



UL Health Sciences Industry Case Study: Skanray Technologies





Skannray Technologies, Mysore India

High Technology medical start-up company in India gains access to global regulatory markets by partnering with UL throughout the product design and development process.

While the medical device industry in India is expected to grow in the double digits to \$11bn by 2023, it is still fairly new and in many cases, lacks formal regulatory oversight. The majority of device manufacturing is limited to low-value produced such as catheters, IV sets, needles, medical electronics, orthopaedic implants, condoms and syringes. Many device manufacturers in India are small to medium enterprises and due to the lack of a strict regulation, high price sensitivity, and unique needs of the population, many of the devices manufactured in India are sold and used in India

In contrast to this description, Skannray Technologies, located in Mysore India designs and manufactures precision X-rays, ultrasounds and cardiology equipment. The company was founded by a core group of engineers who formerly worked for GE Healthcare and has grown so quickly and successfully, that they are now looking to expand operations outside of India to Brazil.

Challenge

Manufacturers of medical devices fall under the regulatory oversight of the countries where they are purchased and used. In most cases, not only do regulators require test and clinical data that shows a device is safe and effective for its intended use, but they also require assurance that the quality of the device and all the components that go into it will not be compromised during the manufacturing process.

“We have been looking at the global market since inception, so the first thing that we established in Skannray was a very robust quality system and compliance to international regulatory requirements” said Mr. Vishwaprasad Alva, Managing Director & CEO, SkannRay Technologies Pvt. Ltd. “For us, compliance is one of the most important things to be in business and a certificate of compliance is an easy way to get into the global market than selling the products on specifications and features without certification.”

As a start-up company, Skannray needed to write procedures and install quality systems that would support their vision of being able to sell their higher risk devices globally.

Solution

Skannray worked with UL from the start to provide them with services that enable Skannray to satisfy the regulatory requirements for multiple markets. Even before the first devices were developed, UL met with Skannray several times to help Skannray map out a plan for regulatory approvals.

“We start with the understanding the market requirements, then benchmarking the competition, then coming up with a draft of the product which will add value, increasing performance and lowering price, and the highest standards in safety,” said





“The advantage of working with UL is they bring the regulatory expertise along with domain knowledge and they are available locally. We work as a team and we get total solutions from UL.”

-Mr. Vishwaprasad Alva
Managing Director & CEO,
Skanray Technologies Pvt. Ltd

Solution (continued)

Mr. Vishwaprasad Alva. “Once the concept of the product is ready, we start getting into prototyping. And then a lot of our time and resources is spent in compliance and reliability.”

The local UL India account team was able to tap into the global UL network of experts who participate in the IEC, US and local committees and looked at Skanray’s timeline to help them understand what changes may be coming.

Skanray devices are covered under IEC 60601, the standard for safety for electromedical devices. The staff at UL India has the engineering expertise and test facilities for this standard and direct access to the network of UL experts globally who serve on the committees that write the standards such as UL.

Locally, UL India engineering experts reviewed the Skanray designs early in the R&D phase, to identify constructions that may not meet the requirements of the standard. This early engagement reduced sourcing errors, allowed for more robust designs, and less test failures. The engineering team also collaborated with the account managers to anticipate the markets Skanray was going to sell to and help understand any construction requirements needed for those regions.

As part of the safety requirements, Skanray took advantage of UL’s leadership in ISO 13485, ISO 14971, risk management for medical devices, through training and having a gap analysis. The risk management file becomes a critical part of the technical files submission to the regulatory bodies, and will be a major part of their future submissions under the 3rd edition of IEC 60601. And Skanray was also able to take advantage for UL’s knowledge and expertise in software assessments for medical devices through training and assessments.

UL EMC experts provided pre-electromagnetic compatibility scans and suggested mitigation techniques on early designs in a collaborative effort to insure the devices passed both international EMC requirements along with demonstrating conformity to the safety requirements. Both UL and CB test reports were generated from our local offices in Bangalore, which could be used by Skanray in their technical file submissions to the regulatory bodies. UL is the leader in CB test reports for the category “MED” and a test report from UL is highly regarded when submitting for regulatory approvals.

Using the same test reports Skanray can submit for approvals to the US FDA through the 510(k) program. Skanray’s devices also qualified under the FDA Accredited Persons program and they used UL as their 3rd party to submit their 510(k) to the FDA and these same test reports and inspections can also be used for INMETRO certification and submission to ANVISA for regulatory approval in Brazil.



“UL came with domain expertise, with local presence and accessibility for the global regulatory requirements. UL certification has given us credibility in the medical device industry as an international medical device company.”

– Parasuramappa Belur
MR and Sr. Manager, Quality & SRE

¹ FICCI-PWC report “Medical Technology in India”, 2011

Solution (continued)

UL experts shared their knowledge of global quality system requirements such as ISO 13485:2003, CMDCAS, the EU Medical Devices Directives, US FDA QSR, Japan PAL, and Brazil INMETRO. While all these countries require quality management systems, each has its unique requirements. UL is accredited as a third party assessor for these global programs and is able to provide integrated audits. Once they received training from UL and were ready, Skanray started with an ISO 13485 preliminary assessment to understand where they may have gaps in their system. They then proceeded with the certification assessment. Once they achieved certification in ISO 13485, Skanray proceeded with UL as its Notified Body under the MDD to assess their X-Ray for conformity with the EU Directives.

Within a short span since its inception Skanray became one of the leading Indian companies to indigenously design and manufacture high frequency X-Ray systems adhering to international quality and safety standards. With the building blocks in place to follow and practice international regulatory requirements, Skanray has successfully demonstrated the ability to compete in the global marketplace.

Results

Today, Skanray has major OEM customers in the United States and is working on supplying equipment to Germany and the EU. In the Indian market, Skanray has been predominantly selling in the South and has expanded sales into the North. The next market is Latin America and they are setting up a manufacturing plant in Brazil to capture the requirements of Brazil and Argentina and the neighboring countries. Beyond that, the next countries to target include Africa and the Arab sub-continent.

By having a clear vision and commitment to quality, Skanray has moved from a start-up company to an international competitor in a short time period. “Our relationship with Skanray has been one of the most successful ones,” said R.A. Venkitachalam, Vice-President, Managing Director Emerging Markets, UL India. “Skanray and UL have been true partners from the day we first met almost three years back to the day when their products were launched in all parts of the world and Skanray is a very successful company today.”



About UL's services for the Health Sciences industries

UL is a leading provider of end-to-end regulatory, certification, and registration services for the medical industry. Through our portfolio of global accreditations, our customers have access to all the major medical device markets. We support manufacturers throughout the product lifecycle.

Before product launch, we provide training, advisory services, and pre-clinical testing such as biocompatibility, materials characterization, packaging, shelf-life and sterility validation, and microbiology.

Our clinical experts can then support your clinical investigations as a CRO by writing your protocols and other documentation, managing site-selection, monitoring, statistical analysis and writing the report. We then provide the testing, systems management registrations and third-party regulatory approvals for global market access. In addition to certification testing to UL/IEC 60601 and IEC 61010, our services include: FDA 510(k) third-party reviews for the U.S., MDD / IVDD Notified Body CE mark for Europe, CB scheme certification, INMETRO certification for Brazil, PAL third party for Japan, risk management registration to ISO 14971, and ISO 13485 under CMDCAS.

We also provide test reports and support with Usability or Human Factors, Software, Security and Interoperability and EMC. As a recognized third party for the major medical market public health organizations, UL can facilitate the timing and predictability of your product launch so you have market access to multiple countries with one set of tests, one quality system audit, and one company evaluating conformance of your technical file.

For more information, visit www.ul.com/medical, or email at Medical.Inquiry@ul.com



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