

Setting the Stage for Electronic Data Exchange

Stephen Wing, Senior Product Manager, Analytical and Logistical Services

Every day, drug manufacturers must consider and address a wide range of challenges and prospects including complex regulatory requirements, intense cost pressures and the business opportunities offered by novel product classes. Transforming biopharmaceutical manufacturing with integration of intensified, continuous, predictive and autonomous operations is one solution that holds promise for streamlining operations, exploring new therapeutic modalities and meeting regulatory expectations which continue to evolve.

Digitization and automation, key elements of Bioprocessing 4.0, will be essential for this transformation, in which the industry will leave behind paper-based procedures, data silos, manual process control and equipment that cannot communicate with each other. The vision offered by Bioprocessing 4.0 is a manufacturing ecosystem, seamlessly connected via uninterrupted data acquisition and analysis and characterized by information transparency and decentralized decision making. Drug manufacturers will be able to control and understand every aspect of their operation, leverage immediate access to data to boost productivity, increase operational efficiency and drive growth more effectively and efficiently.

Adoption of an electronic format for the exchange of data (referred to as eData) from suppliers of raw materials to biopharmaceutical manufacturers is an important step towards making Bioprocessing 4.0 a reality.

Setting the Stage for eData

Digital transformation depends on the ability to share and use information about raw materials such as cell culture media, APIs and excipients, as well as single-use and filtration products, on a batch-by-batch basis in an electronic format.

Suppliers typically provide product certifications, which may include certificates of analysis and quality (CoA, CoQ), genealogy information, and in-process data.

Adoption of an eData platform accelerates and facilitates sharing of raw material quality data, the variability of which can impact process performance, and enables the end user to integrate that data directly into internal knowledge management systems and process analytical tools. In stark contrast, paper-based systems require manual input of data into the end user's systems, and in some cases, a second person is required to verify and validate the information; making the process even more difficult and time-consuming.

Rapid access to the electronic format enables users to monitor and conduct analyses of their own production performance and better understand what might be driving process and product quality variability. In the case of an out-of-spec situation, eData offers an easier, faster and more efficient path toward identifying the root cause and accelerates implementation of corrective actions. Use of eData also eliminates human transposition errors and improves operational efficiencies.

In 2017, the American Standards for Testing and Materials (ASTM) created Standard E3077-17 to define the data format and file structure, including the taxonomy and nomenclature, that are essential for the electronic exchange of data and secure ingestion by customers into their data acquisition platforms. The guide is intended to achieve an industry-wide standard format for seamless electronic data transfer for monitoring and studying variability.

Despite having this ASTM standard in place, adoption of eData has been relatively slow across the industry from both the supplier and end user perspectives.

An essential step toward accelerating adoption is currently underway across our organization and is focused on gathering information from legacy enterprise resource planning (ERP) and laboratory

information systems (LIMS) and translating this into extensible markup language (XML) files to be delivered electronically to our customers (**Figure 1**).

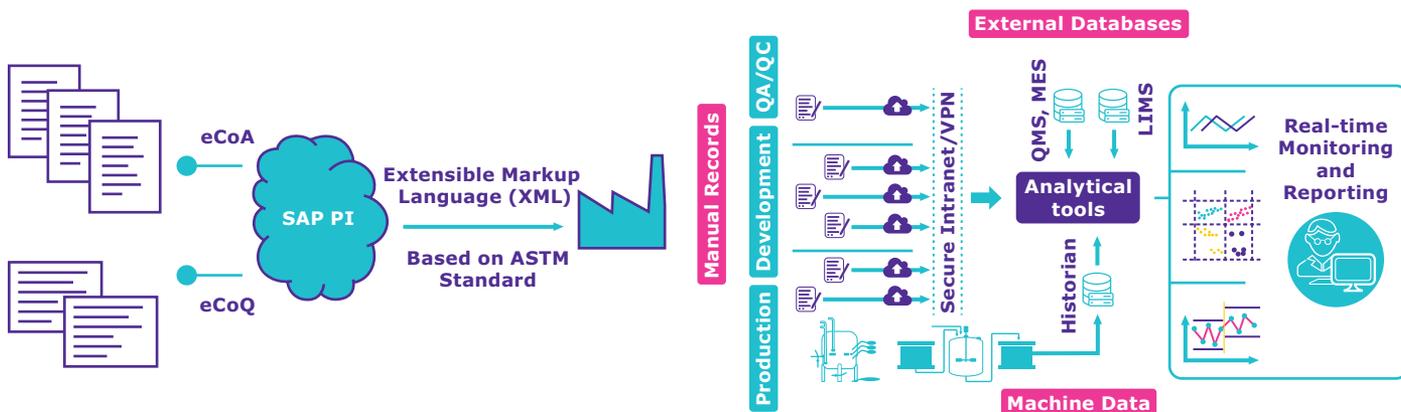


Figure 1. eData includes conversion of certificates of analysis and certificates of quality into an XML machine readable format, based on the ASTM standard.

Analytical and Logistical Benefits of eData

The value offered by eData for analytical applications is evident – it can facilitate and accelerate process optimization, enable advanced process control and support more robust predictive analytics. End users will be able to reduce raw material variability through trending and data analytics and determine which raw materials are contributing to process variability and the reasons why. At the same time, eData will play a central role in the digital transformation of logistical processes, including inventory management,

order replenishment, warehouse optimization and risk management. **Figure 2** provides an overview of the vision for our eMERGE™ Program which is intended to ensure drug manufacturing predictability and control via a seamless, user-friendly and customer-centric digital experience across the biopharmaceutical supply chain. The eMERGE™ platform is compatible with various commercially available analytical tools, including our Bio4C™ ProcessPad, which provides data integration, analytics, process monitoring, and visualization.

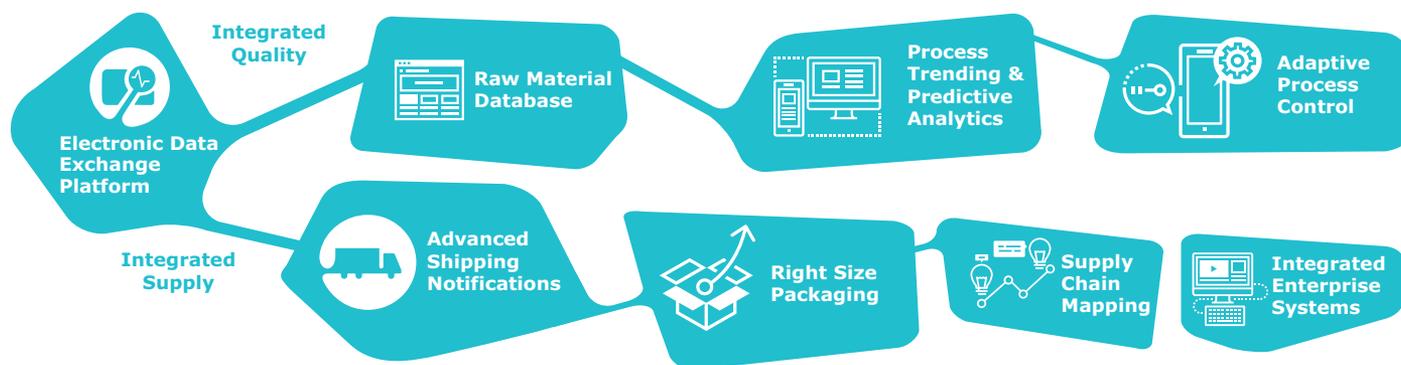


Figure 2. The eMERGE™ eData platform offers potential benefits for analytical and logistical production processes.

eData allows end users to more accurately know when shipments of potentially hundreds of raw materials are expected to arrive and accelerate the process of confirming what the product is and verifying that the quality meets internal specifications. Historically, this verification process and release of certain raw materials can take up to two to three months. Instead, the ability to electronically transfer data means that a product could be received and released much faster, and theoretically go straight into production versus into inventory (assuming materials are packaged to meet production run quantity requirements).

Getting Started with eData

A critical success factor for widespread adoption of eData across the industry will be implementation of a standardized platform for the exchange of data. This will eliminate the problem of suppliers having to establish custom approaches to support end users and ensure that drug manufacturers are developing compatible systems to receive and use the data efficiently. The ASTM standard was an important first step and has helped define the parameters for eData.

Additional factors must be considered prior to implementation. The supplier should understand how and what the data are being used for – whether for analytical applications, logistical applications or both – and how the data will be received and applied. While analytical data platforms are typically more flexible in terms of acceptable data formats, systems used in logistics such as ERP systems may not be as flexible, and this needs to be taken into consideration when establishing eData connectivity requirements.

Collaboration across biopharmaceutical manufacturers, industry groups and suppliers will be essential to advance the potential of eData and create a common infrastructure for sharing data. Close collaboration is also critical between individual suppliers and end users; this is necessary to establish an understanding of specific requirements. Ultimately, our vision is to not only provide information for the packaged finished goods, but to also include non-proprietary data from our genealogy of suppliers and their suppliers, as mutually agreed upon (**Figure 3**).

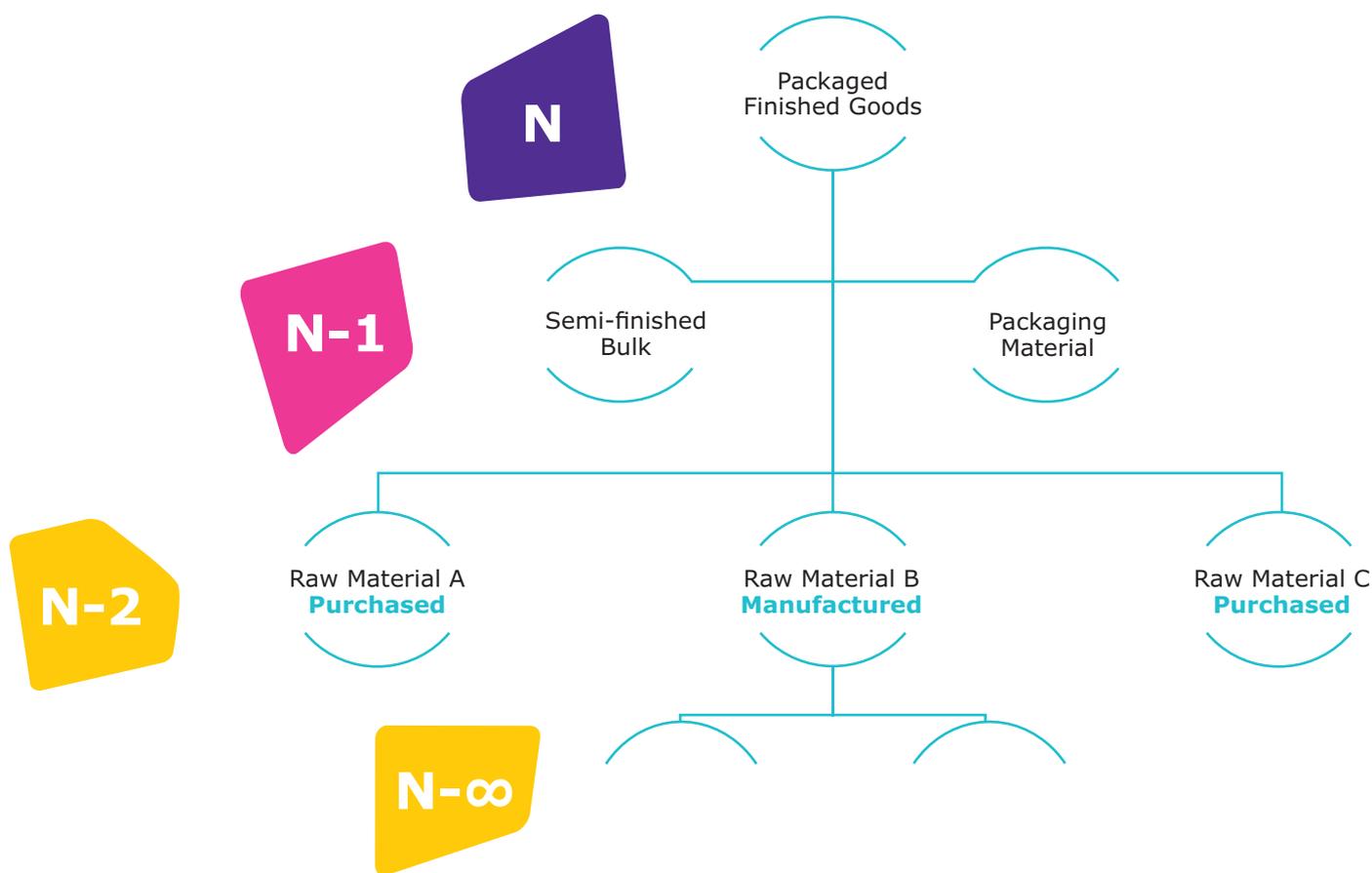


Figure 3. eData platforms offer the potential to include information from the entire supply chain, further improving the ability to monitor and study variability in processes.

Figure 4 provides an overview of a typical eData development framework. Supplier activities are shown on the left and include formatting data from ERP and quality release systems according to the ASTM standard. The process for sharing the eData must

ensure the proper connectivity, secure transmission and data acceptance. End users must ensure process monitoring, analytics and logistical systems are able to accept the data in the standardized format and integrate this with other platforms.

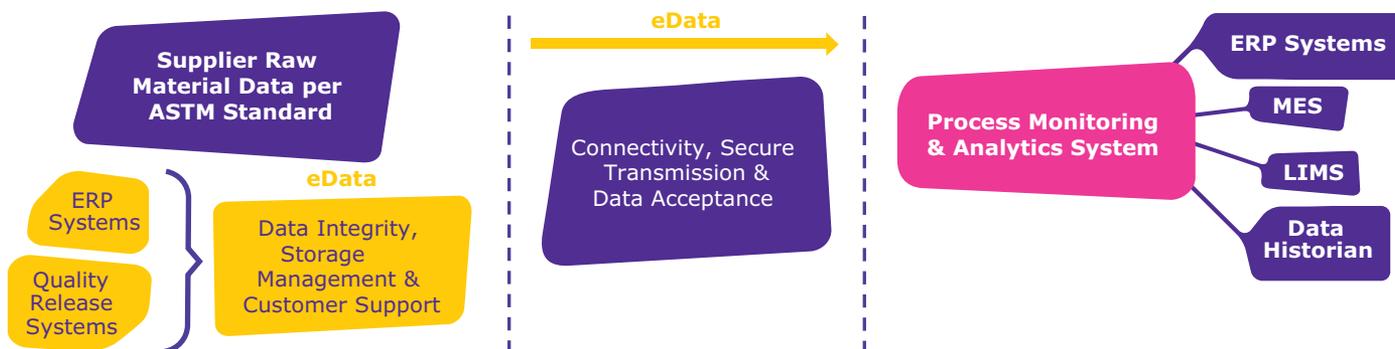


Figure 4. A robust eData platform facilitates data exchange and enhances knowledge management.

The Way Forward

Advancement of digital technologies and capabilities provides biopharmaceutical manufacturers with novel solutions that can be implemented across the enterprise, helping to address regulatory, cost and operational challenges and meet the demand for more and better drug products. Sharing and use of electronic data in a seamless fashion is foundational to this transformation. The ability to make raw materials quality data readily accessible through eData platforms

such as the eMERGE™ Program is key to superior knowledge management and more informed, efficient and timely decision-making. With close collaboration of suppliers, end users, standards organizations and regulatory authorities, these platforms will deliver greater visibility and understanding of raw material variability, the impact on process performance and product quality and ultimately, improve the predictive models used for advanced adaptive process control.

MilliporeSigma
400 Summit Drive
Burlington, MA 018003

For additional information, please visit www.EMDMillipore.com
To place an order or receive technical assistance, please visit www.EMDMillipore.com/contactPS

