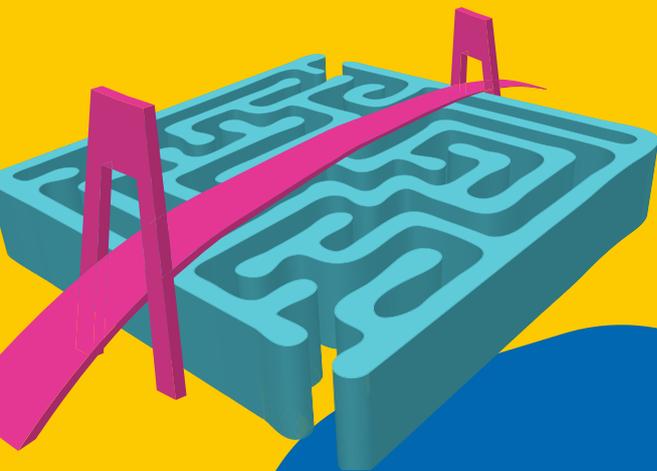
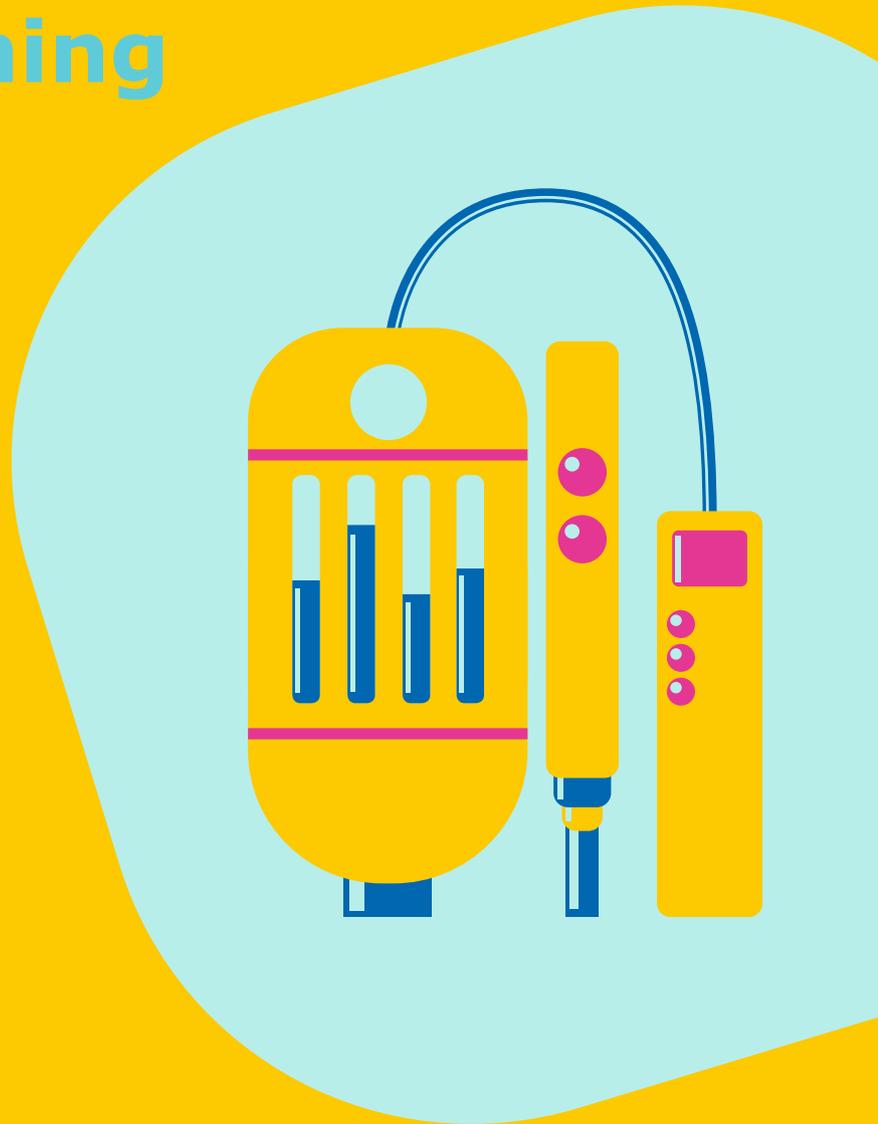
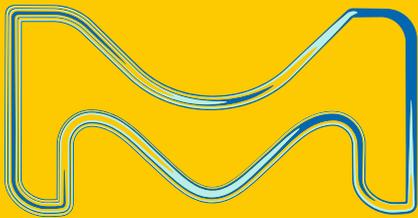


**Chromatography Resins in  
Biomanufacturing Processes**

# High performing resins meet regulatory excellence

Transparency and  
comprehensive  
documentation with  
the Emprove® Program



The life science business of  
Merck KGaA, Darmstadt,  
Germany 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

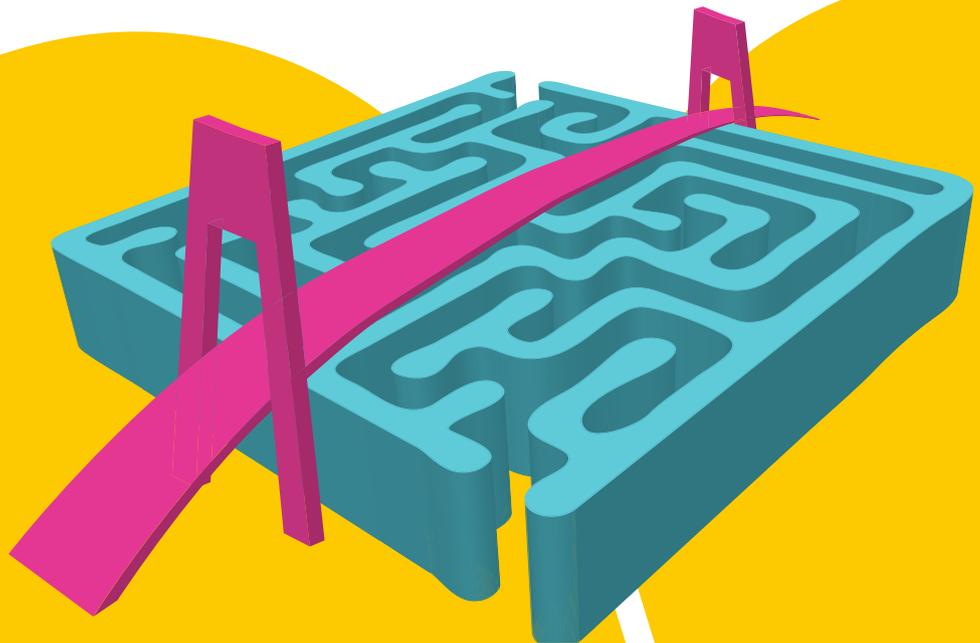
The Emprove® Program supports your risk assessment and management efforts with online access to regulatory information and comprehensive documentation.

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

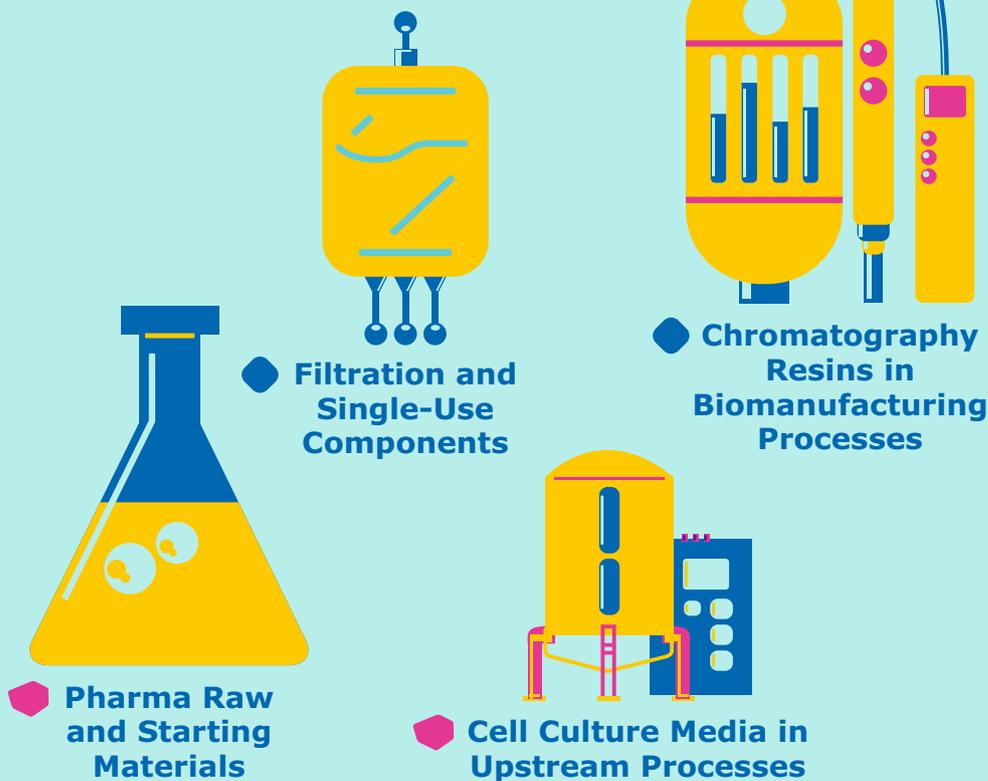


## How does it work?

### 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



### Emprove® Dossiers



# Step up with Emprove® Chromatography.

Taking the right purification steps in Biomanufacturing Processes.

Any component and raw material used at a later stage of the biomanufacturing process is considered a risk, as it could add a bioburden to the final drug product. While being essential, chromatography steps are often present from early to late downstream.

Therefore, information is crucial for manufacturers when selecting chromatography products and methods. With our category Emprove® Chromatography we address the specific needs when selecting and qualifying our chromatography resins.

**The Emprove® Dossiers support you throughout the different stages of your operations:**

## Material Qualification Dossier

Speeds up resin qualification and supports regulatory filing preparation

- General information
- Manufacture quality information
- Specification, release criteria
- Packaging material
- Regulatory statements (BSE/TSE, Allergens...)
- Storage and shelf life
- Environmental statement



**Information to start a material qualification**

## Quality Management Dossier

Supports quality risk assessment

- Supply chain information
- Product quality self assessment
- Supplier and process evaluation statement
- Stability data



**Answers questions during risk assessment**

## Operational Excellence Dossier

Supports process optimization efforts as well as extended risk assessment

- Manufacturing process (detailed information)
- Elemental impurity information
- Residual solvents statement
- Extractables profile
- Reference spectrum
- Product quality report
- Analytical procedure



**Supports process optimization**



## Emprove® Dossiers

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

To support full supply chain transparency and risk mitigation, we offer online access to the Emprove® Dossiers. These provide comprehensive, up-to-date documentation to help you navigate regulatory challenges, manage risks, and improve your manufacturing processes.

More information on the website:  
[EMDMillipore.com/emprove](http://EMDMillipore.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

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