

BUILT TO PARTNER. READY TO DELIVER.

High-Potency Sterile CDMO

*Aseptic Fill-Finish for Liquid & Lyophilized Vial
Formats*

MEET THE TEAM



Name: José Ascensão
Position: General Manager
Mobile no.: +351 917895119
Email: jose.ascensao@maltadevelopmentlabs.com



Name: Luis Castiñeiras
Position: Head of Business Development
Mobile no.: +356 99317433
Email: luis.castineiras@maltadevelopmentlabs.com

Who We Are?

A Reliable Partner for Sterile Injectable Manufacturing specialized in
CDMO for sterile High Potency injectables

We support pharmaceutical and biotech companies from clinical **development through commercial manufacturing**, providing integrated solutions for sterile drug products.

CORE EXPERTISE

- Sterile formulation & process development
- Lyophilisation development
- Sterile fill-finish manufacturing
- Liquid & lyophilised injectables
- High-potency handling & containment
- Secondary packaging
- Clinical to commercial-scale production
- GMP, quality & regulatory expertise

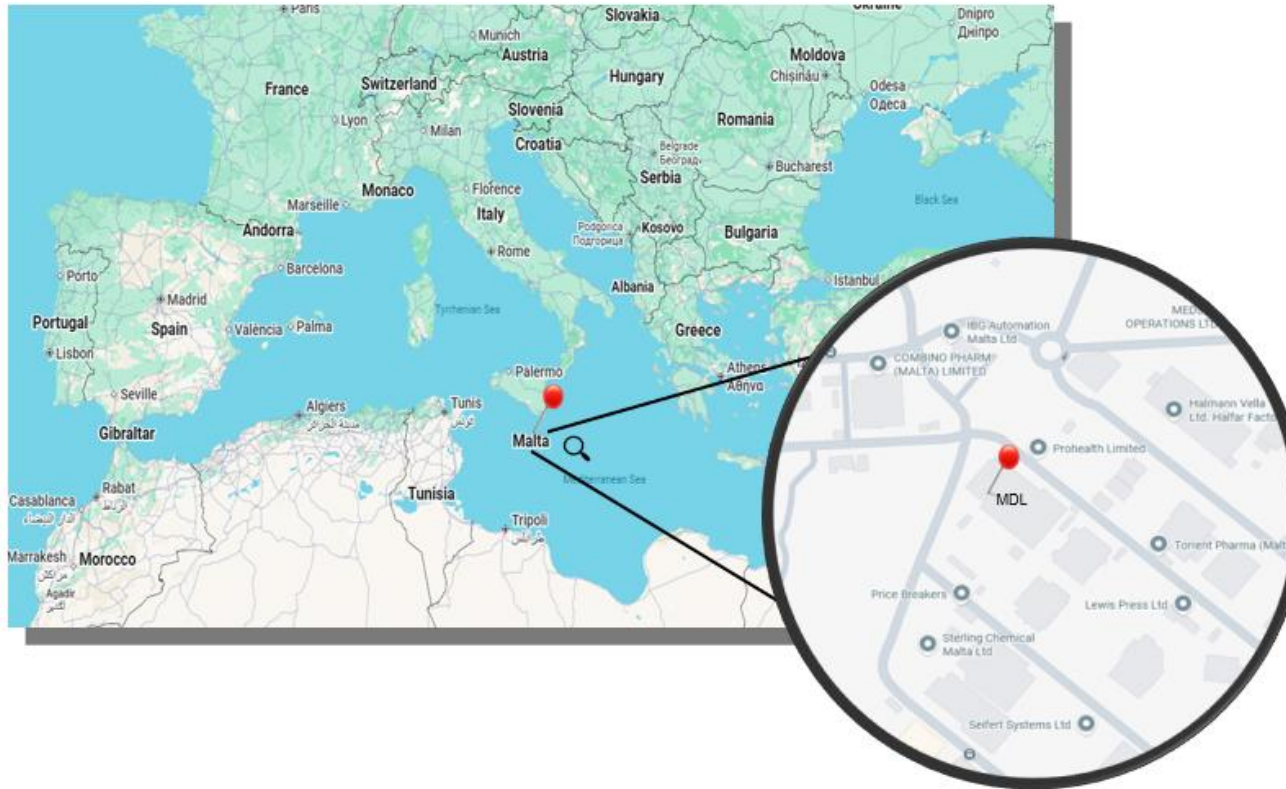
OUR FOCUS

Delivering reliable, high-quality manufacturing solutions that help our clients accelerate development and secure dependable supply.



Where are we located?

Malta a strategic Mediterranean base for high-potency sterile manufacturing



- Access to European pharmaceutical markets
- Established pharma ecosystem & business-friendly environment
- Gateway to Europe and MENA
- FDA-certified capabilities supporting US market access

Why Partner With Us?

A Trusted Development Partner

We support Clients by providing reliable sterile manufacturing capacity, technical expertise,
and regulatory-ready infrastructure

Key Advantages

- Proven sterile manufacturing expertise
- Flexible production capacity
- High-quality GMP manufacturing environment
- Experience supporting complex formulations
- Strong regulatory and compliance capabilities
- EMA, FDA & SFDA approved



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Faster development timelines, RFT reliable manufacturing capacity, and a trusted extension of your team with our production capabilities.



Plant Capabilities

HIGH-POTENCY API HANDLING

- **Containment level → Designed for handling OEB5/high-potency compounds, with a design CPT $<0.1 \mu\text{g}/\text{m}^3$)**
- High-containment isolator for API weighing, dispensing & charging
- 50 L AISI 316L preparation vessel
- 200 L AISI 316L holding tank
- EU GMP cleanrooms → Grade C

STERILE DRUG PRODUCT PROCESSING

- Liquid and lyophilised sterile injectables in glass vials: 2R (liquid), with capability for 6R, 10R, 20R, 30H, 50H formats. (100H format, potential CAPEX Opportunity at customer request.)
- EU GMP cleanrooms → Aseptic filling in a Grade A isolator.
- Secondary packaging, including serialization and traceability capabilities.



DEVELOPING DEDICATED ADC MANUFACTURING CAPABILITY

Building on our established high-potency capabilities, we are developing an integrated ADC manufacturing platform that will bring API handling, ADC conjugation and sterile drug-product manufacturing together under one roof.

DEDICATED ADC CONJUGATION SUITE

- Dedicated manufacturing space
- High-potency containment & controlled flows
- Dedicated conjugation equipment
- Designed for clinical-scale production
- Modular and scalable design

FULLY INTEGRATED SITE

- Dedicated laboratory
- Warehouse
- Utilities
- Office facilities
- Stand-alone site

SMALL-MOLECULE + ADC MANUFACTURING

- Established small-molecule manufacturing capabilities
- New dedicated ADC manufacturing capability
- Supporting scale-up and manufacturing

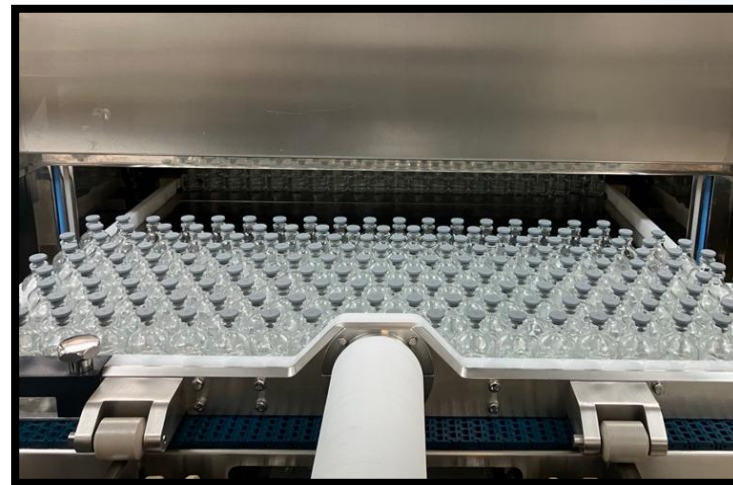
ONE SITE • ONE INTEGRATED FLOW • END-TO-END ADC CAPABILITY

LYOPHILISATION DEVELOPMENT

Supporting robust and scalable lyophilisation process development

LYOPHILISATION PLATFORM

- TELSTAR 10 m² freeze dryer equipped with an automated loading/unloading system.
- Lyophilisation cycle development & optimisation
- Process development and characterisation
- Scale-up and technology transfer
- Support from development through manufacturing



PLANNED DIGITAL ENHANCEMENT

- LYOFLOW integration planned
- Enhanced development support
- Real-time process data monitoring
- Live visibility of critical process parameters
- Improved data capture and process understanding



Development and Manufacturing Services

- Pre-formulation & Formulation Development Services.
- Manufacturing of small batches for toxicological animal studies.
- Manufacturing, labelling, packaging and release of IMP and Placebo.
- Technology Transfer & Scale-Up.
- Sterile Fill-Finish & Lyophilisation.
- Long-Term Commercial Manufacturing Partnerships.
- Co-Development Partnerships.



**Your trusted partner for sterile High Potency programs,
from early stages up to commercial launch.**



Thank you

Production Site



Malta Development Labs Ltd.
HHF014, Hal Far Industrial Estate
Hal Far,
Birzebbugia, BBG3000
Malta.

Email: info@maltadevelopmentlabs.com
Tel.: +356 21 655 300