Information SystemsIn The Pharmaceutical Industry

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According to The Encyclopedia of Computer Science and Engineering, an information system is a collection of people, procedures, and equipment designed, built, operated and maintained to collect, record, process, store, retrieve, and display information. (1) Dr. Andrew Targowski states in an article he wrote for "Data Management" magazine that the first information system was paper money, introduced in China in 970 AD. Other significant information systems that he sites are a cost control system began in Venice in 1410, printed books, made possible by the invention of the printing press in 1440 and double entry bookkeeping in Venice in 14594. All those methods used hand methods of calculation. The mechanization of information systems was first possible in 1884, with the invention of the Holerith Punch Card Machine. The computerization of those tasks began in 1951 when the first business computer, the UNIVAC I was built for the US Census Bureau. (2) Computerization of information systems has come a long way since then. Most corporations have computer information systems to track employee information, payroll, inventory, manufacturing schedules, and sales. And, of course, there are always those information systems kept by individuals that management would rather not hear about. John Bear, in his book, "The Computer Wimp" asked one Chicago businessman how he was using his computer. The gentlemen proceeded to proudly tell him about his database of neckties. He could tell at a glance how many striped. patterned, and solid colored ties he had, what they had cost, when they were last cleaned, and how often he had worn each one. (3)

All industries have particular information systems peculiar to their business. The pharmaceutical industry, by the very nature of its business to produce safe, effective medications, has more than its share of need for special information systems. To explore those needs, we should first look at how the pharmaceutical industry operates.

The discovery and development of new drugs is a long and costly process. Only one of every 10,000 new chemical compounds is ever introduced as a new product. On the average, it takes seven to ten years and more than $100 million to discover and develop a new drug. (4)

A pharmaceutical company first spends millions of dollars and thousands of hours on pharmaceutical research in the laboratory. Animal studies are then conducted to determine if a promising new compound has any safe applications in humans. If the results of the animal studies are encouraging, an Investigational New Drug (IND) application is filed with the FDA. In phase I of human testing, low dosages of the drug are tested in 20 to 80 healthy volunteers to determine how the drug is absorbed, distributed and metabolized in the body and how long it is active. In phase II, the drug is tested for effectiveness in up to 300 volunteers with the targeted illness. In the third and final phase, the drug is tested in 1,000 to 3,000 affected volunteers to confirm earlier efficacy studies and identify low-incidence adverse reactions. A New Drug Application is then filed with the FDA. A typical NDA runs to thousands of pages and contains the results of all tests, drug formulation information, proposed manufacturing procedures and proposed labeling. Even after FDA approval, the manufacturer must continue to provide reports to the agency, including adverse reaction data, quality control information and distribution reports. The FDA may also require additional studies to evaluate the drug's long term effects. (4)

Many unique information systems are necessary to make that process move as smoothly and quickly as possible, and to insure accurate reporting to the FDA. In the initial testing stages of a new compound, computer systems can be used to build and record chemical structures. Through all phases of testing, the data can be stored on the computer, analyzed and reported. Many pharmaceutical companies use SAS for that task. Easily accessible computer databases to track all studies in progress, who is conducting each of them, how much and when money is being paid out, and basic study tracking information can reduce the amount of time it takes to get an NDA submission to the FDA. Of course, a highly sophisticated word processing system is needed to bring all the information together and produce the actual report. A special group in the company is usually devoted entirely to regulatory affairs, monitoring the FDA and company regulations.

Once a drug is approved for sale, the manufacturing and marketing areas are brought into the picture. Due to the very nature of the industry, it is crucial that all manufacturing of the drug compounds be closely controlled and tracked. Therefore there is a group within a pharmaceutical company devoted to "control". It's responsibility is to track each lot of a drug through the entire production process, testing it's quality at each stage. The FDA has a set of guidelines, "Good Laboratory Practices" and "Good Manufacturing Practices" which must be strictly adhered to. The entire drug tracking process needs integrated computerization. Production scheduling uses the data in inventory and marketing forecast databases. Within the manufacturing environment, the Occupational

Health and Safety group must keep track of material safety data and environmental safety monitoring.

In addition to the usual customer and sales databases, a pharmaceutical company must track were each drug lot goes - how much and to whom. Marketing must also track where all sample handouts go. Computer programs are used to determine sales territories and change those as needed.

A pharmaceutical corporation also needs a secure database to track all adverse reactions reported to the company by patients and physicians, and any pending litigation. All patents, trademarks, and registrations need to be kept in such a form as can be quickly accessed, compared and changed when needed.

Are all these information systems computerized? I belive that in most major pharmeceutical companies, I would say the answer is "yes". Information is entered by data entry personnel or in some cases directly into the computer by the people providing that information. Is the information easily accessed? Now, that is another story. Too many of the computer information systems in all companies are built in such a way that the people who need the information cannot readily and easily access it because it is dispersed over many different computer systems and in different database, or they are provided with more information than they really need and are forced to sort through mounds of paper for the piece of information necessary to make a decision. Today more recorded information is being generated each year than in the entire 19th Century, and the rate of accumulation is estimated to be doubling every four years. In 1986, 420 billion pages (82 million miles) of computer printout were produced in the United States. The average corporation produced over 5000 pages of printout per employee. 22% of the Fortune 500 companies produce over 12,000 pages of printouts per employee. A Kepner-Trego survey conducted in 1986 showed that excess or unnecessary data was the number one complaint that executives had with their information systems. (5) As Micheal Hammer once said, "You can't have everything; where would you put it?"

The pharmaceutical industry faces many of the same system problems as all industries, they just have them in greater scope due to the necessity of many special information systems. First we face the problem of merging information from different computers and different systems. That issue is being addressed with company standards for hardware and software and research into software that allows easy data interchange. Secondly we face the challenge of giving the user more relevant information, "value added" information that contributes to the critical success factors of the company?

First, make the user as much a part of the development process as possible. Many familiar terms used to accomplish that end are JAD teams (Joint Application Development - a method to get the end user involved in the process of designing the system) and prototyping (a method to provide iterative refinements of a model of the system, based on close user interaction). Let the user design the screens that interface into the system. With the advent of easier to use software, many users also design their own systems.

Secondly, the system professional must be knowledgeable of the business problem being solved. John Galsworthy says that "Idealism increases in direct proportion to one's distance from the problem." Computer professionals create systems to solve business problems without an understanding of that business problem. A small girl came home from school one day and her mother asked her how she did. "I was the smartest one in the whole class today," she informed her mother. "Really? What happened?" her mother inquired. "We wrote on the blackboard and I was the only kid in the whole class who could read my writing." If we create information systems whose output only computer professionals can interpret, it is useless, like the little girl's writing on the chalkboard.

Finally, practice "data economy" - give a user only the information he or she needs. David Friend, Chairman of Pilot Executive Software, suggests three methods to achieve that goal. One is the "drill down" technique in which the user access a hierarchy of data. Beginning with a general overall report, a user can point to one part and get a detailed report on that part. The user can then repeat that process within that specific part, getting another subset of the data. Another technique is that of "trend monitoring", which basically is showing the data graphically so trends can be visualized. The final technique is that of "exception reporting", the process of automatically surfacing problems and variances in data. (5)

These suggestions may help us design information systems that make the output produced more valuable to the people who need that information. Computerized information systems are invaluable to all industries, but especially so to the pharmaceutical industry where so many additional, unique systems are needed.

1) Encyclopedia of Computer Science and Engineering, Athony Ralston & Edwin D. Reilly, Van Nostrand Reinhold Company, 1983

2) "Historic Information Milestones Provide Sound Base for Future Systems", Kuriakose Athappilly & Andrew Targowski, Data Management Magazine, March, 1986

3) The Computer Wimp, John Bear, Ten Speed Press, 1982

4) "Upjohn Intercom", The Upjohn Company, June, 1987

5) "Electronic Reporting Systems Overcome Limitations of Paper Reports", David Friend, Chairman, Pilot Executive Software, Inc., handout from speech given at Hammer Forum West, May 18, 1987