

GUIDE TO BIO/PHARMA ENGINEERING SERVICES

Vessel and Tank Design
for Demanding Bio/Pharma
Processing Applications

The exacting production requirements for Bio/Pharma processing equipment systems present the most rigorous manufacturing challenges of any industry. Here's how Lee Industries meets those challenges for the wide variety of production vessels required for batch formulation, mixing, fermentation and holding Bio/Pharma products.



[1] Design, Engineering and Fabrication

The Lee Industries team of skilled fabrication professionals has built thousands of tanks, kettles, and related mixing and processing equipment for the world's largest and most recognized names in the pharmaceutical, biological, and formulation industries. Our deep experience in solving safety, high sanitation and processing challenges, while meeting delivery schedules and budgets, can be a valuable contributor to success in the Bio/Pharma industry.



We provide a full range of process engineering services to Bio/Pharma manufacturers, as well as to subcontractors and skid manufacturers providing engineered design/build process systems to their Bio/Pharma customers.

Our design and engineering teams understand the many changes and approvals required during the processing vessel design process. We work alongside both plant owners and skid manufacturers to incorporate these changes into the vessel design, both before and during the fabrication stage.



Tech Focus:

Meeting Vessel Fabrication Challenges for Bio/Pharma Applications

Production requirements for Bio/Pharma processing applications pose these critical fabrication and performance challenges:

Multiple vessel penetrations:

Bio/Pharma vessel designs often require many different attachments that penetrate the body of the vessel to allow for monitoring, measurement, sampling, agitation and other specialized process requirements. Since each of these penetrations may create individual hot and cold spots on the vessel's surface; special precautions must be taken during the layout and design stages to maintain the vessel's heating and cooling performance requirements. In addition, during fabrication, special skill is required to prevent heat warpage to the vessel surface as fittings and attachments for these openings are welded in close proximity to each other.

[2] Project Management

Our approach to project management is a key difference between Lee Industries and other Bio/Pharma vessel manufacturers. For example, at other vessel manufacturers once the customer places an order, ongoing management of the project may shift from the initial salesperson to several others inside the company to handle day-to-day management of vessel design and production.

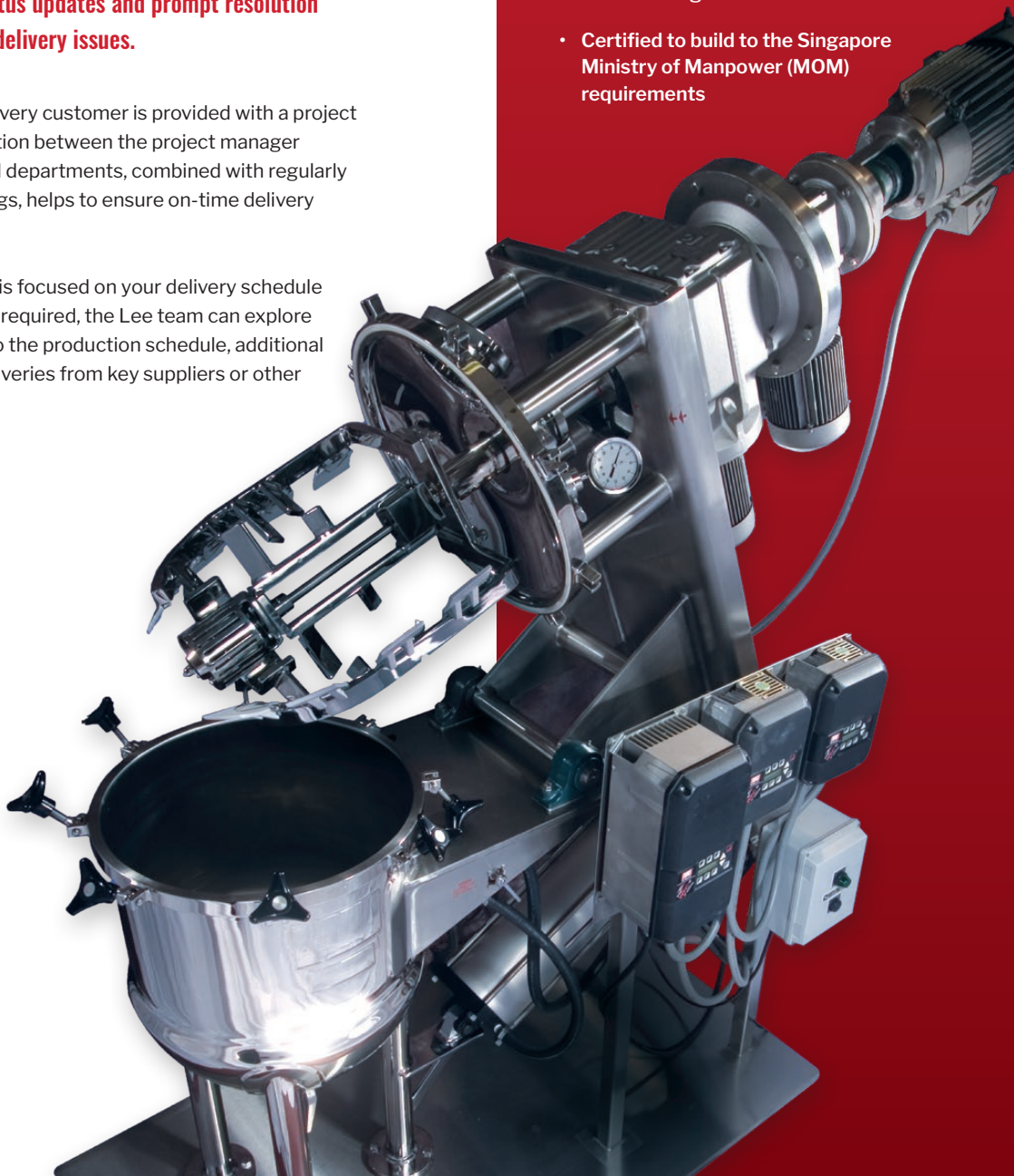
At Lee Industries, every member of our sales team is a highly-skilled and experienced applications engineer who becomes your project manager and sole point of contact throughout the entire design, fabrication, QA and delivery stages of your project. Having a single point of contact enables you to resolve important issues quickly on every aspect of your complex vessel design. As the project manager, your Lee applications engineer provides all updates for approval prints, shipping and delivery dates, and regular milestone progress and status reports.

Your Lee applications engineer becomes the project manager for your vessel fabrication project and is your single point of contact, ensuring clear communication, regular status updates and prompt resolution of vessel design, production and delivery issues.

Upon receipt of approved drawings, every customer is provided with a project schedule and delivery date. Coordination between the project manager and production floor supervisors in all departments, combined with regularly scheduled weekly production meetings, helps to ensure on-time delivery of your project.

The Lee design and production team is focused on your delivery schedule requirements. If expedited delivery is required, the Lee team can explore extra measures, such as alterations to the production schedule, additional overtime work, negotiating faster deliveries from key suppliers or other critical project path adjustments.

The Lee Industries Tri-Mix™ Turbo-Shear™ mixing system (at right) integrates robust scrape surface agitation with a unique, proprietary high shear mixing unit to blend miscible and non-miscible ingredients commonly used in Bio/Pharma and personal care products, to viscosities as high as 2,000,000 cps and particle sizes as small as 2 microns. The Tri-Mix™ system overcomes the drawbacks of conventional dual-head mixing systems and multiple vessel processing, and is significantly less expensive than more complex bottom shear recirculating mixing systems.



Lee Industries Certifications:

- ISO 9001:2015 Registered Quality Management System
- American Society of Mechanical Engineers (ASME) Certification of Authorization to use U and UM stamps
- 3-A Certified Ball Valves
- National Board Certification of Authorization to register and repair pressure vessels using an R stamp
- European Pressure Equipment Directive (PED) and CE marked vessel certifications
- Canadian registration
- Certified to build to the Singapore Ministry of Manpower (MOM) requirements

Ultra-high surface finish requirements:

Vessels for Bio/Pharma processing applications often require ultra-fine surface finishes.

Lee's in-house polishing capabilities provide surface finishes of less than 6 Ra average for mechanical finishing and 12 Ra maximum for electropolishing, to help you meet the most demanding surface finishing requirements.

To address these and many other complex requirements the Lee Industries team has a long track record in meeting the most challenging design, engineering and fabrication requirements for Bio/Pharma processing.

[3] Validation and Quality Assurance

To meet your project's stringent validation and QA requirements for Bio/Pharma applications, Lee Industries holds ISO, ASME, European PED, CE, Canadian and Singapore pressure vessel and manufacturing certifications.

Before vessel production begins, source materials are inspected upon receipt with our Positive Material Identification (PMI) gun for non-destructive verification of chemical alloy composition of stainless steels and other metals used in production. Lee Industries performs routine vendor audits to verify ongoing quality for materials and components used in the manufacture of its vessels. During vessel fabrication, welds are carefully inspected throughout the project to verify weld integrity. Other tests, such as comprehensive dimensional checks, surface measurements and hydrostatic testing, are performed throughout the vessel fabrication stage.

We provide full documentation to meet your company's critical Factory Acceptance Testing and Site Acceptance Testing validation requirements, with complete traceability to QC certificates, welding logs and material test reports.

For Bio/Pharma vessel projects, your company can make use of our offsite inspection facility in Tipton, PA, where vessels can be moved to provide for sprayball tests and additional extensive performance testing by your company's QA, validation and inspection teams.

In addition to the required international, industry and ASME pressure vessel certifications, Lee Industries implements a seven-point internal inspection process prior to releasing every vessel for shipment. Here, every design and production team member involved in a vessel project, performs their own rigorous independent inspection on each production vessel before it ships from our facility.



[4] Installation, Start-Up and Commissioning

Proper installation and start-up of complex vessels for Bio/Pharma applications is critical to prevent installation damage and to ensure safe operation compliant with your company's processing requirements. To assist you at this stage, our ASME-certified field service crew is available to travel to any location in the U.S. or internationally to provide installation supervision and start-up assistance for your new processing vessel.



Our field service team can support skid manufacturers by making on-site repairs and post-delivery modifications, such as nozzle modifications and additions. When field modifications are made, our team can also A.S.M.E re-certify the vessel on-site.

Our Production Facility: Size and Capabilities

With the addition of our new 43,000 square-foot facility in 2017, our production floor area now totals 130,000 square feet. This newly expanded capacity not only allows us to increase our production, but enables us to create larger-capacity vessels.

We maintain a complete in-house vessel production capability, which includes all forming, welding and related machining and finishing operations. Our reputation for quality is the net result of the skill and knowledge of our design and engineering teams, and especially our team of production craftsmen, whose decades of skilled fabrication experience in all of the metalworking trades—forming, welding, fabrication and finishing—ensure that your final production vessel will meet or exceed the challenging requirements of your Bio/Pharma process.





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At Lee Industries, our goal is to build vessels of the highest production quality to meet our customer's most challenging needs. Contact us for more information, or to discuss your project.