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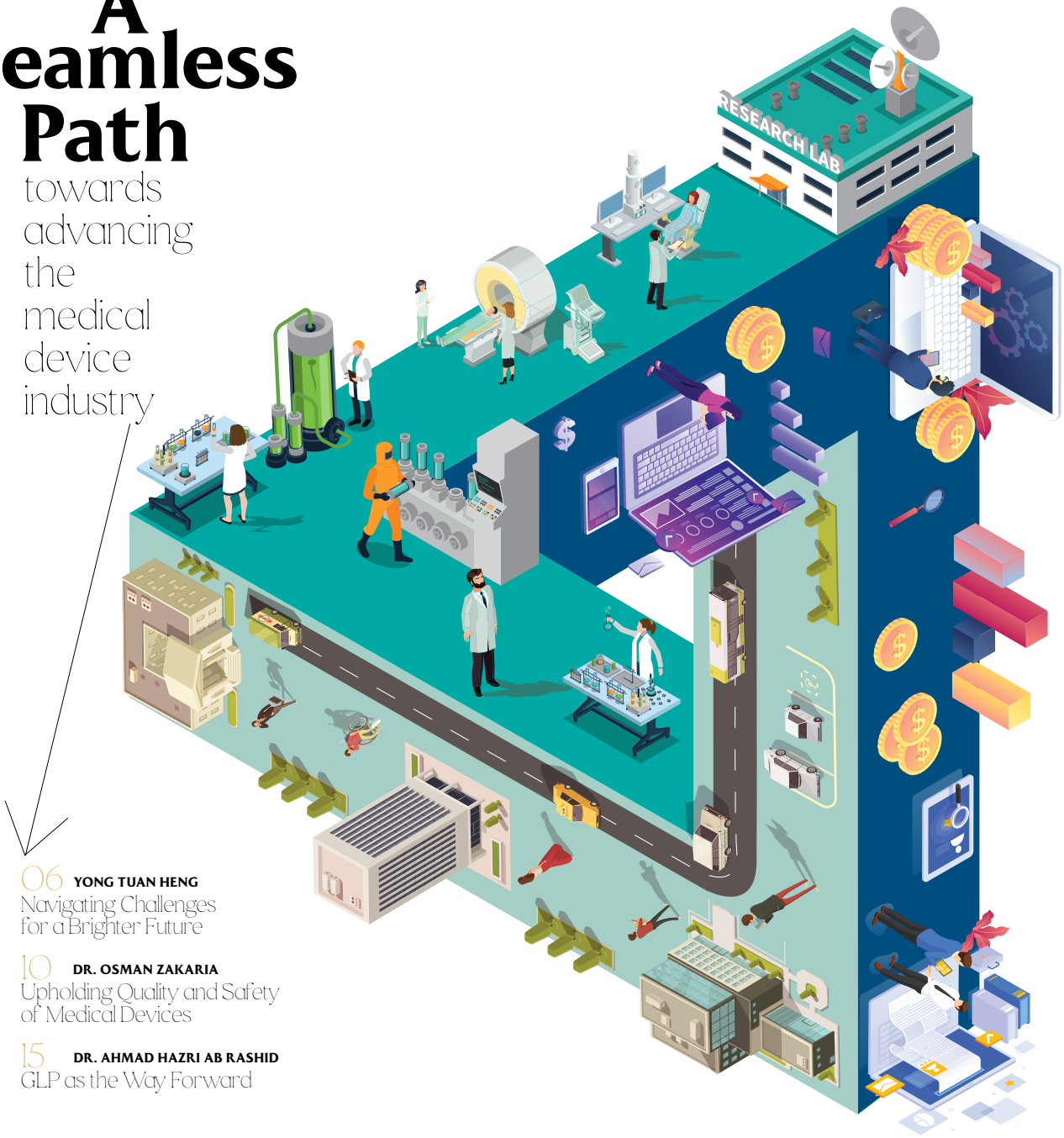
SIRIM Link

BEST PARTNER FOR INNOVATION

Forging A Seamless Path

towards advancing the medical device industry



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Foreword

maintaining the quality of Healthcare Devices

Upholding the quality of medical devices is essential to ensure their functionality, performance, safety and reliability. Calibration and testing are two critical steps in this process.

At SIRIM, we have a strategic combination of industry expertise and accredited facilities to offer a wide range of solutions, which is driven by the National Metrology Institute of Malaysia, Industrial Biotechnology Research Centre, IC Innovation in Biomedical and IC Innovation in Nanotechnology. This allows medical device manufacturers to not only demonstrate the reliability of their products but also meet the necessary requirements around the world. Furthermore, our strong network with both small and medium enterprises (that make up a significant segment of Malaysia's medical device industry players) and the relevant authorities places us in an ideal position to facilitate the consistent growth of the industry.

According to Financialnewsmedia.com, a study by ResearchAndMarkets.com projected that the global medical device market will experience a compound annual growth rate (CAGR) of 4.5% between 2018 and 2023. With the right facilities and competencies in place, we look forward to establishing a solid platform that all stakeholders of the medical device industry will be able to use to good advantage.

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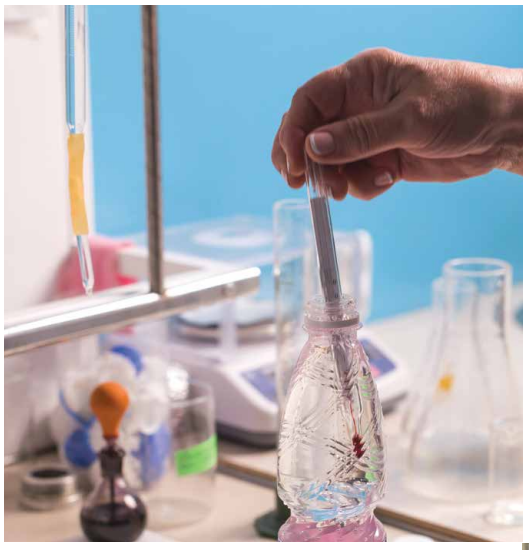
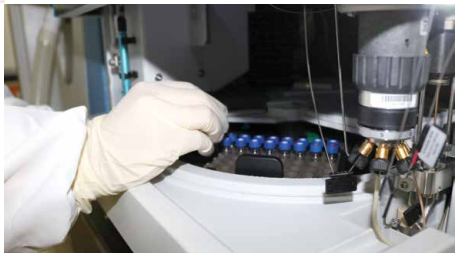
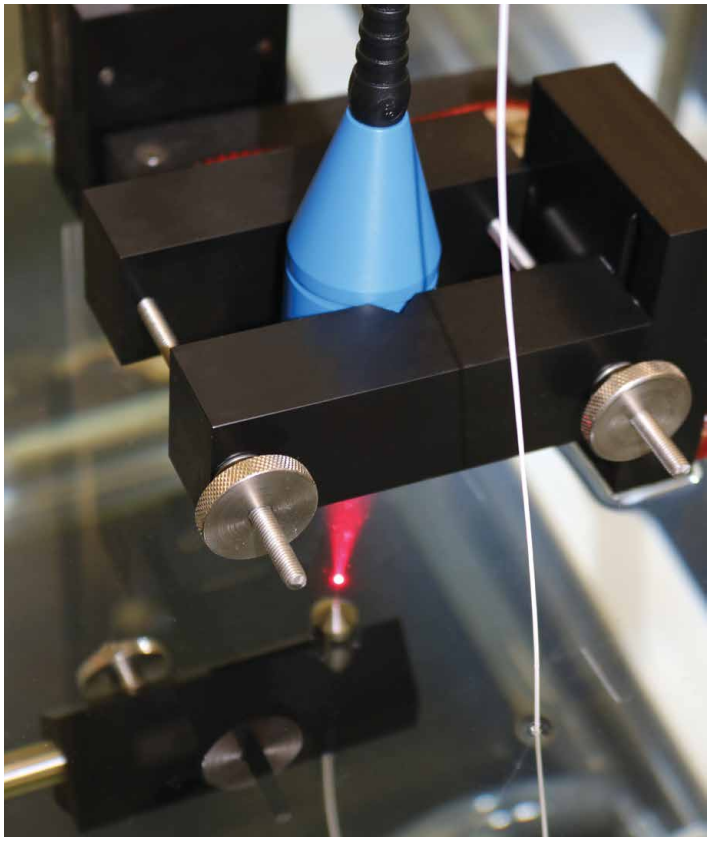
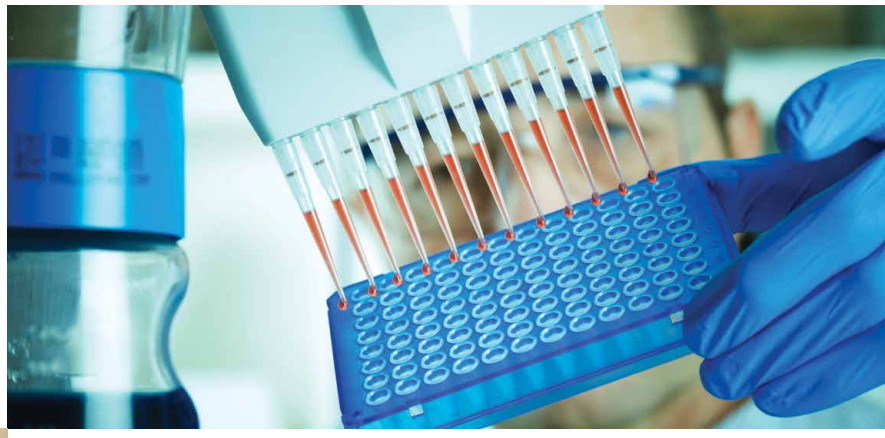








contents.

INDUSTRY SPEAKS:

Navigating Challenges for a Brighter Future

Yong Tuan Heng, the President of the Malaysia Medical Device Association (MMDA), describes the current state of Malaysia's medical device industry from the industry players' perspective, bringing to light the issues they face here.

THE VOICE OF THE MEDICAL DEVICE INDUSTRY

The Malaysia Medical Device Association (MMDA) is a non-profit organisation comprised of local manufacturers, authorised representatives, importers, suppliers, distributors, multinational corporations and service providers involved in the distribution and sales of medical devices and related healthcare products and equipment in Malaysia. In representing the interest of the country's medical device industry players, MMDA offers:

- A premier voice of representation for industry players
- A platform for members to keep abreast with the latest industry developments
- An intermediary role in interceding on behalf of industry on issues affecting members at large

The global medical device industry has been on a rapid upswing in recent years. In Malaysia, the government has identified the industry as a high growth sector under the Eleventh Malaysia Plan, as well as one of the growth areas under the Healthcare National Key Economic Area (NKEA).

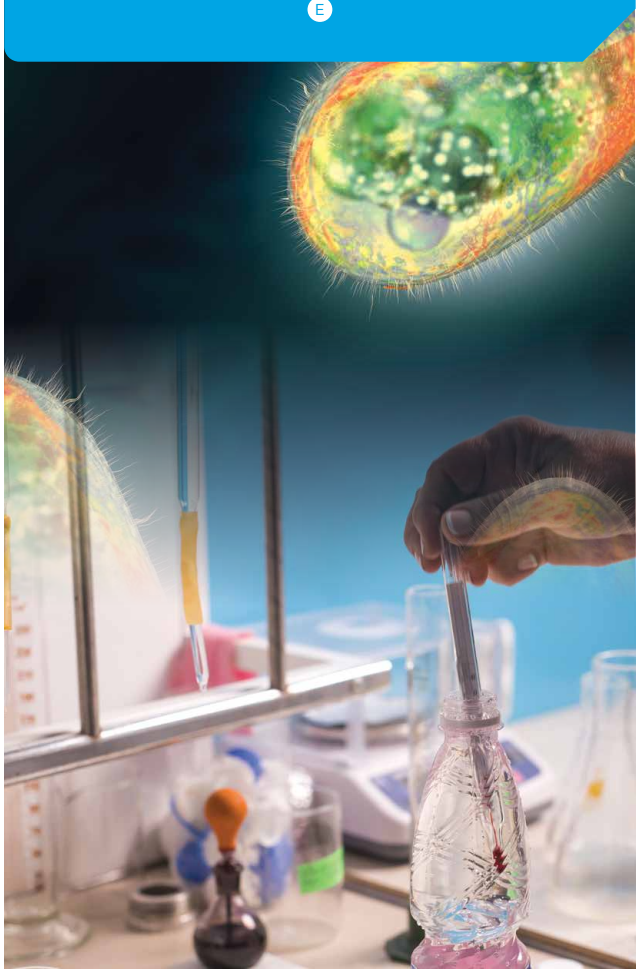
Currently, the majority of medical device manufacturers are small and medium enterprises (SMEs) that manufacture surgical and medical gloves, in addition to encompassing higher value-added and high-technology products such as cardiac pacemakers, stents, orthopaedic implants and monitoring devices, to name a few. More importantly, there is a lot of potential to grow the industry further.

Ensuring Sustainable Growth

Nevertheless, to ensure the seamless growth of the industry, it is imperative for the nation as a whole to look into overcoming numerous issues. There are many factors that come together in the creation of a medical device ecosystem. One of them is a competent talent pool that is able to sustain the growth of the industry.

> *Penang has been known as the Silicon Valley of the East for good reason; it was home to a multitude of manufacturing companies. Although many of the industry players closed their operations down when there was a downturn in the electronics industry, the state continued to be rife with talents who had developed their skills and experiences.*

> *Education institutes would have to do their part in increasing interest in areas like engineering and technology, and biomedical sciences among the youth, as well as ensuring the provision of good programmes to develop their competencies.*



Yong Tuan Heng, the President of the Malaysia Medical Device Association, feels that the country is adequately equipped in this respect. Citing Penang as an example, he observed that the state has an excellent medical device ecosystem, attributing this to its strong electronics foundation.

"Penang has been known as the Silicon Valley of the East for good reason; it was home to a multitude of manufacturing companies. Although many of the industry players closed their operations down when there was a downturn in the electronics industry, the state continued to be rife with talents who had developed their skills and experiences," he explained.

He further elaborated that while a large percentage of the workforce had ventured overseas to explore career opportunities, significant amounts are making their way back, thus adding depth to the nation's talent pool.

Nevertheless, he cautioned that the number of new talents is declining. This is where education would have to play a more active role. "Education institutes would have to do their part in increasing interest in areas like engineering and technology, and biomedical sciences among the youth, as well as ensuring the provision of good programmes to develop their competencies," he added.

Yong went on to commend the Malaysian Investment Development Authority (MIDA) for its efforts in bringing in an increasing number of medical device investors to the country. "Presently in Malaysia, we have the necessary land and infrastructure available," he said, acknowledging that the presence of more medical device investors here has enabled many manufacturing facilities to focus on medical device manufacturing.

While the potential to build up Malaysia's capabilities towards becoming a regional medical device hub is there, the nation has to be prepared to keep enhancing and nurturing the growth of the industry. "Within the Southeast Asian region, Malaysia needs to be diligent in our endeavours. We have to be aware of what is happening in neighbouring countries, such as Vietnam and Indonesia. They are beginning to outstrip us in terms of garnering investments, for example," stated Yong.

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Under the **Healthcare NKEA**,

8

Entry Point Projects (EPP)

were announced and targeted to generate:

RM 17.1 bil in **REVENUE**

RM 11.4 bil in **GNI**

86,000 **JOBS**

by 2020

Source: Ministry of International Trade and Industry

Malaysia's Medical Device Industry

at a glance

9.7%

COMPOUNDED ANNUAL GROWTH RATE

until 2021

DID YOU KNOW?

The medical device industry in Malaysia encompasses a diverse range of industries, including latex, textiles, plastics, electronics and machineries.

> *We are in constant dialogue to look for the best way to ensure we can facilitate the growth of the industry.*
>
> E

> *We already have a host of regulations in place. Perhaps now we can focus on the enforcement aspect to ensure that all manufacturers comply properly with them.*
>
> E

Export Activity

2016	2017	2018	2019 projected	2020 projected
RM 15.8 bil	RM 17.7 bil	>RM 20 bil	RM 23 bil	RM 27.3 bil

US - LARGEST EXPORT MARKET (¼ OF ALL MALAYSIAN EXPORTS)

50% *Medical Gloves*

28% *Surgical, Medical & Dental Instruments*

13% *Other Consumables*

SIRIM offers a lot of creative initiatives – including technological innovations, cutting-edge equipment and facilities, and guidance for grant applications, paving the way for medical device industries to further grow their manufacturing capabilities.

I have participated in many of SIRIM's events and would like to extend my gratitude to them for giving MMDA and our committee members a platform to share our thoughts and opinions.

In the end, we all want the same thing - the best for our country!

Yong Tuan Heng
President,
Malaysia Medical Device Association (MMDA)

A Highly Regulated Industry

As the medical device industry involves people's health and wellbeing, it is well-regulated in order to uphold patient safety. Yong welcomes the strict regulations but cautions against over-regulation as that could push up the costs of the devices. "This is essential to maintain the affordability of the devices," he explained.

This does not mean that the safety of the devices should be disregarded, though. According to Yong, MMDA communicates closely with the country's Medical Device Authority. "We are in constant dialogue to look for the best way to ensure we can facilitate the growth of the industry."

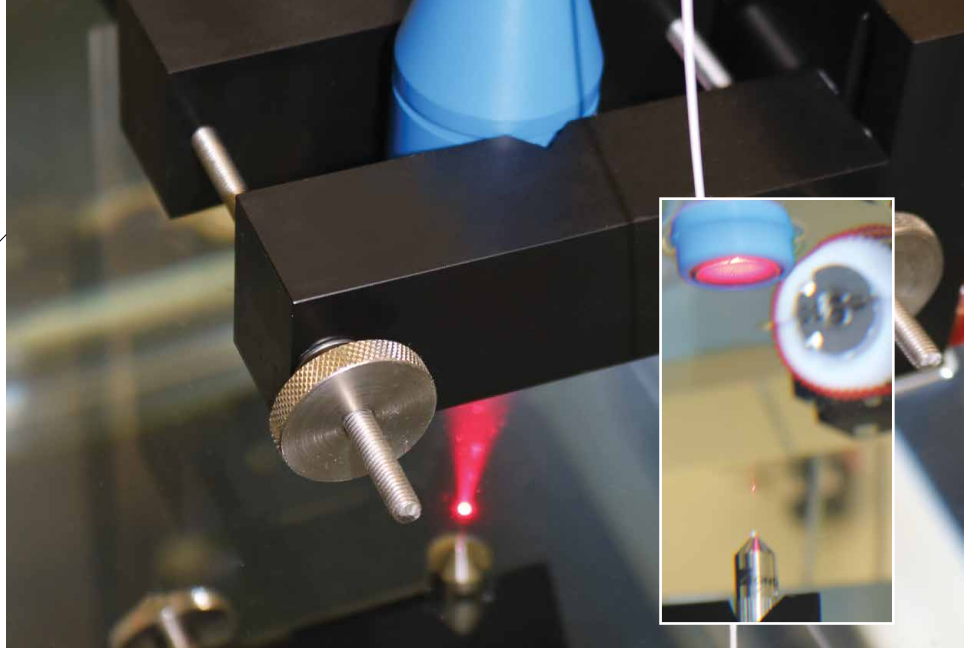
Besides that, along with the regulations, there needs to be sufficient enforcement of the regulations. "We already have a host of regulations in place. Perhaps now we can focus on the enforcement aspect to ensure that all manufacturers comply properly with them," continued Yong.

He shared that MMDA also maintains close communication with other authorities and organisations, including Bank Negara Malaysia, the Ministry of Finance, the Ministry of Health and, of course, SIRIM, actively participating in talks, briefings and forums with them.

He applauds SIRIM's efforts in helping industry players. "SIRIM offers a lot of creative initiatives – including technological innovations, cutting-edge equipment and facilities, and guidance for grant applications, paving the way for medical device industries to further grow their manufacturing capabilities," he declared.

"I have participated in many of SIRIM's events and would like to extend my gratitude to them for giving MMDA and our committee members a platform to share our thoughts and opinions," he added.

Yong hopes that SIRIM, together with the relevant authorities, will be able to help the medical device industry players in meeting the demands of the industry. "In the end, we all want the same thing - the best for our country!" he concluded.



Calibration pervades our daily lives. It is especially important when it comes to healthcare, where precision is required. Dr. Osman Zakaria, Senior Director of the National Metrology Institute of Malaysia (NMIM), delves into the role of and challenges faced by calibration in supporting the burgeoning growth of Malaysia's medical device industry today.

Upholding Quality and Safety of Medical Devices

Calibration refers to the process of comparing a measurement reading on a particular equipment or system to that of another piece of equipment, which has been calibrated and referenced to a determined set of parameters, such as temperature, mass and pressure. The latter would be directly traceable to equipment calibrated according to the International Standard for accreditation of Testing and Calibration Laboratories.

Calibration is crucial wherever measurements are needed. Generally, the calibration of measuring instruments is done to check that they are measuring correctly, thus instilling confidence among users in the results that the instruments monitor, record and subsequently control.

It comes as no surprise then that it plays an important role in the medical device industry, where patient safety and lives are at stake. After all, in a healthcare setting, precise measurement readings are imperative to ensure accurate diagnoses and effective treatments.

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

"A simple example would be if a thermometer is not providing accurate readings. The doctor might think the patient has a fever when he or she does not and prescribe the wrong medication. Calibration will provide reliable results!" he continued.

DID YOU KNOW?

The International Bureau of Weights and Measures formally defines calibration as "Operation that, under specific conditions, in a first step, establishes a relation between the quantity values with measurement uncertainties provided by measurement standards and corresponding indications with associated measurement uncertainties (of the calibrated instrument or secondary standard) and, in a second step, uses this information to establish a relation for obtaining a measurement result from an indication."

ABOUT NMIM

The National Metrology Institute of Malaysia (NMIM) is a statutory business unit under SIRIM that serves to facilitate domestic and international trade as well as ensuring safety, health and wellbeing in the country. It plays an important role in disseminating the traceability of measurement to the whole country based on the International System of Units and ensuring that our national metrology infrastructures meet and comply with global measurement standards.

NMIM ensures traceability of measurements in the country via:

- a comprehensive set of national measurement standards
- a well-controlled laboratory environment
- competent metrologists
- excellent connections to the international metrology system

NMIM is mandated as the National Measurement Standards Laboratory and Custodian under the National Measurement System Act 2007 (Act 675) and Weights and Measures Act 1972 (Act 71) respectively. The institute also works closely with the Department of Standards Malaysia to ensure traceability to accredited testing and calibration laboratories, and provide Proficiency Testing and Measurement Audit programmes.

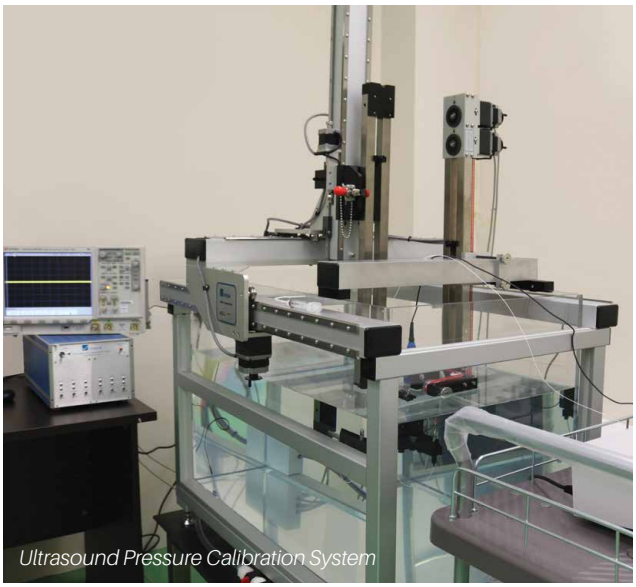
At international level, NMIM is actively involved in the Asia Pacific Metrology Programme (APMP) and Asia Pacific Legal Metrology Forum (APLMF), and is a signatory to the CIPM Mutual Recognition Arrangement (CIPM-MRA). It is also a member of various international bodies, such as the General Conference of Weights and Measures (CGPM)/Metre Convention, International Organization of Legal Metrology (OIML), ASEAN Consultative Committee on Standards and Quality (ACCSQ), ASEAN Consultative Committee on Standards and Quality on Legal Metrology (ACCSQ-WG3) and National Conference of Standards Laboratories International (NCSLI).

As the country's authority on measurements, NMIM plays a significant role in ensuring the continued growth of the medical device industry. "The industry is currently growing at a tremendous rate," revealed Dr. Osman. "Just last year, Malaysia's medical device exports exceeded the RM20 billion mark, and the forecasted year-on-year growth continues to be promising, with exports anticipated to reach over RM27 billion in 2020!

"In tandem with the rapid expansion of the industry, NMIM has to be able to do our part in supporting the quality system of medical device manufacturers and service providers," he continued.

Among others, NMIM supports the medical device industry with its capabilities in:

- calibration of audiometers
- calibration of ultrasound power and pressure
- calibration of ear thermometers
- calibration of temperature probes (down to -200°C)
- calibration of blood pressure monitors
- calibration of glass thermometers



Ultrasound Pressure Calibration System

"These are common devices used at hospitals and clinics. We need to verify the systems and the accuracy of the values to ensure that the relevant healthcare professionals are able to properly determine the right levels of readings and the results are harmonised in different healthcare settings. The temperature probe of -200°C, for example, is essential when it comes to storage of certain medications that require low temperatures. If the device is not properly calibrated, it could affect the quality of the medicine," elaborated Dr. Osman.

> *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.*

> *A simple example would be if a thermometer is not providing accurate readings. The doctor might think the patient has a fever when he or she does not and prescribe the wrong medication. Calibration will provide reliable results!*

Precise Results

There are several aspects that are taken into consideration during calibration. For example, the physical aspect of calibration encompasses parameters like pressure and temperature. Calibration during chemical processes, on the other hand, will involve special standard solutions, such as that used to check the composition of cholesterol. In terms of biological standards, we are looking at checking haemoglobin levels or DNA, to name a few. All these require certified reference materials or standards.

Measurements are one way to obtain results, and calibration will determine their accuracy. This is true, not just for medical devices that come in direct contact with the patient, but also equipment used during the process of manufacturing the medical devices.

As such, even during the initial production stage in the factory, it is very important for the manufacturer to ensure that both the manufacturing equipment and the devices being produced are verified and calibrated. "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," explained Dr. Osman.

The calibration process does not stop after manufacturing and distribution. In fact, it is just as important to ensure that the devices are properly calibrated throughout their lifetime. This could help to reduce the device's downtime and/or repair costs.

"Calibration should ideally provide continued support to the medical device industries," said Dr. Osman.

Quality Control

In line with this, calibration also forms an important component in the quality control process. Presently, many manufacturers have quality control systems that they adhere to before releasing their products into the market.

> *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.*

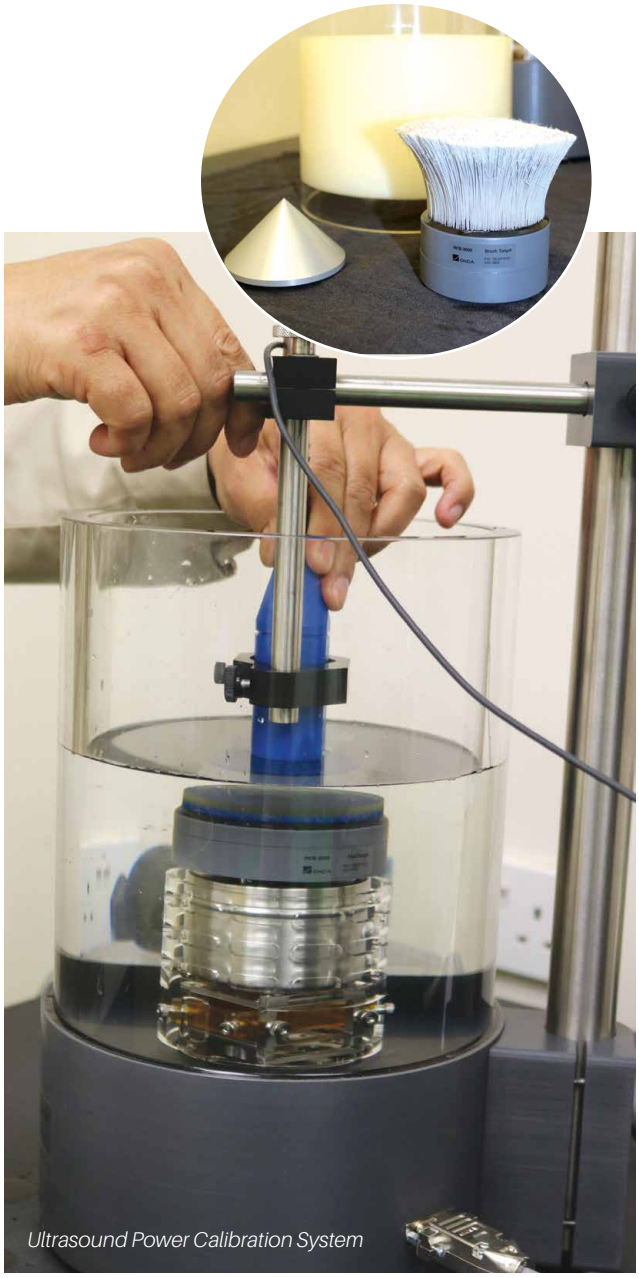
> *Calibration should ideally provide continued support to the medical device industries.*

"Many of the more established names have good quality control systems in place. These will typically run thorough checks involving calibration to ensure that their devices are properly monitored and controlled," stated Dr. Osman.

This process will often extend to the devices' destination, where the manufacturer or technical support staff may be on hand to verify the devices' accuracy and ensure that this is not compromised during the transportation process or due to wear and tear.

"In Malaysia, we have medical authorities from the Ministry of Health who will regularly calibrate the devices used in the healthcare sector according to best practices," shared Dr. Osman. "These are some of the ways that calibration supports the medical device ecosystem within and outside the country."

The integral role of calibration amidst the growth of the medical device industry is also addressed in the Medical Device Act 2012 and ISO 13485, which include requirements for medical devices with measuring functions to be calibrated.



Ultrasound Power Calibration System


Audiometer Calibration System

Increasing Public Awareness

Dr. Osman finds the general awareness level on the importance of calibration in the medical device industry to be moderate. He attributes this to the ease with which the public is able to obtain information via the internet as well as increased networking among medical device associations.

"The medical device associations in the country are active in providing the relevant information on safety requirements and calibration. We also need to educate patients to ask the doctors or health facilities if their devices are properly calibrated. Otherwise, we won't know if the results obtained are correct," he said.

More often than not, standards are calibrated annually. The stability history of the device is an important consideration in determining this. If the instrument has been historically found to be very stable, it should be fine to go for longer intervals between the calibration exercises. However, if the device often fails in calibration, it would be wise to have it calibrated more often.

The consequences of bad or irregular calibration may include:

- failure to meet the quality system
- safety risks for employees and customers
- poor product quality and loss of reputation
- product recalls
- failure to meet regulations, causing loss of licence to operate
- unexpected downtime
- economic losses

Closing the Gaps

With the rapid growth of the medical device industry, it is essential that the country's capabilities are on par with industry demands. According to Dr. Osman, we would benefit by following Europe's lead in establishing a dedicated national guideline on maintaining equipment via calibration.

Additionally, NMIM would need to ensure that it has the right level of capabilities to support industry and regulators. This could potentially help industry players to reduce their operational costs and maintain the quality of their products. "We need to have sufficient facilities and infrastructures in place. Otherwise, manufacturers would have to send their products to other countries for calibration!" exclaimed Dr. Osman.

He finds that there is a widening chasm between the expanding medical device field and calibration capabilities, as required by Skim Akreditasi Makmal Malaysia (SAMM) in Malaysia, and would like to look into closing this gap. "We should look into providing customised training related to the manufacturing process of medical devices, and educate the manufacturers on the importance of accurate measurements," he added.

STANDARD OF QUALITY

A **primary standard** in metrology is not calibrated by or subordinate to other standards. As the national metrology institute, NMIM is considered to be the keeper of primary standards; these are the best parameters for measurement in the country with only a 1% error margin.

At the next level are **secondary standards**. These are calibrated against a primary standard. The third level, which is calibrated with reference to the secondary standard, is known as a **working standard**.

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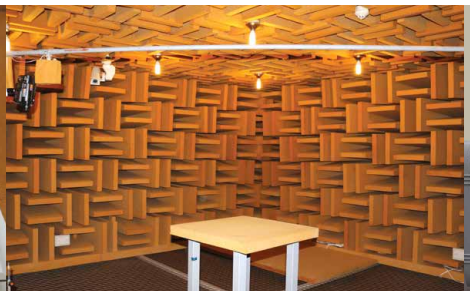
Audiometer Calibration System



Anechoic Chamber

Ultrasound Pressure Calibration System

In upholding its role of supporting accredited laboratories and ensuring that they possess the calibration capability for the different parameters to provide this service to industry, NMIM would require the right resources.

"Among others, we need more metrologists who are well versed in the area of medical devices. Currently, several of our staff members are pursuing their PhD, with three of them focusing on medical devices," explained Dr. Osman.

This also applies to professionals in the calibration field in general. "It is essential for calibration companies to constantly upskill their staff members in order to support the growth of the medical device industry," said Dr. Osman. Furthermore, with the constant advancement of technologies, it is important for the calibration industry to progress alongside them.

Engaging with All

Engagement with the public is important to increase overall awareness on the importance of calibration. With that in mind, NMIM actively holds awareness programmes, including Metrology Day, roadshows and workshops.

"NMIM has stepped up our engagement with medical device associations. I feel that this is very important as it lets us garner more information and find out the issues faced by industry players. This way, we are able to take the necessary action to request for the resources and budget to build up the national infrastructure in support of the medical device industry," declared Dr. Osman.

NATIONAL LABORATORY ACCREDITATION

Introduced in 1990, Skim Akreditasi Makmal Malaysia (SAMM) is a national unified laboratory accreditation scheme aimed at providing a credible accreditation service to testing and calibration laboratories.

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

GLP as the Way Forward

The testing processes for medical devices have to be conducted under properly controlled conditions to ensure the efficacy of the results obtained. A Good Laboratory Practice (GLP) certification provides this assurance.

> *Due to all the regulations, data submitted by medical device manufacturers have to be of very high quality. This is assured by going through the GLP process.*

Good Laboratory Practices (GLP) are a set of international principles intended to assure the quality and integrity of non-clinical laboratory studies and data. These were developed by the Organisation for Economic Co-operation and Development (OECD) to ensure that products being exported to OECD countries conform to certain qualities.

The medical device industry is heavily regulated across the world; in the US, for example, there is the Food and Drug Administration (FDA). Malaysia's medical device industry is regulated by the Medical Device Authority (MDA), which is expected to implement new regulations requiring products to be GLP-compliant.

"Due to all the regulations, data submitted by medical device manufacturers have to be of very high quality. This is assured by going through the GLP process," explained Dr. Ahmad Hazri Ab Rashid, General Manager of the Industrial Biotechnology Research Centre in SIRIM.

DID YOU KNOW?

Non-clinical studies refer to a stage of research before clinical trials are conducted to collect integral data. The laboratory studies are conducted using different protocols, including animal studies.

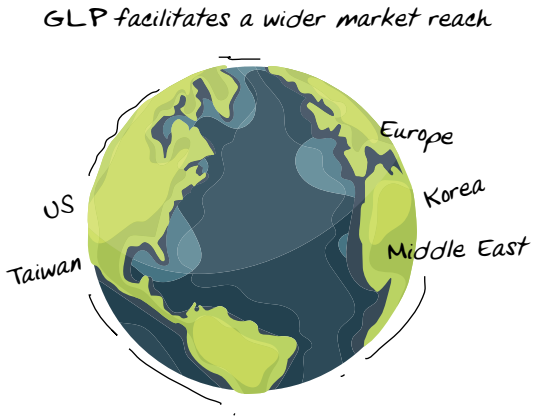
A Necessary Step

Before the GLP, many product claims were not properly substantiated. "A lot of the data was 'cooked up', not derived from the laboratory. There were experiments that were not reproducible and data that were tempered with," revealed Dr. Hazri.

Subsequently, the GLP ensures that new medical devices are safe, meet minimum quality standards and function as intended for patients. "For example, if the manufacturers claim that their medical implant is safe for legs, they have to submit the necessary data to support this. This way, it is proven that when implanted in a patient's leg, the device will not pose any safety issues and will be compatible with the patient's body," he said.

From a marketing perspective, adherence to GLP principles increases the value of the product, allowing the manufacturer to provide assurance of quality to their customers. "After having gone through testing, the products will have a higher value as they will be safe, compatible and able to do what they are intended to do. In fact, it is the highest quality assurance programme there is!" exclaimed Dr. Hazri.

He acknowledged that local medical device manufacturers are very aware of the necessity of obtaining GLP compliance, particularly if they are looking to export their products. "In addition to validating the safety aspect of the medical device, getting it GLP-compliant can also facilitate market reach internationally, as the manufacturers will find it easier to penetrate more advanced markets like the US, Europe, Korea, Taiwan and the Middle East."



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Cutting-edge Facilities

Among a few research institutes in Malaysia with GLP-compliant laboratories, SIRIM invites enquiries from local manufacturers. "GLP testing can be conducted for any medical device. The task at hand for industry players is to make sure that their products are of high quality in all aspects – from manufacturing and packaging to logistics. At SIRIM, we can provide them with consultancy services to help them see what testing is needed," explained Dr. Hazri.

Typically, a company with a new product in hand may approach SIRIM to get advice on the kinds of testing needed. Upon receiving the advice and quote from SIRIM, the company will then decide if it wants to proceed with the testing, after which SIRIM will provide it with a study plan to walk through what is needed and how the testing will be conducted.

> *In addition to validating the safety aspect of the medical device, getting it GLP-compliant can also facilitate market reach internationally, as the manufacturers will find it easier to penetrate more advanced markets like the US, Europe, Korea, Taiwan and the Middle East.*

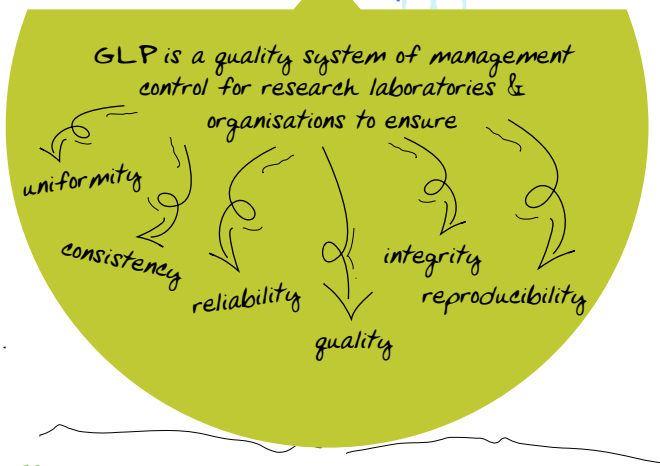
> *GLP testing can be conducted for any medical device. The task at hand for industry players is to make sure that their products are of high quality in all aspects – from manufacturing and packaging to logistics. At SIRIM, we can provide them with consultancy services to help them see what testing is needed.*

Once the study plan has been agreed and approved by the company, it will send the samples to SIRIM, which will then proceed with the testing. Even after the tests are conducted, SIRIM is on hand to provide consultation on interpreting the results and assisting with the reports to be submitted to the relevant regulators.

SIRIM's GLP-compliant facilities are carefully maintained all year round. "This is essential as it is especially important that all the parameters, such as humidity, temperature and lighting, are properly controlled and monitored during testing. Even the animal husbandry has to be done correctly," elaborated Dr. Hazri.

DID YOU KNOW?

According to the Medicines & Healthcare products Regulatory Agency in the UK, good laboratory practice or GLP is a quality system of management controls for research laboratories and organisations to ensure the uniformity, consistency, reliability, reproducibility, quality and integrity of chemical (including pharmaceutical) non-clinical safety tests, from physio-chemical properties through acute to chronic toxicity tests.



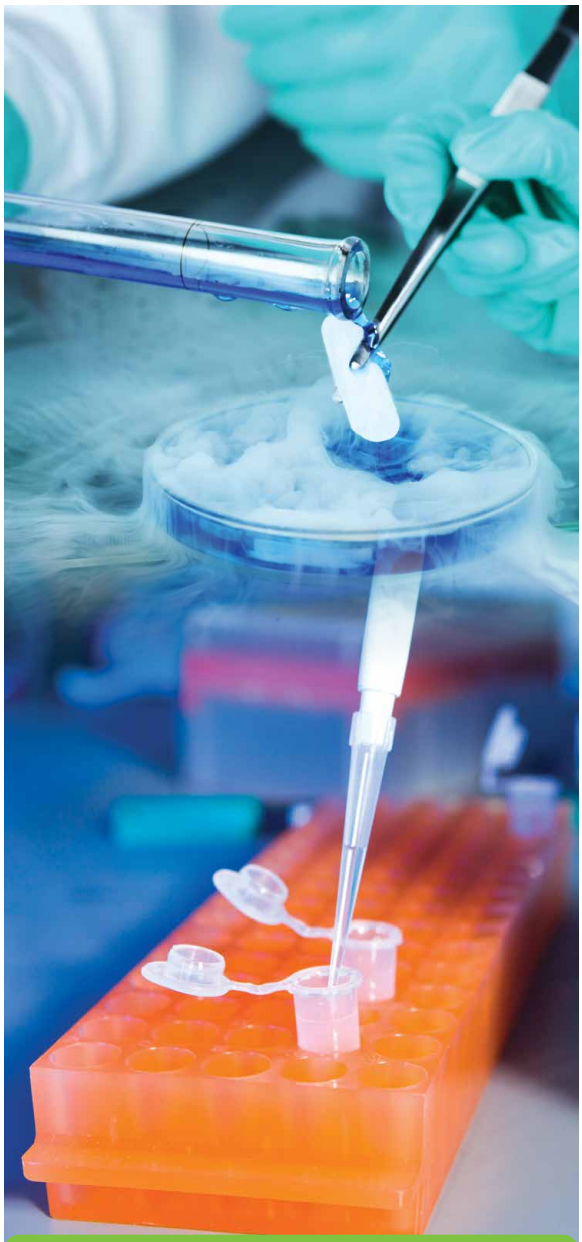
GLP applies to

medical devices

chemicals

food packaging

food & colour additives



With many regulators insisting on GLP compliance, and regulators in Malaysia jumping on board, he believes that the demand for GLP testing among medical device manufacturers is set to increase. "GLP compliance is definitely worth it for industry players looking to maximise their market reach. They can rest assured that SIRIM provides high-value services in this respect. In fact, if they have any concerns regarding their products, they are welcome to come to us for advice and help," he offered.

Obtaining *GLP Testing* from SIRIM

Consultation with SIRIM

↓

Obtain quote from SIRIM

↓

Agree to proceed with testing

↓

Receive study plan from SIRIM

↓

Agree to study plan

↓

Submit samples

↓

Testing is conducted

↓

Receive results

E

"GLP compliance is definitely worth it for industry players looking to maximise their market reach. They can rest assured that SIRIM provides high-value services in this respect. In fact, if they have any concerns regarding their products, they are welcome to come to us for advice and help.

Dr. Ahmad Hazri Ab Rashid
General Manager,
Industrial Biotechnology Research Centre, SIRIM

An Assurance of Safety

Microbiology, chemical and toxicity tests need to play an important role in the medical device industry. SIRIM sheds some light on why this is a necessary step.

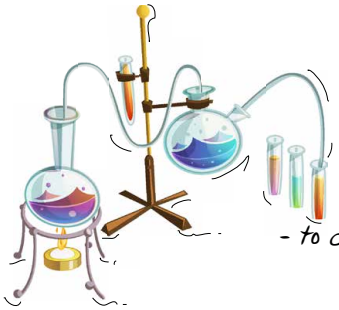
Stringent testing should be a necessity when it comes to medical devices. Among others, SIRIM offers three essential testing services, namely the microbiology, chemical and toxicity testing, to ascertain that the safety of medical devices is assured.

Zooming In

Microbiology testing is a crucial aspect, particularly in the medical device industry where products, processes and human health are at risk of being negatively affected from the presence of microorganisms such as bacteria.

Equally important are chemical and toxicity tests. The former involves the testing of the chemical properties of medical devices while the latter tests the devices for poisonous substances.

Microbiology Testing
- to test for the presence of microorganisms



Chemical Testing
- to determine the chemical properties

Toxicity Testing
- to test for poisonous substances

INTERPRETING ISO TERMINOLOGY

ISO 13485 specifies requirements for a quality management system where an organisation needs to demonstrate its ability to provide medical devices and related services that consistently meet customer and applicable regulatory requirements.

ISO 10993 primarily aims to protect humans from potential risks arising from the use of medical devices.

> *As most medical devices are intended for human use, we need to be able to eliminate or at least reduce the risk of these devices causing harm to the end user, in accordance with ISO 13485 standards.*

> *Even the slightest bit of contamination could be harmful to patients who already have compromised immune systems.*

"As most medical devices are intended for human use, we need to be able to eliminate or at least reduce the risk of these devices causing harm to the end user, in accordance with ISO 13485 standards," explained Mohd Mahayuddin Hussin, a Researcher at SIRIM.

"It is essential for medical devices to adhere to requirements set by specific medical device authorities. For example, devices that need to be sterilised should have zero microbes present. Even the slightest bit of contamination could be harmful to patients who already have compromised immune systems," he added.

According to Part 1 of ISO 10993, the material characterisation of the medical device should be conducted prior to testing. We need to know the properties of the materials and, as such, will conduct a chemical analysis to determine the stability and chemical characteristics of the sample provided.

It is essential for medical devices to adhere to requirements set by specific medical device authorities. For example, devices that need to be sterilised should have zero microbes present.

"According to Part 1 of ISO 10993, the material characterisation of the medical device should be conducted prior to testing. We need to know the properties of the materials and, as such, will conduct a chemical analysis to determine the stability and chemical characteristics of the sample provided," revealed Dr. Nur Ellina Azmi, a Senior Researcher who is involved in analytical chemistry and chemical testing at SIRIM's Industrial Biotechnology Research Centre (IBRC). This allows the scientists to find out more pertinent information, such as if the chemicals are dangerous and the level of safety required to conduct further testing on the device.

After acquiring the necessary data, the sample will then undergo biocompatibility testing. "Biocompatibility is an important aspect of toxicity testing and refers to the ISO 10993," chimed in Noor Rabihah Aid, a Researcher at SIRIM's Toxicology Laboratory. "There is a whole range of medical device-related standards that we have to follow to ensure that the devices are biocompatible, that is to say, safe for human use."

The SIRIM Advantage

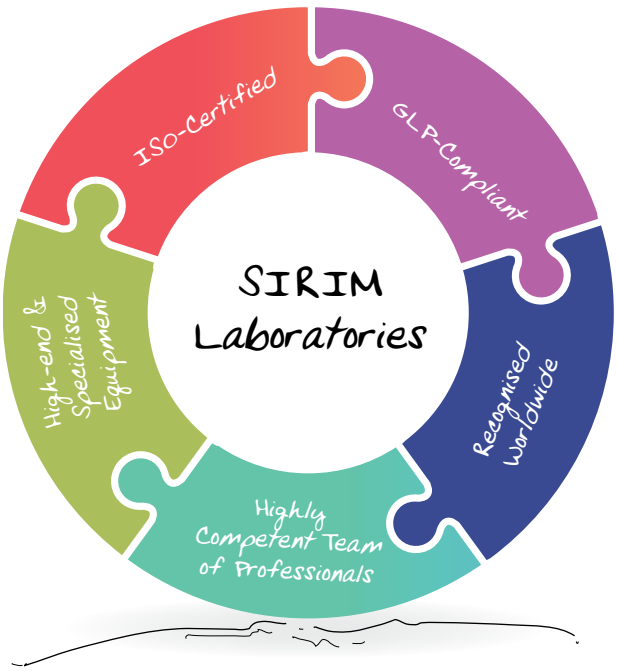
As a premier industrial research and technology organisation in Malaysia, SIRIM is able to provide a wide range of testing services as well as other complementary services, including customised testing and evaluation services, consultation and advice on regulatory issues and even research and development to help companies progress to the next stage.

The organisation is equipped with a wide range of facilities, most of which are properly accredited with the respective ISO and Good Laboratory Practice (GLP) standards. The laboratories are furnished with high-end and specialised equipment employing the latest methods to assess and validate the medical devices.

Besides that, SIRIM is also home to a team of highly competent staff. "In fact, 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; for example, chemists will have to be registered with Institut Kimia Malaysia. We must have the right knowledge and experience," declared Dr. Nur Ellina.

"To obtain accreditation, an organisation has to have good facilities, systems and personnel in place. As our laboratories are ISO-certified with GLP status, this means that your test reports will be accepted worldwide," added Noor Rabihah.

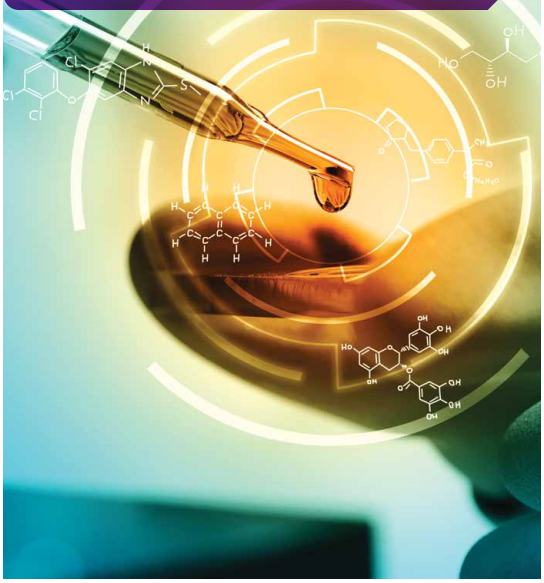
Furthermore, SIRIM has invested significantly in developing its competencies. According to Mohd Mahayuddin, "We continue to develop as industry leaders with continuous investment in our facilities, equipment and technical capabilities."



DEFINING BIOCOMPATIBILITY

Biocompatibility is, by definition, a measurement of how compatible a device is with a biological system. The purpose of performing biocompatibility testing is to determine the fitness of a device for human use, and to see whether use of the device can have any potentially harmful physiological effects.

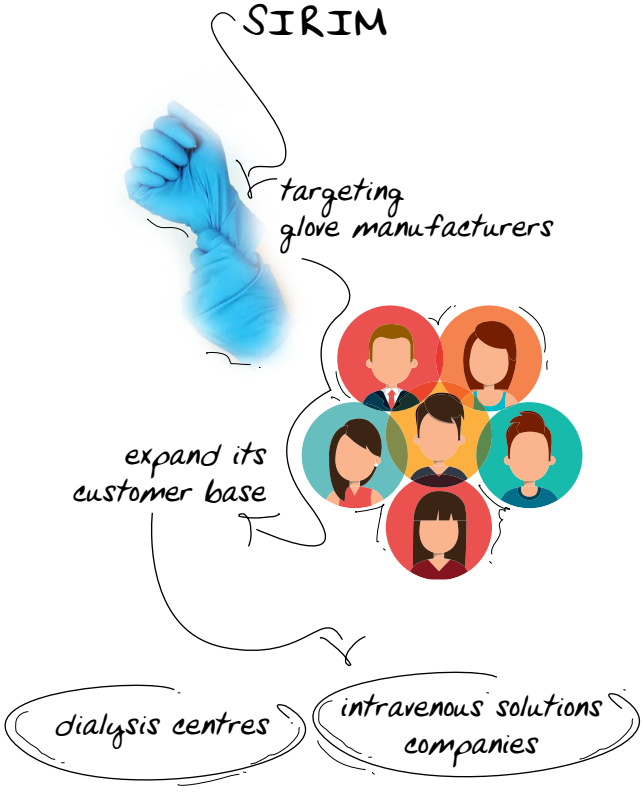
> *To obtain accreditation, an organisation has to have good facilities, systems and personnel in place. As our laboratories are ISO-certified with GLP status, this means that your test reports will be accepted worldwide.*



Increasing Awareness

SIRIM is currently targeting glove manufacturers and plans to expand its customer base to include dialysis centres and intravenous solutions companies in the near future. Parallel to this, it is doing its part in increasing awareness on the regulations and requirements that medical device industry players need to comply with.

The team attends related exhibitions, hosts industry engagement days during which they conduct training sessions to share details of the different types of testing SIRIM provides and visits potential clients to discuss the possibility of collaborations.



> *We also work closely with associations like the Malaysian Rubber Glove Manufacturers Association (MARGMA) to organise events on rubber-related medical devices and invite their members to visit our facilities.*
>
> E

"We also work closely with associations like the Malaysian Rubber Glove Manufacturers Association (MARGMA) to organise events on rubber-related medical devices and invite their members to visit our facilities," added Mohd Mahayuddin.

As the medical device industry continues to grow, so too will the demand for medical device testing, and SIRIM is ready to help the industry players to spread their wings internationally. Global regulators are demanding more in-depth testing and evaluation of medical devices such as long-term testing, and SIRIM is continually enhancing its services to ensure industry meets these stringent regulatory requirements.

"Our prices are competitive compared to the US, for example, and our test reports are accepted the world over, including major markets like the US and Europe. This shows that our capabilities are on par with our international counterparts," concluded Noor Rabihah.

> *We continue to develop as industry leaders with continuous investment in our facilities, equipment and technical capabilities.*
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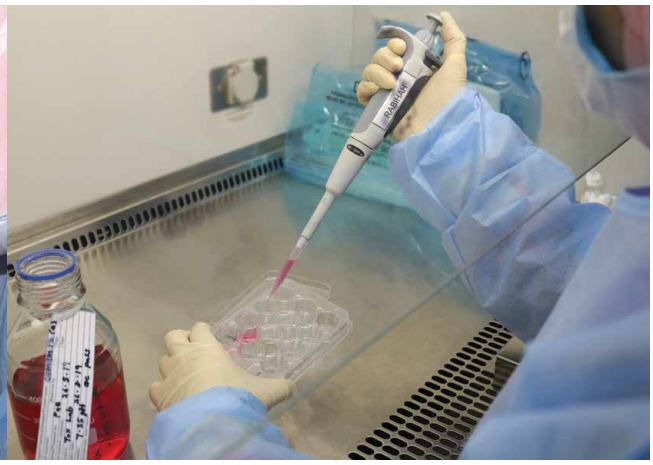
Dr. Nur Ellina Azmi

Mohd Mahayuddin Hussin



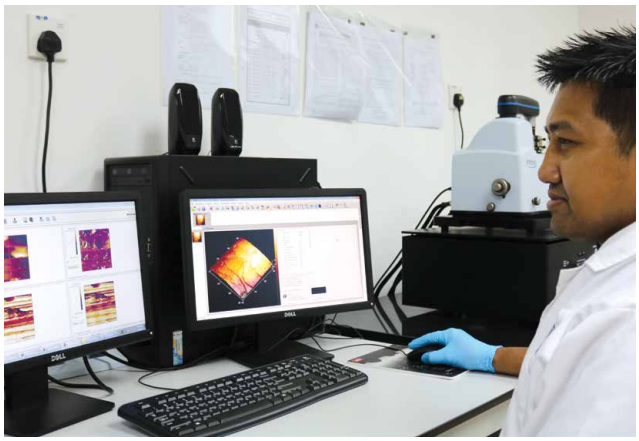
Biocompatibility is an important aspect of toxicity testing, and refers to the ISO 10993. There is a whole range of medical device-related standards that we have to follow to ensure that the devices are biocompatible, that is to say, safe for human use.

Noor Rabihah Aid

Verifying Safety & Performance of Medical Devices

Medical device manufacturing requires the use of a variety of high quality materials to ensure optimal functionality as well as compatibility with the human body. Mohamed Izat Mohd Ezwan and Mat Tamizi Zainuddin, both Senior Researchers at SIRIM, highlight the importance of material characterisation in ascertaining this.

> *The materials that will be used for the devices as well as related equipment and technologies must be thoroughly tested for safety and performance even before the first product can be rolled off the assembly line.*



> *When we talk about medical devices, it is very crucial to know more about the product. Typically, the physical properties will contribute to the performance of the material, while the chemical properties will determine if the material used is pure or contaminated.*

High quality materials are essential when it comes to the production of medical devices. These materials can generally be characterised based on their physical and chemical properties.

Material characterisation involves the process or act of describing the material via physical or chemical examination, which can be conducted using various measurement techniques. Physical properties describe the features of the material that can be observed and tested without changing the chemical make-up of the substance. These include size, shape, colour, melting and/or boiling point, density, porosity and degree of crystallinity. Chemical properties, on the other hand, include oxidation number, bonding energy, bond frequency and pH level, to name a few.

DID YOU KNOW?

The medical device industry is currently gearing up for the most extensive regulatory reform in years. Among others, industry players are getting ready for the updated ISO 10993 standards while laboratories are looking at the ISO 17025 accreditation in order to be recognised as technically competent and being able to produce accurate results.

Mohamed Izat Mohd Ezwan
Senior Researcher,
SIRIM's Industrial Centre of Innovation in Nanotechnology

With these testing services that depict product quality, Malaysian small and medium enterprises (SMEs) will be able to build credibility and the reputation of their brand to be on par with renowned brands internationally.

Our testing services cover physical and mechanical properties, chemical and compositional analysis, imaging and surface analysis, and thermal, corrosion and structural analysis. We are also in the process of offering nanosafety testing to nano-based product manufacturers.

We have it all here at SIRIM!

As patient safety is paramount for the medical device industry, material testing is vital in the verification process, determining the right materials and reliability for an application, and meeting regulatory and standard requirements. This needs to be done right at the start of the manufacturing process. According to Mohamed Izat Mohd Ezwan, a Senior Researcher at SIRIM's Industrial Centre of Innovation in Nanotechnology, "The materials that will be used for the devices as well as related equipment and technologies must be thoroughly tested for safety and performance even before the first product can be rolled off the assembly line."

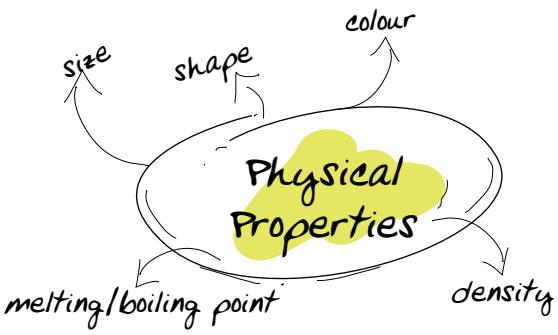
Furthermore, there is a potential for certain materials to release chemical compounds over time; this could result in biocompatibility issues that may be harmful to patients. This is also where reliable identification and accurate quantification and characterisation of these compounds will be helpful in ensuring the device's overall safety and biocompatibility.

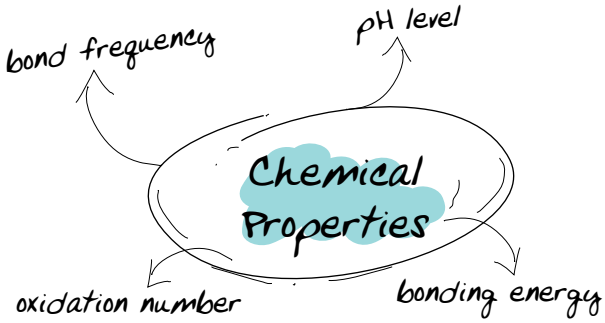
Mat Tamizi Zainuddin, a Senior Researcher at SIRIM's Industrial Centre of Innovation in Biomedical, concurs. "When we talk about medical devices, it is very crucial to know more about the product. Typically, the physical properties will contribute to the performance of the material, while the chemical properties will determine if the material used is pure or contaminated," he said. Importantly, the physical and chemical properties will need to meet the criteria stipulated by the relevant regulatory bodies.

According to Mat Tamizi, part of SIRIM's agenda is also to look into strengthening the enforcement of the regulations in Malaysia. With that in mind, physical and chemical testing will provide the required details regarding the materials to the proper parties, which include the public, regulatory bodies and government. This, in turn, will help to curb the proliferation of self-claim benefits of medical devices without any evidence as well as facilitating medical practitioners' efforts in gathering accurate information on the medical devices.

DID YOU KNOW?

Phases of matter are a common physical property. Currently five phases of matter have been identified: solid, liquid, gas, plasma and Bose-Einstein condensate. The first four can be found around us, while the fifth is man-made.

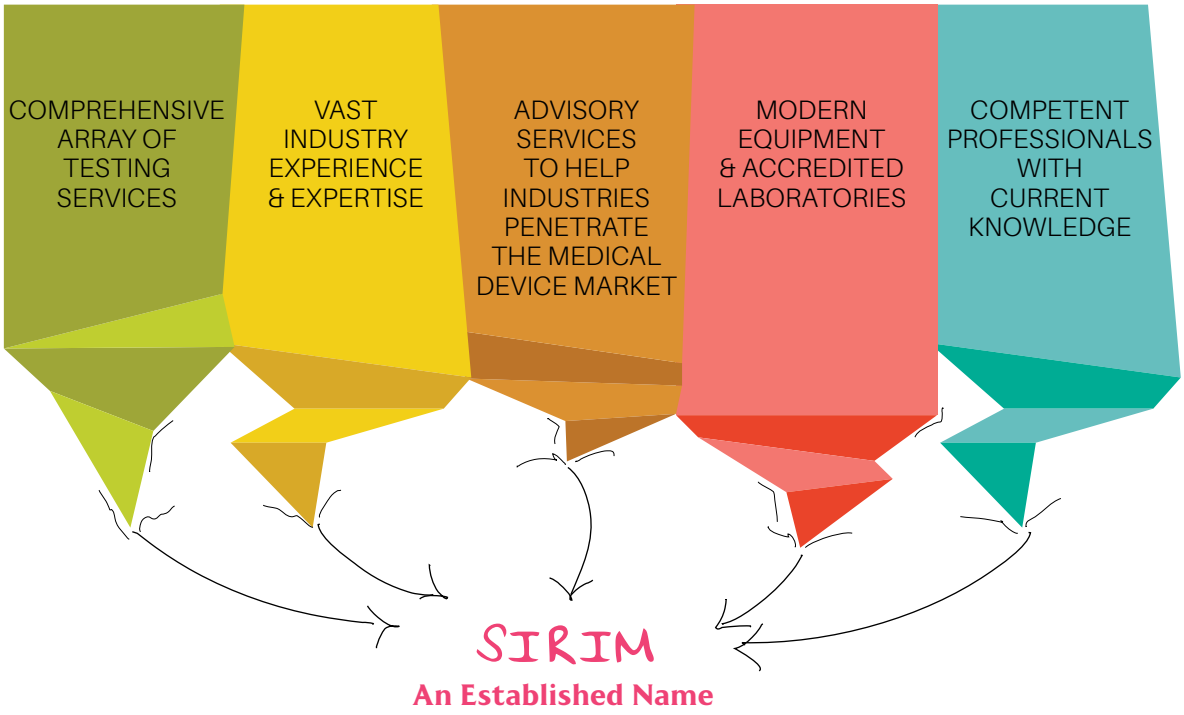




"With these testing services that depict product quality, Malaysian small and medium enterprises (SMEs) will be able to build credibility and the reputation of their brand to be on par with renowned brands internationally," chimed in Mohamed Izat.

Leading the Industry

With decades of in-depth experience in material characterisation under its belt, SIRIM is an established name among Malaysia's laboratories, offering a significant range of testing services. "Our testing services cover physical and mechanical properties, chemical and compositional analysis, imaging and surface analysis, and thermal, corrosion and structural analysis. We are also in the process of offering nanosafety testing to nano-based product manufacturers", explained Mohamed Izat. "With regards to our medical device testing portfolio, we have also included numerous physical and chemical characterisation services under the ISO 17025 scope."



"We have it all here at SIRIM!" quipped Mat Tamizi.

He feels that SIRIM has a distinct perspective and is able to provide customers with invaluable industry insights. "Coming from a research and development background, our competent personnel are constantly exposed to new regulatory schemes and abreast with the latest industry news. Thus, we are well-versed with what needs to be updated and such."

Additionally, SIRIM offers further understanding of the performance of the devices based on their physical and chemical properties. "We advise on the classification of the various devices based on the categories outlined by the Medical Devices Regulatory in order for manufacturers to strategise their market niche," he added. The classification of medical devices is important as it helps manufacturers select the proper testing procedures needed to comply with current regulatory requirements.

Similarly, Mohamed Izat encourages industry players to take advantage of SIRIM's years of experience and expertise to better comprehend the importance of standards in the medical device industry toward ensuring the quality, safety and performance of the devices.

Mat Tamizi reveals that because of the extent of material characterisation services offered, SIRIM is a hotspot for academicians, research institutes and the government. "Currently, we offer eight types of services from various categories including imaging, physical criteria determination and material identification," he shared.

"Since we cover a wide range of material characterisation testing services, other industries, such as those involved in electronics, plastics, chemicals or precision engineering, can also benefit," added Mohamed Izat. In fact, SIRIM has a good share of clientele from other industries, which further attests to its competent laboratory system.

Stepping Up

SIRIM has big plans in increasing awareness of the role of material characterisation as well as other forms of testing in growing the medical device industry, which will lead to the eventual establishment of a medical device hub. "To do this, it is imperative that we get the collaboration of all the main players, such as the Association of Malaysian Medical Industries (AMMI) and other medical-related associations," said Mat Tamizi.

SIRIM is also involved in various promotional activities, including the International Invention, Innovation and Technology Exhibition (ITEX), Malaysia Technology Expo (MTE) and various other exhibitions and seminars. "We hope to create as many engagement opportunities as possible to be able to explain to industry players how we can assist them," declared Mohamed Izat.

CATALYSING THE GROWTH OF MALAYSIA'S MEDICAL DEVICE INDUSTRY

The Industrial Centre of Innovation in Nanotechnology and Industrial Centre of Innovation in Biomedical are part of SIRIM Kulim. With cutting-edge facilities and experienced professionals under its roof, SIRIM Kulim is also instrumental in facilitating Malaysia's journey towards become a medical device hub.

CUTTING-EDGE EQUIPMENT

Among the equipment used in material characterisation are the Fourier Transform Infrared (FTIR) Spectroscopy and specialised microscopes.

FTIR Spectroscopy - An analytical technique commonly used to identify organic and polymeric materials. It uses infrared light to scan test samples and observe chemical properties.

Scanning Electron Microscope - Identifies particle shape and size. With this method, the sample is imaged using a high energy electron source, which enables high magnification of up to 500,000 times.

Atomic Force Microscope - Measures surface roughness using a small touch probe with a nano-sized tip to "touch" the surface. Invasive medical devices like implants require several degrees of roughness to facilitate tissue and protein adsorption as well as to avoid inflammation or further fibrosis and thrombosis.

> *We hope to create as many engagement opportunities as possible to be able to explain to industry players how we can assist them.*

Mat Tamizi Zainuddin
Senior Researcher,
SIRIM's Industrial Centre of Innovation in Biomedical

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