



Bioprocessing

Aseptic fill-finish constraints jeopardize commercialization

Overcoming scale-up challenges with a custom fill-finish solution

Often a bottleneck in the workflow, aseptic fill-finish is a critical step in drug product manufacturing. Supply assurance and assembly integrity are essential. Contract development manufacturing organizations (CDMOs) and biopharmaceutical companies need fill-finish assemblies that fit their process design needs and provide the best product recovery, while maintaining the quality of the drug product. Long lead times or delays in consumables delivery jeopardize a manufacturer's ability to meet deadlines and distribute important drug products to consumers.

Customer challenge

- A leading CDMO looking for fast market entry of a critical mRNA vaccine needed a partner who could quickly develop and supply a fill-finish solution to meet their specific needs
- All major vendors quoted long lead times with severe supply constraint, some as high as 52 weeks
- The CDMO was deeply concerned about product delays that would impact global distribution

How we partnered together

- The CDMO partnered with Thermo Fisher Scientific on an engineered-to-order project to build a fill-finish assembly that was customized to fit their specific needs and that provided excellent product recovery
- In nine weeks, Thermo Fisher completed design revisions and delivered the first prototype
- Ten weeks following, Thermo Fisher delivered a GMP product that passed the CDMO's engineering validation and fit test with companion equipment
- Through collaboration and a fast design process, Thermo Fisher was able to customize a solution that met the customer need and had short, reliable lead times
- The customer was pleased with their drug product recovery and Thermo Fisher was able to partner as the primary supplier moving forward for the CDMO's mRNA vaccine fill line

Customer feedback

"We experienced very fast lead times and Thermo Fisher met their delivery commitments. This availability of service and Thermo Fisher's excellent knowledge of compounding bags made the difference. We were especially happy with the level of cleanliness of the filling assembly and the inclusion of a Thermo Scientific™ BioTitan™ Retention Device, which gave better closure and sterility."
–CDMO partner

Learn more at thermofisher.com/fillfinishesolution

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