

White Paper

Bio-Pharmaceutical Knowledge Management

A Comprehensive Model

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Executive Summary

The complex process of drug or technology discovery and development is rarely isolated within the bio-pharmaceutical company. Throughout the process, key steps are outsourced, requiring disparate Collaborative Commerce Entities (CCE) to interact and coordinate during the creation and exchange of the information required for drug or technology approval. If not properly managed, inconsistencies across this nebula of information can create systemic inefficiencies that delay a drug or technology candidate from being advanced or approved.

Collectively called Pharma-informatics, separate solutions exist for the management of the individual CCE's information, however, the industry lacks a comprehensive knowledge management model for the overall process. I propose a new model for Pharma-informatics: a single, comprehensive knowledge management design that successfully integrates the three major dimensions of discovery and development into a single system. The three dimensions of the model are: process information management, business management, and knowledge management. These dimensions emerge from the data hierarchy, which categorizes data based on its proportional increase in context: as context increases, the value of the data increases. The five data hierarchy categories are raw data, data, information, knowledge, and wisdom.

For the new model, the information management (IM) dimension is composed of a Pharmaceutical or Process Information Management System (PIMS). The PIMS manages the generation, storage, transmission, processing and exchange of the raw data, data, and information required to bring a drug or technology to approval. The business management (BM) dimension is composed of the Enterprise Resource Planning (ERP) system. The ERP dimension manages the raw data, data, and information from the business processes; these processes enable the bio-pharmaceutical company to function: human resources, accounting, sales, procurement, etc. The Knowledge Management (KM) dimension is composed of the Business Planning Intelligence (BPI) system. The BPI transforms the information from the PIMS and ERP into knowledge and wisdom.

Once properly established, the PIMS dimension synchronizes and standardizes information across the value chain, reducing inefficiency of information exchange and speeding the overall drug or technology discovery and development process. The ERP

dimension facilitates efficient business administration by integrating and streamlining business functions. The information from the PIMS and ERP dimensions flows upward to the corporate BPI dimension, where it is used to create knowledge and wisdom. The knowledge and wisdom derived from the lower dimensions drives the strategic planning process, resulting in cascade of strategy and policy that starts at the corporate level and flows down through the business level, to the functional level. The development and implementation of strategy and policy through these levels ultimately affirms or redefines the vision and mission at the corporate level, completing a cycle of continuous improvement.

The new Pharma-Informatics model mitigates systemic inefficiencies and provides a comprehensive system to manage data, information, knowledge, and wisdom. Using a coordinated application of the Systems Design and Analysis process, the dimensions of Pharma-informatics can be successfully designed, developed, implemented, and integrated, creating the optimal bio-pharmaceutical knowledge management system.

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