

Purchase Order - Terms and Conditions for Critical suppliers

Benra Pty Ltd trading as Gelflex Laboratories, 52 Mulgul Road, Malaga. WA 6090

ABN 28 009 304 723

Acceptance of Purchase Order

- By accepting this PO, the Supplier agrees to deliver goods and/or services as specified, in compliance with the terms and conditions herein, as well as applicable regulatory requirements.
- Acceptance of this PO constitutes acknowledgment of adherence to all referenced quality and regulatory clauses.

Price and Payment

- Prices listed in this PO are firm and not subject to change unless agreed upon in writing.
- Payment terms as agreed and effective upon receipt of a valid invoice and acceptance of goods or services.
- Invoices must include the PO number, description of goods or services, and batch or lot numbers (if applicable).

Delivery

- Deliveries must adhere to the schedule and location specified in the PO.
- Any delay in delivery must be communicated promptly, with a revised delivery schedule subject to Gelflex's approval.
- Goods must be packaged and labelled as per agreed specifications to ensure integrity and compliance with regulatory standards.

Title and Risk of Loss

- Unless otherwise specified in the Order, risk of loss for the Goods remains with Supplier, and title will not pass to Gelflex until the Goods are delivered to the delivery location, inspected by Gelflex and accepted. The risk and title transfer occurs only after Gelflex's inspection and formal acceptance of the Goods.

Inspection, Acceptance, and Non-Conformance

- All goods and services are subject to inspection and testing by Gelflex upon receipt.
- Non-conforming goods may be rejected, returned, or reworked at the Supplier's expense.
- Non-conforming goods must be documented and reported to the Supplier, with corrective actions initiated promptly.

Quality Requirements

- **Quality Management System (QMS):** The supplier must maintain an ISO 13485 (or equivalent) compliant QMS or must enforce alternative quality controls (proper storage, complaint handling, CAPA, and communication) and present a manufacturer's certification confirming compliance upon request. Gelflex reserves the right to audit any party if non-compliance or risk is identified.
- **Traceability:** The Supplier must maintain full traceability of all materials, components, and processes used in manufacturing goods supplied under this PO. Lot and batch numbers must be included in shipping documents.
- **Certificates of Compliance (CoC):** CoC or equivalent documentation must accompany each shipment, verifying compliance with specifications, standards, and agreed requirements.
- **Change Control:** The Supplier shall notify Gelflex in advance of any changes to materials, processes, suppliers, or manufacturing locations that could affect the quality, form, fit, or function of the goods. Written approval from Gelflex must be obtained prior to implementing such changes.
- **Audits:** Gelflex reserves the right to audit the Supplier's facilities, processes, and records to ensure compliance with any quality and regulatory requirements.
- **Record Retention:** The Supplier must retain quality and manufacturing records for a minimum of (e.g., 7 or 10 years) or as required by applicable regulations, and shall provide Gelflex prompt access to these records upon request.
- **Corrective and Preventive Actions (CAPA):** In the event that Gelflex identifies any non-conformance, the Supplier shall promptly investigate and implement CAPA to prevent recurrence, providing Gelflex with relevant records of actions upon request.

Warranties

The Supplier warrants that:

- Goods meet all specifications, drawings, and standards provided by Gelflex.
- Goods are free from defects in material and workmanship.
- Goods comply with all applicable regulatory requirements.

Packaging and Labelling

- Packaging must protect goods during transit and storage while complying with agreed standards.
- Labelling must include PO number, product identification, quantity, lot/batch number, and expiration date (if applicable).

Product Recall and Field Actions

- The Supplier must notify Gelflex immediately of any product recall, field action, or regulatory inquiry involving the goods supplied.
- The Supplier will cooperate fully in corrective actions, investigations, or recalls as necessary.

Confidentiality

- The Supplier agrees to treat all information provided by Gelflex as confidential and use it solely for fulfilling this PO.

Termination

- Gelflex reserves the right to cancel the PO in whole or in part for Supplier non-compliance with these terms or if goods fail to meet quality and regulatory requirements.
- Upon termination, the Supplier must refund payments made for undelivered goods or services.

Force Majeure

- Neither party shall be liable for delays caused by circumstances beyond their control, such as natural disasters, acts of government, or labour disputes.

Indemnification

- Gelflex shall indemnify and hold the Buyer harmless against any claims, damages, or liabilities arising from non-compliance, negligence, or breach of this agreement.

Governing Law

- These conditions are governed by the laws of Western Australia, and any disputes shall be resolved under its legal framework.