March 23, 2004
AnGes MG, Inc.

AnGes MG Seeks Faster New Drug Approval-Applications via Document Management System
-Infocom to be systems integrator for application submission system-

AnGes MG Inc. is establishing an electronic document management system for new drug approval-applications, in order to accelerate the entire process of new drug approval-application up to the actual granting of approval. In December 2003, AnGes entrusted systems development to Infocom Corporation (Chiyoda-ku, Tokyo; CEO: Atsushi Numa). Since then, Infocom has taken charge of everything from establishing the required parameters up to development and deployment, with rollout planned for April 2004.

In recent years, the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) (Note 1) has promoted a framework for the pharmaceutical industry to enable the simultaneous submission of applications for approval of new drugs in Europe, the United States and Japan.
Since July 2003, use of the CTD (a standardized application form common to the three regions) (Note 2) has been mandatory. For pharmaceutical firms, this means the time required for application and approval can be reduced, enabling quicker profitability.
Since AnGes also seeks quicker new drug approval applications, the company is determined to leverage IT technology so that applications may be submitted more efficiently; for instance, through the introduction of a CTD electronic document management system and an overall CTD management policy.

The system now being installed by AnGes is based on the PharmaPortalR/RD platform, an electronic document management system for new drug approval-applications released by Infocom last year. Because Infocom has handled everything from requirement analysis to overall systems integration, AnGes was able to realize a high-quality system in a relatively short time.

This system has special capabilities that support document processing for inter-organization projects, and since it is preconfigured with information such as standard CTD hierarchical structures, and templates for saving materials to be used when preparing applications, it is

possible to greatly reduce the time required for systems development.
Processing tasks such as the preparation, review, checking, correction and storage of application documentation can also be implemented quickly and reliably, so that document quality can be increased and business in general can be accelerated.
Furthermore, since AnGes has a US subsidiary that will also use the system, Infocom has developed an English version of PharmaPortalR/RD to complement the original Japanese version.

By adding the English version of PharmaPortalR/RD to its lineup of document management solution models for the pharmaceutical industry, Infocom plans to provide services for systems integration and permanent support to pharmaceutical firms that want to use the system from their overseas business units.

AnGes embarked a day ago on Phase Three clinical trials through multi-centered double-blind tests of genetic treatments. With this milestone AnGes is enhancing its fundamental business environment with information technology so that new drug approval-applications and the approvals themselves can be achieved without delay.
This ongoing development has also been conducted while taking into account the shift to the Electronic Common Technical Document (eCTD) format, thus steadily laying the groundwork for the electronic submission standard that is sure to arrive in the future.

Notes
(Note 1) International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH)
An international conference that has engaged in activities for the purpose of harmonizing technical requirements concerning new drug applications in the US, the EU and Japan since April 1990. The organization consists of 6 industrial and administrative bodies from the U.S., the European Union (EU) and Japan; 3 observers from the Insurance Bureau of Canada, the European Free Trade Association (EFTA), and the World Health Organization (WHO); as well as the Secretariat of the International Federation of Pharmaceutical Manufacturers Association (IFPMA). To date the ICH has prepared approximately 50 guidelines concerning the research and development of new drugs, and has promoted areas such as the research and development of new drugs, as well as the improvement in quality of resources and their more effective use during the course of examination.

(Note 2) CTD (Common Technical Document)

Denotes the application forms for new drugs shared by the US the EU, and Japan. While the Japanese Ministry of Health, Labor and Welfare started to accept CTD submissions in July 2001, in July 2003 the CTD became mandatory as a result of studies conducted by the ICH.