

# THE IMPORTANCE OF AN INTEGRATED INFORMATICS SOLUTION

FOR LIFE SCIENCE ORGANIZATIONS

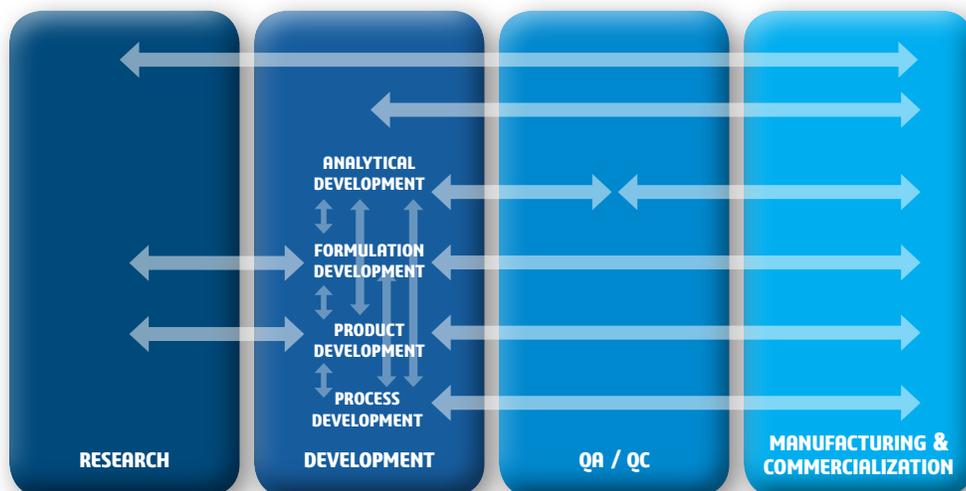
White Paper



The exorbitant cost of bringing a new pharmaceutical product to market in the U.S. is well documented, with estimates as high as 12 years and \$ 2.6 billion USD.<sup>1</sup> There are many factors that drive this cost, including rework due to a lack of access to information from previous experiments, loss of intellectual property (IP), and data mining inefficiency. The goal in drug development is to be the “first to file” for approval of a new drug in order to maximize return on investment (ROI) and increase profit potential, all while producing a high-quality product and remaining regulatory compliant.

For a drug development program to be successful, product and process knowledge should be managed along the entire product lifecycle. Knowledge management is a systematic approach to acquiring, analyzing, storing, and disseminating information related to a product, its components, and the manufacturing processes used to develop it. Sources of knowledge include prior knowledge, innovation, pharmaceutical development studies, manufacturing experience, continual improvement, change management activities, process validation studies, and technology transfer activities.<sup>2</sup>

Generally speaking, technology transfer is the intersection between business, science, engineering, law, and government.<sup>3</sup> Within drug development, it pertains to moving data, information, and knowledge across the various domains, including research and development (R&D), manufacturing, and commercialization so that new products can be made available to the public (Figure 1). Technology transfer becomes even more important when any activities like research, development, and/or manufacturing are outsourced to third-party contract organizations.



**Figure 1** – Technology transfer will occur between research, the different areas of development, quality assurance and quality control, manufacturing, and commercialization. This includes parameters, data, methods, and documentation.

Over the last few decades, replacement of outdated paper-based data management systems has been identified as a means to accelerate this process. While the implementation of electronic systems led to reduced cycle times and compliance risk, issues remain with systems existing in departmental silos and non-standardization of data across the drug development continuum. The result is poor data mining, inefficiencies, and hindered collaboration among the different domains. To satisfy the requirement of drug development companies for efficient data and technology transfer, standardization of data and technology transfer across the entire pharmaceutical product lifecycle is needed.

A system that spans multiple domains also needs to be able to satisfy different needs and purposes. For example, scientists require an electronic environment for process management and compliance that supports both flexible authoring as well as more structured execution. In manufacturing, access to data generated in development allows companies to investigate and adjust the parameters of a formula in order to make improvements that can optimize factors like product purity, yield, and cost of production.

Successful deployment of an integrated informatics solution can address issues with ineffective data and technology transfer.

### THREE KEYS TO SUCCESSFUL DEPLOYMENT

#### 1. Establish a single application platform

Traditionally, the transfer of methods between development and quality control (QC) areas in drug development required companies to physically relocate the development team to the actual production site for extended periods to ensure complete and accurate technology transfer. This process creates an enormous burden for organizations, not to mention the potential for information to be lost or incorrectly incorporated.

Life science companies have sought to enable and optimize the management of both R&D information and manufacturing QC and batch record data. Fragmented systems have been used in an attempt to bridge the gap between instruments used in the laboratory and data management systems. Customized interfaces of these types of systems require custom coding and heavy information technology (IT) support, resulting in a high cost of ownership and risk of validation and compliance violations.

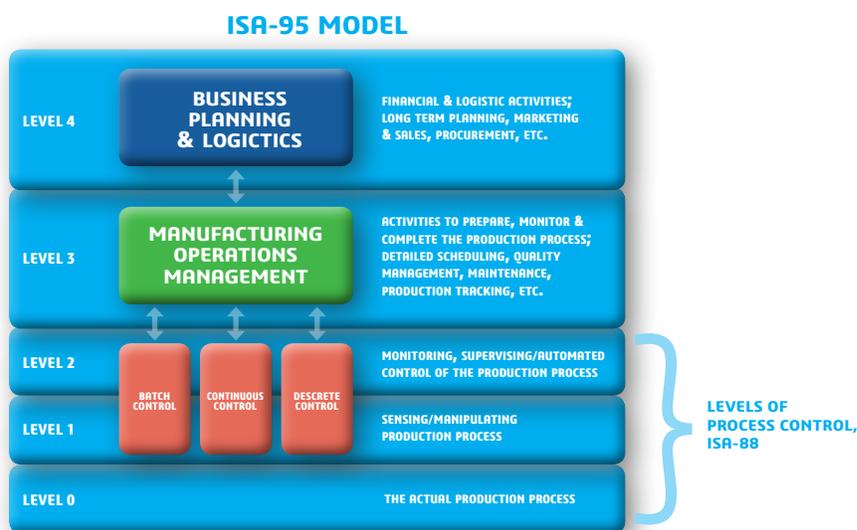
A unified scientific informatics platform, however, bridges the gap between instruments used in the lab such as electronic laboratory notebooks (ELNs), laboratory information management systems (LIMS), and other scientific applications. This type of system is designed to enable the transfer of data and information across domains to enable “cross-talk” and real organizational productivity improvement.

In a regulated environment, scientific documentation requirements change dramatically as a product moves from R&D to commercialization. What was relatively open and free-form in drug discovery becomes more structured for QC in manufacturing. Processes are driven by the need for compliance with regulations, Standard Operating Procedures (SOPs), Good Laboratory Practice (GLP), Good Manufacturing Practice (GMP), and other guidelines. When organizations can electronically capture and transfer structured and unstructured data in a single system across the product lifecycle, management gains insight into process and product quality. Data can be leveraged both upstream as well as downstream in the product development process.

## 2. Follow ISA-88 and ISA-95 standards

ISA-88 is an international standard for batch control in manufacturing. ISA-95 is the standard for the integration of enterprise and control systems.<sup>4</sup> Together these standards pertain to the way software is designed in order to allow for data and technology transfer between the various domains in product development (Figure 2).

Quality by Design (QbD) initiatives are demanded by both the Food and Drug Administration (FDA) and the European Medicines Agency (EMA), stressing that quality be built into a product as a fundamental part of the development process from the earliest phases of the product lifecycle to final commercialization using standardization for consistency and control.<sup>5</sup> The ISA-88 and/or ISA-95 process definitions were derived from QbD initiatives to help companies embed quality into their processes and mitigate risks. Structures used in manufacturing—system control, process management systems, and business systems—are defined in the software using ISA-88 and ISA-95 standards, allowing for uniform storage of enterprise data in a centralized database. This type of standardization facilitates integration and speeds data mining and transfer.



**Figure 2** – ISA-95, the international standard for an automated interface between enterprise and control systems, acts as the operating framework for manufacturing. ISA-88 defines the physical model and is especially focused on the level of the process cell and the lower levels.

Using the ISA-88 and ISA-95 standards in the upfront design of a system creates a powerful data and method exchange capability. This proficiency reduces the time to re-implement a given method by enabling electronic technology transfer, thereby reducing the time, costs, and other burdens of traditional technology transfer while simultaneously providing the process definitions for QbD initiatives.

## 3. Include regulatory compliance requirements

In the life science industries, compliance with regulatory requirements is mandatory. As a new product moves from R&D through commercialization to become available for sale in the U.S., the FDA requires that electronic records be maintained throughout the process along with electronic signatures and audit trails to ensure data integrity and compliance.<sup>7</sup>

In R&D, documentation and workflow management systems like ELNs need to have an open structure to handle experimental data, including the ability to adjust scale, reorder process steps, and substitute components in creating a formulation. Scientists can capture both the processes they perform and the interpretation of experimental results. However, in a regulated environment, open structure presents a compliance liability. A system must be capable of handling highly structured operational protocols (instrument records, SOPs, etc.) within a validated system. This applies to operational reporting as well as data mining and technology transfer. Any software application platform used across domains needs to be flexible enough for R&D while also being compliant with regulatory requirements to ensure data integrity throughout a product lifecycle.

## BENEFITS OF AN INTEGRATED INFORMATICS SOLUTION

By electronically capturing and accessing data from early design and optimization experiments through commercialization, drug development companies can examine and optimize their own process and product quality.

A solution that can replace paper-based systems and outdated and/or fragmented electronic systems with an efficient electronic environment helps streamlining data access and technology transfer. Standardizing data capture using a single common data structure and format following the ISA-88 and ISA-95 standards will enable Tech Transfer.

When business rules and quality standards are built into the solution, companies can ensure that information complies with the necessary standards and regulations as it moves across the development continuum. A single platform design enables flexible data mining in early R&D as well as the compilation of more structured outputs and documents required for later regulatory submissions.

Organizations that have deployed such solution have reported<sup>7</sup>:

- Up to 25% improvement in productivity
- 50% reduction in cycle time
- Significant reductions in regulatory compliance risk.

Overall an integrated informatics solution supporting “science to compliance.” helps improving knowledge management, data mining, and technology transfer among the various domains - including R&D, manufacturing, and commercialization, adherence to QbD initiatives, and an overall faster time to market.

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