

Case study

Customized automation tips for new FDA approved system

Thermo Scientific™ Automation Tips

Company

Well known medical device and instrumentation company

Background

As a medical device and instrumentation manufacturer, the client continuously launches new platforms with automated liquid handling for a wide-range of diagnostic purposes. In response to an older platform becoming obsolete, the client began to develop a new FDA-approved system. After a decade of history as a Thermo Fisher Scientific customer, the client came to us and asked if we could provide automation consumables, including customized options, for the new and refined system.

Challenges

In the early stages of development, the client faced a problem of nonconformity with some existing automation tips and packaging components for the new system. While Thermo Fisher Scientific supplied several appropriate automation tips, the client would also need an integrated development and manufacturing team to provide customized solutions to fit their automation process. This would include lengthening an existing tip and updating their packaging.

Capabilities

- Dedicated custom development team, equipped with designers, engineers and manufacturing scientists, to work closely with client from initial concept and design through quality control and logistics
- Breadth of automation tip portfolio, including off-the-shelf and custom solutions to complement the client's needs. With vast expertise in development and manufacturing



of automated consumables, Thermo Fisher Scientific provides rapid prototyping and precision molding

- ISO 13485–certified facility with rigorous standards of product testing, process controls, and adherence to comprehensive SOPs

Partnership

An established and trusted partnership formed between Thermo Fisher Scientific and the client, after a decade of meeting their liquid handling needs. This allowed our specialized OEM team to fully understand the client's technical and business requirements, leading to a customized solution to match their needs.

Results

- The client chose to work with Thermo Fisher Scientific because we have technical-know how, manufacturing capabilities and specialized service and support. Although we have worked with our client previously, it was our willingness to design a custom solution that built a stronger, long-term partnership.
- Our OEM development team collaborated with the client to design an extended tip that would fit their new automation system. To accommodate the lengthened tip, our team also created an upgraded packaging design.
- To deliver the final extended tip and upgraded packaging before the start of the FDA validation project, we utilized our rapid prototyping capabilities to provide a functional sample for test-use. Open communication with the client was critical in delivering an accurate solution to fit in their platform. This integrative connection between both R&D teams allowed us to respond to any changes quickly and reduce overall manufacturing time.
- Thermo Fisher Scientific provided documentation for supply chain, manufacturing, process verification, and validation. The production ran according to ISO 13485 guidelines with complete traceability and process controls.

Summary

Partnering with our client to co-develop and manufacture an innovative solution, the Thermo Fisher Scientific OEM team delivered both a custom automation tip and three other automation tips, within the required timeline. This allowed our client to perform significant testing before the FDA approval process started. Our continuous commitment to the client helped them avoid potential pitfalls and meet their needs for commercialization.



About Thermo Fisher Scientific OEM and Commercial Supply

The breadth of our product portfolio affords our partners a range of options in selecting tailored technologies to help shorten their development timelines and maximize return on investment. Our dedicated commercial-supply cross-functional team understands the unique nature of OEM requirements to make the partnership process a smooth one.

Our best-in-class manufacturing processes, with available certified cleanroom facilities, integrated quality management system, and extensive R&D experience enable us to produce the high-quality products, and develop innovative workflow solutions for partners in life science research, diagnostic manufacturing and industrial markets.

A solid worldwide infrastructure helps ensure on-time delivery, long-term sustainability, and superior service and support. Our team works with you every step of the way.

Find out more at thermofisher.com/oempld

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