Case Study:

Regulatory Consulting Services for Laboratory Equipment

Intertek
Valued Quality. Delivered.

Industry
Laboratory Equipment

Region
United States

Intertek Solution
Regulatory Consulting

"The Intertek Consulting team is an integral part of our team.

We keep a bank of hours open with them to allow our team to seek advice and guidance on demand."

When a small, entrepreneurial manufacturer of hospital room disinfection systems incorporating revolutionary novel technology experienced repeated test failures delaying its time to market, it turned to Intertek for help and guidance. Its design team was looking for a partner to work side by side with them to guide them through, and streamline the process, to commercialization. Like all venture backed start-up companies, they knew that time to market was of the essence to drive revenue and achieve profitability.

Intertek's consulting team reviewed their design and helped them re-design their product to comply with 61010-1, UL/IEC 60730, the Machine Directive, RoHS 2, and NFPA 99. They worked hand-in-hand with component suppliers to ensure critical components met certification requirements. What's more, they identified marking requirements and created the required documentation for compliance, including the FMEA, Risk Management File, and technical file for CE Marking.

By removing roadblocks and putting in place a test plan, Intertek's consulting team helped the company bring its new innovation to market on schedule and break the cycle of costly re-testing and re-designs.

Challenge

When an entrepreneurial manufacturer of a revolutionary hospital disinfectant system found itself trapped in a cycle of product testing failures and re-designs, it sought out a partner to help its team achieve certification and get to market on schedule and within budget. With limited venture funding, it realized that time to market was critical to achieving profitability and maintaining its competitive edge. Costly re-designs and re-testing were negatively impacting the bottom line and wasting valuable time.

It looked for a partner who knows the standards and how to apply them to identify its existing design's weaknesses. More than that, it needed guidance throughout the entire design and development process, from identifying standards to developing a comprehensive testing plan, to preparing risk management and technical files, to reviewing components for use, and more.

Solution

With Intertek, this entrepreneurial company found exactly what it was looking for— and more!

The pathway from design to commercialization for a new laboratory product can be unclear and complex. Even the best designed products may stumble and get bogged down with lengthy re-testing.

Intertek's consulting team collaborated with the design team to review the existing test plan to highlight and correct gaps that could lead to failure. Weaknesses in the design were identified and design guidance was provided.

With a new test plan in hand, the product was re-designed to conform to the standards.

This time around, Intertek's consultants reviewed all the components prior to selection and met with manufacturers to ensure that they complied with the standards.

The required documentation was then prepared by the consultants, including the Risk Management File, FMEA, and the Technical File for CE marking.

What's more, Intertek's team developed and put in place in-house quality and compliance test procedures as part of its standard operating procedures to help the company achieve its goal of speeding up its time to market.

"It's been an enormous help to have a partner that has been there and done it before that you can call on at any time to answer technical questions as they arise.

It has allowed us to stick to our core competency."

An entrepreneurial manufacturer of a novel disinfectant system found success in partnering with Intertek's consulting team for training.

The company had been seeking technical guidance on CE marking. Intertek was able to provide training to support their engineers' understanding of how to meet all of the essential requirements of the European directives, including preparation of the technical file to demonstrate compliance to the RoHS 2 and Machine Directives. By removing complexities and clarifying the directives, Intertek helped this company gain access to the European market.

Results

With the guidance of Intertek's team of consultants and a risk management file in place, the company's successfully re-designed the product to conform to the standards allowing it to pass testing and achieve certification.

When called upon, the Intertek Consulting Team was able to help the company avoid unnecessary costly testing and market delays by overcoming the hospitals' insistence that the disinfectant system needed to be tested to NFPA 99.

The consultants know the standards and this company's product. As a 'plug and play' sterilization system, it does not fall within the standard because it is not a permanent installation.

Working with the Intertek's consultant team gave this company the expert knowledge needed to overcome its customers' objections saving both valuable time and money.

Intertek
601 California Ave
Sunnyvale, CA 94086
1-800-WORLDLAB

www.intertek.com

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