Technology Use Among **REGULATORY AFFAIRS PROFESSIONALS** Rising

Many regulatory affairs professionals rely on both paper and electronic submissions, and 70% of these professionals expect this trend to continue into the future, according to Thomson Scientific's 2006 Liquent Regulatory Affairs Trends Survey.

Two-thirds (66%) of survey respondents say they use submission publishing software, a significant increase over 2005. Additionally, 26% of those respondents not currently using software say they are very likely to implement electronic submissions software into their processes.

The survey also found that 74% of respondents currently use a document management system, and 38% of those polled plan to upgrade their current version — significantly more than in 2005.

At least one-third of the regulatory professionals surveyed say their organizations plan to adopt submission quality management, an eCTD viewer, and labeling management; 20% of respondents report that their organizations plan to adopt the HL7's regulated product submission (RPS) format, EVMPD standard, SDTM standard, SPD standard, commitment/correspondence management, and a regulatory product team/executive dashboard. Also, 78% of respondents plan to migrate to the eCTD.

The 447 regulatory affairs professionals polled represent large pharmaceutical companies (29%), medium/small pharma companies (31%), and biotechnology companies (15%) across the United States and Europe.

Combating **ILLEGAL ONLINE PHARMACEUTICAL** Sales

Counterfeit and illegal drug sales pose significant risks to both pharma companies and consumers. Illegal sales of prescription drugs cost the pharmaceutical industry about $46 billion a year; for consumers, the consequences of ingesting uncontrolled and counterfeit substances can be deadly.

> Illegal sales of prescription drugs cost the pharmaceutical industry about $46 billion a year.

The most effective countermeasures to illegal online distribution of pharmaceuticals require collaboration among brand managers, online commerce managers, legal departments, investigators, law enforcement officials, and R&D departments, according to a new report from Cyveillance Inc., Combating Illegal Online Distribution of Pharmaceuticals: Best Practices for the Pharmaceutical Industry.

The report's authors say a successful approach involves comprehensive and continuous online risk monitoring, providing all parties with relevant and actionable intelligence in a secure environment where they can easily share and cooperate across departmental lines.

"The distribution of illegal drugs online not only impacts pharmaceutical companies' revenue and brand reputations but also poses a threat to public health," says Todd Bransford, VP of marketing at Cyveillance. "To combat these risks, public and private sectors need to work together and take proactive steps."

Interest in **ANTIVIRAL DEVELOPMENT** Increases

Until recently, much of the effort to develop new antiviral agents was directed toward improved agents for the treatment of HIV and hepatitis C. Now, several new developments have reignited interest in antiviral disease R&D. These developments include concern about the evolution of avian influenza into a lethal pandemic, as well as recent approvals for vaccines against certain strains of human papillomavirus (HPV) that are associated with high rates of cervical cancer.

In fact, sales of antiviral agents currently constitute 25% of the anti-infective drug market, according to a new CHA Advances study, Antiviral Therapeutics: Pipelines and Competitive Dynamics.

The report finds that the ability of viruses to develop resistance against drugs, coupled with suboptimal treatment outcomes as a result of failure of patients to comply with the full course of therapy, will continue to provide the commercial and medical incentive for intense R&D activity.

For example, with the exception of a Phase II gel formulation analog of imiquimod, there is limited interest in HPV as a therapeutic target for the development of novel antivirals. But the development of prophylactic vaccines is of considerable interest because of the high association of infection by certain HPV serotypes with the development of cervical cancer.

The recent U.S. approval of Merck's Gardasil, and the possible EU approval of GlaxoSmithKline's Cervarix in late 2006, is the first entry.


Dr. Peter Norman

While HIV and hepatitis C continue to attract R&D dollars, the antiviral market is also being driven by developments in the areas of avian influenza and human papillomavirus, says Peter Norman, Ph.D., author of Antiviral Therapeutics: Pipelines and Competitive Dynamics.

FDA Strengthens **ADVISORY COMMITTEE PROCESSES**

The U.S. Food and Drug Administration (FDA) believes it is crucial that the public have complete confidence in the integrity of the advisory committee process. Therefore, over the next few months, the agency plans to take several steps to help ensure that its advisory committees continue to be scientifically expert and independent and that the advisory committee process is transparent.

The effort includes developing guidances to provide greater clarity and transparency in the disclosure of waivers of relationships that could present the appearance of conflicts of interest. The FDA plans to issue a guidance identifying more clearly the conditions under which conflict-of-interest waivers are granted.

Currently, for example, waivers can be granted to committee members under certain circumstances for participation in scientific endeavors related to the work of the committee, as well as for certain unrelated activities. FDA will also issue a guidance specifying when waivers of conflict of interest will be disclosed to the public and what information will be made available.

The FDA also is looking to make the work of the advisory committees more transparent. The agency will issue a guidance specifying when briefing materials used at advisory committee meetings will be made publicly available.

The FDA will provide greater public dissemination of advisory committee schedules by: increasing mailings to public groups, providing electronic notifications through an FDA advisory committee list serve, and posting on the FDA Website.

Finally, the agency is increasing its efforts to implement more streamlined approaches that will improve the transparency in the appointment of members to its drug-related advisory committees.

"The advisory committee process is integral to examining the intersection between medical practice and clinical research, to spark debate about it, and to subject scientific work to close public scrutiny," says Dr. Scott Gottlieb, FDA's deputy commissioner for medical and scientific affairs. "Some of the most valuable input often comes from people who are active practitioners but also heavily engaged in clinical research, and we need to make sure that we continue to have the ability to recruit top clinical trialists."

Clinicians Name MOST TRUSTED PHARMACEUTICAL COMPANIES

When it comes to safeguarding patient and practitioner data, Johnson & Johnson is the most trusted pharmaceutical company, according to the 2006 Privacy Trust Study of the Pharmaceutical Industry.

The study, conducted by Ponemon Institute and sponsored by Vontu, was designed to determine how privacy issues affect relationships between clinicians, consumers, and pharmaceutical companies.

The study also identified those pharmaceutical companies considered to be most trustworthy by medical practitioners when it comes to safeguarding their and their patients' personal information.

Privacy is a critical concern for medical practitioners, according to the study; 88% of respondents said it is important or very important for the pharmaceutical company to protect personal information.

Moreover, mishandling of information could have serious consequences for pharma companies; 27% of respondents said they would file a complaint, 29% said they would disengage, and 15% said they would participate in a boycott against a company in the event of a data breach.

THE MOST TRUSTWORTHY PHARMA COMPANIES*

1. Johnson & Johnson
2. Pfizer
3. Merck
4. Wyeth
5. Eli Lilly

*According to Medical Practitioners

Source: 2006 Privacy Trust Study, The Ponemon Institute, Elk Rapids, Mich.
For more information, visit ponemon.org.

Additionally, 73% of the medical practitioners polled listed overly aggressive marketing, sales, and promotional tactics as a big issue that could negatively impact their sense of privacy.

Nearly half of respondents (48%) said they worried about an increased risk of data breach because of the use of wireless devices such as tablets and PDAs, while 38% expressed concern over RFID tagging on packaging.

Little Growth Expected in VACCINE R&D

Since 2000, the number of anti-infective vaccines entering clinical study each year has been higher, on average, than it was in the 1990s. Despite this trend, there may be little growth globally in this product area for the rest of this decade, according to industry analysis by the Tufts Center for the Study of Drug Development (CSDD).

Since 1990, the number of companies initiating study of new vaccines and the number of pathogens targeted have remained essentially unchanged — 38 companies and 35 targets.

While success rates and development times for new vaccines are similar to new biopharmaceuticals, Tufts analysts say the benefit-to-risk profile for vaccines is typically more stringent, liability concerns are often greater, and the return on investment is frequently lower, which partly explains why there aren't


Kenneth Kaitin

Despite widespread agreement that new vaccines are an important public health priority, development remains slow, expensive, and risky, says Kenneth I. Kaitin, Director, Tufts CSDD.

more vaccine-development programs in place.

The study shows that overall approval success rates for anti-infective vaccines developed in the 1990s ranged from 17% to 25%. Also, clinical development and FDA approval phases for innovative vaccines approved in the United States during the past decade averaged 80.0 and 13.9 months, respectively.

According to Tufts, near-term vaccine R&D is likely to focus on readily transmitted pathogens, such anthrax, dengue fever, and Ebola.

The Tufts CSDD study also found that of eight new vaccines approved in the U.S. during 2000-2005, only three targeted pathogens that were not associated with childhood diseases or influenza. Hepatitis B, hepatitis C, herpes simplex, smallpox, and West Nile viruses have been the five most-studied targets so far this decade, accounting for 60% of all antiviral vaccines currently in development.

Strong Growth for **GI DRUGS AND WOMEN'S PHARMACEUTICALS**


Melissa Elder

Technological advancements such as virtual colonoscopy and PillCam ESO are providing increased ability to detect and diagnose a wider range of GI disorders. These advances are making testing procedures more agreeable for those suffering from GI disorders, says Melissa Elder, Kalorama Analyst.

Advances in the detection and treatment of gastrointestinal (GI) disorders, as well as the wide acceptance of popular GI remedies by an aging population, will help the global market for gastrointestinal drugs increase by 9% over the next several years to surpass $44 billion by 2010.

According to The Worldwide Market for Prescription Gastrointestinal Drugs, a study from Kalorama Information, growth is expected to continue for all segments as testing and therapeutic advancements continue to develop. Advanced treatments are expected to provide the cancer segment with the highest growth of 19.8%, followed by the Crohn's disease segment, which is expected to grow by 15.9%. In 2005, sales of GI drugs — including popular antiemetics, H2 receptor antagonists, proton pump inhibitors (PPIs), and antacid/antiulcer therapeutics — topped $29 billion, up 11.9% from 2003.

In other news, Kalorama analysts are predicting substantial growth in the market for women's pharmaceuticals. According to Women's Health: Worldwide Prescription Drug Markets, revenue in the women's pharmaceuticals market could reach nearly $64 billion by 2010.

In 2005, revenue for therapeutics addressing women's needs — such as autoimmune diseases, cancer, and menopause, among others — exceeded $45 billion. From 2000 to 2005, the market grew by 10.5%.

Sales of hormone replacement drugs fell sharply from 2002 to 2004 on the heels of much-publicized reports of the adverse health effects of long-term HRT treatment. But sales in most other segments have continued to show positive trends.

NANOTECH PATENT BATTLES are Brewing

As companies, universities, and government entities explore the applications of nanomaterials, they have gone to the patent office in droves — yielding a continued increase in nanotech patents, which totaled 4,996 U.S. issued patents through 2005.

With so many patents, legal battles over intellectual property rights are on the rise, according to Nanotech IP Battles Worth Fighting, a report from Lux Research Inc. in collaboration with Foley & Lardner LLP.

The report finds that the rate of new nanotech patent issuances stalled at 4% in 2005 after exceeding 20% in the last few years. At the same time, the number of public patent applications for nanotechnology continued to increase, growing by 52% to 2,714 outstanding nanotech patent applications.

According to the report, crowded patent domains with overlapping claims have pushed the pending rate (the time from the submission of a nanotech patent application to the issuance of a patent) to nearly four years on average, up from two and half years in 1993.

Carbon nanotube and quantum dot applications in electronics are battles worth fighting, the report says. The large addressable markets relevant to these nanomaterials justify the cost of navigating the unfavorable patent outlook.

Additionally, in healthcare/cosmetics applications, nanomaterials with crowded or vulnerable patent landscapes — like dendrimers, ceramic nanoparticles, and metal nanoparticles — are also battles worth fighting because of the broad applicability of these materials to a number of large addressable markets.

"The increasing number of patents in key areas is opening the door to new licensing opportunities, as patent owners seek to consolidate groups of patents needed to access those key areas," says Stephen Maebius, an IP partner at Foley & Lardner.


Vahé Mamikunian

With the number of pending public nanotech patent applications in 2005 outnumbering issued nanotech patents by more than three to one, there is a wave of innovation that the USPTO has yet to process, says Vahé Mamikunian, Research Analyst, Lux Research.

Follow up

CHA ADVANCES REPORTS, Waltham, Mass., partners with industry experts to offer reports that evaluate the salient issues in pharmaceutical technology, business, and therapy markets. For more information, visit advancesreports.com.

CYVEILLANCE INC., Arlington, Va., provides online risk monitoring and management solutions to global 2000 organizations. For more information, visit cyveillance.com.

FOLEY & LARDNER LLP, Boston, provides a full range of corporate legal counsel. For more information, visit foley.com.

KALORAMA INFORMATION, New York, a division of MarketResearch.com, supplies independent market research for the life sciences. For more information, visit kaloramainformation.com.

LIQUENT INC., Philadelphia, a division of Thomson Scientific, provides regulatory compliance software. For more information, visit liquent.com.

LUX RESEARCH INC., New York, provides market intelligence on nanotechnology and the physical sciences. For more information, visit luxresearchinc.com.

THE PONEMON INSTITUTE, Elk Rapids, Mich., is dedicated to advancing responsible information and privacy-management practices in business and government. For more information, visit ponemon.org.

THE TUFTS CENTER FOR THE STUDY OF DRUG DEVELOPMENT, Boston, provides strategic information to help drug developers, regulators, and policymakers improve the quality and efficiency of pharmaceutical development, review, and use. For more information, visit csdd.tufts.edu.

U.S. FOOD AND DRUG ADMINISTRATION, Rockville, Md., is responsible for protecting the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, and the nation's food supply. For more information, visit fda.gov.

VONTU INC., San Francisco, provides data-loss prevention solutions for both data at rest and data in motion. For more information, visit vontu.com.