

**“Gathering top-quality safety data as soon as a drug hits the market is critical to ensuring public health.”**



## Automation Brings Public Safety

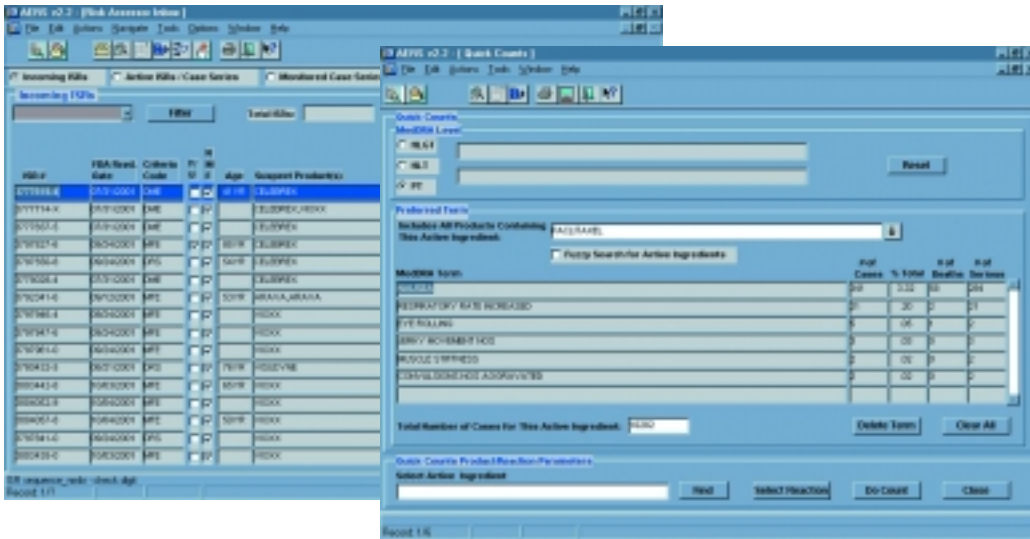
### U.S. Food and Drug Administration

Television ads promise cures for everything from heartburn to heart disease. Indeed, people in the United States have become so attuned to the healing benefits of therapeutic drugs that manufacturers barely can keep up with the demand for new remedies. But the proliferation of new pharmaceuticals and an accompanying boom in prescriptions have created an unwanted side effect: a meteoric rise in the number of unforeseen negative reactions by individual patients and dangerous interactions among drugs. The rapid disclaimer at the end of all those TV spots can't hide the fact that 51 percent of approved drugs end up having serious side effects that aren't detected until they reach the marketplace.

The situation put the U.S. Food and Drug Administration (FDA) in a delicate position: People not only wanted new medicines, they also needed them. But rigorous scientific testing during the pre-market phase cannot always fully disclose the side effects of a new drug, and many drugs may have the potential for serious, unidentified problems when they enter the marketplace. So in 1995 the FDA presented

Booz Allen Hamilton with a challenge: Work with it to find a better way to collect, evaluate, coordinate, and communicate reports of the drug reactions that occur once new products reach the marketplace.

The solution was the Adverse Event Reporting System (AERS), an automated system that not only enabled the FDA to act in a timely manner, but also reinforced the agency's



The introduction of AERS has enabled the FDA to routinely identify drug-safety problems before they become public knowledge. At right, the FDA's Ralph Lillie (l) confers with Booz Allen's Rajesh Dhingra (c) and Karen Shore (r).

## Today, AERS automatically routes Internet reports of critical drug reactions to FDA safety evaluators in seconds. |

preeminence as a worldwide leader in drug-safety monitoring. When *Computerworld* magazine honored AERS as a laureate for its 21st Century Achievement Award, it cited the innovative use of information technology that had significant and lasting benefit to society.

"The Booz Allen team had a solid understanding of the significance of what we were doing," says Greg Brolund, associate director for technology and policy in the FDA's Drugs Division. "They recognized that the FDA has been trying to complete new-drug reviews faster. And while we don't think the quality and safety of drug supplies has been diminished in the meantime, there has been concern from citizen groups about the pace of reviews. Booz Allen

knew that these review times must remain faster without causing a public health crisis.

"There are more and more novel drugs out there," says Brolund, whose involvement in AERS focuses on electronic submissions of adverse reaction reports. "There has always been the problem that we don't necessarily find reactions as quickly as we'd like, and we want and need to find them in the minimum amount of time. So this is a very important program, and the Booz Allen team really understood that and devoted some of their best people to getting AERS put together."

Meanwhile, the success of the project has also been embraced by Booz Allen, providing a strong sense of purpose to

those involved and leading to significant new business for the firm both with other government agencies and with commercial pharmaceutical companies.

"We set the bar very high for this assignment," says Booz Allen Associate Karen Shore, the assignment's Rockville, MD-based project manager. "And when someone calls to report that there is a glitch in the system or it needs enhancement, our people don't just regard it as some IT or systems problem. Lives are at stake; not every project gives you that kind of opportunity."

### Replacing the Manual Process

Not every possible reaction among highly complex chemicals can be predicted or discov-



ered, even in the exhaustive pre-approval. In fact, new drugs are the fourth-biggest killer in the U.S., according to the *Journal of the American Medical Association*, causing the deaths of at least 106,000 Americans a year and disabling another 2.1 million. The rise in prescriptions, and congressional approval of shorter drug-approval cycles, made a bad situation even more dangerous. And before the introduction of AERS the FDA was using a largely manual, paper-driven process that had created a significant backlog of adverse events to be reviewed.

By 1995, former FDA Commissioner Dr. David Kessler and other senior agency officials had recognized the dire need to overhaul their existing drug-safety tools and processes—and

to do it quickly. So the agency allocated more than \$5 million for the task and turned to Booz Allen, based on the firm's previous work for the agency and Booz Allen's reputation for providing integrated management consulting and technology implementation expertise.

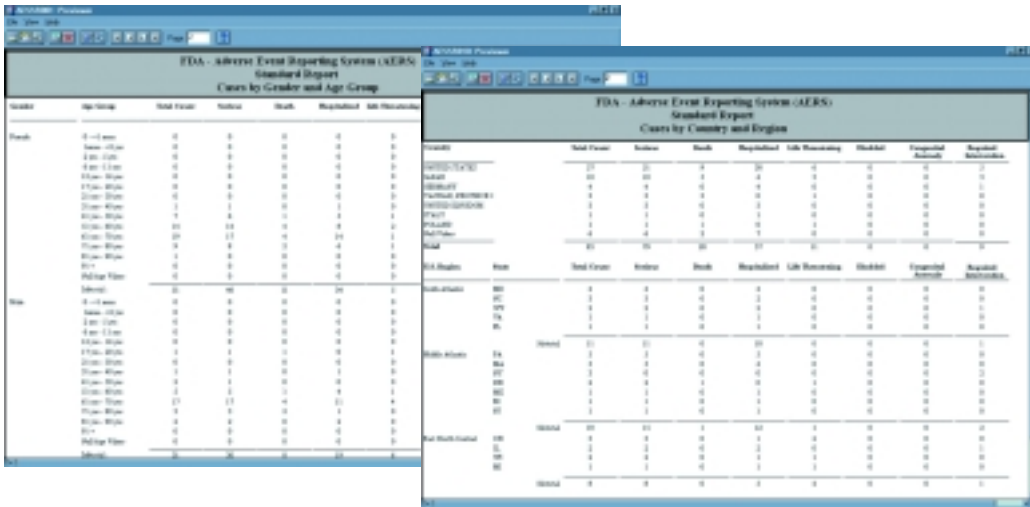
Designing and launching an automated review system required Booz Allen to aggressively broaden its understanding of drug safety. To that end, consultants convened advisory panels and a conference of industry experts, conducted in-depth workshops with data-entry clerks, pharmacists, physicians, and other workers on the front lines of the discipline, and identified best practices in the industry. "You can develop the best system," says Senior Associate Lucy Stribley,

Booz Allen's program manager for AERS, "but it's only successful when people adopt it."

### **Standardized Medical Glossary**

The challenges were daunting: Booz Allen had to incorporate a completely new, standardized medical glossary of more than 40,000 terms, many of which didn't have universal definitions. It had to integrate FDA requirements with new, untested international standards for drug-safety data that hadn't yet been implemented in any system. And it even had to convert more than 1.2 million records, representing nearly three decades of adverse-event reports, into the new system.

One of the most crucial tasks was taking data collection



AERS has reinforced the FDA's preeminence as a worldwide leader in drug-safety monitoring. At right, Booz Allen's Brianna Broderick (l) and Chidambaram Murugappan (r).

## The success of AERS drove and supported the re-engineering of the FDA's entire drug-safety program. |

online with electronic submission of drug-safety reports. The change to real-time data collection was critical; under the manual-reporting mechanism, it often took six months for the report of an adverse drug reaction to reach FDA safety evaluators.

For the FDA, the faster distribution of information has become an integral part of an increasingly proactive approach to dealing with adverse events. "Gathering top-quality safety data as soon as a drug hits the market is critical to ensuring public health," says Shore.

Some parts of the pharmaceutical industry were skeptical when the FDA promised to have a functional electronic-submission capability in place by 2000. But Booz Allen

helped the agency make good on its word, delivering the first e-submission capability in October 1999.

Such measures are now routine at the FDA. Today, AERS can automatically route Internet reports of critical drug reactions to FDA safety evaluators in seconds. Critical reports submitted on paper arrive in evaluators' AERS electronic in-boxes within 24 hours. Because e-submissions allow for a quicker, richer data set, the overall quality and accuracy of information about drug reactions is much more valuable. Last year, for instance, some of the largest pharmaceutical manufacturers began submitting their own adverse-drug reports to the FDA over the Internet. And it's likely that at least a dozen more companies will follow their example.

### Considerable Savings

The transition to an Internet-based system has saved the FDA \$7 million a year in data-entry costs. Much more importantly, it has dramatically accelerated both the agency's and industry's response to the first indication of possible adverse interaction. When Viagra's mass distribution led to AERS reports of new risks, the FDA quickly improved warning labels on the well-publicized drug. And this past February, acting on AERS data collection, the agency removed from the market drugs containing phenylpropanolamine, after reports linked this active ingredient in many cold remedies and diet drugs to an increased risk of stroke.

The introduction of AERS has



enabled the FDA to routinely identify drug-safety problems before they become public knowledge, ensuring Americans' confidence in the pharmaceutical industry and in drug therapies in general. The program's success also drove and supported the re-engineering of the FDA's entire drug-safety program, which has transformed the agency into a recognized leader and model for pharmaceutical companies as well as other regulatory agencies around the globe.

For Booz Allen, the AERS assignment has led to new relationships with the FDA and with other such entities as the National Institutes of Health, the Social Security Administration, and the Centers for Disease Control, not to mention several pharmaceutical firms—

a major boon to the growth of commercial-pharmaceutical and government-healthcare business for the firm.

“The credibility that AERS has given us in this industry is enormous,” says the program's officer-in-charge, Heather Burns. “And it isn't just the extra business that it has generated; it also has been the impact on people, on individuals within Booz Allen. AERS brought together a group of people who created a key proprietary base of knowledge and understanding, and many of them have been cycling into and out of AERS over the last few years. And some people who worked on AERS have gone off to become leaders in our healthcare industry practice and have had a tremendous impact on the rest of the firm.” |