

MAKMAL BIOSERASI

CORPORATE PROFILE

MAKMAL BIOSERASI



MAKMAL
BIOSERASI™



“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.

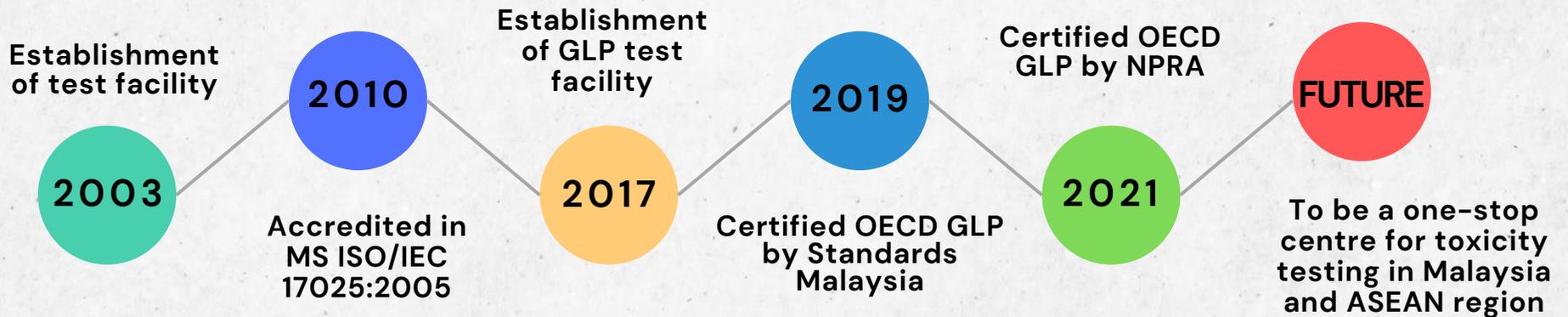
MISSION & VISION

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



CONTACT US



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Makmal bioserasi UKM – Biocompatibility Laboratory



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