MADE WITH CARE

medichem

FDF

Generics

Chlorhexidine

API

medichem


EXPERTISE
VALUE-ADDED SOLUTIONS
RELIABILITY

MEDICHEM

At a Glance

Meet an independently-owned **developer and manufacturer of Finished Dosage Forms (FDF) and Active Pharmaceutical Ingredients (API)**.

From its headquarters in Barcelona, Spain, Medichem has grown into **one of the largest worldwide manufacturers of Generics and Chlorhexidine in the pharmaceutical industry**.

Over the years, Medichem has been **at the forefront of innovation** and as such has developed 70 value-added and high-quality drug products.

1972

HQ
Barcelona, Spain

OFFICES, R&D AND MANUFACTURING

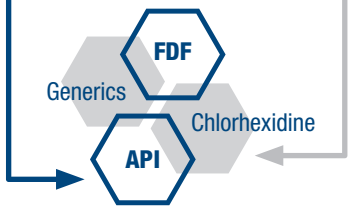
Spain
USA
Malta
China

DELIVERING TO 70 MARKETS

USA
Europe
ROW

VERTICAL INTEGRATION

2 INDEPENDENT BUSINESS UNITS



VALUE-ADDED SOLUTIONS

HPAPI

Intermediates

Contract Services

Patent friendly-environment

UNPARALLELED REGULATORY INSPECTIONS RECORD IN SPAIN AND MALTA FOR DECADES

Among others:

U.S. FOOD & DRUG ADMINISTRATION

cGMP GOOD MANUFACTURING PRACTICE

ISO ISO 14001

46 YEARS

OF WORLDWIDE EXPERIENCE AND RELIABILITY!

People First

OUR GREATEST ASSET

Without the commitment of our 480 employees around the world, Medichem wouldn't be one of the worldwide leading manufacturers in the pharmaceutical industry.

Empowering team members to deliver results at this level requires ongoing investment in our workforce, from recruiting to training to quality-of-life considerations. This is how Medichem supports team members to go above and beyond in their daily work.

MADE WITH CARE

A SIMPLE PLEDGE

Medichem team members have many different backgrounds and talents, yet we share the same perspective: that quality comes first and special care needs to be given to every step of development and manufacturing and during each customer interaction.

EMPLOYEES
480

R&D
18%

QUALITY
16%

LEGAL, IP, REGULATORY
16%

UNIVERSITY GRADUATES
75%

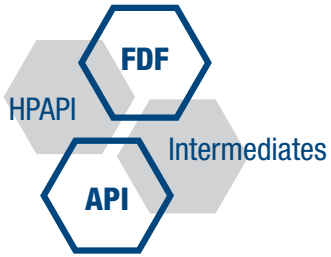
PhDs
15%

medichem

100%
DEVOTED TO EXCELLENCE!

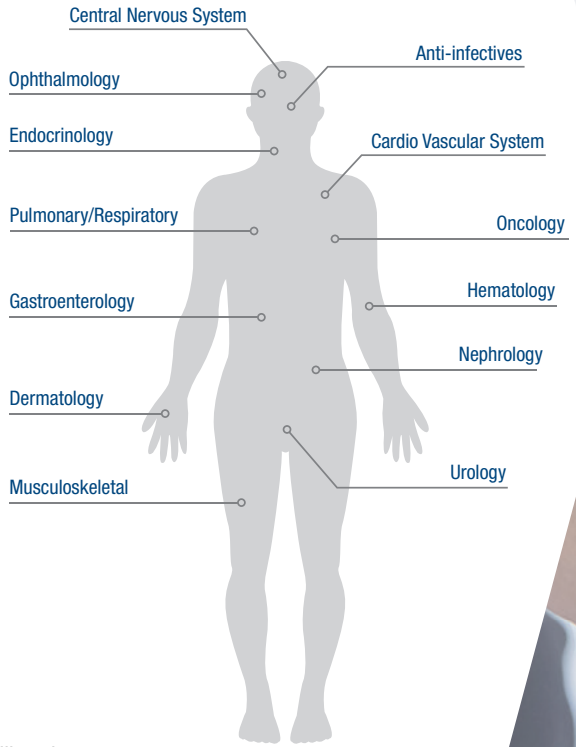
MADE WITH CARE

Specialised Generics



Medichem develops and manufactures cGMP Active Pharmaceutical Ingredients (API), including Highly Potent APIs (HPAPI) and Finished Dosage Forms (FDF).

Over the past few years, Medichem has focused on APIs and FDFs with particular technological barriers, creating 70 value-added products aimed at **various therapeutic areas**.



FINISHED DOSAGE FORMS

More recently, Medichem has turned the **spotlight on FDF, focusing on innovative formulations of injectables and solid oral drugs**.

SOLID ORAL DOSAGE

- Capsules
- Tablets
- Film-coated tablets
- New! Multiparticulates

ORAL SOLUTIONS

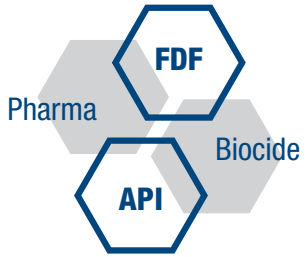
- Oral Solution in bottle

STERILE FORMS

- Nebulizer solution in plastic ampoule blow-fill-seal
- Powder for solution for injection or infusion in glass vial
- Pre-filled syringe
- Solution for injection or infusion in plastic bags

Unstoppable Chlorhexidine

Medichem started manufacturing chlorhexidine salts back in 1985. Since then, we have become one of the world's largest manufacturers while enlarging our portfolio and expanding into new markets.



CHLORHEXIDINE API

BASE

- **Digluconate** 20% solution
- **Diacetate**
- **Dihydrochloride**

READY TO LICENSE-OUT DOSSIERS

PHARMACEUTICAL

0.5% solution
70% alcoholic

Transparent or colored solutions

BIOCIDE

0.5% and 2% solutions

Aqueous, transparent or colored alcohol solutions

Despite the numerous applications for chlorhexidine, we manufacture it using the same quality system we apply to Active Pharmaceutical Ingredients.

ECHA EUROPEAN CHEMICALS AGENCY

Medichem CDG* is listed under article 95 of the EU Biocidal Products Regulation (BPR).

FDA

Successful FDA inspections of our Spanish site since 1999.

edqm European Directorate for the Quality of Medicines & HealthCare

First manufacturer to obtain the CEP back in 1998.

European Pharmacopoeia

Collaboration in the development of the CDG* monograph.

* Chlorhexidine Digluconate

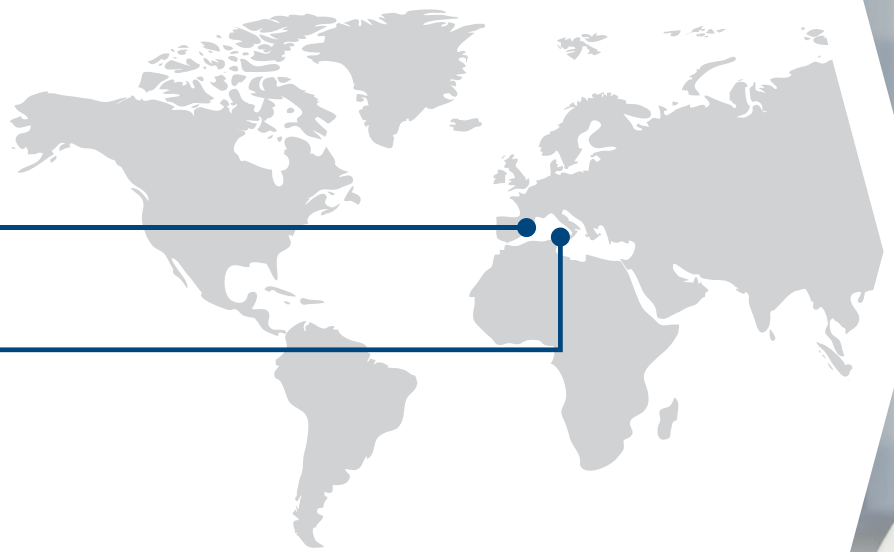
EXPERTISE

Innovation and Excellence

R&D is the root of Medichem's strategy and success. Highly-qualified personnel engage daily in technically challenging projects, with the objective of developing high-quality value-added drug products. Medichem has extensive and proven know-how in solid and injectable dosage forms; moreover, we have HPAPI capabilities that enable us to develop breakthrough products.

From the very first step, every development program is designed to meet all regulatory requirements, to the highest standard of quality, with set goals and achievement monitoring.

WORLDWIDE DEVELOPMENTS



SPAIN
Celrà and Barcelona
API and FDF

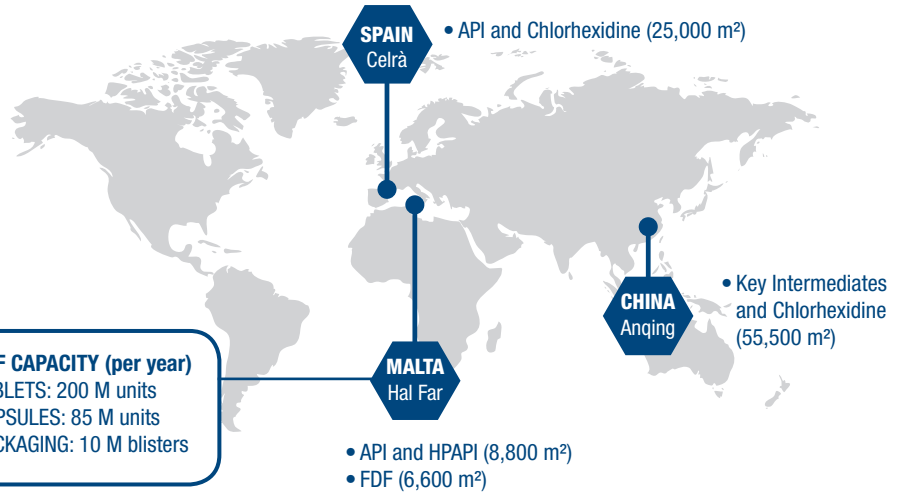
MALTA
Hal Far
API, FDF and HPAPI

20%	Company turnover dedicated to R&D
API & FDF	Extensive API pipeline FDF business exponential growth
UNIQUE	High-value products, combined with new technology platforms
USA	Several new 505(b)2 opportunities in progress

Safety, Quality and Delivery. In that order

When managing multi-purpose production lines, our primary goal is to maintain a safe workplace for our team to be able to manufacture to the highest quality standards of the pharmaceutical industry, while ensuring a timely delivery to our clients.

VERTICALLY-INTEGRATED: FROM INTERMEDIATES TO FDF



STATE-OF-THE-ART TECHNOLOGIES

API

- Flow chemistry
- Nanofiltration
- Chromatographic purification – Ø200 mm
- Hydrogenation – Biazzi®, 10 bar

FDF

- Wet and dry granulation
- Roller compaction
- Coating
- Capsule filling
- Blistering and bottling

HPAPI

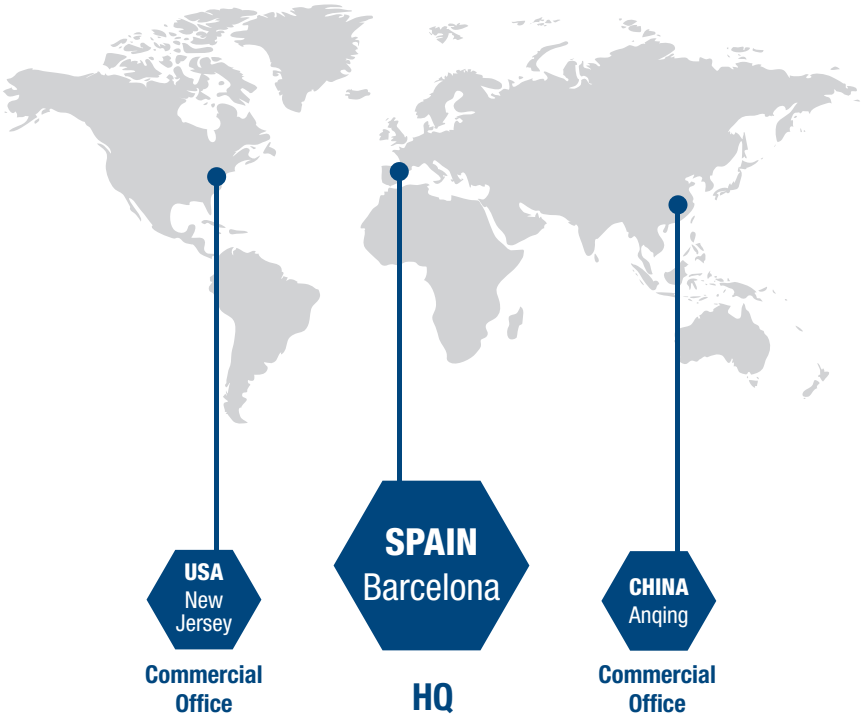
- OEL (Occupation Exposure Limit) down to 40 ng/m³

EXPERTISE

Essential Partnerships

Medichem has developed a solid base of international clients and delivers products to more than 70 countries, including the United States and within Europe, while consolidating alliances with strategic partners.

To better answer our global growth and customer requests, last year Medichem opened an **office in the USA** in addition to our **headquarters in Barcelona**, Spain, and our **commercial office in China**.



Regulatory Affairs

Requests for **scientific data that supports the quality, safety and efficacy of drugs** from Regulatory Authorities all over the world are addressed on a daily basis by Medichem's regulatory team. These key staff members have long-standing expertise dealing with diverse requirement-based scenarios across the world, with a focus on Europe and the USA.

In our team you will find **personalized, agile support** to ensure access to any market in a rapid manner, supported by reliable, scientifically-driven documentation. We provide the best possible grounds for success regardless of how hard to reach it may seem. Nothing is out of reach for us.

LONG-STANDING EXPERTISE

866 MARKETING AUTHORIZATIONS

327 DMFS

15 CERTIFICATES OF SUITABILITY

…submitted to date to Regulatory Agencies around the globe

VALUE-ADDED SOLUTIONS

Be first-to-market

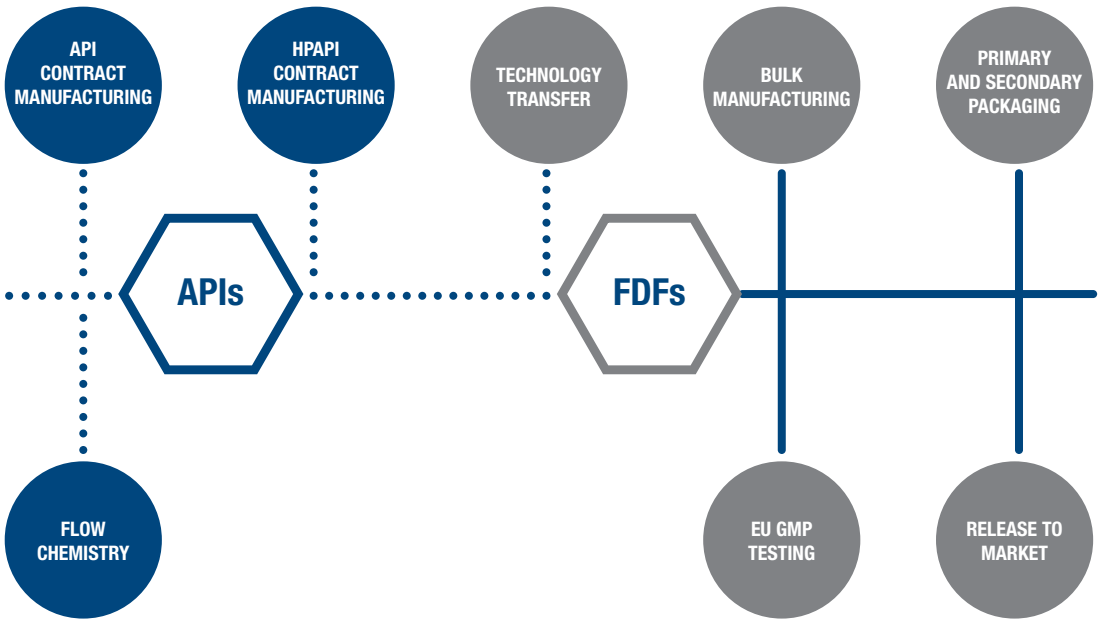
INTELLECTUAL PROPERTY is a key strategic asset at Medichem, which fully supports and protects the business interests of Medichem and its clients. Thanks to its two strategic facilities in Malta, Medichem can provide clients with first-to-market opportunities. While in full respect of intellectual property rights, the country's unique patent situation allows **generic drugs to be produced in advance of patent expiry to ensure medicines are available from the first day after their expiration date in any given market**.

Products are selected with an advantageous patent strategy, ensuring the freedom to operate and at the same time protecting Medichem's innovative ideas with a global patent portfolio. Medichem's experienced IP team employs multiple IP approaches creating both long- and short-term competitive advantages.

Contract Services

Medichem offers a wide range of contract services, whether that be the manufacturing of APIs (including HPAPI) or the manufacturing and packaging of the finished dosage form, testing or release services.

TAILOR-MADE SOLUTIONS



The strategic planning and location in Malta of Medichem and Combino Pharm allow the launch of new products to the market, from the first day after the expiration date of the patent. Being the first to launch is without a doubt key to achieving optimal market penetration.

RELIABILITY

Reliability, a company value built over 46 years

Medichem consolidated its business model between 1972 and 1985. During this time, a generic company earned the first “Paragraph IV” patent certification from the US regulatory agency, the FDA, using the API produced by Medichem. **This paved the way for Medichem’s market expansion in the USA and globally**.

medichem

Combino Pharm

1972 — **THE FOUNDING OF MEDICHEM**

1985-2004 — **US MARKET ENTRY**

- The first **FDA** audit, API – Spain – 1985

2005-12 — **EU EXPANSION**

Start of Malta facilities

- The first EU **GMP** certification: **API** – 2007, FDF – 2006
- The first **FDA** audit: API – 2007
- **FDF** licensing-out in Europe
- Start of the **HPAPI** unit in Malta

The first EU GMP Certification, Spain – 2008

2009-14 — **ASIAN EXPANSION**

- The first Japanese **PMDA** inspections, Spain – 2009
- The founding of the **R&D** center in Nanjing, China
- Joint Venture – **API intermediates** plant, China
- The first Korean FDA (**MFDS**) inspection, Spain – 2012

2015-16 — **SPANISH ENTITIES CONSOLIDATION**

- Medichem and Combino Pharm **merge**

2016-18 — **US EXPANSION AND ESTABLISHMENT**

- **The first FDA** audit: **FDF** – 2016
- Five **ANDAs** filed
- Opening of the **US Office**

TODAY — **WORLDWIDE EXPERTISE AND RELIABILITY**

- Final client distribution

40% North America **30%** Europe **30%** ROW

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