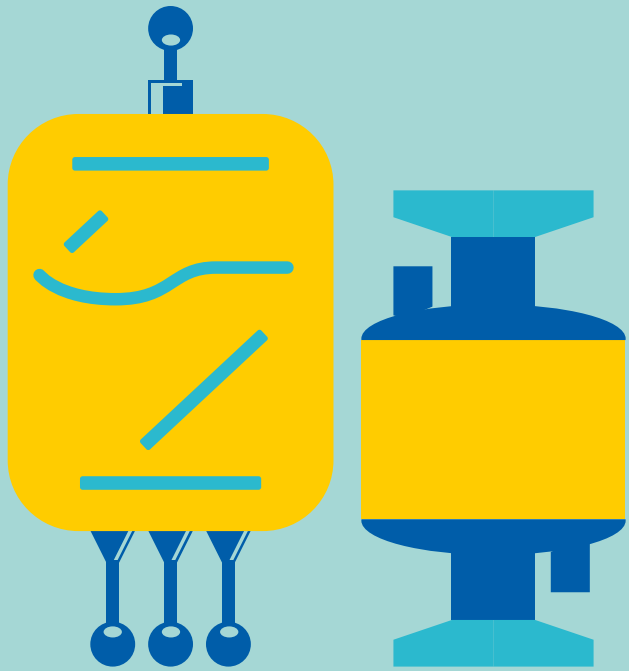
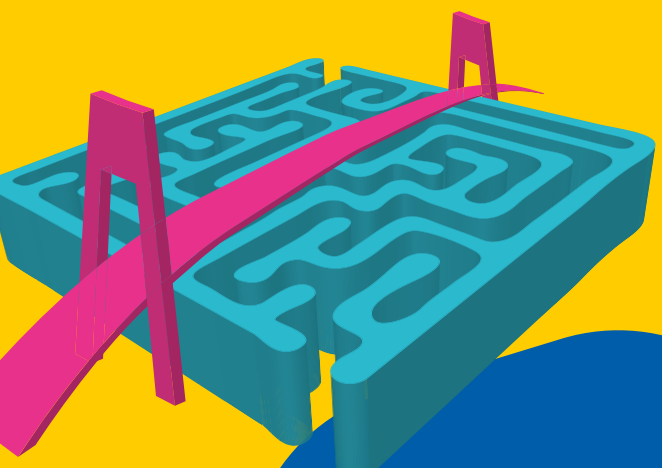
MERCK

Emprove® Filters and Single-Use Components

Enabling a more robust risk assessment

Transparency and comprehensive documentation with the Emprove® Program





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

Millipore®

Preparation, Separation, Filtration & Monitoring Products

The Emprove® Program

Confidently speed your way through the regulatory maze and fast track your new drug to market.

The Emprove® Program - more documentation, less struggle

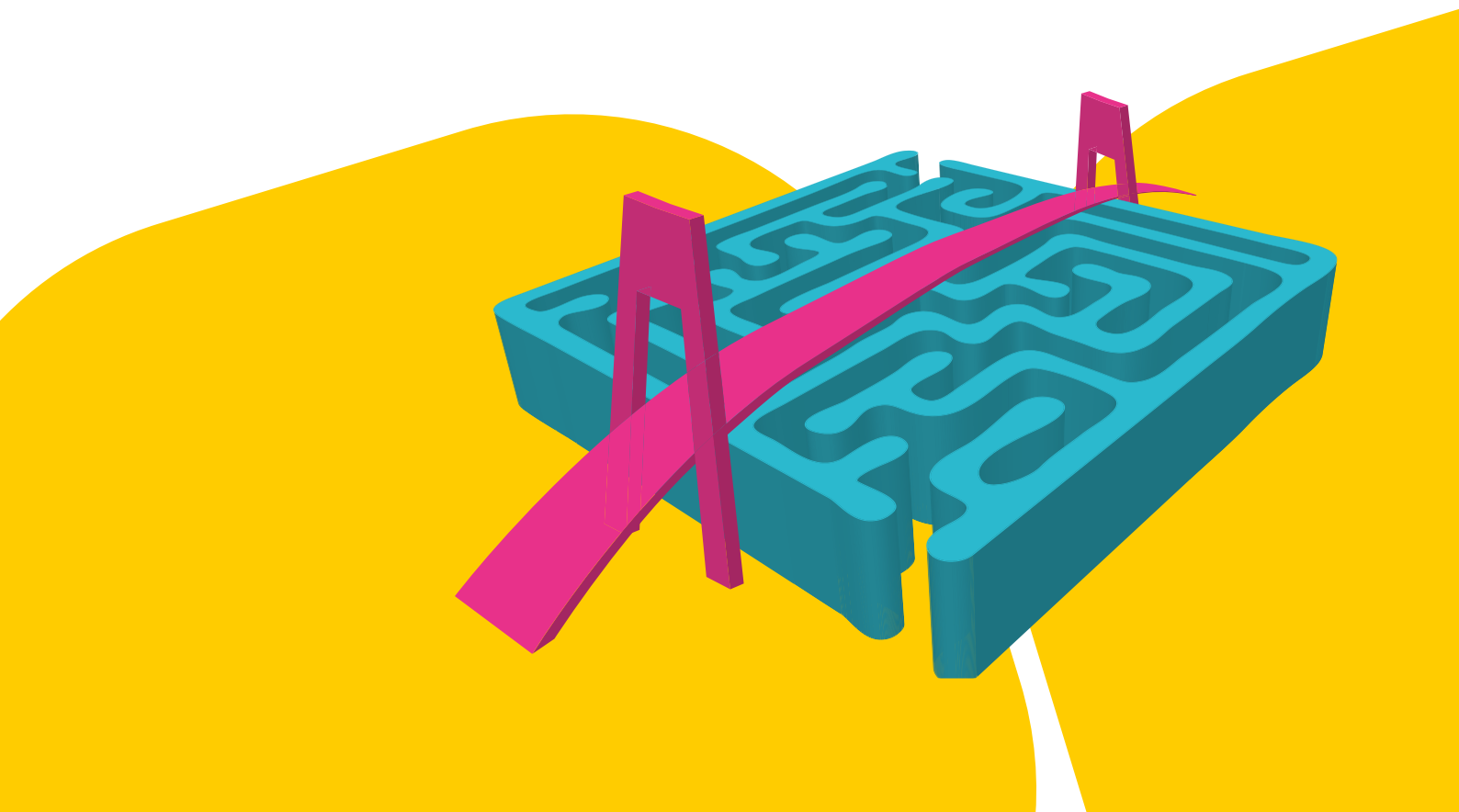
The Emprove® Program supports your risk assessment and management efforts with online access to regulatory information and comprehensive documentation.

With the Emprove® Program, full supply chain transparency is available at your fingertips.

Our Emprove® Dossiers help you to simplify your qualification, risk assessment and process optimization.

Our Emprove® Program enables you to reduce time, effort and utilize your resources optimally by providing:

- Full supply chain transparency
- Support of risk assessment and management
- Online access to regulatory information
- Comprehensive up-to-date documentation

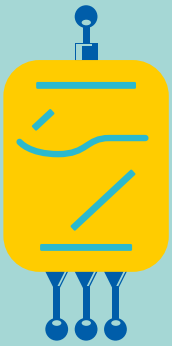


How does it work?

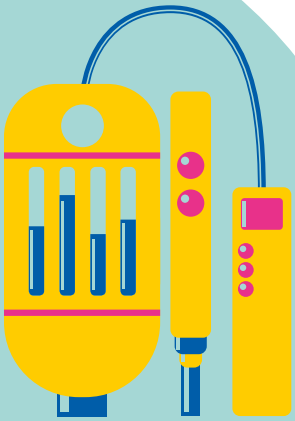
Qualification, risk assessment and process optimization

The Emprove® Program contains over 400 raw and starting materials, 30 filter and single-use product families, as well as selected chromatography resins and cell culture media. Each product portfolio is supported with Emprove® Dossiers which provide comprehensive, up-to-date documentation to help you navigate regulatory challenges, manage risks, and improve your manufacturing processes.

Emprove® Portfolio

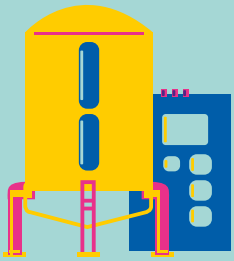


Filtration and Single-Use Components



Chromatography Resins in Biomanufacturing Processes

Pharma Raw and Starting Materials



Cell Culture Media in Upstream Processes

Emprove® Dossiers

Material Qualification

Quality Management

Operational Excellence

Millipore® products

SAFC® products/services

Emprove® Dossiers for Filtration and Single-Use Components

Easily address your material qualification, risk assessment and process optimization

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.

The industry-wide demand for increasing levels of transparency for single-use products used in the manufacturing process has been answered with our expanded Emprove® Program. Now our portfolio includes filtration and single-use components used in the major steps of the biopharmaceutical process.

Material Qualification Dossier

Supports product qualification and speeds up regulatory filing preparation

- General information
- Manufacturing flow chart
- Product validation and qualification
- Specifications (design and release criteria)
- Materials of construction
- Extractables summary
- Regulatory statements (Animal Origin, BPA etc.)

Information to start material qualification

Quality Management Dossier

Provides valuable information on how quality variability attributes are controlled

- Quality self-assessments
- Chain of custody
- Supplier and CMO management
- Shelf life testing and results
- Packaging and sterilization validation

Answers questions during quality risk assessment

Operational Excellence Dossier

Supports process optimization and safety risk assessment with detailed extractables profile

- Extractables report
- Elemental impurities summary
- Analytical procedure

Supports process optimization

Enabling a more robust extractables and leachables risk assessment

All polymeric components such as the filters and single-use systems used in biopharmaceutical manufacturing must be assessed for manufacturing process and drug product impact through an evaluation of extractables information.

Extractables are compounds that can be extracted from these materials under stressed model conditions. Leachables are compounds that leach under normal process conditions. An understanding of extractables is essential as it can help identify leachables that may end up in the final drug product.

Fast-track your extractables risk assessment

With our Emprove® Program, developing an extractables profile for filters and single-use systems used in bio-pharmaceutical manufacturing no longer requires a time- and resource-intensive compilation of a vast amount of data.

Our Emprove® Operational Excellence Dossiers provides reliable extractables data based on industry standards and guidelines recommended by BioPhorum (BPOG) and adopting the USP 665 guidance. The datasets generated facilitate your safety risk assessment, accelerating your ability to identify potential leachables and calculate patient exposure based on process conditions.

Together with our BioReliance® Validation Services experts, we can support you through all stages of your risk assessment.

Ensuring Patient Safety

REQUIREMENTS

COLLECT → **INTERPRET** → **EVALUATE & MITIGATE**

Compile standard Extractables data for contact material present in the process, including BPOG protocol and USP <665> (draft) approaches

Identify process specific extractables in drug product by interpreting standard extractables data (model streams, scale, timepoints)

Calculate potential risk associated to drug intake on the basis of Extractables Compounds

If negligible risk can not be demonstarted, mitigate with Leachables study or a process design change

EMPROVE® PROGRAM

BIORELIANCE® VALIDATION SERVICES

Transparency and confidence with Mobius® Single-Use Portfolio

We offer Emprove® Dossiers specific to our Mobius® Single-Use components such as sterile filters, sterile connectors and process container films.

The Mobius® Select Single-Use Assemblies dossiers cover essential Mobius® Assemblies information for all certificate levels - Gold, Silver and Bronze - and include critical information such as validation tests and results. These include additional information to what can be found in the Single-Use Assemblies with Mobius® Technology dossiers.

Emprove® Dossiers Content specific for Mobius® Single-Use Assemblies

Material Qualification Dossier

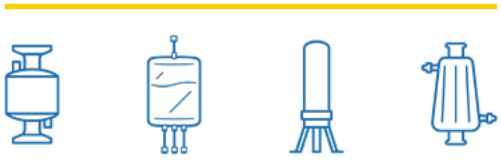
Supports product qualification and speeds up regulatory filing preparation

- Manufacturing process flow diagram
- Design and release criteria for Gold, Silver and Bronze assemblies
- Validation information including visual inspection and leak testing
- Supplier information for material of construction and regulatory statement information at the component level

Quality Management Dossier

Answers questions during quality risk assessment

- Sterilization testing requirements and approach including Gamma Irradiation
- Sample certificates for irradiation
- Packaging and test requirements and results
- RX360 self assessment



Emprove® Dossiers

The documentation you need to speed your way through the regulatory maze

Emprove® Dossiers for Filters are grouped according to product families with the same materials of construction, production processes, and packaging components.

Emprove® Dossiers for Single-Use Components are available beginning with the most commonly used components in the process. Assembly level information can be developed from the individual dossiers available for components forming the part of the single use assemblies.

More information on the website: MerckMillipore.com/emprove

Emprove® Suite

Unlock 24/7 online access to all Emprove® Dossiers

Getting the relevant information is now more convenient than ever with the Emprove® Suite.

The Emprove® Suite offers:

- 24/7 online access to all dossiers of the entire Emprove® portfolio
- Subscriptions available for 1, 2 or 5 years
- Current and up-to-date information optimized for easy and targeted search
- Dossier updates notifications

For more information, our terms and conditions as well as the subscription form, please visit: **MerckMillipore.com/emprovesuite**

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