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Standard Guide for Raw Material eData Transfer from Material Suppliers to Pharmaceutical & Biopharmaceutical Manufacturers[1]

This standard is issued under the fixed designation E3077; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

ε[1] NOTE—Editorial corrections were made to Table 1 in July 2017.

1. Scope

1.1 This guide is applicable to all elements of raw material electronic data (eData) transfer from a Supplier which provides a raw material to a Customer which receives the raw material.

1.2 This guide is developed for pharmaceutical and biopharmaceutical manufacturers and their suppliers, but may be suitable for other industries that routinely transfer data.

1.3 The guide may also be applicable to raw material eData transfer between companies in the supply chain.

1.4 The guide is applicable to new and existing raw materials.

1.5 This guide is applicable to the life-cycle of a raw material (that is, data generated throughout the processing stages of the raw material) and is not dependent on the Supplier or Customer.

1.6 This guide describes two major areas of eData standard: the data format and the data content including the taxonomy and nomenclature.

1.7 The guide currently only covers data content and data format in the English language. The data format shall not be translated. Use of other languages for the data content outside the scope of this guide.

1.8 The format is based on Extensible Markup Language (XML) 1.0.

1.9 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

2. Referenced Documents

2.1 *ASTM Standards:*[2]

E2363 Terminology Relating to Process Analytical Technology in the Pharmaceutical Industry

E2500 Guide for Specification, Design, and Verification of Pharmaceutical and Biopharmaceutical Manufacturing Systems and Equipment

E3051 Guide for Specification, Design, Verification, and Application of Single-Use Systems in Pharmaceutical and Biopharmaceutical Manufacturing

2.2 *Other Documents:*

Extensible Markup Language (XML) 1.0 (fifth edition)[3]

ISO 8601 Data Elements and Interchange Formats[4]

XML Signature Syntax and Processing (second edition)[5]

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[1] This guide is under the jurisdiction of ASTM Committee E55 on Manufacture of Pharmaceutical and Biopharmaceutical Products and is the direct responsibility of Subcommittee E55.03 on General Pharmaceutical Standards.

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[2] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

[3] Available from World Wide Web Consortium (W3C), https://www.w3.org/TR/REC-xml.

[4] Available from International Organization for Standardization (ISO), ISO Central Secretariat, BIBC II, Chemin de Blandonnet 8, CP 401, 1214 Vernier, Geneva, Switzerland, http://www.iso.org.

[5] Available from World Wide Web Consortium (W3C), https://www.w3.org/TR/xmldsig-core.

3. Terminology

3.1 *Definitions*—For definitions of terms used in this guide, refer to Terminology E2363.

3.2 *Definitions of Terms Specific to This Standard:*

3.2.1 *certificate, n*—a document that confirms a product meets its specifications and is issued by the Supplier or third party per individual lot and commonly contains actual testing results that are part of quality control of the product lot; the certificates are sometimes called by other names such as: Certificate of Analysis (CoA), Certificate of Conformance (CoC), Certificate of Quality, Certificate of Conformity, or Declaration of Conformity.

3.2.2 *customer, n*—the receiver of the raw material; the content of the CoA (including specifications of the raw material) is based on agreement between the Customer and the Supplier.

3.2.3 *eData, n*—electronic data is generated by the Supplier and received by the Customer which includes data found within the CoA and any additional data agreed upon by the Supplier and the Customer for transfer.

3.2.4 *raw material, n*—in the Biopharmaceutical industry, raw material includes all consumables in manufacturing of a drug product or drug substance such as media, buffers, disposable, bioreactor additives, process titrants, resin, filters, excipients, and primary containers, for instance, syringes, vials, cappers, and stoppers.

3.2.5 *supplier, n*—manufactur or distributor of the raw material that is required to generate a Certificate of Quality, such as CoA, CoC and deliver the raw material to its Customer.

4. Summary of Guide

4.1 This guide describes a data format that can be adopted by Suppliers and Customers to transfer raw material data in a standardized and scalable way.

4.2 This guide also describes critical data content that should be included and offers recommendations for optional but informative data parameters that Suppliers and Customers may want to adopt for mutual benefit.

5. Significance and Use

5.1 Application of the approach described within this guide is intended to achieve a biopharma industry-wide standard format that will be available for electronic data transfer between Supplier and Customer for monitoring and studying variability.

5.2 This guide supports and facilitates fast data transfer, thereby avoiding data recapture, human interaction, and transcription errors; and thus enables a more streamlined business process.

5.3 If the eData structure does not conform to the XSD defined by this guide then it is not guaranteed to be inter-operable. Feedback or change requests should be directed to ASTM Headquarters, to the attention of the Committee E55 Staff Manager.

5.4 Digital Signature can be adopted and used as part of the eData transfer. XML and XSD are provided in two formats: with and without digital signature configuration. User can follow either format for implmenation to ensure conforming with the ASTM eData XSD structure.

6. Key Concepts

6.1 This guide applies the following key concepts:

6.1.1 Risk management approach,

6.1.2 Use of Supplier documentation, and

6.1.3 Data transfer methods.

6.2 *Risk Management Approach:*

6.2.1 The scope and extent of quality risk management for data transfer activities and documentation are based on the risk to product quality and patient safety. Variation in raw materials is a concern and in order to understand the variability, the first step is to have an efficient way of obtaining the data. Having a standardized eData format for both the Suppliers and Customers is the first step in achieving this goal.

6.2.2 Having a standard way to generate and consume data will avoid multiple formats that one Supplier has to generate to suit various Customer requirements. In addition, using eData standard format as a template, the Supplier's data source system built will allow simpler compilation of data on an ongoing basis. This will reduce cost and resources for implementing eData transfer between Supplier and Customers.

6.2.3 Following the format described in this guide, change management can be provided in a dependable mechanism for tracking and prompt implementation of technically sound improvements.

6.3 *Use of Supplier Documentation:*

6.3.1 Supplier documentation should be used provided that the regulated company has assessed the Supplier, and has evidence that the Supplier has: an acceptable supplier quality system, technical capability, and demonstrated application of good engineering practice (GEP) such that information obtained from the supplier will be accurate. Details on Supplier documentation can be found in Guides E2500 and E3051.

6.4 *Data Transfer Methods:*

6.4.1 It is critical that the data transferred from Supplier to Customer are intact during the transfer. Since computer systems and networks are vulnerable to data loss and unauthorized manipulation, it is important that the Customer has some means of verifying the integrity of the data. Suppliers and Customers should agree on methods to ensure that the transferred data is not modified accidentally or intentionally. This guide describes an optional digital signature (including checksum) capability to ensure the integrity of the transferred data. Data encryption is not addressed in the scope of this guide. Additional means such as Secure File Transfer Protocol (SFTP) or Internet Protocol Security (IPsec) may be employed to provide additional security for the transfer of eData documents via internet.

6.5 *Detect Data Transfer Error*—If digital signature is not implemented, in order to ensure data integrity and to detect error that may have been introduced during transmission and storage, it is recommended that Checksum should be implemented to the data files transferred between Suppliers and the end users.

6.6 *Utilizing XSD Schema to Generate XML*—Third-party solutions on the market can be used to generate XML based on the XSD schema provided in this guide.