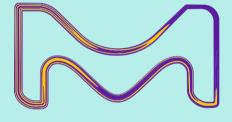


**Emprove® Cell Culture Media** 

# Ease your regulatory efforts with Cellvento<sup>®</sup> CHO media

Transparency and comprehensive documentation with the Emprove<sup>®</sup> Program



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

# **SAFC**®

Pharma & Biopharma Raw Material Solutions The Emprove® Program Confidently speed your way through the regulatory maze and fast track your new drug to market

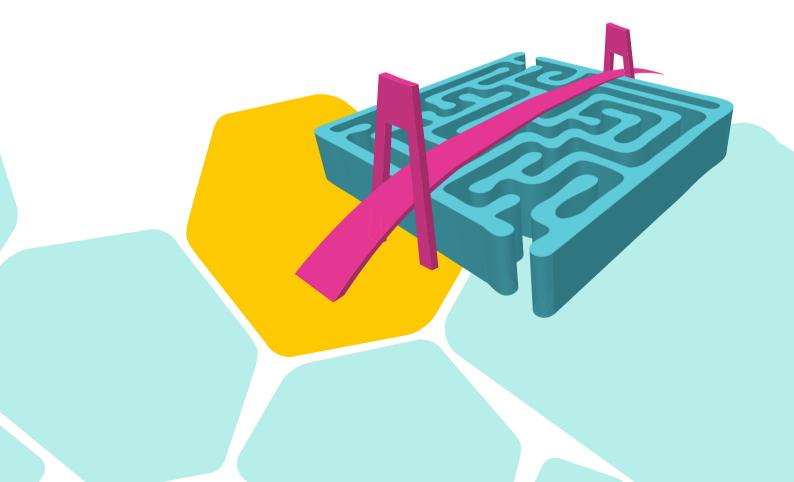
#### The Emprove® Program – more documentation, less struggle

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

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

Our Emprove<sup>®</sup> Dossiers help you to simplify your qualification, risk assessment and process optimization. Our Emprove<sup>®</sup> Program enables you to reduce time, effort and utilize your resources optimally by providing:

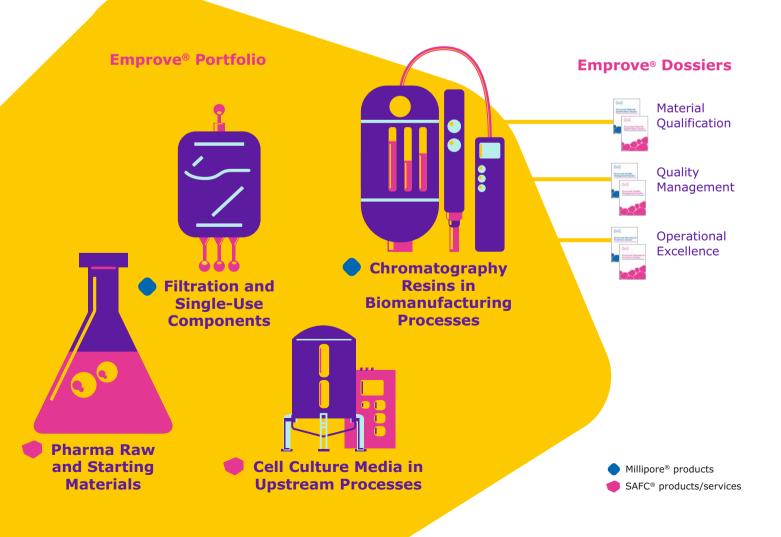
- Full supply chain transparency
- Support of risk assessment and management
- Online access to regulatory information
- Comprehensive up-to-date documentation



#### 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® CCM: transparency and comprehensive documentation**

#### Emprove® Dossiers for cell culture media products in biomanufacturing

Cell culture media (CCM) are of utmost importance to biopharmaceutical processes as they support cellular productivity and critical quality attributes of the final drug products.

Because of this critical role in manufacturing, along with increased regulatory focus on raw materials, a high level of information for the media is needed to support the entire process risk evaluation. With Emprove<sup>®</sup> CCM we address the specific needs when selecting and qualifying products of our Cellvento<sup>®</sup> CHO cell culture media platform.

The platform consists of specially designed catalog media supporting the needs of process intensification in fed-batch and perfusion applications. The product formulations are chemically defined and of non-animal origin.

# Three Emprove® Dossiers form material qualification, risk assessment and process optimization

## Material Qualification Dossier

- General information
  - Manufacture: – Manufacturing flowchart, ISO Cert, GMP statement
    - Homogeneity statement
- Characterization statements:
  TSE/BSE, virus safety, GMO, components of interest
- Control of CCM:
  - CoAs, label, batch numbering
  - Packaging material
  - Stability

Information to start a material qualification



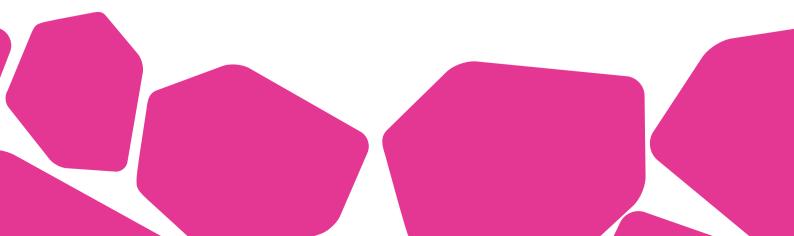
- Supply chain information
- Product quality self assessment
- Site quality self assessment
- Supplier management
- Stability data

## Operational Excellence Dossier

- Trace element information
- Origin of raw materials
- Analytical procedures

Answers questions during risk assessment





### **Emprove® Dossiers**

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

In line with the existing Emprove<sup>®</sup> product categories, detailed information is available in three different types of dossiers, supporting you throughout the different stages of your operations: material qualification, risk assessment, and process optimization.

#### More information on the website: MerckMillipore.com/emprove



## **Emprove®** Suite

Unlock 24/7 online access to all Emprove<sup>®</sup> Dossiers Getting the relevant information is now more convenient than ever with the Emprove<sup>®</sup> Suite.

The Emprove<sup>®</sup> Suite offers:

- 24/7 online access to all dossiers of the entire Emprove<sup>®</sup> 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

## Click. Explore. Learn more.

Find out more on:

#### MerckMillipore.com/emprove

Gain 24/7 online access to all your dossiers with our Emprove<sup>®</sup> Suite at:

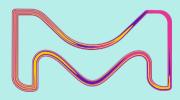
#### MerckMillipore.com/emprovesuite



We provide information and advice to our customers on application technologies and regulatory matters to the best of our knowledge and ability, but without obligation or liability. Existing laws and regulations are to be observed in all cases by our customers. This also applies in respect to any rights of third parties. Our information and advice do not relieve our customers of their own responsibility for checking the suitability of our products for the envisaged purpose.

For additional information, please visit MerckMillipore.com To place an order or receive technical assistance, please visit MerckMillipore.com/contactPS

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