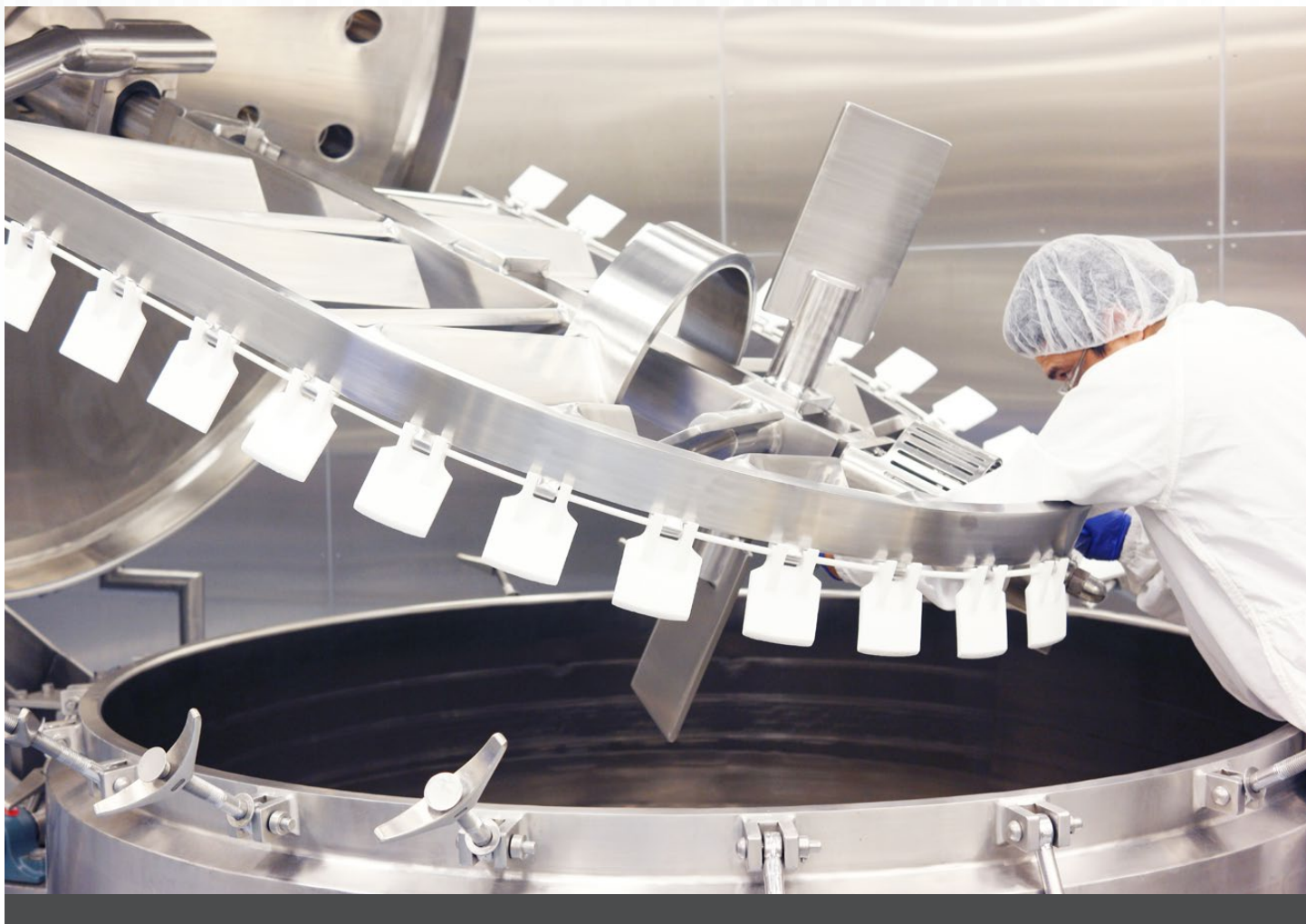


Mixing Topical Ointments, Gels and Lotions **in High-Viscosity Applications**



**Selecting the Best Mixing System
for Superior Performance**

Manufacturers of topical ointments, gels and lotions for BioPharma, personal care and other high-viscosity products face several critical product quality challenges in their mixing processes. The more you understand the nature of these challenges, the better you will be able to design and configure processing equipment to optimize the quality of your product and maximize your plant's productivity. Selecting the most efficient and cost-effective mixing solution for your product can put your manufacturing process in the best position for success.

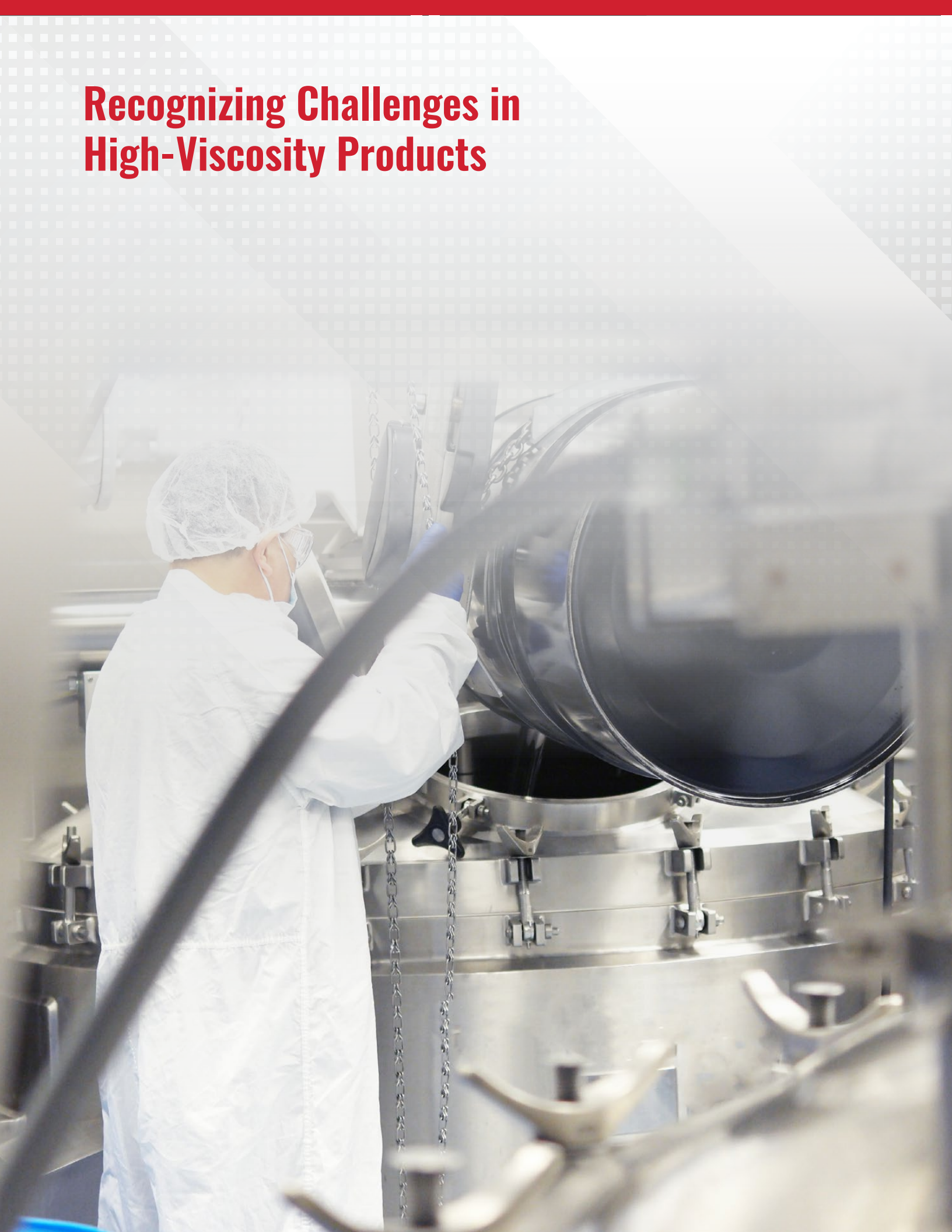
High-viscosity formulations include these kinds of products:

- Ointments
- Medical gels
- Lotions
- Personal care products
- Silicone emulsions
- Penicillin emulsions
- Gelling agents
- Suspensions
- Wax emulsions
- Suppositories
- Vitamins
- Food additives
- Dental materials
- Transdermal patches
- Plant extracts





Recognizing Challenges in High-Viscosity Products



Processors face diverse critical challenges in the manufacturing of high-viscosity products:

1

Powerful, robust mixing requirements

Typically-applied products are among the highest viscosity manufactured products. Viscosities can range from water-like to more than 1,000,000 centipoise (cps). Mixing systems for these products must have sufficient power to move thick, heavy ingredients for consistent blending. Robust, heavy-duty design and construction of the drive system, mixing components and vessel are a must to produce the energy to ensure long service life, especially in high-volume processing conditions.

2

High-shear mixing

High-viscosity products typically rely upon dispersion, emulsification and/or high-particle shear rates to adequately blend batch ingredients. As viscosities approach and exceed 10,000 cps, the mixing action of a conventional high-shear mixer acting alone becomes confined to a highly localized area around the mixing head. This can mean little or no mixing action occurs throughout the rest of the vessel.

3

Preventing ingredient loss during batch loading and ensuring complete blending

Some formulations require highly precise amounts of dry powder ingredients to be charged into the batch, demanding thorough and consistent mixing. Loading dry ingredients into the top of a conventional open vessel can allow unmixed ingredients to collect at the top of the vessel and may release small amounts of fine powder ingredients into the atmosphere instead of into the product mix. Moreover, unmixed dry ingredients may also collect at the top edges of the vessel wall during the mixing process, or may form into unmixed lumps, instead of being thoroughly blended into the batch. Both situations can adversely impact ingredient precision.

4

Operator safety

When dry powder ingredients are loaded in a conventional open vessel, operators may also be exposed to repeated dust particle inhalation, which may have adverse health effects. Using a closed vessel designed to load ingredients under vacuum will help to mitigate these risks.

5

Reliable batch de-aeration

Air bubbles created in the product during batch mixing and processing can make it difficult to accurately dispense the correct amount of product into each package. This makes it important to eliminate—or “de-aerate”—air bubbles, particularly for high-value products dispensed in small containers or vials. Loading and mixing ingredients under vacuum solves air bubble problems.

6

Stringent clean-in-place (CIP) requirements

CIP and steam sterilization requirements are critical for many high-viscosity applications, but the design and configuration of the mixing system can reduce the effectiveness of vessel CIP operation. This can result in longer cleaning times or unforeseen complications in the cleaning process.

Why Conventional High-Viscosity Mixing Systems Don't Always Address Those Processing Challenges



Conventional mixing systems may limit the ability of product manufacturers to optimize productivity and efficiency:

Conventional System 1: Separate, dual mixers

Manufacturers may use a single vessel with dual-mixers to process their high-viscosity products. A vessel with both slower-moving scrape surface agitation and a separate top-entry, high-shear mixer can provide the two kinds of mixing action required. For high-viscosity products, however, this design is inefficient. Mixing action is reduced due to the limited amount of mixing bars on this style of agitation, which increases mixing time and can leave pockets of unmixed ingredients throughout the vessel.

Conventional System 2: Multiple vessels

Processors may also use two separate mixing vessels to handle high-viscosity products. In this configuration, a manufacturer would use one vessel with a propeller or high-shear mixer alongside a separate mixing vessel with a double-motion, scraped surface agitator, mixing their high-viscosity product in a two-stage process. In this case, the propeller or high-shear mixing vessel would be used to pre-mix certain ingredients into solution before final processing in the second, slower-speed mixing vessel. These steps require additional processing time as well as additional transfer lines and pumps to move product from one vessel to the other. For FDA-regulated products, use of multiple vessels and product transfer steps may also require additional regulatory approval to keep the product's manufacturing process in compliance.

Conventional System 3: Recirculating shear mixing systems

Some manufacturers use recirculating high-shear mixing systems in their high-viscosity processing operations. These mixers are high-performance systems that constantly recirculate the product through a high-speed mixing apparatus and are capable of mixing products to fine sub-micron consistencies. Although this system may perform better than a single vessel with dual-mixing heads or multiple-stage vessel configurations, it utilizes additional components and a product transfer recirculation loop during batch processing, potentially complicating clean-in-place (CIP) requirements.

Conventional System 4: Bottom-entry shear mixing systems

Bottom-entry shear mixing systems introduce the shear mixer at the lowest point in the vessel, optimizing minimum batch potential. However, a bottom-mounted shear mixer has its setbacks. The penetration of the mixer in the bottom of the vessel eliminates heat transfer surface area in a portion of the vessel. It also requires clearance from other agitation, thus reducing its ability to fully scrape the vessel. Reduction in the scraped-surface agitation can further impact heat transfer and could lead to potential burning or scorching of product on the jacketed vessel walls.

The Drawbacks of Conventional Mixing Systems for High-Viscosity Products

MIXING SYSTEM	CONFIGURATION	DRAWBACKS
Separate, Dual Mixers	Single mixing vessel with scrape-surface agitation and separate high-shear mixing head	<ul style="list-style-type: none"> Fewer mixing bars make agitation less efficient Design can leave pockets of unmixed material throughout the vessel
Multiple Vessels (Separate Pre-Mix and Main Blending Vessels)	Propeller or high-shear vessel used to pre-mix into solution; second slower-speed agitation vessel used for final blending	<ul style="list-style-type: none"> Additional processing time required Added product transfer lines and pumps may require additional FDA approval
Recirculating Shear Mixing System	Product constantly recirculated through external high-shear mixing head via product transfer recirculation loop	<ul style="list-style-type: none"> Added transfer lines can complicate CIP requirements
Bottom-Entry Shear Mixing Systems	Shear mixer mounted at the lowest point in the vessel	<ul style="list-style-type: none"> Reduce heat transfer surface area Reduced scraped surface agitation

A More Efficient, Cost-Effective System for High-Viscosity Mixing Applications

The inefficiency of conventional dual-agitated vessels, multiple mixing vessels and the operational complexity of recirculating- and bottom-entry shear systems—are a challenge to process engineers seeking the most efficient and cost-effective mixing solution for their high-viscosity products.

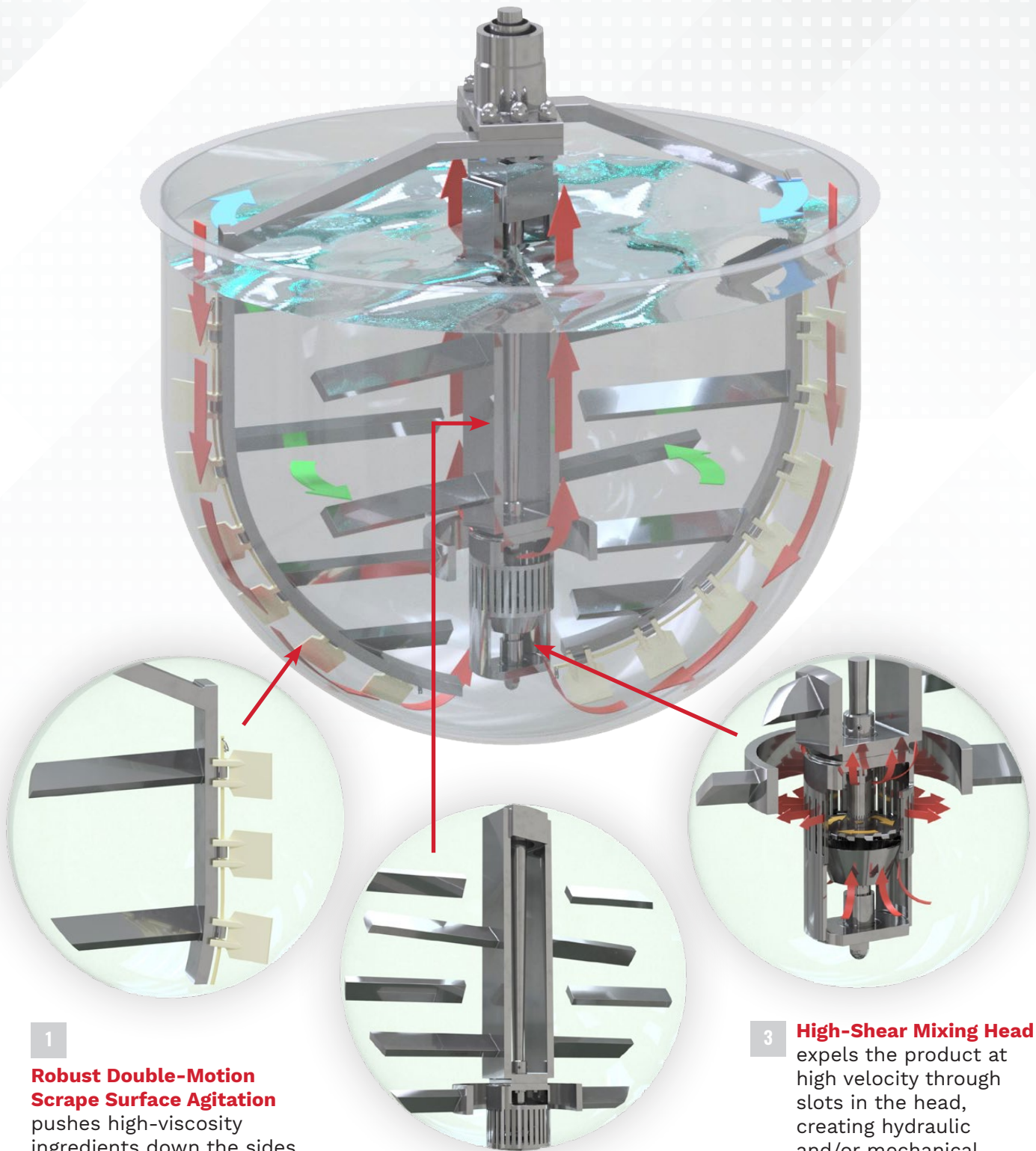
The Lee Industries Tri-Mix™ Turbo-Shear™ mixing system integrates robust scrape surface agitation with a unique, proprietary high-shear mixing head to blend miscible and non-miscible ingredients commonly used in BioPharma and personal care products. It is built to handle viscosities as high as 2,000,000 cps and particle sizes as small as two microns.

Through its unique design (see figure on page 9), the Tri-Mix™ system overcomes the drawbacks of conventional dual-head mixing systems and multiple vessel processing. It is also less expensive than bottom-entry and recirculating shear mixing systems.

The Tri-Mix™ system is available in many customized configurations to meet a wide variety of product and process requirements for high-viscosity products.

Lee Tri-Mix™ Turbo-Shear™ High-Viscosity Mixing System

Combining Double-Motion Agitation and High-Shear Mixing for Fast, Consistent Mixing of High-Viscosity Bio-Pharma Products up to 2,000,000 cps.



1

Robust Double-Motion Scrape Surface Agitation pushes high-viscosity ingredients down the sides of the vessel into the high-shear mixing head.

2

Inside Counter-Rotating Mixing Bars provide additional mixing power to move ingredients forcefully around the vessel.

3

High-Shear Mixing Head expels the product at high velocity through slots in the head, creating hydraulic and/or mechanical shear to force the product to the top or bottom of the vessel, depending on head configuration.

A Lee Process Engineer Can Review Your Specific Processing Requirements

Designing a processing system to handle high-viscosity products can be a demanding process, and there are many factors to consider. To learn more about how Lee Industries can help you meet these challenges, search our website for the **Guide to Bio/Pharma Process Engineering Services: Vessel and Tank Design for Demanding Bio/Pharma Processing Applications** or contact a Lee process engineer to discuss your specific requirements.



About Lee Industries

The mission of Lee Industries is to assure our customers are successful by focusing on their custom processing needs and providing them with the highest quality, most durable products and services available.

Lee Industries is committed to the success of your company by providing you with world-class, high-quality stainless alloy process equipment and service. We design and manufacture the most technologically advanced equipment in the industry. Our customer service team, backed by over 90 years of innovation and experience, provides Lee clients with a single source for all their processing system needs.



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