

Case Study:

Regulatory Consulting Services for Medical Devices



Valued Quality. Delivered.

Industry

Medical Devices

Region

United States

Intertek Solution

Regulatory Consulting

“We’re in a competitive market place. We need to be out there in front of our competitors. With the help of Intertek’s Consulting Team we have been able to cut our time in half.”

When a global medical device leader faced with a competitive threat recognized the need to streamline its development and commercialization process to achieve its objective of reducing time to market, it turned to Intertek. Like all medical device manufacturers, it recognized launching innovative technology sooner rather than later helps protect market share and grow revenue. However, the pathway from design to commercialization for a new medical device or IVD can be unclear and complex. Intertek’s consultant team provided the hands on support needed to get to market on time and within budget by conducting analysis and pre-compliance reviews in the earliest stages of the prototype design, overcoming regulatory roadblocks and reducing certification delays.

The end result, the company achieved regulatory compliance the first time around, avoiding costly re-testing and re-designs. More importantly, this new approach reduced time to launch by 50%, significantly improving revenue generation. Senior Management was so impressed with the results that the company incorporated this best practice into its Standard Operating Procedure. As part of the development process, the design team now partners with an Intertek consultant to assess new product concepts and identify a test plan before development starts.



Challenge

A global leader in innovative medical technologies sought to get its products to market as quickly as possible to preserve its market share. Their team understood that in the high tech world of medical devices, the company that can bring its new products to market fastest has a true competitive advantage. It realized that its innovations were being delayed to market because of the constant need to re-test and re-design due to initial design testing failures, incurring not only significant cost, but loss of valuable time in the market. The net result was a negative impact to its bottom line and brand.

The company sought out an accessible partner who could collaborate with their design team to help them understand the

standards and how to apply them to their innovations.

More than that, the company needed guidance to help them manage their product portfolio’s transition to the third edition of IEC 60601-1 to break the cycle of repeated test failures.

“What we were looking for is a partner to work as an extension of our design team with whom we could collaborate with early on in the development cycle to expedite our time to market.”



Valued Quality. Delivered.



“We wanted the ability to create a new product, send it to a NRTL and gain certification without having to continually readjust the design to comply with current medical standards.

With the help of Intertek’s consulting team we achieved our objectives.”

Solution

With Intertek, this global technology medical device manufacturer found exactly what it was looking for – and more! “Intertek reduced our time to market by 50%.”

Current medical testing regulations can be a complicated maze, where even the best designed products may stumble and get bogged down with lengthy re-testing.

Our team of medical device consultants was challenged with identifying the steps and implementing the most efficient process to achieve certification, overcoming hurdles and eliminating delays to keep the product on an aggressive timeline.

Intertek’s consultant team was engaged early on in the product development process. With a preliminary design in place, we, together with the company’s design team, developed a compliance roadmap with their specific goals in mind. With the test plan in place, our team then reviewed the existing design against it to highlight and correct potential gaps that could lead to failure.

By taking the time to understand this company’s product portfolio and identifying potential issues from the start, Intertek was able to limit their need for retesting, speed up their process, and keep their product launch on track.

This major medical device manufacturer found success in partnering with Intertek’s medical device consulting team.

The company had been seeking technical guidance to prepare for the third edition of IEC 60601-1. Intertek was able to provide training to support its engineers’ understanding of the new standard and the specific requirements for Risk Management. By helping them to remove complexities from the process, we played an integral part in getting this global medical device manufacturer ready to transition all of its current and future products to the third edition.

Results

With Intertek, the company was introduced to a new best practice, design for conformance.

Critical decisions made at the beginning of a project can greatly impact market outcome. Because Intertek’s consultant services bring together the most experienced regulatory engineers who know the standards and how to apply them, weak design points were quickly identified allowing the company’s design team to re-design their product without slowing their process. Working hand in hand with Intertek, the design team was able to quickly prepare their product for the required medical testing.

Overall, Intertek’s consultants helped to facilitate a smooth transition to testing, allowing the client to mitigate issues down the line, and supporting a more efficient process overall.

This global player now incorporates design for conformance into its standard operating procedures. It partners with Intertek’s consultant team to help assess its product needs and identify a test plan before development starts.

“By integrating design for conformance into our standard operating procedure and partnering with Intertek’s consultants to identify a test plan at the start of the project, we have been able to reduce our time to market by 50%.”

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