

mithra cdmO



Bridging expertise for successful
pharmaceutical development



Overview

- 15,000 m² facilities in Liège (Belgium)
- 55,000 m² land
- 3 Production Units: Polymeric forms, Sterile injectables, Hormonal tablets
- Dedicated R&D and production areas
- Full drug development services
- Pilot, clinical & commercial batches
- GMP standards compliance (EMA / FDA)

An integrated business solution

- **An integrated R&D and manufacturing platform** specialized in polymer technology, sterile injectables and hormonal tablets
- **A pharmaceutical ecosystem:** open platform accessible to partners willing to leverage our technological know-how and capabilities across the drug life-cycle
- **Drug development services:** pharmaceutical development, clinical supply manufacturing, stability studies, contract manufacturing, logistics and supply chain, quality assurance and regulatory services.

Drug Development services



+ Quality assurance and Regulatory services



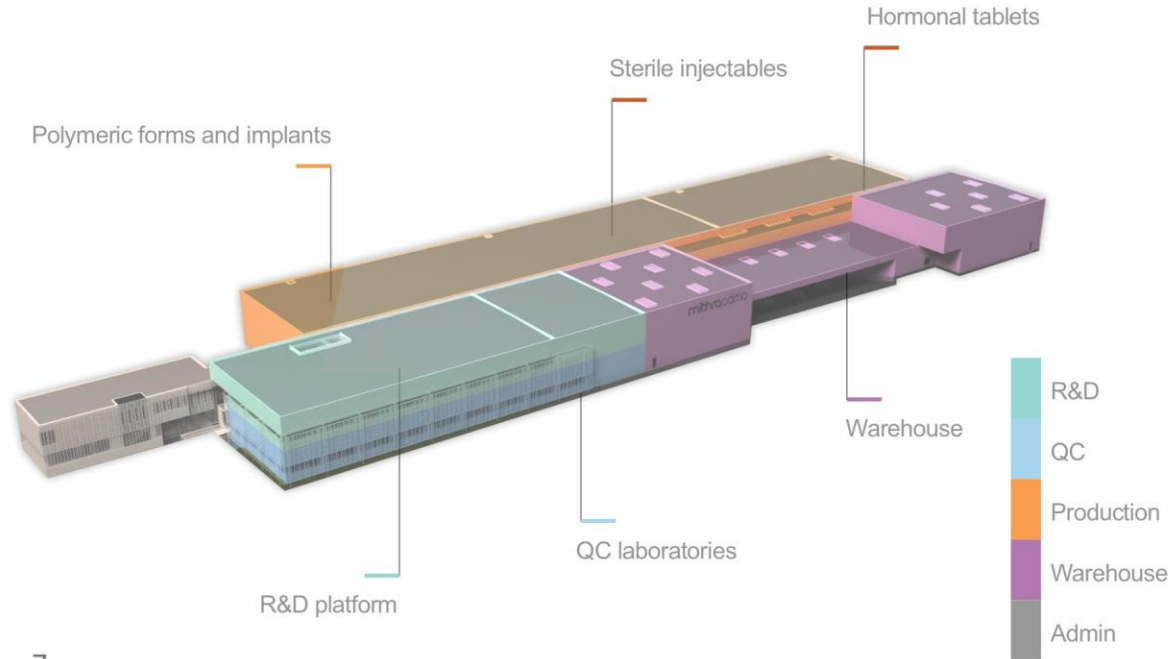
R&D & Manufacturing
platform

Estetrol (E4)

mithra^{cdmo}

Complex
Therapeutic
Solutions

Mithra cdmo is an integrated R&D and manufacturing platform



Rationale of the facility

- Ability to take products from proof of concept to manufacturing
- Quality control, IP and expertise in-house
- Operate independently from 3rd parties using its own proprietary production technology

Construction started as two-phase process

Phase I completed

- R&D facility and production lines for polymeric forms, implants and sterile injectables
- Facility complies with FDA and EMA GMP standards

Phase II (completed by H2 2018)

- Production line for tablets (e.g. Estelle® and Donesta®)

Sterile Injectables



Key figures

- Volume of 5 million units/year - 2 shifts/day
- Production in batch and/or campaign
- Formulation on grade C classification and aseptic filling under isolator, grade A
- Final sterilization (filtration or steam sterilization)
- Cold chain
- Secondary packaging in a non-classified area

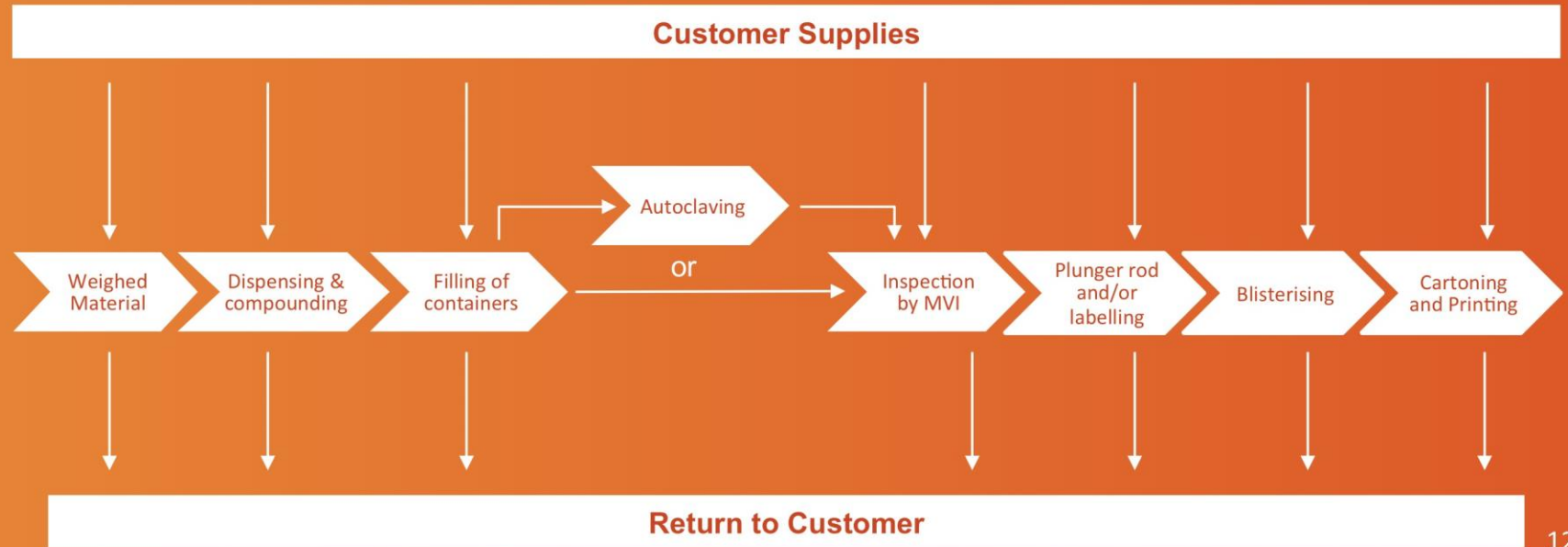


A tailored solution for each customer



- Project Management
- Small & medium batch size
- Depot solution (crystal suspension)
- Possibility to process low and high viscous product (regular and vacuum technology)
- Possibility to process under nitrogen atmosphere
- Full Containment filling line for your products (till OEB 4)
- High security level (Isolator technology)
- Up to 100% automated IPC rate

Flexibility of our production line





Plural Polymer Technology

Long-acting drugs

A complex expertise shared
by only few companies in the
world

- Exclusive expertise in polymer technology for long-acting drugs
- Controlled release
- Duration ranging from 1 month to 5 years
- Multiple drug delivery strategies (intra-uterine devices, vaginal rings, implants,...)
- Multiple therapeutic fields





Processes

- Extrusion and co-extrusion technology for a full range of polymeric forms
- Sampling and weighing of critical and non-critical products in a classified grade C area

Sustainability

- High environmental safety standards: cleaning in place stations (CIP)

Mithra's experience

Non/biodegradable (co)polymers

- EVA
- PCL
- PEG
- PVP
- PLGA
- PLA
- PGA
- PDMS

Broad API's compatibility

- Antivirals (cidofovir)
- LHRH analogs (goserelin, triptorelin, leuprorelin etc.)
- Sexual hormones (levonorgestrel, etonogestrel, and other progestins)
- Aromatase inhibitors (anastrozole)

PCL: Polycaprolactone; LHRH: Luteinizing hormone releasing hormones agonist;
PDMS: polydimethyl siloxane ; EVA: ethylene vinyl acetate; PLA: Polylactide; PGA : Polyglycolide; PLA/PGA: copolymers of
PLA/PGA; PVP: Polyvinylpyrrolidone and derivatives; PEG: Polyethyleneglycol



Multiple administration routes

- Biocompatible rings
- Implants / (hydro) gel
- Intra uterine systems
- Flexible durations:
1 month to 5 years+
- Customizable drug
concentration release

Mithra CDMO offers our partners a full-fledged platform

- Mithra has the equipment, facilities, personnel and over 15 years of experience to support your product development from “proof of concept” to market
- Our facilities and equipment are qualified and documented to meet international industry quality standards
- Mithra can propose a wide variety of technical, regulatory and scientific support to partners looking for a global expertise in the pharmaceutical industry



Ideally located at the heart of Europe

- Optimal motorway network (intersection of the E25, E40 and E42 motorways)
- Rail network with a high-speed railway station
- Liège Airport (7th largest cargo airport in Europe)
- The Port of Liège (3rd biggest river port in Europe) and the multimodal platform Liège Triligiport





Thank you for your attention

www.mithracdmo.com



Inspired by Women