

Information Technology & FDA Compliance in the Pharmaceutical Industry

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EXECUTIVE SUMMARY

Given the recent profitability of and demand for pharmaceuticals, from prescription antibiotics and analgesics like Ciproflaxin™ and OxyContin™ and men's health drugs such as Viagra™ and Vardenafil™ to over-the-counter Senokot™ laxatives and Betadine™ antiseptics, the rush to develop and market new pharmaceuticals has never been greater. The current process is complex and it often takes several years for a drug to reach the market due to the myriad of Food and Drug Administration (FDA) guidelines. Furthermore, the recent FDA guidelines mandating that all New Drug Applications (NDA) be submitted in electronic (paperless) format by the end of 2002 is a catalyst for change in the pharmaceutical industry (FDA Proposes First Requirement for Electronic Submission, 2002; New Drug Application (NDA), 2001). Bayer Pharmaceutical, like its competitors Purdue Pharma and Boots Healthcare, has begun to take steps to assure that its use of information technology will allow it to not only meet FDA guidelines, but achieve its corporate goals of improved efficiency and reduced operating costs.

BACKGROUND

The company has a long history, having been founded by Friedrich Bayer and Johann Friedrich Weskott in 1863 in Wuppertal, Germany. From its meager beginnings as a dyestuffs factory, Bayer has grown into a multi-billion dollar international chemical and health care company. Expansion took place rapidly for Bayer. In 1865, Bayer and Weskott entered the coal tar dye business in the United States and began exporting intermediates. Further growth was achieved in 1876 with the opening of another dyestuffs factory in Moscow with the descendants of Bayer establishing the joint stock company Farbenfabriken vorm. Friedr. Bayer & Company. Additional factories soon opened in France and in 1884, under the guidance of chemist Carl Duisberg, Bayer scientists began receiving recognition for their pioneering discoveries. With the establishment of the Pharmaceutical Department in 1888,

the stage was set for the most famous and historical discovery yet for Bayer. Dr. Felix Hoffman first synthesized acetylsalicylic acid in a chemically pure and stable form in 1897. Aspirin was registered as a trademark two years later in 1899; it is still the world's most popular over-the-counter pain medication. In 1925, Farbenfabriken vorm. Friedr. Bayer & Company merged with another company and became I.G. Farbenindustrie AG, which was later seized and broken up following the Second World War. Farbenfabriken Bayer AG was re-established in 1951, then changed its name to Bayer AG in 1972. The company remains Bayer AG; it reacquired the rights to the Bayer logo and trademark from Sterling Pharmaceuticals in 1986. Today, Bayer AG is ranked as the 117th largest company in the world with revenues topping \$30 billion (see Appendix). With headquarters in Leverkusen, Germany and with about 350 affiliated companies worldwide, the Bayer Group is represented on every continent. Bayer AG's business organization includes healthcare, agriculture, chemicals and polymers. Within the healthcare segment, the North American Pharmaceutical Division headquartered in Pittsburgh, Pennsylvania, accounts for more than \$10 billion in annual revenues. The division has also recently achieved many business milestones, including \$1 billion in annual sales for its antibiotic Ciproflaxin™ in 1999 and 2000 and a growth rate of 23% in 2000, which easily outpaces the prescription drug industry as a whole (BAYER AG Homepage, 2002). Bayer's highly recognizable trademark logo will unify the individual Bayer divisions as the company will migrate to a new corporate structure on January 1, 2003, when Bayer will become a management holding company with four legally independent operating subsidiaries (A New Bayer—A New Bayer Cross, 2002).

SETTING THE STAGE

To better understand the scope of the changes Bayer must undergo to comply with the FDA's New Drug Application (NDA) process (FDA Proposes First Requirement for Electronic Submissions, 2002), a background in the FDA's role is important. The next section provides an overview of the process pharmaceutical firms must follow and the need to meet these guidelines.

New Drug Application Process

The Center for Drug Evaluation and Research (CDER) is a government agency whose job is to evaluate new drugs before they can be sold to the public. The CDER focuses on prescription and over-the-counter drugs, both brand name and generic, to ensure that they work correctly and that the health benefits outweigh the known risks. The information is also made available to doctors and patients to provide them with the information they need to use these medicines wisely.

The regulation and control of new drugs in the United States has been based on the New Drug Application (NDA). Each new drug has been subject to a NDA approval before it is allowed into the U.S. commercial market. Any data gathered during animal studies and human clinical trials become part of the NDA. (About CDER, 2002)

The Food & Drug Administration (FDA) has evolved considerably since its founding in 1938. When the Food, Drug, and Cosmetic Act (FD&C Act) was passed in 1938, NDAs were only required to contain information about an investigational drug's safety. In 1962, the Kefauver-Harris Amendments to the FD&C Act required NDAs to contain evidence that a new drug was effective for its intended use, and that the established benefits of the drug

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