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we innovate

R&D Pilot Plant

01

From Lab to Market: Seamless Integration and Excellence at Every Stage

Famar reinforces its **commitment to innovation** and **excellence** with the **fully operational GMP Pilot Plant** in **Alcorcón (Madrid), a 1,000 m² facility** designed to accelerate the development of **oral solid drugs –** covering from early lab scale formulation through to clinical, bioequivalence, registration, and small-scale commercial batches.

This plant has been conceived to **provide a fully integrated workflow**, eliminating the need for unnecessary technology transfers that often delay or jeopardize development. From initial formulation to **GMP manufacturing under EU-GMP certification —** and with plans underway to align with **FDA standards —** our clients benefit from a seamless path from lab-scale to pilot and commercial batches, ensuring a traceable and efficient transition.

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02

Designed to Handle HPAPIs with Safety and Flexibility

The facility is equipped to operate with **high-potent APIs (Safebridge 3A / OEB-4)**, incorporating **advanced containment technologies** and high-segregation zones.

This ensures safe handling of compounds with **OELs as low as 1 µg/m³,** safeguarding both personnel and product integrity. Areas are supported by **automatic cleaning systems (CIP/WIP),** decontamination fog shower, zoned segregation, environmental controls, HEPA filtration, and continuous monitoring and ATEX compliance.

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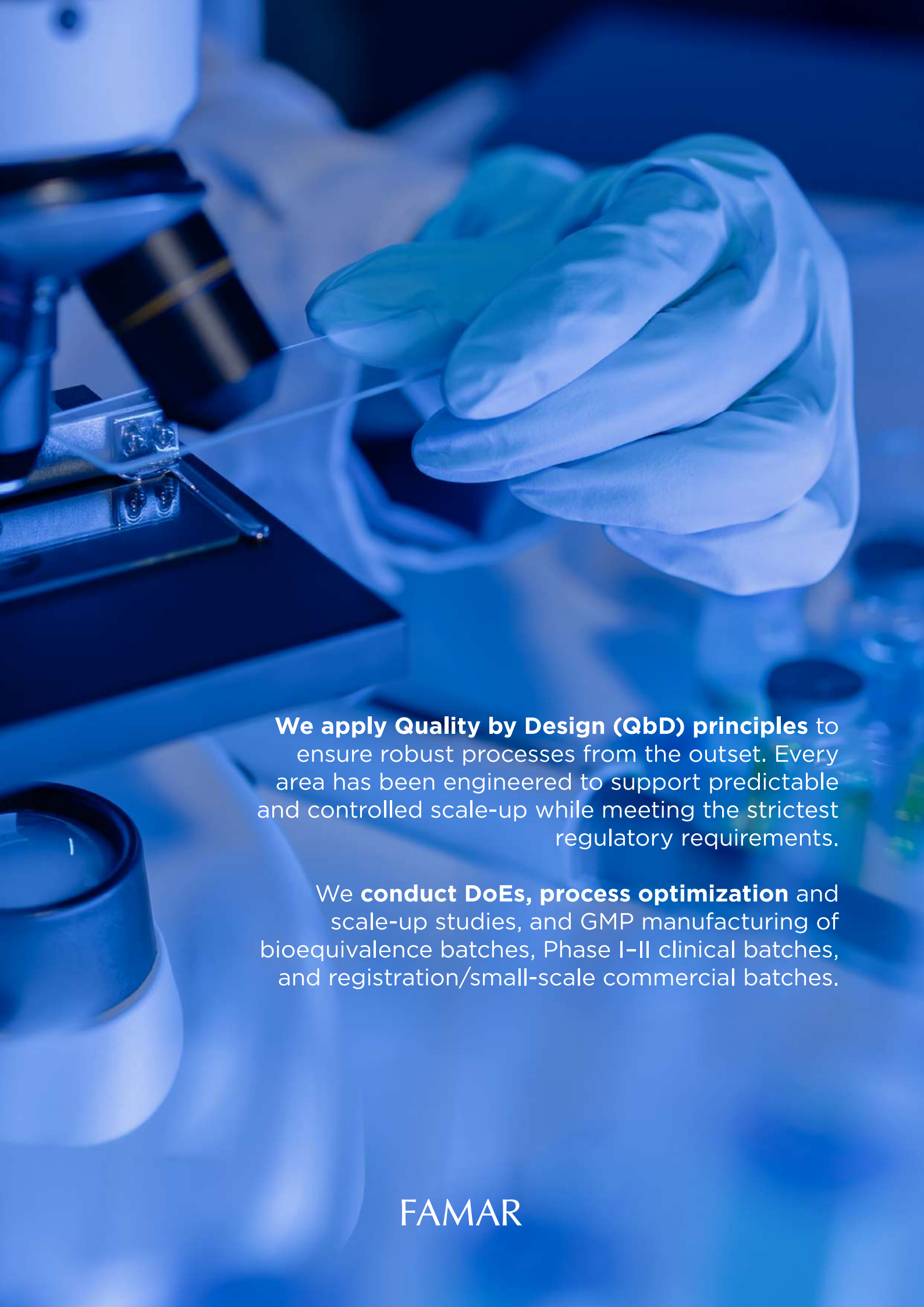
03

Quality by Design: Our QbD Approach



We apply Quality by Design (QbD) principles to ensure robust processes from the outset. Every area has been engineered to support predictable and controlled scale-up while meeting the strictest regulatory requirements.

We **conduct DoEs, process optimization** and scale-up studies, and GMP manufacturing of bioequivalence batches, Phase I–II clinical batches, and registration/small-scale commercial batches.

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04

Modular Technology for Every Process Step

Our **pilot plant** features a modular architecture, enabling us to configure each space to the specific requirements of each project. Rooms are equipped with mobile equipment that allows flexible adaptation to different technologies and batch sizes.

This setup enables us to operate a multipurpose room, designed to support a broad range of processes while ensuring full compliance with containment and GMP requirements.

Our facilities are engineered to accommodate the full range of operations required for oral solid dosage forms, including:

- Pellet formation (extrusion & spheronization, spherical pellets)
- Pellet coating (aqueous & organic)
- Tabletting (tablets and mini tablets)
- Encapsulation (hard capsules)
- Tablet coating (aqueous and organic)
- Clinical Labelling
- Packaging activities
- Weighing
- Sieving
- Mixing
- API micronization
- Direct compression
- Wet granulation (High shear mixer and Fluid bed dryer)
- Dry granulation

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The installed equipment - including technologies from Freund-Vector, Riva, Lugaia, ChargePoint and GEA - has been selected for its robustness, validated containment, and scalability.

All processes can be conducted under **GMP conditions** for **HPAPIs**, handling **OELs** as low as **1 µg/m³** for blends ranging from circa 0,6 Kg to circa 60 Kg. In addition, the system allows for **100% in-process weight control** for both capsules and tablets, ensuring full compliance with quality requirements.

05

Tailored Investments for Strategic Partnerships

Beyond our existing capabilities, we offer the flexibility to adapt or expand specific process areas through targeted investments aligned with product or customer needs.

Whether to support **novel technologies,** or market-specific requirements, our team evaluates and co-develops **custom solutions** together with our partners. This **client-centric approach** ensures maximum alignment with development objectives, regulatory expectations, and **commercial strategy.**

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