bsi. compliance navigator

Time-saving. Efficient and reliable

BSI Compliance Navigator is recommended by the Biomedical Technology Laboratories of ITRI.

Background

The Industrial Technology Research Institute (ITRI) is a world-class applied research institute in Taiwan with 6,000 R&D professionals, with a mission to drive industrial development, create economic value, and foster social well-being through scientific and technological research. Founded in 1973, it pioneered in IC development and has nurtured emerging tech ventures. With nearly 30,000 patents, ITRI has launched and incubated listed companies, including TSMC, UMC, Taiwan Mask Corp., Epistar Corp., Mirle Automation Corp., and Taiwan Biomaterial Co.

Technology always evolves from the needs of human beings. With the increasingly aging global population, and diseases threatening people's well-being and quality of life, the advancement of cutting-edge biomedicine and innovative medical device technology has become a common priority for future worldwide development.

ITRI's biomedical and medical device technology industry has enjoyed double-digit growth in output value over the years and currently serves as a key development industry in Taiwan. In line with government policy, ITRI has identified it as one of the primary strategic R&D sectors. Faced with the increase of civilized and chronic diseases and the rising concept of preventive medicine, ITRI's Biomedical Technology and Device Research Laboratories has invested substantially in all

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ITRI
Industrial Technology Research Institute

aspects of R&D, from prevention, diagnosis, pharmaceuticals and surgical techniques to medical devices and healthcare. These achievements have been the strongest pillars of industrial development in Taiwan.

Customer Needs

The Biomedical Technology Laboratories of ITRI centres on technology development, while the main user of BSI Compliance Navigator is the Regulatory Affairs Office of the Laboratories. “The R&D of the Regulatory Affairs Office specializes in medical devices. As medical devices are used directly on the human body, there are many special regulatory requirements for medical devices in both the international and Taiwan markets.” Associate Researcher of the Regulatory Affairs Office, Wendy Ho, said. In response to diversified regulations, many medical device manufacturers have sought the assistance of the Laboratories in R&D to guide companies in presenting evidence for product compliance. Therefore, in addition to internal R&D cases, the Regulatory Affairs Office also acts as an important support organisation for many external companies in product development.

As the reference to country-specific regulatory standards is necessary (for the Regulatory Affairs Office) to verify the correctness of the manufacturer’s test reports and compliance with regulations, external vendors often require various products from the Laboratories and consult on the standards, compliance, and testing to be followed. As a result, it can be time-consuming and costly to purchase standards for specific needs. A database that allows quick access to Taiwan and global standards would be valuable to the Regulatory Affairs Office and is highly demanded.

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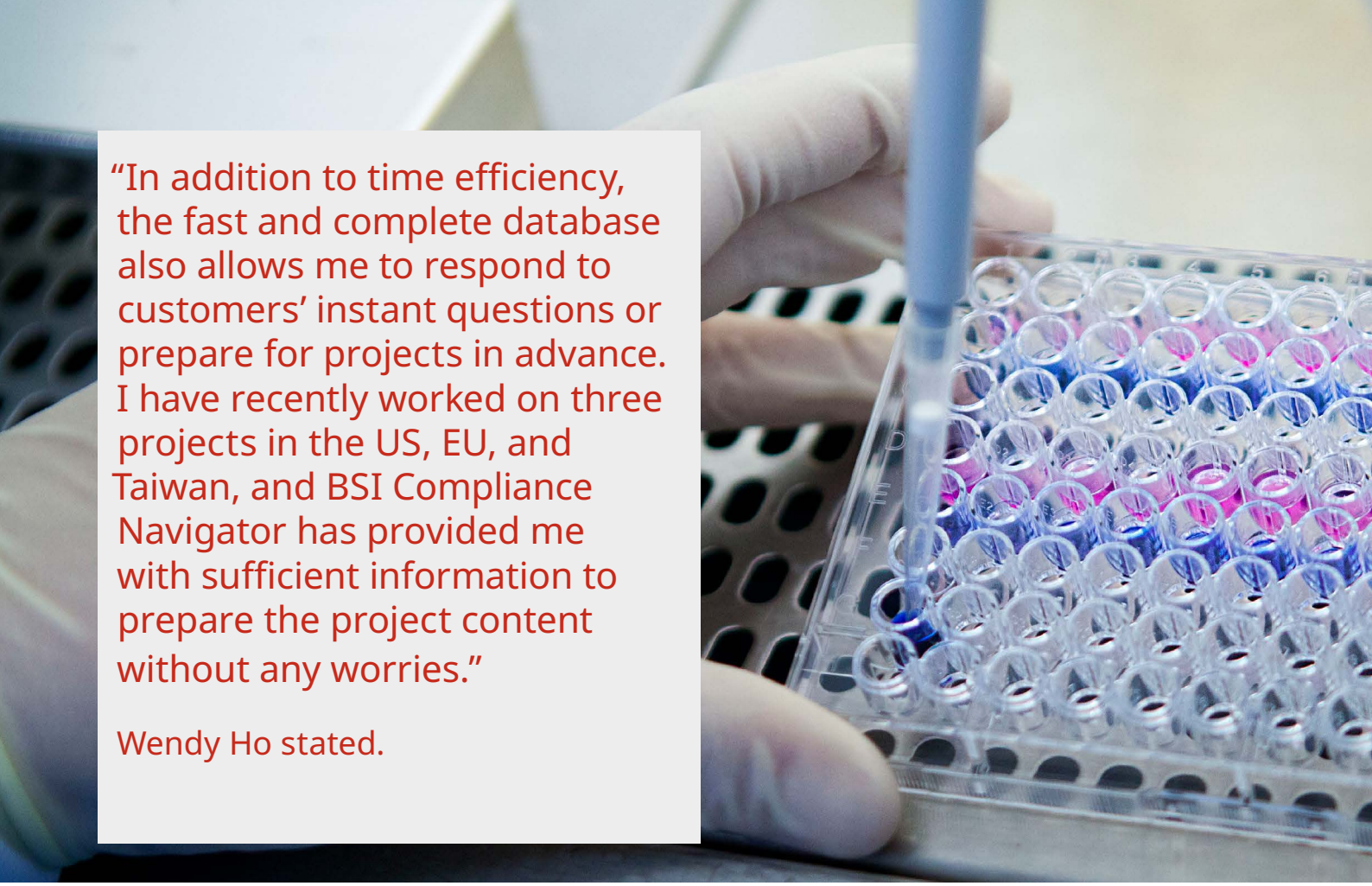

> “In addition to time efficiency, the fast and complete database also allows me to respond to customers’ instant questions or prepare for projects in advance. I have recently worked on three projects in the US, EU, and Taiwan, and BSI Compliance Navigator has provided me with sufficient information to prepare the project content without any worries.”
>
> Wendy Ho stated.

The Solution

BSI Compliance Navigatoris a Cloud database with user-friendly interface. According to Wendy Ho, the most frequently used function is the query function of medical devices and keywords. This feature enables queries on relevant standards and regulatory documents within seconds.

In addition, the “Filter” function comes in handy to identify quickly if the standard has been adapted, repealed, or exists in the EU. Even when the ISO is evaluating its updated version, advance warnings for upcoming changes to BS standards will be sent to users.

Customer Benefits

BSI Compliance Navigator incorporates over 6,500 key documents for medical device and in vitro diagnostic device compliance, including internationally recognized standards, EU and Medical Device Single Audit Program (MDSAP) regulations, and guidance. The introduction of the system has resulted in significant time savings in the work of the Regulatory Affairs Office in the Laboratories. Wendy Ho explained, “If you have to buy the standard when you need it, it usually takes about two weeks. With BSI Compliance Navigator, we can check directly within the system, which saves time significantly.”

BSI Compliance Navigator has facilitated the work of the Regulatory Affairs Office of the Biomedical Technology Laboratories, which highly recommends its adoption by medical device manufacturers.

Why BSI?

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