

# MAKMAL BIOSEKERASI

## CORPORATE PROFILE



**MAKMAL  
BIOSEKERASI™**



***“Health & Safety is Our Priority”***

# ABOUT US

We are a **biocompatibility and toxicity testing laboratory** providing in vitro and in vivo testing services for medical devices, pharmaceuticals, supplements, agrochemicals, pesticides, industrial chemicals, cosmetics, food and biotechnology industries worldwide.

We are committed to **helping our customers deliver safe products and devices** to patients and the general public, gain approval of the regulatory authorities and bringing them to market successfully.

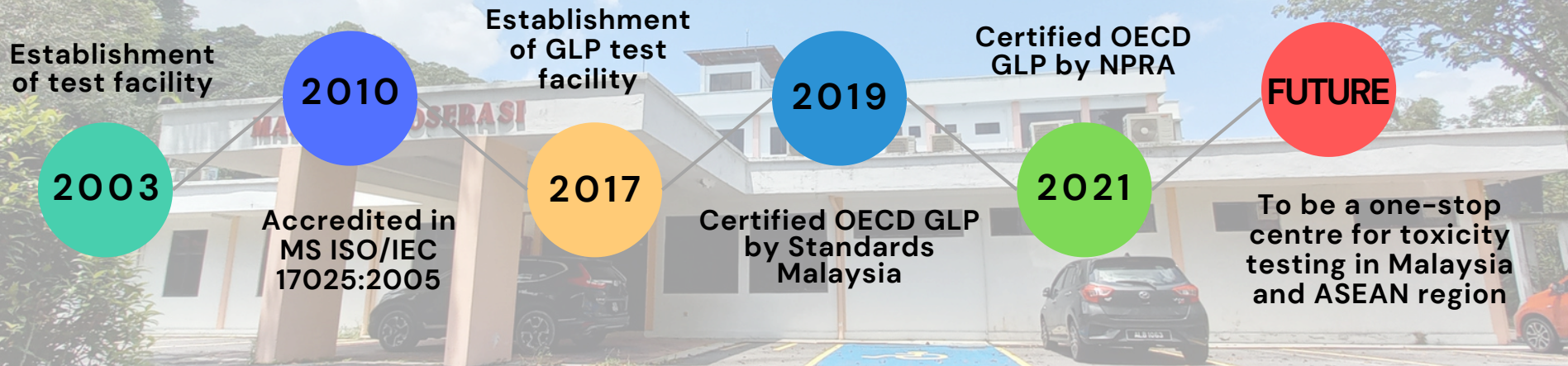
# MISSION & VISION

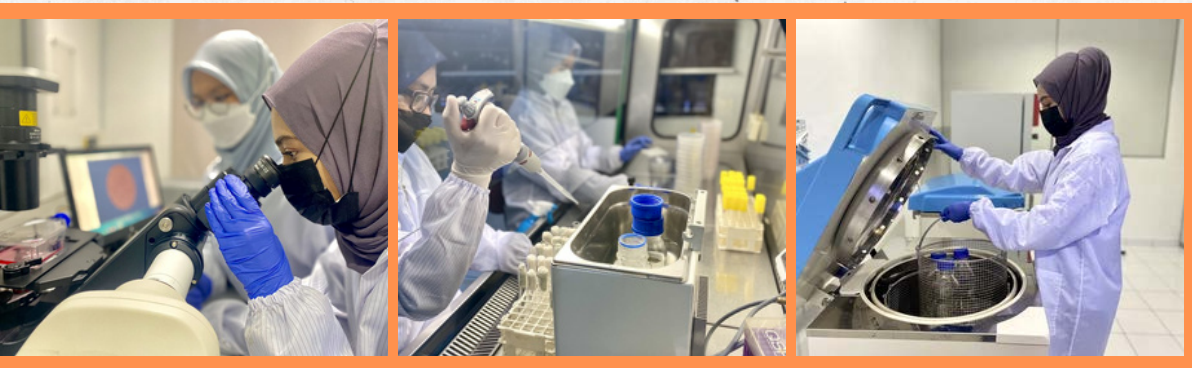
To deliver quality services in biological safety assessment that conform to international standards and regulations with integrity and professionalism.

To be a one-stop centre for biocompatibility and toxicity testing laboratory in Malaysia and ASEAN region.



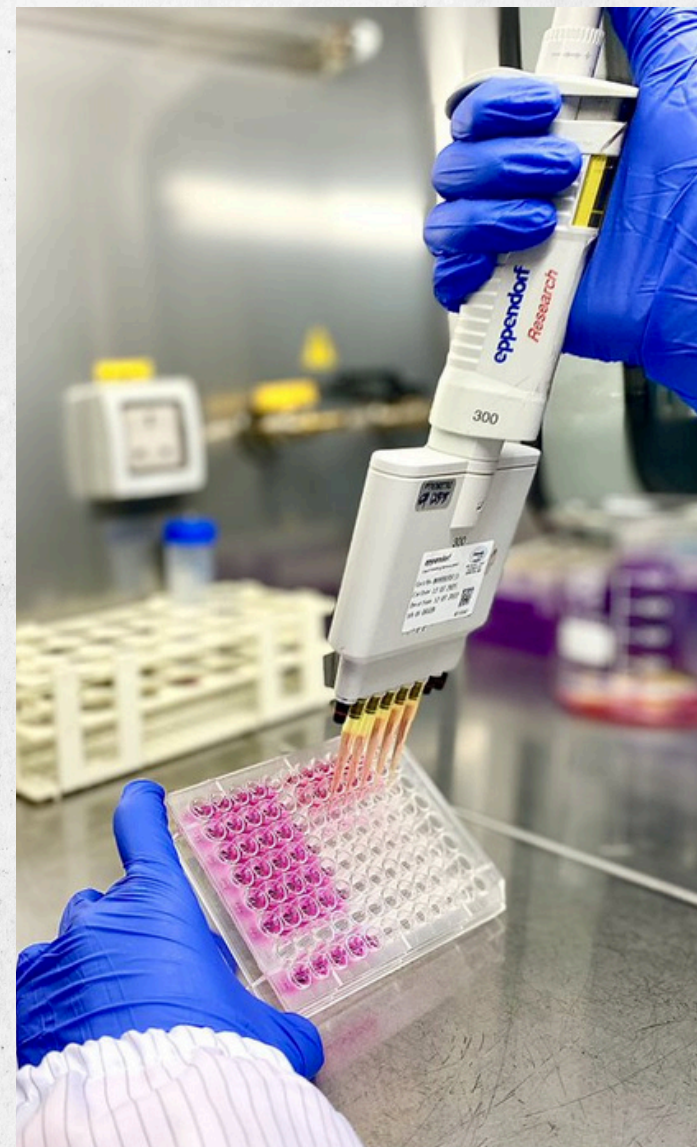
# OUR JOURNEY





# WHY CHOOSE US?

- ✓ OECD GLP Compliant Test Facility & ISO 17025:2017 Accredited Laboratory.
- ✓ Expert in Toxicology & Biocompatibility Testing.
- ✓ Report generated accepted by Regulatory Authority.
- ✓ Continuous technical support & services: pre, during and post.



# OUR SERVICES

## Medical Devices

- Cytotoxicity Test ISO 10993-5
- Genotoxicity Test ISO 10993-3
- Irritation Test ISO 10993-23
- Sensitization Test ISO 10993-10
- Systemic Toxicity Test ISO 10993-11
- Pyrogen Test USP
- Implantation Test ISO 10993-6
- Haemocompatibility Test ISO 10993-4

## Pharmaceutical

- Cytotoxicity Test
- Mutagenicity Test OECD 471, 487
- Alkaline Comet Assay
- Acute Oral Toxicity Study OECD 423
- Sub-acute Toxicity Study OECD 407
- Sub-chronic Toxicity Study OECD 408
- Chronic Toxicity Study OECD 452
- Heavy Metal Test
- Microbe Test

## Food / Supplement

- Cytotoxicity Test
- Mutagenicity Test OECD 471, 487
- Alkaline Comet Assay
- Acute Oral Toxicity Study OECD 423
- Heavy Metal Test
- Microbe Test
- Antioxidant Assay

*\*Please reach out to us to inquire about the accreditation status of each test.*



# OUR SERVICES

## Agrochemicals/Pesticide

- Cytotoxicity Test
- Mutagenicity Test OECD 471, 487
- Acute Oral Toxicity Study OECD 423
- Acute Dermal Toxicity Study OECD 402
- Acute Dermal Irritation/Corrosion Study OECD 404
- Acute Eye Irritation Study OECD 405
- Skin Sensitization Test OECD 406
- Acute Inhalation Toxicity Study OECD 406

## Cosmetics

- Cytotoxicity Test
- Mutagenicity Test OECD 471, 487
- Acute Dermal Irritation/Corrosion Study OECD 404
- Skin Sensitization Test OECD 406
- Heavy Metal Test
- Microbe Test

## Scheduled Waste

- Scheduled waste testing (Appendix 1 and Appendix 2) as per Guidelines for The Application of Special Management of Schedule Waste.

*\*Please reach out to us to inquire about the accreditation status of each test.*



# OUR SERVICES

## Consultation in regulatory submission and R&D

- Product safety assessment (local and international) - US FDA 510K, Medical Device Authority, Pesticide Board, DOSH, NPRA
- Product development
- Histopathology slide observation

## Training

- Quality system (ISO 17025, OECD GLP)
- Animal husbandry
- Cell culture handling
- Biocompatibility evaluation as per ISO 10993



# CERTIFICATE & ACCREDITATION

<p>S/N: 1306</p> <p> <b>STANDARDS MALAYSIA</b></p> <p><i>Certificate of Accreditation</i></p> <p>No: SAMM 479      Accredited since: 19 October 2010</p> <p>This is to certify that</p> <p>MAKMAL BIOSERASI CENTRE FOR RESEARCH AND INSTRUMENTATION MANAGEMENT (CRIM), UNIVERSITI KEBANGSAAN MALAYSIA BANGI, SELANGOR MALAYSIA</p> <p>has been granted accreditation in respect of the scope of accreditation described in the schedule, subject to the terms and conditions governing the <i>Skim Akreditasi Makmal Malaysia</i> (SAMM), the Laboratory Accreditation Scheme of Malaysia.</p> <p>Laboratories accredited under SAMM meet the requirements of MS ISO/IEC 17025. This Malaysian Standard is identical with ISO/IEC 17025 published by the International Organization for Standardization (ISO).</p> <p> (DATUK FADILAH BAHARIN) Director General Department of Standards Malaysia</p> <p>Date of issue: 29 October 2019</p> <p></p>	<p>S/N: 0055</p> <p> <b>STANDARDS MALAYSIA</b></p> <p><i>Certificate of Compliance to OECD Principles of GLP</i></p> <p>No: GLP 008      Dates of Inspection: 11-12 January 2023</p> <p>MAKMAL BIOSERASI CENTRE FOR NATURAL AND PHYSICAL LABORATORY MANAGEMENT UKM (ALAF-UKM) UNIVERSITI KEBANGSAAN MALAYSIA 43600 UKM BANGI SELANGOR MALAYSIA</p> <p>Category of Test Item : Industrial Chemicals &amp; Pesticides Area of Expertise : Toxicity Testing Mutagenicity Testing</p> <p>Date of 1<sup>st</sup> Compliance : 10 January 2019</p> <p>The Director General of Department of Standards Malaysia hereby endorses the Test Facility has been inspected and found to be operating in compliance to the OECD Principles of Good Laboratory Practice and Standards Malaysia GLP Compliance Programme. The inspection of compliance is conducted at regular basis.</p> <p> (SHAHARUL SADRI BIN ALWI) Director General Department of Standards Malaysia Date of issue: 19 May 2023</p> <p></p> <p><small>Issuance of this Certificate is governed by Section 16 Subsections (2) and (3) of Standards of Malaysia Act, 1996 (Act 549)</small></p>	<p>Serial no: 20230801</p> <p> <b>STANDARDS MALAYSIA</b></p> <p><i>OECD GOOD LABORATORY PRACTICE COMPLIANCE CERTIFICATE</i></p> <p>A GLP Inspection was carried out as follows:</p> <p><b>Test Facility:</b> Makmal Bioserasi Centre for Natural and Physical Laboratory Management UKM (ALAF-UKM) Universiti Kebangsaan Malaysia, 43600 UKM Bangi, Selangor Darul Ehsan, Malaysia</p> <p><b>Area of Expertise:</b> Toxicity Mutagenicity</p> <p><b>Type of product:</b> Pharmaceuticals Cosmetics Veterinary Drugs Food Additives Medical Device</p> <p>The above mentioned Test Facility has been inspected by the National Pharmaceutical Regulatory Agency (NPRA) and found to be in compliance with the OECD Principles of Good Laboratory Practice (GLP) and NPRA GLP Compliance Programme. This certificate is valid from 10 May 2023 to 9 May 2025.</p> <p>Date of First Recognition: 10 May 2021 Registration Number: GLP 008</p> <p> Rofliawan Ahmad Director National Pharmaceutical Regulatory Agency (NPRA) Ministry of Health Malaysia</p> <p><small>(Version: July 2022)</small></p>
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MS ISO/IEC 17025 : 2017

OECD GOOD LABORATORY PRACTICE

# CONTACT US



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[www.ukm.my/makmal\\_bioserasi](http://www.ukm.my/makmal_bioserasi)



**Makmal Bioserasi**

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**Makmal bioserasi UKM – Biocompatibility Laboratory**



**@makmalbioserasiukm**



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