News Release

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BASF Pharma Solutions and Life Science business of Merck KGaA, Darmstadt, Germany introduce a new standard for electronic exchange of quality and regulatory data.

- **The collaboration focuses on the development and sharing of Standard Quality and Regulatory Documentation (StaQRD), a standard guide for the electronic transfer of information**
- **StaQRD supports the streamlining of data transfers between suppliers and pharmaceutical manufacturers**

Florham Park, New Jersey, June 6, 2023 –

BASF Pharma Solutions and the Life Science business of Merck KGaA, Darmstadt, Germany announce the launch of a new standard for the electronic transfer of quality and regulatory documentation from suppliers to users in the pharma/biopharmaceutical industry. The Standard Quality and Regulatory Documentation (StaQRD) electronic data standard includes quality and regulatory compliance data.

A previous eData standard, ASTM-E3077, published by the American Society for Testing and Materials (ASTM), was primarily designed for transferring CoA content and did not include the exchange of additional information. Building on this CoA standard, StaQRD includes nine additional types of compliance documentation in the initial launch, such as nitrosamine risk assessment, allergen statements and GMP compliance documents. StaQRD is available to all suppliers and manufacturers with the goal of facilitating a streamlined electronic documentation

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exchange while ensuring data integrity, speed and efficiency, and flexible data management.

“Currently, the exchange of quality and regulatory information requires a manual process of transferring text and PDF files and copying and pasting information. The process is not only time-consuming but also prone to errors,” states Dr. Dominik Odenbach, Director Global Quality & Regulatory Compliance & External Affairs, BASF Pharma Solutions. “We developed StaQRD in partnership with the Life Science business of Merck KGaA, Darmstadt, Germany, and with input from leading pharmaceutical companies, to streamline the transfer of quality and regulatory information from suppliers to users using widely adopted Extensible Markup Language (XML) to define the required and optional information, propose exact names for the attributes to ensure consistency, harmonize descriptions and reduce the risk for error,” Dr. Odenbach explains.

“Our customers expect 24/7 access to accurate real-time data and vital information to minimize supplier risk and accelerate the time-to-market for new drug therapies. We are meeting these demands through a growing number of digitalization investments and initiatives, including our collaboration with the Life Science business of Merck KGaA, Darmstadt, Germany to develop StaQRD,” states Marion Kuhn, Vice President Business Management, Pharma Solutions.

The StaQRD document is available to download free of charge. To learn more, visit https://pharma.basf.com/about-basf-pharma/quality-and-regulatory-services/staqrd.

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