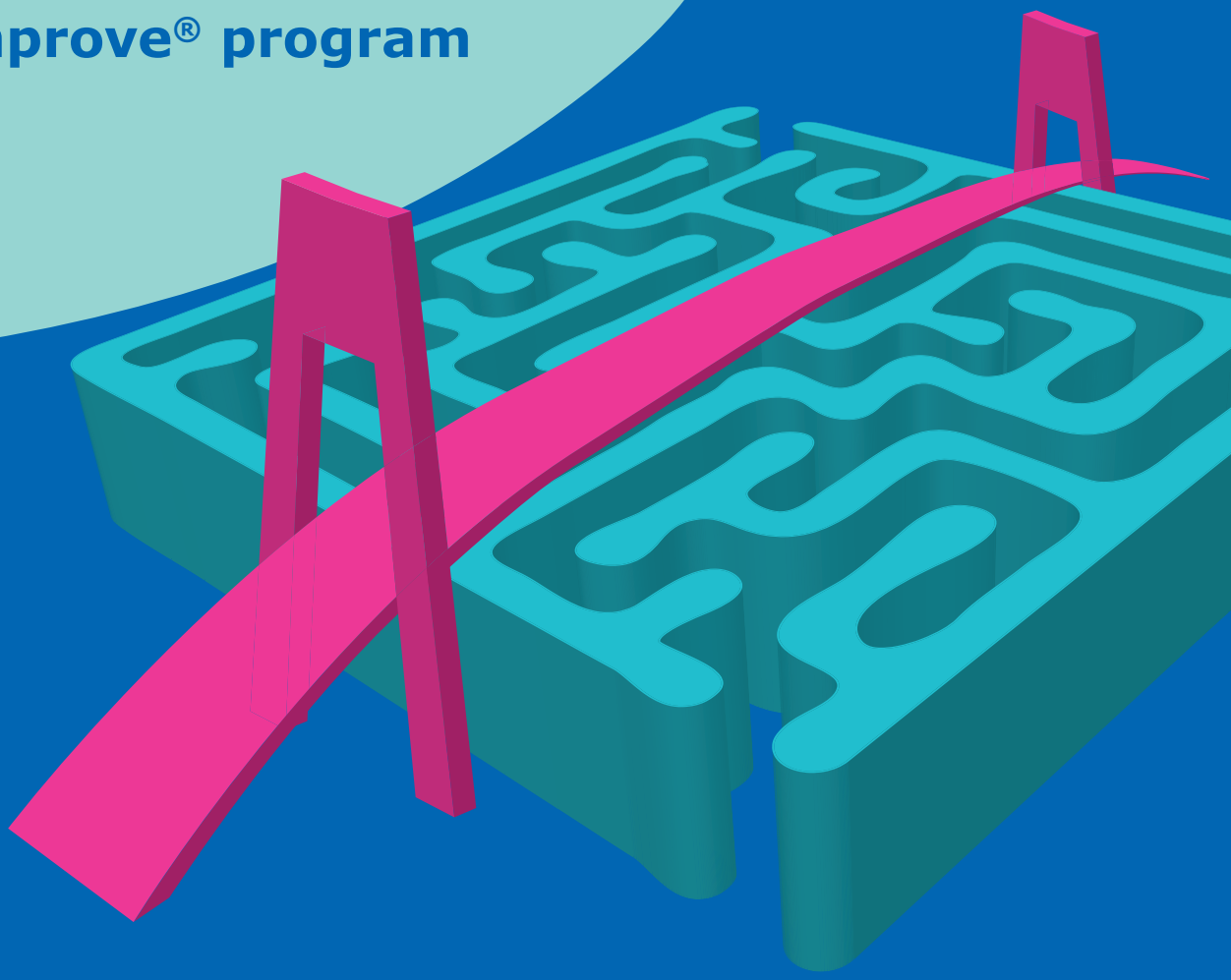
YOUR FAST TRACK

through regulatory challenges

The Emprove® program



The life science business of Merck operates as MilliporeSigma in the U.S. and Canada.

MERCK

Filtration and single-use

As the biopharmaceutical industry evolves, it also shapes the need for higher transparency along the supply chain and standardization. Information is crucial for manufacturers when selecting filtration and single-use technologies and other materials. The more you know about your materials and the risks involved, the more confidence you can have to move forward with your product development. After all, careful assessment ensures manufacturers select the right materials from dependable suppliers.

Regulatory guidelines surrounding chemicals continue to direct and alter the flow of information between supplier and end user. Industry-wide demands and expectations are pushing for the same level of transparency for devices used in the manufacturing process.

With these demands in mind, we are extending the Emprove® program to include filtration and single-use, starting with sterile and virus filters as well as single-use components used at the major steps of the biopharmaceutical process.

An overview of products available with Emprove® documentation can be found at **www.merckmillipore.com/emprove**

Dossier Library

With the new Emprove® program, we address tomorrow's regulatory questions today. Three different types of dossiers will support you throughout the different stages of your operations: qualification, risk assessment, and process optimization.

Emprove® dossier library

	Material Qualification Dossier Information to start a material qualification	**Quality Management Dossier** Answers questions during risk assessment	**Operational Excellence Dossier** Supports process optimization
Raw and starting materials	• General information • Manufacturing flow chart • Product characterization and qualification • Control of drug substance • Reference standard • Materials • Container closure systems • Stability summary	• Quality self assessment • Audit report summary • Supply chain information • Stability data	• Product quality report • Element impurity information • Analytical procedure
Filtration and single-use	• General information • Manufacturing flow chart • Product characterization and qualification • Specification, release criteria • Materials of construction • Extractables summary* • Residual solvents statement • Regulatory statements (Animal origin, allergens...)	• Quality self assessment • Audit report summary • Supplier and CMO management • Supply chain information • Shelf life testing and results • Critical raw materials	• Extractable report* • Elemental impurity information • Analytical procedure

* Standardized Extractable Protocol, BPOG, published in Pharmaceutical Engineering, 11.2014

Raw and starting Materials

Risk levels vary depending on your product and its application. Our Emprove® portfolio of raw and starting materials, which includes excipients, is divided into three categories to help simplify and streamline the selection process.

EMPROVE® ESSENTIAL product line is designed for moderate risk levels. The best-in-class regulatory support is combined with our high quality standards.

EMPROVE® EXPERT product line addresses higher risk applications, where the lowest microbiological and endotoxin levels are of utmost importance. These products are documented as being manufactured with low microbiological and endotoxin levels.

EMPROVE® API product line provides the right quality and regulatory documentation required for active pharmaceutical ingredients. All the products in this line are manufactured in Europe and comply with the ICH Q7 requirement.

Following the acquisition of Sigma Aldrich we aim to integrate the well-known PharmaGrade portfolio of SAFC into the Emprove® program. Updates on the progress can be found at **www.merckmillipore.com/emprove** and **www.sigmaaldrich.com/safc/bioprocess/pharmagrade.html**

qualification Made easy

Emprove® program now includes raw materials, filters and single-use components

The innovative Emprove® program has been providing efficient regulatory documentation to the pharma and biopharma industry for over a decade, even as the number of regulations has increased. Now we're broadening our scope by expanding our portfolio and providing detailed information on filters and single-use components for biopharma production.

The Emprove® program simplifies your processes by:

- Expediting approval preparation and extending compliance
- Facilitating qualification processes
- Supporting risk assessment, management and mitigation
- Increasing supply chain transparency
- Saving you time and money

comprehensive regulatory information at your fingertips

Accessibility to relevant information is essential. The new Emprove® Suite is your online gateway to conveniently access all of our Emprove® dossiers on demand. The Suite is always up to date and optimized for any targeted search.

Subscribers with a two-year license can navigate regulatory challenges with access to dossiers from our entire portfolio. The Material Qualification Dossier is available free of charge on our website.

For more information on how to subscribe, visit:
www.merckmillipore.com/emprovesuite

Full access to all dossiers of the Emprove® library

- One time registration
- Includes 5 email addresses per company
- Access for 2 years

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