

MEDICHEM

**UNIQUE
PHARMACEUTICALS
AND MUCH MORE...**



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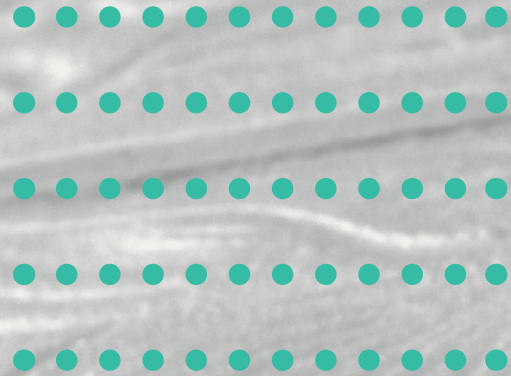
MEET MEDICHEM

Meet an independently-owned **Active Pharmaceutical Ingredients (APIs) and Finished Dosage Forms (FDFs)** developer and manufacturer. Based in Barcelona (Spain), active in Malta and China, delivering medicines to over 60 markets across the world –including the U.S. and EU- Medichem is a fully-integrated pharmaceutical company with a unique portfolio of non-infringing APIs and FDFs.

Our **FDA-inspected APIs manufacturing plants** are located in Spain and Malta, with capacity to develop and produce **Highly Potent APIs (HPAPIs)**. Medichem manufacturing capabilities for solid oral forms are located in Malta. Some ANDAs have already been filed with FDA and we are waiting to receive a pre-approval inspection. The Maltese plants also offer contract services for third parties in search of a patent-friendly environment. Additionally, our premises in China are fully equipped for the synthesis of intermediates and APIs.

Each and every achievement along the past four decades comes from our highly committed and talented staff, 20% of which work in R&D. Medichem's specialised team includes more than 400 professionals, 39 years old as average, 53% of them university graduates, 100% devoted to excellence.

OUR MISSION, as agreed by the whole team, is to become a trustworthy partner in the development, manufacturing and marketing of unique high quality Active Pharmaceutical Ingredients and Medicines and delivering value to all stakeholders based on efficiency, transparency and innovation.



OUR BUSINESS UNITS

GENERIC APIs & FDFs
CHLORHEXIDINE
CONTRACT SERVICES





WHAT WE DO

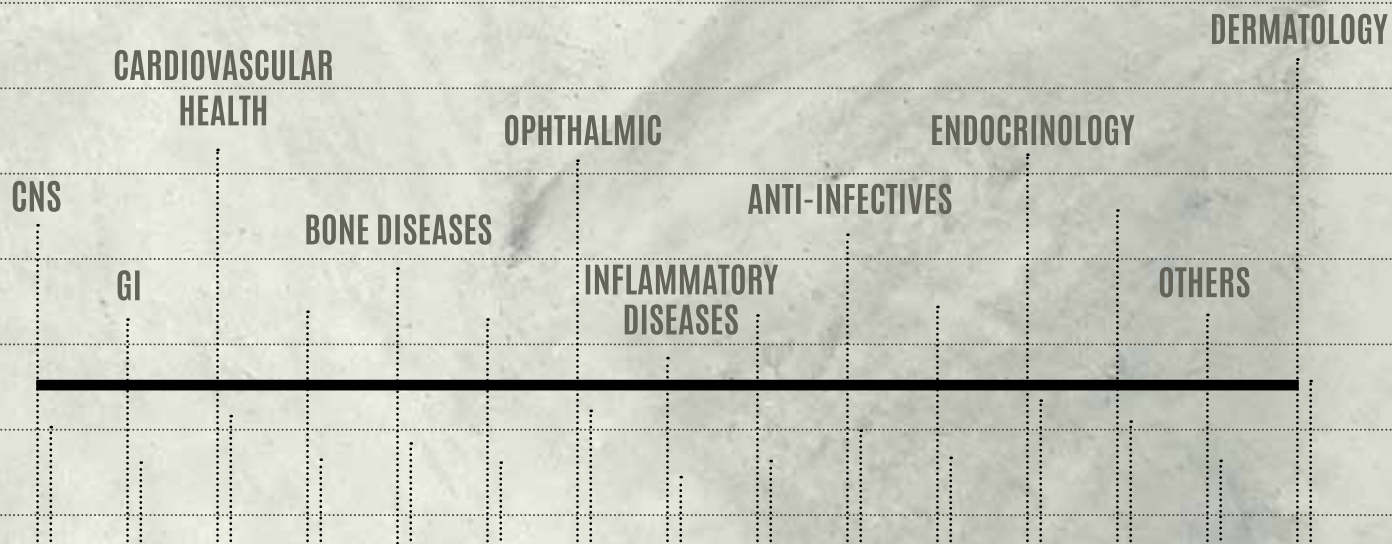
GENERIC APIs & FDFs

Medichem develops and manufactures non-infringing cGMP Active Pharmaceutical Ingredients (APIs), including Highly Potent APIs (HPAPIs), and Finished Dosage Forms mainly injectable and oral generic drugs. We have a long-standing experience and know-how in the development and manufacture of generic medicines, together with the registration of generic medicines' dossiers.

Over the past few years, Medichem has developed a focus on APIs and FDFs with particular technological barriers, which limits competition considerably.

Our portfolio includes over 65 products in 15 areas: CNS, cardiovascular health, ophthalmic, anti-infectives, endocrinology, dermatology, bone diseases, GI and inflammatory diseases, among others.

By entering the HPAPIs arena Medichem is ready to offer customers an even broader portfolio.





LEADING CHLORHEXIDINE

Medichem started manufacturing chlorhexidine salts back in 1985. Since then, we have been able to grow our market share and become one of the largest manufacturers worldwide. We produce:

CHLORHEXIDINE
BASE

CHLORHEXIDINE
DIGLUCONATE 20% SOLUTION

CHLORHEXIDINE
DIACETATE

CHLORHEXIDINE
DIHYDROCHLORIDE

Although there are a number of different applications for chlorhexidine, we manufacture using the same quality system as we apply to the manufacture of the pharmaceutical active ingredients. The last FDA inspections to our Spanish site also covered chlorhexidine with good results (no form 483 in the last 12 years). We were also the **first chlorhexidine digluconate manufacturer to obtain the CEP by the EDQM back in 1998**. Medichem also contributed to the development of the current monograph for chlorhexidine digluconate in collaboration with the European Pharmacopoeia.

The three salts are registered as pharmaceutical active ingredients in the US, Australia, Taiwan, Korea and European countries to name just a few. Medichem has also notified chlorhexidine digluconate as a biocidal active ingredient for product-types 1, 2 and 3 under the EU Biocidal Products Directive (BPD) and is therefore included in the list of active substances and suppliers according to Article 95 of the **EU Biocidal Products Regulation (BPR)**. Registration of chlorhexidine digluconate according to Regulation 1907/2006/EC (REACH) is also available, as well as pre-registration of the other salts, chlorhexidine diacetate and chlorhexidine dihydrochloride.

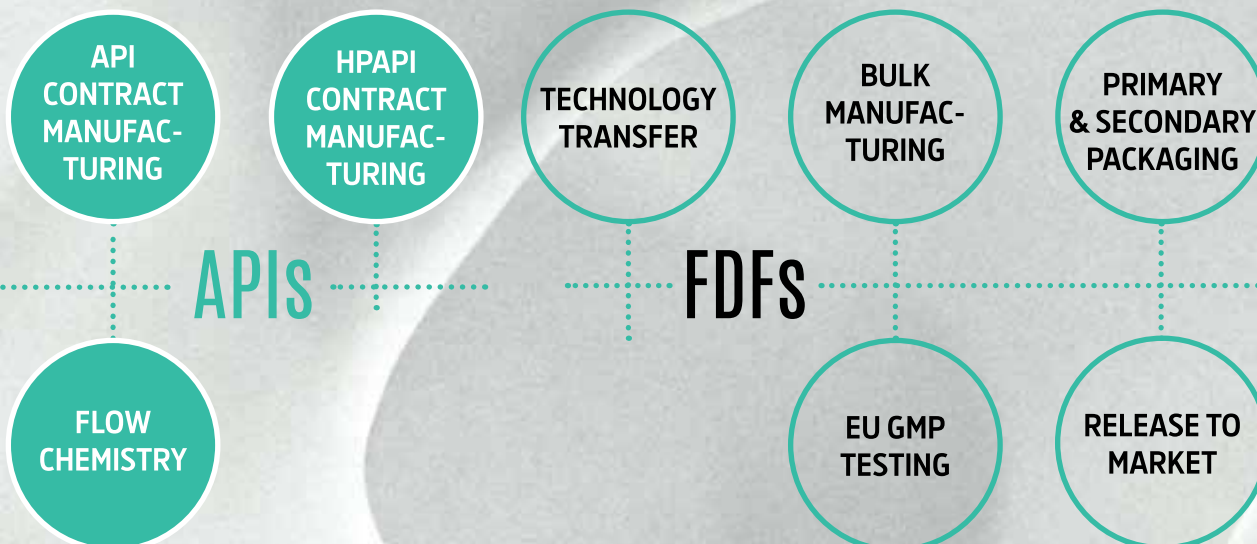
Regarding formulation, **we have 2 products already on the market (2% CHG alcoholic and 2% CHG aqueous)** and we are about to register 2 more products. Our aim is to have a broad range of chlorhexidine formulations in the market which will be available for licensing.

Medichem has also applied for Halal certification.



WHAT WE DO

CONTRACT SERVICES



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

The strategic planning and location of Medichem and Combino Pharm plants allows the launch of new products on market starting day 1 from patent expiry. **Being first to launch is without a doubt key to achieve optimal market penetration.**



OUR SITES

MANUFACTURING SITES:

SPAIN [CELRÀ]

APIs and Chlorhexidine [25.000 m²]

MALTA [HAL FAR]

APIs [8.800 m²] and oral finished dosage forms [6.600 m²]

CHINA [ANHUI]

APIs intermediates and Chlorhexidine [97.000 m²]

R+D CENTERS:

SPAIN [CELRÀ AND BARCELONA]

Development of APIs and FDFs

MALTA [HAL FAR]

Development of APIs and FDFs

CHINA [NANJING]

Development of APIs



OUR CAPACITIES

API Capacity

SPAIN

- **GLASS LINED:**
60 m³, 20 reactors
- **STAINLESS STEEL:**
70 m³, 20 reactors
- **TANK FARM:**
600 m³

MALTA

- **GLASS LINED:**
7 m³, 4 reactors
- **STAINLESS STEEL:**
4 m³, 3 reactors
- **TANK FARM:**
40 m³

CHINA

- **GLASS LINED:**
76 m³, 54 reactors
(155 m³, 72 reactors
from 2016)
- **TANK FARM:**
160 m³

FDF Capacity

MALTA

- **TABLETS:**
200,000,000 / year
- **CAPSULES:**
85,000,000 / year
- **PACKAGING:**
10,000,000 blister / year

Equipment

Common:

- Reactors
- Centrifuges
- Filter-dryers
- Paddle-dryers
- Pin mills
- Conical mills
- Micronizers

Special features:

- Corning® Continuous Flow G4
- Hydrogenator Biazzi® to 10 bars
- Preparative HPLC 200 Ø mm
- Micronizer from 50 Ø to 300 Ø mm
- Temp -80° C to +200° C

HPAPI Capacity

MALTA

- **Class 4:** OEL down to
40 ng/m³
- **Reactors:** 2 x 15 lt
- Nutsche Filter, Dryer,
Mill and Micronizer.

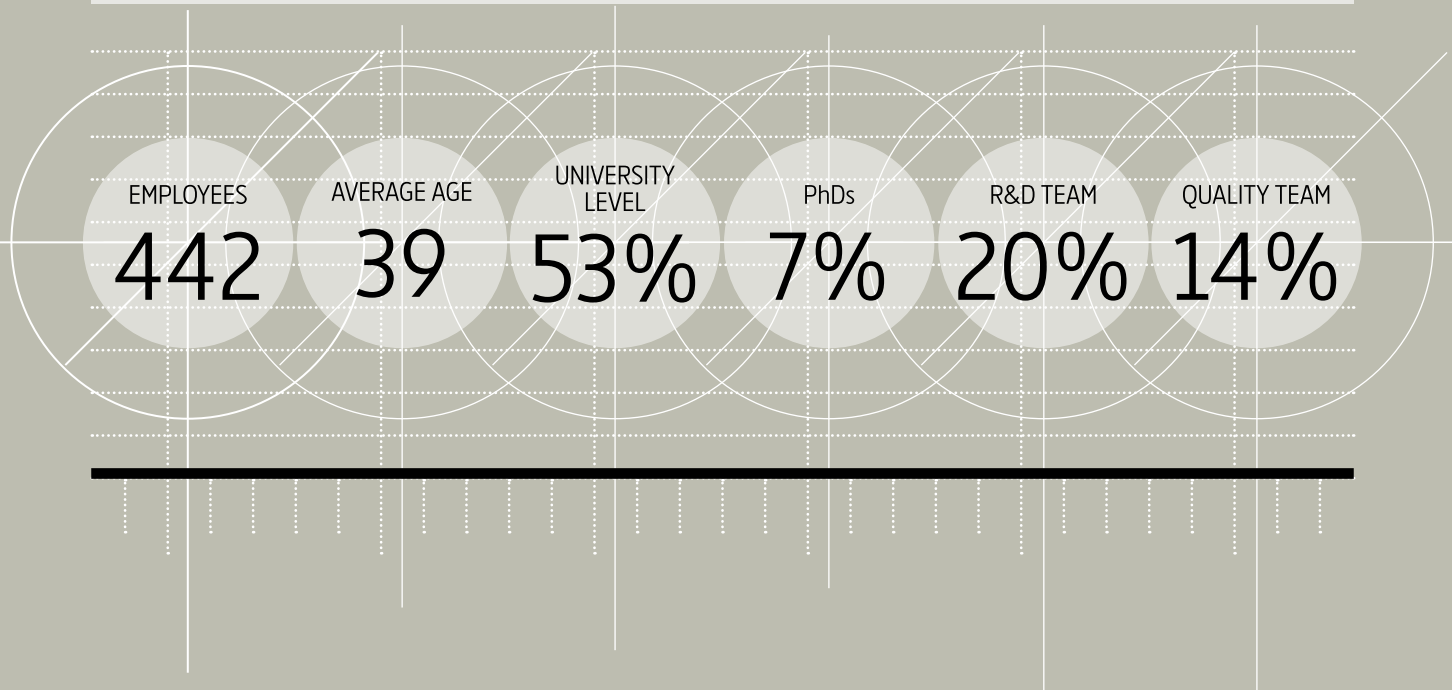


OUR TEAM, YOUR TEAM

Think of Medichem's people as 'your people'. In them you will find a commitment with excellence as a trademark. A dynamic group used to co-operation with geographically and culturally diverse teams which largely explains Medichem's skills to perform in markets around the world.

As our alliances with strategic partners grow and consolidate, our team's hand has reached over 60 countries where the best services will be provided to your company.

Medichem's staff includes over 400 people carrying on with their work in Spain, Malta and China, with partners across the world.





BUSINESS DEVELOPMENT

Medichem has a solid base of international customers and delivers products to more than 60 countries (United States and European countries, among others).

COMING TOGETHER...

Medichem's flexibility is largely based in a collaborative approach to our customers' needs, seeking the best partners so that the best and the brightest in every field are at hand whenever required.

Ad hoc solutions are provided not only by our team, but also by others who join us in creative, long-lasting partnerships to minimise costs and speed-up all processes.

Challenge us with creative, outside-the-box thoughts regarding collaboration formulae.

AD HOC SOLUTIONS



INNOVATION MOVES US

Medichem's strategy and success are firmly based on our R&D division. Highly qualified personnel are prepared to engage in technically challenging projects, with the main objective of developing high quality drug products with added value. **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 developing programme is designed to meet all regulatory requirements, under the highest standards of quality, with set goals and while monitoring achievements. At Medichem, clinical studies are carried out strictly under the most demanding quality requirements and aimed at delivering the best pharmaceutical products.

Medichem is also proud to be one of the first generic firms to incorporate flow chemistry in its manufacturing processes.

As the world around us gets more competitive, **INNOVATION** and **MASTERY** of state-of-the-art technology are a must. Medichem's focus on R&D guarantees growth and hands over the capacity of seizing new opportunities to improve healthcare.

R+D

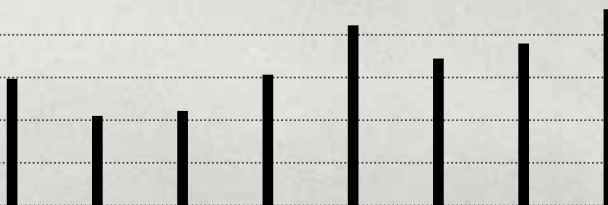


REGULATORY AFFAIRS: SETTING THE BAR HIGHER

Demands of scientific data supporting drugs' safety, efficacy and quality from regulatory authorities worldwide are addressed on a daily basis by Medichem's regulatory team. This key staff have long-standing expertise dealing with diverse requirement-based scenarios across the world, with a focus on Europe and U.S.

Medichem and Combino Pharm add up to over 810 Marketing Authorisations, over 250 DMFs and 13 Certificates of Suitability for APIs submitted to regulatory agencies around the globe.

In our team you will find personalized, agile support to ensure access to any market in a rapid manner, supported by reliable, scientific-driven documentation. **The best possible grounds for success regardless how far it may seem, there is no "out of reach" for us.**





INTELLECTUAL PROPERTY: HOW TO BE FIRST

IP is a key strategic asset in Medichem by fully supporting and protecting 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 producing generics drugs in advance of patent expiry to ensure medicines are available starting day 1 from the expiration date in any given market.

Products are selected with an advantageous patent strategy, ensuring 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 long- and short-term competitive advantages.





Medichem consolidated its business model from 1972 to 1985. That year, a generic company won the first “Paragraph IV” patent certification by U.S. regulator FDA using the API produced by Medichem. Three decades later, history continues to be made in Medichem as we embrace the challenge of the latest, most complicated molecules.

In a changing, ever more challenging arena, Medichem has steadily adapted and grown thanks to our customers’ support and our team’s enthusiasm.

HISTORY REVEALED

1985-2004

Medichem: 1st FDA audit and growth of the US market
Combino Pharm: Launch of the hospital generics division in Spain

2005-2011

Opening of Malta sites (API & oral FDF)
Combino Pharm: Sales of licensed FDFs in Europe
Combino Pharm Portugal operational in hospitals

2012-2014

Medichem: R&D center in Nanjing
Joint Venture in China
Medichem: HPAPI unit in Malta

2015-2016

Combino Pharm: Divestment of B2C hospital business in Spain and Portugal

2016

Merger of Medichem and Combino Pharm



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MEDICHEM BARCELONA 2016

Images from the modernist architecture of Barcelona