can be priced in a way that is consistent with their very high delivered value to patients.

FRESHLEY. It is obvious that the pharmaceutical industry is really struggling to get products out the door and I sense a great deal of frustration. It is not caused by a lack of spending. Many industry critics will say there is a lack of innovation, but this seems too broad a statement. There are many scientists who have eagerly embraced the latest tools and technologies and who are discovering interesting and exciting new compounds, but there seems to be a lack of creativity in how to bring these discoveries through the clinic and into the marketplace. Pharmaceutical companies could embrace these technologies and approaches and guide their own future, or they can fight tooth and nail and let the biotechnology companies and payers change the future for them. Each company must choose its own course.

S. LEVY. New computer modeling, new understanding of genomics, and new designs of radically more sophisticated devices, all require significant research before paying off in novel therapies. Genomics, MEMS (micro-electromechanical machines), and nanotechnology, to name just a few examples, offer new frontiers for pharmaceuticals and medical devices. In terms of genomics, the more we learn, the more complex we realize the human body really is. Futurists a few years ago forecast that understanding of the genome could bring us closer to rational drug design and personalized medicine. It's doing just that, but the industry has to learn how to enrich its clinical trials so that it can understand which groups respond with the best safety and efficacy. This is not an overnight process. Plastics and electronics took years to revolutionize the medical-device world. Computers and genetics took years to revolutionize pharmaceuticals in the 1980s and 1990s. We are investing in a quantum leap, and it won't show linear growth. Company executives need to take the long view with pharmaceuticals. If we are looking for R&D to produce genomically targeted drugs that can pass the blood-brain barrier using nanotechnology, while achieving 12-week efficacy, we may need to wait until the 2010s.

ZELDIS. The long-term value of these technologies is unclear. Without a doubt, the successes will be touted as quite remarkable and a new standard for pharma development. But much of drug development will remain empirical. Even with empiric developments, much can be learned about defining markers for drug sensitivity and for defining those who might respond better to a drug, or for defining more sensitive surrogate markers for response, or for predicting untoward drug-related events. Increasingly pharmaceutical companies will partner with diagnostic companies to create diagnostics to accompany new therapeutics.

CARABELLO. Leveraging data-driven tools to supplement traditional patient-recruitment techniques can go a long way toward increasing the number of NDAs submitted to the FDA. By using this approach, pharmaceutical companies can enjoy a stepped-up schedule of clinical trials by significantly reducing capital requirements and time to market. The data-driven approach allows for more effective study modeling to determine the viability of a particular trial before the trial is actually initiated. In time, companies will become more astute as to the types of products and therapies in which they invest R&D dollars; this will lead to a higher percentage of FDA approvals. The entire industry can benefit from this increased efficiency as dollars become more rationally and effectively allocated.

SHANAHAN. From a technology standpoint, the need to capture secure electronic records of all research presents an enormous challenge to an industry still reliant on paper-based systems and fragmented solutions in the laboratory and clinic. The most widely used tools for planning and documenting research remain the word processor, spreadsheet, e-mail, and Internet browser.

MCNAMARA. There are a number of new technologies available today that will make a significant impact on drug development in the months to come. One of the most exciting

What's Your Opinion?

2005 — A LOOK AHEAD

What are the most significant business challenges you believe the industry will face in 2005?

Technology-enhanced clinical research

The industry has no alternative but to begin to transition from traditional to technology-enhanced clinical research; it has to embrace technology to improve efficiencies and accelerate timelines in the clinical drug-development process.

Mandates for online meetings, EDC, online document exchange, e-diaries, portals, and so on, are becoming part of mainstream clinical trials. Companies rarely question the value of technology anymore; rather they question which technology to use. Many companies have either selected, or are in the process of selecting, their preferred vendors for each category.

So, what is the issue? The clinical site is the issue. Can we expect sites to quickly become proficient with five different EDC products, six e-diaries, four trial-management systems, and so on? And, is it reasonable to expect them to be effective with each of these tools while concurrently managing five trials for five different sponsors?

As an industry, we have placed much emphasis on GCP-related training, and for good reason. Now it's time to focus on study-specific training. Not just protocol training, but the training required to conduct the trial with all of the tools being used to accelerate and improve trials. We can't expect to scale technology-enhanced clinical trials without the effective use of e-learning tools to ensure sites clearly understand the protocol, the procedures, and the tools they are being asked to use. E-learning in the clinical-trial environment is proving to be more effective than traditional methods.

Lance Converse
FOUNDER AND CEO
EPHARMALEARNING INC.

areas includes technologies such as electronic patient diaries that allow for greater validity of patient-reported outcomes in clinical trials. For years, data collected from patient diaries in clinical trials were marginalized because patient reporting was so difficult to validate and trust. There are countless tales of patients who filled out their diaries for the month on the day they saw their physician. But new electronic diaries have changed this landscape significantly, boosting patient compliance from as low as 10% to as high as 90%. Having patient experiences be more integral to drug development is a great evolution. This information puts more emphasis on patients, provides greater clarity for data collection around clinical endpoints, and creates better products.✦

PharmaVoice welcomes comments about this article. E-mail us at feedback@pharmavoice.com.