

Emprove® Advanced Qualification Dossier

Simplifying the qualification of Mobius® Custom Assemblies

The Emprove® Advanced Qualification Dossier (AQD) is the first-of-its-kind “On-Demand” Emprove® Dossier to address qualification needs for custom and configurable Mobius® Assemblies. Find all the information you need for your assembly in one place. No need to find information for each individual component, we do it for you based on your assembly drawing.

This new comprehensive document contains extensive USP <665> extractables data for product contact components (including 3rd party components) in preparation of upcoming regulatory requirements. The AQD also provides all the qualification information to expedite the risk assessment and patient safety evaluation for each specific Mobius® Assembly and streamline the use of the assembly in biopharmaceutical production.

Features

This new Emprove® Dossier includes the following content based on the specific Mobius® Assembly.

Advanced Qualification Dossier (Section)	Specific Content
General Information	<ul style="list-style-type: none"> • Assembly SKU • Assembly Drawing Revision • Description • Certification Level • Storage & Shelf Life
Component Information	<ul style="list-style-type: none"> • Assembly Drill Down, including Sub-Assembly • Materials of Construction • Product Contact • Surface Area • Original Manufacture Information
Specifications	<ul style="list-style-type: none"> • Specific Certification Level Specifications
Test Summaries & Results	<ul style="list-style-type: none"> • General Qualification • Visual Inspection Criteria • Packaging Information
USP <665> Extractables Data for Product Contact Components, When Available	<ul style="list-style-type: none"> • Extractables Reports <ul style="list-style-type: none"> - Organic Extractables Summary - Elemental Impurities Summary
Regulatory Statements	<ul style="list-style-type: none"> • Custom Regulatory Statements for Specific Assembly based on Assembly Components
Appendix	<ul style="list-style-type: none"> • Customer-Approved Assembly Drawing

Key Benefits

- Significant savings in time - both in level of effort and lead time associated with compiling all the information for specific Mobius® Assemblies
- Savings in costs with reduced extractables testing and easy access to all the required extractables data to support their patient safety evaluation
- Gain peace of mind with a high-level of security for the AQD as it is accessed by users within the same domain on **EmproveSuite.com**
- AQD is kept current with unlimited updates to AQD based on changes initiated by us to the drawing and one update to AQD for customer-initiated change (if purchased separately from Emprove® Suite Platinum Subscription)

Are you Ready for USP <665>?

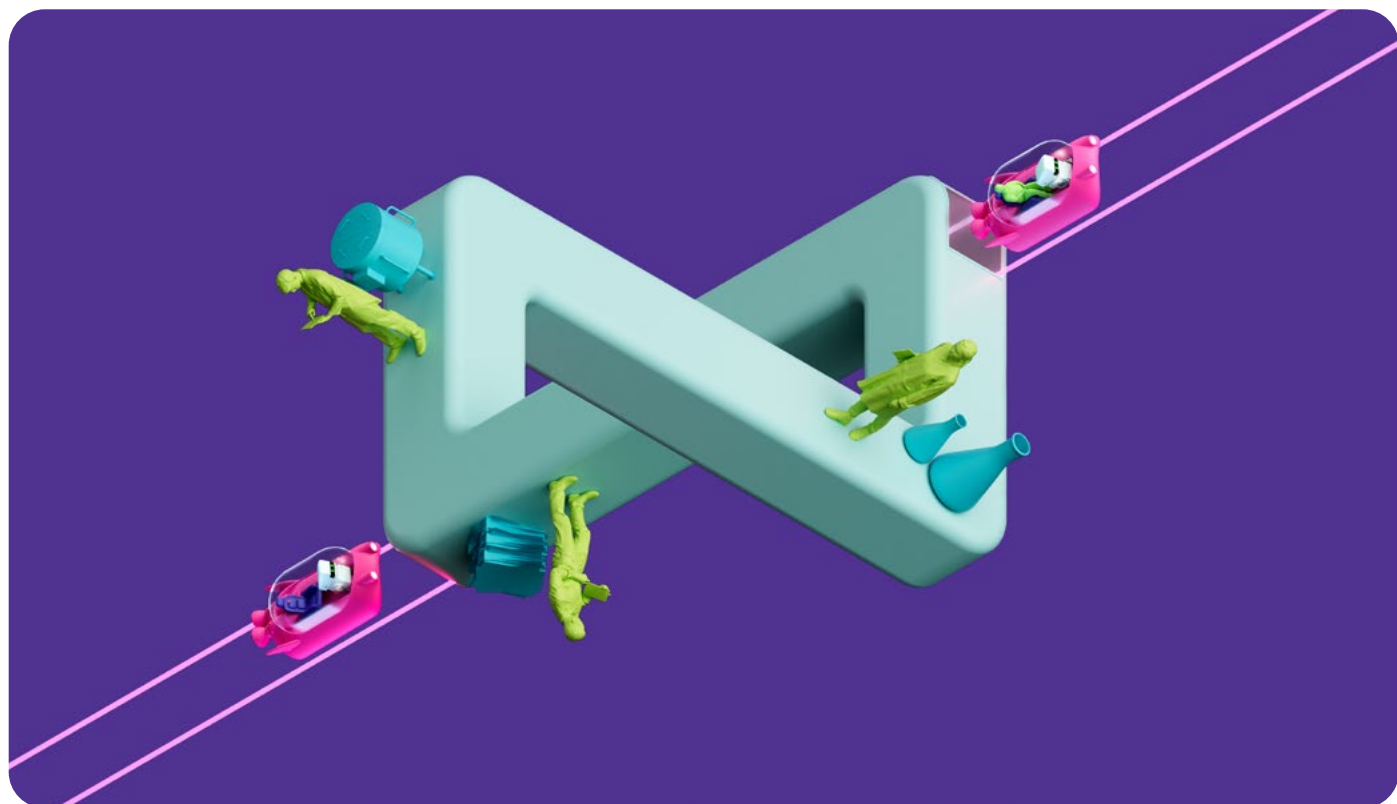
Are you using Mobius® Assemblies to manufacture drug substances or drug products? The new USP chapter “Plastic Components and Systems Used to Manufacture Pharmaceutical Drug Products and Biopharmaceutical Drug Substances and Products” was finalized November 1, 2021 and is expected to be effective May 1, 2026. Based on a risk assessment, product contact components should be classified to low, medium and high risk based on the process. Medium- to high-risk component will require organic extractables data which is covered in the Emprove® Operational Excellence Dossiers and Component Extractable Reports. Better yet, the AQD evaluates all product contact components for USP <665> and provides each extractables report or references the supplier information.

The Smart Way To Master Compliance And Control

Maintaining compliance with Good Manufacturing Practices (GMP's) at any given time in your drug manufacturing process can be a complex and challenging task – especially in a global, dynamic environment. As a drug manufacturer, you need to compile a vast amount of information from your suppliers to ensure that the raw materials and components you purchase continue to meet the technical, regulatory and supply needs for your designated use and function. This can be resource- and time-intensive, as well as expensive

To help facilitate and accelerate this risk assessment continuum process, we have developed the Emprove® Program. Offering convenient access to reliable information for a broad portfolio of high-quality products, the Emprove® Program enables you to:

- make more agile, risk-based decisions
- maintain compliance and
- demonstrate control – saving you time and money.



Obtaining the Advanced Qualification Dossier

The Emprove® Suite Platinum Subscription Tier is best suited for those customers using two or more Mobius® Custom or Configurable Assemblies in medium to high-risk applications, such as cGMP manufacturing and final filling. In addition to the ADQ, platinum subscribers have access to all content available under

the Emprove® Program including Operational Excellence Dossiers and Component Extractable Reports. For more information on the Emprove® Program visit <https://sigmaaldrich.com/emprove>

Emprove® Suite Subscription Tiers			
Features	Prime (Free)	Premium (€)	Platinum (€)
Unlimited # of Users	✓	✓	✓
Enhanced Search Features	✓	✓	✓
Notification Updates to Document Changes	✓	✓	✓
Download Metrics & Reports	✓	✓	✓
High-Level of Security	✓	✓	✓
New Emprove Dossiers & Content	✓	✓	✓
Software Updates	✓	✓	✓
ADQ Updates: Customer-driven	1X	1X	✓
Information Access			
Quality Management Dossier	Unlimited	Unlimited	Unlimited
Material Qualification Dossier	Unlimited	Unlimited	Unlimited
API Information Package	Unlimited	Unlimited	Unlimited
Elemental Impurities Information for API	Unlimited	Unlimited	Unlimited
Operational Excellence Dossier	Paid	Unlimited	Unlimited
Component Extractables Reports	Paid	Paid	Unlimited
Advanced Qualification Dossiers	Paid	Paid	Unlimited

Key Features & Benefits of the Platinum Subscription

Features	Benefits
Access to extractables data for Mobius® components and Millipore® filters	Enables fast and easy fit for use analysis, patient safety evaluation, and USP <665> compliance for our own components
Access to extractables data for 3rd party components	Enables fast and easy fit for use analysis, patient safety evaluation, and USP <665> compliance for our outsourced components
Unlimited Advanced Qualification Dossiers (AQD's) to qualify your Mobius® Assemblies	Saving significant money on extractables testing and time spent compiling data for multiple Mobius® Assemblies
Processing on unlimited updates to the AQD	Whether there's an update or a change initiated by us or an update or a change initiated by the customer, let us know and we will revise their AQD to ensure the document is up-to-date
Ability to leverage the Emprove® Suite as a customer-specific global database of Advanced Qualification Dossiers for all their Mobius® Assemblies	Supports a central design authority and reduces the proliferation of new "custom" Mobius® Assemblies
Assembly level certifications and regulatory information e.g. Animal Origin Elemental Impurities Nitrosamine Risk etc.	Prevent manual effort to find information by yourself or send request to suppliers to get information. Everything in one place with right signatures and transparency

Ordering Information:

To request additional information or if you would like to order the AQD or sign up for a subscription you can submit a request through our webform.

sigmaaldrich.com/services/product-services/emprove-program/emprove-suite

Cat.No.	Description
EMPDSAQD	Advanced Qualification Dossier for Mobius® "Custom" Assembly
EMPSUITEPLAT1YR	Emprove® Suite Platinum Subscription 1 Year
EMPSUITEPLAT2YR	Emprove® Suite Platinum Subscription 2 Years
EMPSUITEUPGRADE	Upgrade Premium Subscription to Platinum

Link to the Demo Dossier



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For other countries across Europe and the world, please visit: SigmaAldrich.com/offices

For Technical Service, please visit: SigmaAldrich.com/techservice

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