
International
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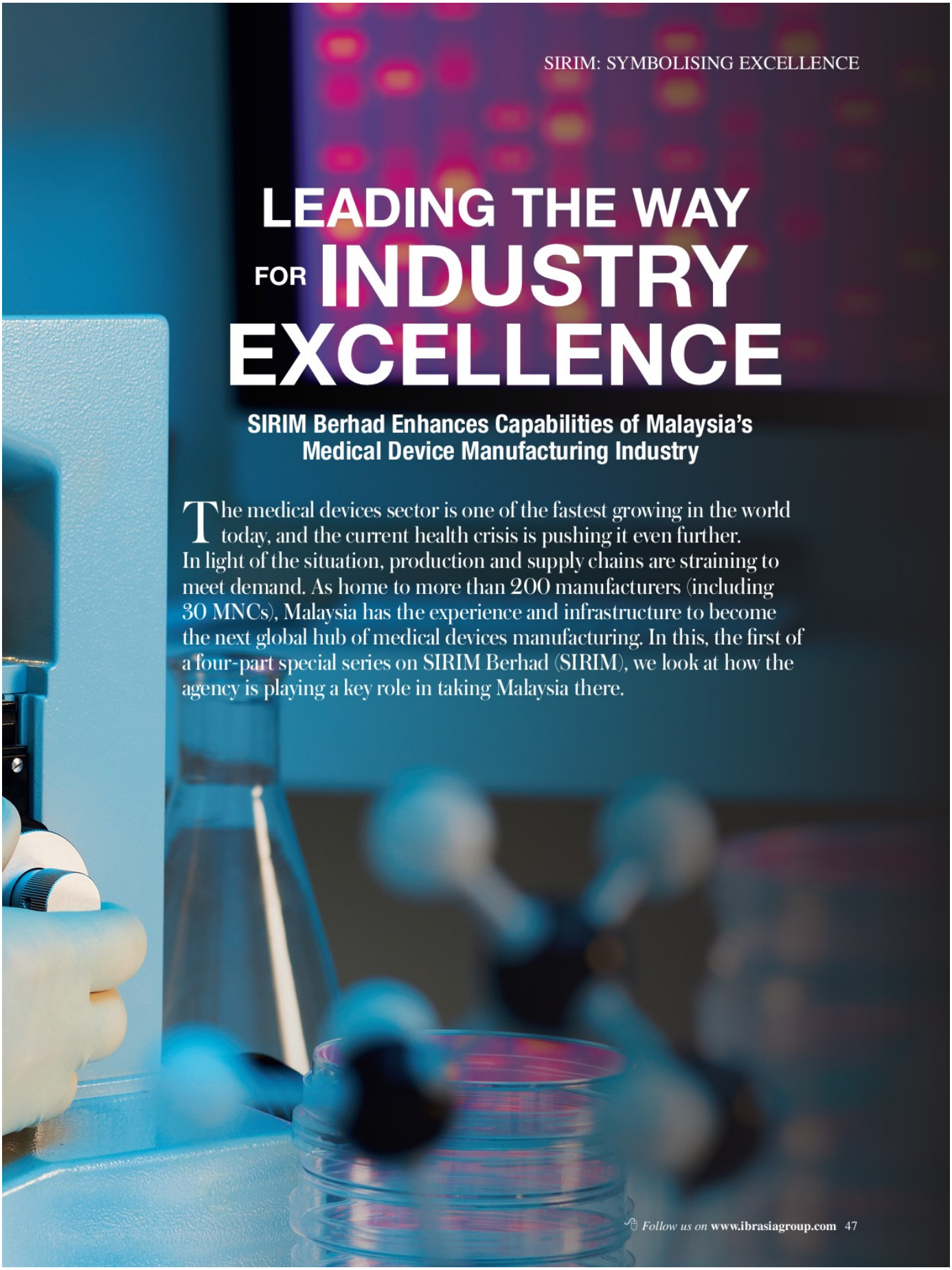

LEADING THE WAY FOR INDUSTRY EXCELLENCE

SIRIM Berhad Enhances Capabilities of Malaysia's Medical Device Manufacturing Industry

The medical devices sector is one of the fastest growing in the world today, and the current health crisis is pushing it even further. In light of the situation, production and supply chains are straining to meet demand. As home to more than 200 manufacturers (including 30 MNCs), Malaysia has the experience and infrastructure to become the next global hub of medical devices manufacturing. In this, the first of a four-part special series on SIRIM Berhad (SIRIM), we look at how the agency is playing a key role in taking Malaysia there.

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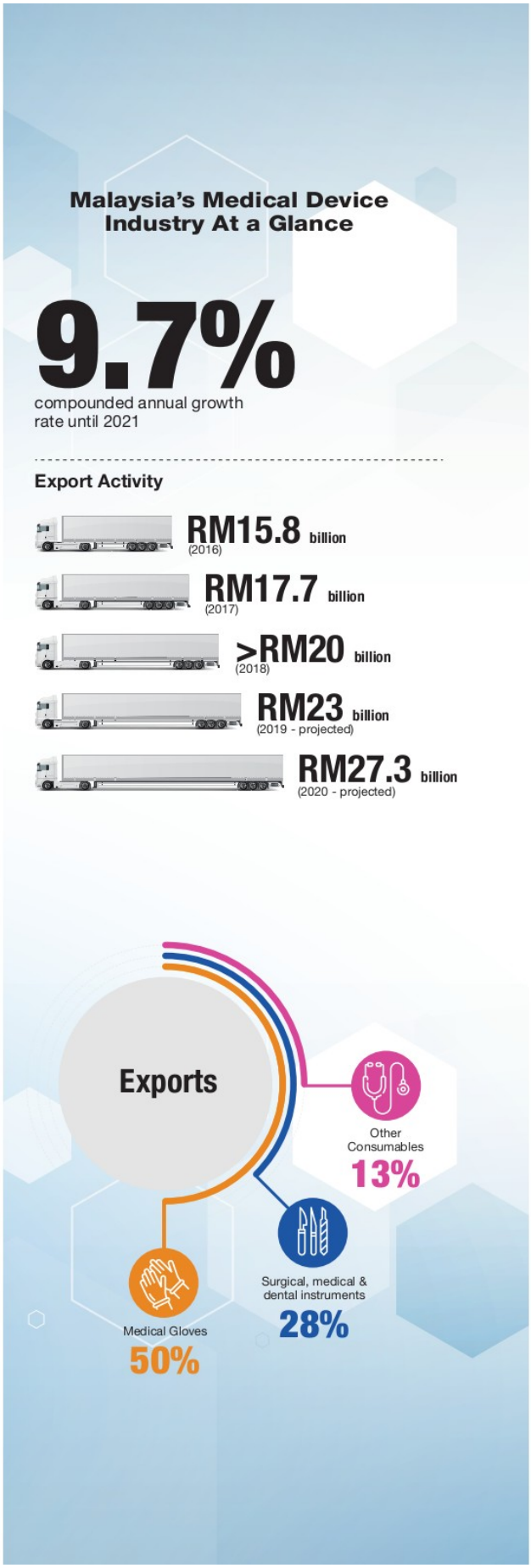
"SIRIM is a well-established name in the industry, and we offer a wide range of services that include bio-modelling and prototyping, industrial research and product innovation, technology commercialisation, accredited testing, certifications, training and consultation."

– Prof. Ir. Dr. Ahmad Fadzil Mohamad Hani,
President and Group Chief Executive,
SIRIM Berhad



It should be noted that long before the COVID 19 outbreak, the Malaysian government had already recognised the potential of medical devices manufacturing. As such, the industry was identified as a high-growth sector under the 11th Malaysia Plan (2016 – 2020), and slated to be a prime driver of economic growth.

The results have been more than impressive. Already, more than RM14 billion worth of investments have flowed into the sector. At the same time, exports reached RM22.9 billion (US$5.7 billion) in 2018 and are expected to grow by 12 percent to RM25.7 billion (US$6.2 billion) in 2019 and RM28.8 billion (RN6.8 billion) in 2020. In total, the medical devices sector in Malaysia enjoyed Compound Annual Growth Rate (CAGR) of 15.9 percent from 2013 to 2020.

Furthermore, according to the Fitch Malaysia Medical Devices Report, released in May this year, the Malaysian medical devices market is expected to grow by a CAGR of 8 percent in ringgit terms from 2019 to 2024. This includes exports reaching RM25.7 billion in 2019 and RM28.8 billion in 2020.

Of course, Malaysia is already the global leader in the manufacture of medical gloves, accounting for around 63 percent of world supply. Having already made its mark in one area of the medical devices field, the nation aims to become a leader in others, namely in the manufacture of stents, implantable devices, and pacemakers, as well as electro-medical, therapeutic and monitoring devices.

However, in order for that to happen, Malaysian medical devices manufacturers – especially those that are SMEs – need to overcome a technological gap. And that is where SIRIM, being the country's leading research and technology development organisation comes in to help with its expertise.

A Partner in Technology and Research Development

According to Dr Kartini Noorsal, Director of the Industrial Centre of Innovation in Biomedical at SIRIM, "The research and development capabilities of our (Malaysia's) medical device manufacturers remain low." This is despite the drive to embrace the principles of the Fourth Industrial Revolution or I4.0.

As Dr Kartini revealed, the biggest challenge is to get small and medium enterprises (SMEs) on board. As SMEs make up the majority of medical device manufacturers in Malaysia, their buy-in is vital for the industry to reach its full potential. However, at present

"We can offer market access programmes to help companies meet the necessary requirements, or even business strategy programmes for those who might need help in this area."

– Dr Kartini Noorsal,
Director of the Industrial Centre of Innovation in Biomedical, SIRIM

less than six percent of their total spending is dedicated to R&D.

The main contention though is cost. Being SMEs, a significant number of them do not have the financial resources to dedicate to acquiring technology and expertise. At the same time, it is also difficult for them to allocate the time and manpower needed to do so. As such, they continue to focus on their core competencies, which is to manufacture low-tech, generic products that reach the market faster.

In many ways, their model is very much a subsistence based one. Just doing enough to make a profit but not more that will allow them to ramp up their offerings and move up the value chain. For them to take the step to the next level, they need a partner that will help them on the way.

And SIRIM is that partner, as it offers a number of services through various divisions and subsidies that are helping the medical devices industry in Malaysia to bridge that aforementioned gap. These include research, aiding in product development, quality and safety testing, calibration, commercialisation, certification and even marketing.

In other words, SIRIM is involved in the entire value chain, and is well-positioned to be the trusted partner that can help medical device manufacturers in each step – from conceptualisation to market.

Getting Certified

Given that 90 percent of all medical devices manufactured in Malaysia are destined for exports, manufacturers in the country need to demonstrate that they have been properly certified compliant with requisite international standards.

SIRIM Berhad is able to provide these services through its subsidiary SIRIM QAS International (SIRIM QAS). As the country's leading testing, inspection and certification (TIC) centre, SIRIM QAS has the capability to audit and certify that a manufacturer is compliant with such standards. In addition, the organisation has been appointed as a Conformity Assessment Body (CAB) by the Medical Device Authority (MDA) – an agency under the Ministry of Health (MoH).

Being a CAB enables SIRIM QAS to audit and certify if a manufacturer complies with standards such as ISO 13485 Medical Devices and Good Distribution Practice for Medical Devices (GDPMD), which are both management system certifications.

ISO 13485 for instance is applicable to any entity that designs, develops and produces medical devices. It should be noted that under the Medical Device Act 2012, all medical device manufacturers must have ISO 13485 certification. At the same time, companies involved in storage, distribution, installation, servicing or disposal of medical devices are encouraged to be certified.

Just as ISO 13485 applies to manufacturers of medical devices, GDPMD is a vital certification for those involved in the medical devices supply chain, as it demonstrates that the holder has the competency to ensure the quality, safety and performance of medical devices under its care. This covers importers and distributors of medical devices and representatives of foreign manufacturers in Malaysia.

Ensuring Safety and Performance of Medical Devices via Radiofrequency and Electromagnetic Testing

SIRIM QAS also carries out tests to certify if medical devices meet safety and performance standards. This is necessary in order for the product to be sold on the local and international markets.

These include, but are not limited to electrocardiogram (ECG) machines, incubators, and high frequency surgical devices.

While such devices are vital to diagnosing and treating a number of medical conditions,

which makes it even more important that they do not have any faults or malfunctions. For example, power surges and voltage spikes might not only damage the equipment but cause serious injury to operators and patients.

Under the International Electro-technical Commission (IEC), medical electrical equipment can be certified compliant with the IEC 60601 series. SIRIM QAS carries out testing and certification for IEC 60601-1, IEC 60601-1-2, and IEC 60601-2-x.

This demonstrates the comprehensiveness of its competency, and assures medical device manufacturers hoping to set up in Malaysia that they can get their products properly certified.

Top: SIRIM's labs carry out in-depth testing and evaluation of medical devices to ensure that industry meets stringent regulatory requirements.

Bottom: Craniofacial biomodelling helps surgeons fix broken skulls by designing customised titanium plates for each patient.

Assuring the World by Ensuring Quality

The COVID-19 pandemic has also highlighted the importance of ensuring that the quality of all medical devices, especially medical face masks and gloves is guaranteed. The latter is especially important as far as Malaysia is concerned as the country is the world's largest supplier of such products.

As such, SIRIM QAS is aiming to extend its testing and certification services to include medical face masks and gloves that are manufactured, imported into or sold in Malaysia. With the current global health situation, this service not only helps protect public health but also ensures that Malaysia will have a positive reputation as a source of such equipment.

Leading the Way for 5G in Medical Devices

Also, with the Internet of Things (IoT) becoming more prevalent, an increasing number of medical devices also have wireless connectivity features. For example, people with Type-1 Diabetes might have insulin pumps that record their time and level of dosage and send the reports via Bluetooth to their mobile devices, enabling them to keep track of their medication.

In Malaysia, connected devices that have communications capability fall under the purview of the Malaysian Communications and Multimedia Commission (MCMC). SIRIM QAS is the appointed certifying agency for such devices, and carries out testing and certification to determine if they meet Malaysia's spectrum plan, regulatory requirements and technical requirements covering radio frequency (RF), interoperability, safety, electromagnectic compatibility (EMC) and specific absorption rate (SAR), if applicable.

One of the aims under Malaysia's 5G verticals is to boost the digital healthcare industry. As a

> "If the devices are produced without any calibration or standards, we won't be able to identify any anomalies; this could ultimately affect the quality of the products being passed on to the end users. Calibration should ideally provide continued support to the medical device industries."

– Dr. Osman Zakaria,
Senior Director of the National Metrology Institute of Malaysia (NMIM)

catalyst to accelerate the adoption of 5G related technologies into the local healthcare industry, MCMC in its 5G Demonstration Project has provided a platform for collaborations between the healthcare industry and telcos to take place. For example, the collaboration between the Hospital Sultanah Maliha, Digi and CREST to showcase 5G connected ambulances that enable real-time medical data transfer between paramedics attending to emergency cases and the hospital.

Another strategy to boost the industry is by enhancing the capacity of the medical device manufacturing sector to produce connected medical devices. SIRIM QAS therefore plays a key role in taking Malaysia to that level.

Ensuring Internationally Recognised Calibration

As the custodian of the nation's metrological system, SIRIM is also responsible for running the National Metrology Institute of Malaysia (NMIM), which ensures that all weights and measures are calibrated properly.

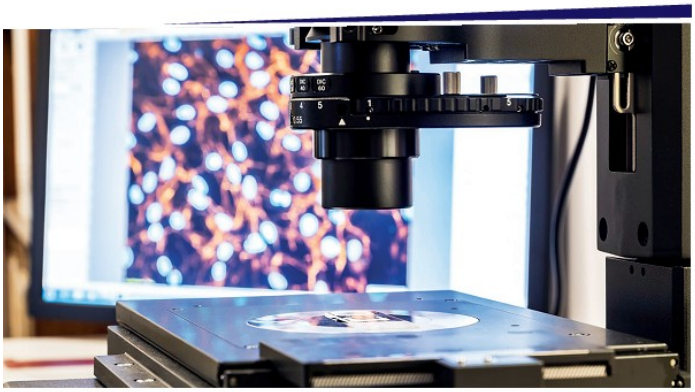
The importance of calibration in the medical device field cannot be underestimated. As Dr. Osman Zakaria, the Senior Director of the NMIM, explained, "At the doctor's, data extracted from the medical devices will be used to diagnose the patient and prescribe treatment and medication. If a system or device is not calibrated, you will get inaccurate readings. This could lead to the wrong course of treatment which, in turn, may cause dire or even fatal consequences to the patient."

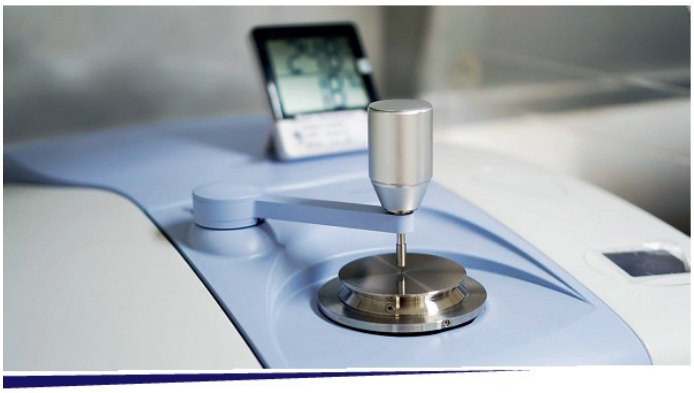
The NMIM is there to prevent such catastrophic consequences by ensuring that relevant medical devices manufactured in Malaysia are tested and calibrated according to set international standards. The CPIM Mutual Recognition Arrangement (CIPM MRA) is the framework through which NMIM demonstrate the international equivalence of their measurement standards and the calibration and measurement certificate they issue.

Ascertaining Safety in Manufacturing and Use

Aside from ensuring that medical devices used for measurements are calibrated properly, SIRIM is also involved in ascertaining that they are safe for use. It does this by carrying out essential testing services, namely microbiology, chemical and toxicity.

For microbiology testing, SIRIM ensures that the device in question is sterile and free from microorganisms. This is because the slightest presence of microbes of the equipment could lead to severe medical complications. For example, an unsterile needle or syringe would likely introduce pathogens into a patient thus causing infections.





SIRIM uses advanced technologies such as the Scanning Electron Microscope (top) and Fourier Transform Infrared (FTIR) Spectroscopy (above) to ensure that medical devices have been made with only approved materials and are free from flaws.

Similarly, chemical tests are carried out to check that the chemical properties of medical devices are in line with proper standards, while toxicity tests are necessary to make sure that the devices are free from harmful substances.

Aside from testing for microbiology, chemicals and toxicity in medical devices, SIRIM also carries out tests that ascertain whether the devices have the proper material or physical characteristics.

The importance of this cannot be underestimated. For instance, implants must have a certain degree of roughness to help in tissue and protein absorption when inserted into the body, otherwise inflammation may occur.

SIRIM is able to test the roughness of microscopic medical implants using a state-of-the-art Atomic Force Microscope. Other advanced technologies employed by SIRIM for its medical device testing services include a Fourier Transform Infrared (FTIR) Spectroscopy and Scanning Electron Microscope.

The former uses infrared to scan the devices and to identify organic and polymeric materials. This ensures that the device has been manufactured using only the approved materials. The latter is used to magnify images up to 500,000 times, thus making it useful for detecting the most minuscule of cracks or flaws in medical devices.

Excellence in Hardware and Software

SIRIM is the trusted partner to carry out these tests as it has both the necessary hardware and software, in the form of technology, facilities, and expertise. To illustrate, all its testing laboratories are accredited with the necessary ISO 17025 and Good Laboratory Practice (GLP) standards. In addition, they are all equipped with the latest specialised equipment and technologies. This ensures that the test reports are accepted worldwide.

Having the right equipment and technology is only one part though. It is equally important to have quality people. And SIRIM has just that. As explained by Dr. Nur Ellina Azmi from SIRIM's Industrial Biotechnology Research Centre (IBRC),

"To be an approved signatory for the tests, we have to be registered with the relevant authorities and audited by the Department of Standards Malaysia under ISO 17025 accreditation and National Pharmaceutical Regulatory Agency for GLP Compliance for example, chemists will have to be registered with Institut Kimia Malaysia. We must have the right knowledge and experience."

Having a Competitive Edge

Another key advantage that SIRIM has is that of costs. Being based in Malaysia, it can carry out all the aforementioned testing, calibration, accreditation, and R&D services for a more competitive price than other overseas-based providers. And since SIRIM's test results are accepted internationally, manufacturers can fulfil global regulatory obligations without having to break the bank.

Also of note is that while there are other providers that offer services such as technological development, research partnerships, calibration, testing or certification, SIRIM is able to offer all of them. In other words, rather than having to go to many different organisations for different needs, they can get everything settled through SIRIM.

Encouraging Excellence through Medical Device Innovation Centre

As Malaysia aims to become a medical devices manufacturing hub, SIRIM is taking the step to enhance the industry's ecosystem. This encompasses research and development, component manufacturing, manufacturing and assembly, sales and distribution, and post sales services.

The performance of these various components differ, as noted in a study carried out by Roland Berger for the Malaysian Investment Development Authority (MIDA). For instance, the best performer was that of post sales services, while component manufacturing, manufacturing and assembly, sales and distribution were rated as moderate.

The worst ranked in the Roland Berger report was research, development and innovation. This can be attributed to the fact that, save for a few MNCs, there are almost no medical devices R&D centres in Malaysia.

SIRIM is addressing that gap with the establishment of the Medical Devices Innovation Centre (MDIC) in SIRIM Kulim, which is strategically located at Kulim Hi-Tech Park in Kedah, where 30 percent of medical device manufacturers in the northern region are located. The state-of-the-art MDIC will offer R&D, testing, inspection, certification and accreditation, as well as business incubation services, with SIRIM having proposed programmes which have been submitted for consideration in the 12th Malaysia Plan.

Set to be launched in August 2020, the MDIC will bring together the various stakeholders of the medical devices industry – namely industry players, academics, healthcare providers and regulators. This meeting of minds will enable better collaborations that will address the challenges faced by the sector.

Through the establishment of the MDIC, SIRIM is set to enhance its services to the medical devices industry in Malaysia in a number of ways. This includes helping to build capability and capacity, strengthening innovativeness in Malaysian medical devices SMEs, and expediting the transfer of technology and commercialisation of technology innovation in medical devices. wAll these will help grow the size and competitiveness of the industry.

SIRIM offers a comprehensive and diverse range of services in testing, inspection, calibration and measurement to meet the needs of the medical devices manufacturing sector.

SIRIM is very much a one-stop solutions hub for the medical device manufacturing sector, playing an important role in uplifting the capabilities and standards of local players. More than that, by providing quality, internationally-accredited, and cost competitive services for the industry, it also helps to bring in international manufacturers and investors in that field. And with that, Malaysia will soon take its place as a leader and driver of the global medical device manufacturing sector, ready to meet the expected boom in demand.