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News Release

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EMD Millipore Introduces Enhancements to its EMPROVE® Program of Pharmaceutical Raw Materials to Facilitate Risk Assessment

- **Access to information required for risk assessment and supplier qualification**
- **Expanded dossiers and categorization of raw materials by risk**
- **Instant, online access to regulatory and technical information on portfolio of 400 products**

Billerica, Massachusetts, September 14, 2015 – EMD Millipore, the Life Science business of Merck KGaA of Darmstadt, Germany, today introduced enhancements to its industry-leading EMPROVE® portfolio of pharmaceutical raw materials. The expanded documentation and regulatory information facilitates drug product manufacturers' risk assessment workflows and supplier qualification. The enhancements also help drug product manufacturers meet their own internal quality guidelines as well as those recently published by the European Commission. This was the first regulatory body to formalize risk assessment requirements for pharmaceutical excipients, despite the practice being common in industry.

The EMPROVE® portfolio includes approximately 400 raw and starting materials used in the manufacture of drug products and includes excipients, process chemicals and active pharmaceutical ingredients.

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The newest enhancements enable the selection of raw and starting materials best suited for applications, based on their risk assessment:

- EMPROVE® Essential products target moderate risk level applications.
- EMPROVE® Expert products are specified for higher risk applications where low microbiological and endotoxin levels are critical. Our manufacturing processes are designed to create products with low microbiological and endotoxin levels.
- EMPROVE® API products provide the quality and regulatory documentation required for active pharmaceutical ingredients. GMP requirements are fulfilled, as all products are produced in Europe, according to the ICH Q7 guideline.

In addition to the currently-available Material Qualification Dossier (formerly referred to as the Basic Dossier) drug manufacturers can obtain two new dossiers for regulatory information. These new dossiers help streamline and accelerate the costly and time consuming information collection and risk assessment process. The **GxP Dossier** is structured according to the new EU guideline 2015/C 95/02 and supports risk assessment and supplier qualification for excipients. With greater detail on raw material properties, the new **Operational Excellence Dossier** helps drug manufacturers design more consistent and predictable processes and quality. This dossier includes elemental impurity profiles that address the ICH Q3D guideline requirements published in December 2014.

Drug manufacturers have an option to use the new online EMPROVE® Suite website. This platform provides product information and dossiers for the entire EMPROVE® portfolio and enables direct, 24/7 access to the comprehensive regulatory information.

“The global pharmaceutical industry adheres to the strictest standards, and risk assessment plays a critical role in supplier qualification,” said Andrew Bulpin, Executive Vice President, Process Solutions, EMD Millipore. “With these enhancements, customers can continue to rely on the EMPROVE® documentation to guide, facilitate and speed their process of qualifying raw materials from EMD Millipore. The content is invaluable when filing their drug products, resulting in greater confidence and minimized risk throughout the manufacturing process.”

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EMD Millipore representatives will be available at stand #7K40 at the CPhI conference in October in Madrid, Spain to discuss the EMPROVE® portfolio and these new enhancements.

For more information, please visit www.emdmillipore.com/emprove.

About EMD Millipore
EMD Millipore is the U.S. Life Science subsidiary of Merck KGaA, Darmstadt, Germany. As part of the global Life Science business of Merck KGaA, Darmstadt, Germany, EMD Millipore offers a broad range of innovative, performance products, services and business relationships that enable our customers' success in research, development and production of biotech and pharmaceutical drug therapies. Through dedicated collaboration on new scientific and engineering insights, and as one of the top three R&D investors in the life science tools industry, the Life Science business of Merck KGaA, Darmstadt, Germany, serves as a strategic partner to customers and helps advance the promise of life science. Headquartered in Billerica, Massachusetts, the global business has around 10,000 employees, operations in 66 countries and 2014 revenues of €2.7 billion.

For more information, please visit www.emdmillipore.com.

About Merck KGaA, Darmstadt, Germany
Merck KGaA, Darmstadt, Germany, is a leading company for innovative and top-quality high-tech products in healthcare, life science and performance materials. The company has six businesses – Biopharmaceuticals, Consumer Health, Allergopharma, Biosimilars, Life Science and Performance Materials – and generated sales of € 11.3 billion in 2014. Around 39,000 employees work in 66 countries to improve the quality of life for patients, to foster the success of customers and to help meet global challenges. Merck KGaA, Darmstadt, Germany, is the world's oldest pharmaceutical and chemical company – since 1668, the company has stood for innovation, business success and responsible entrepreneurship. Holding an approximately 70% interest, the founding family remains the majority owner of the company to this day. Merck KGaA, Darmstadt, Germany holds the global rights to the Merck name and brand. The only exceptions are Canada and the United States, where the company operates as EMD Serono, EMD Millipore and EMD Performance Materials.

For more information, please visit www.emdgroup.com.