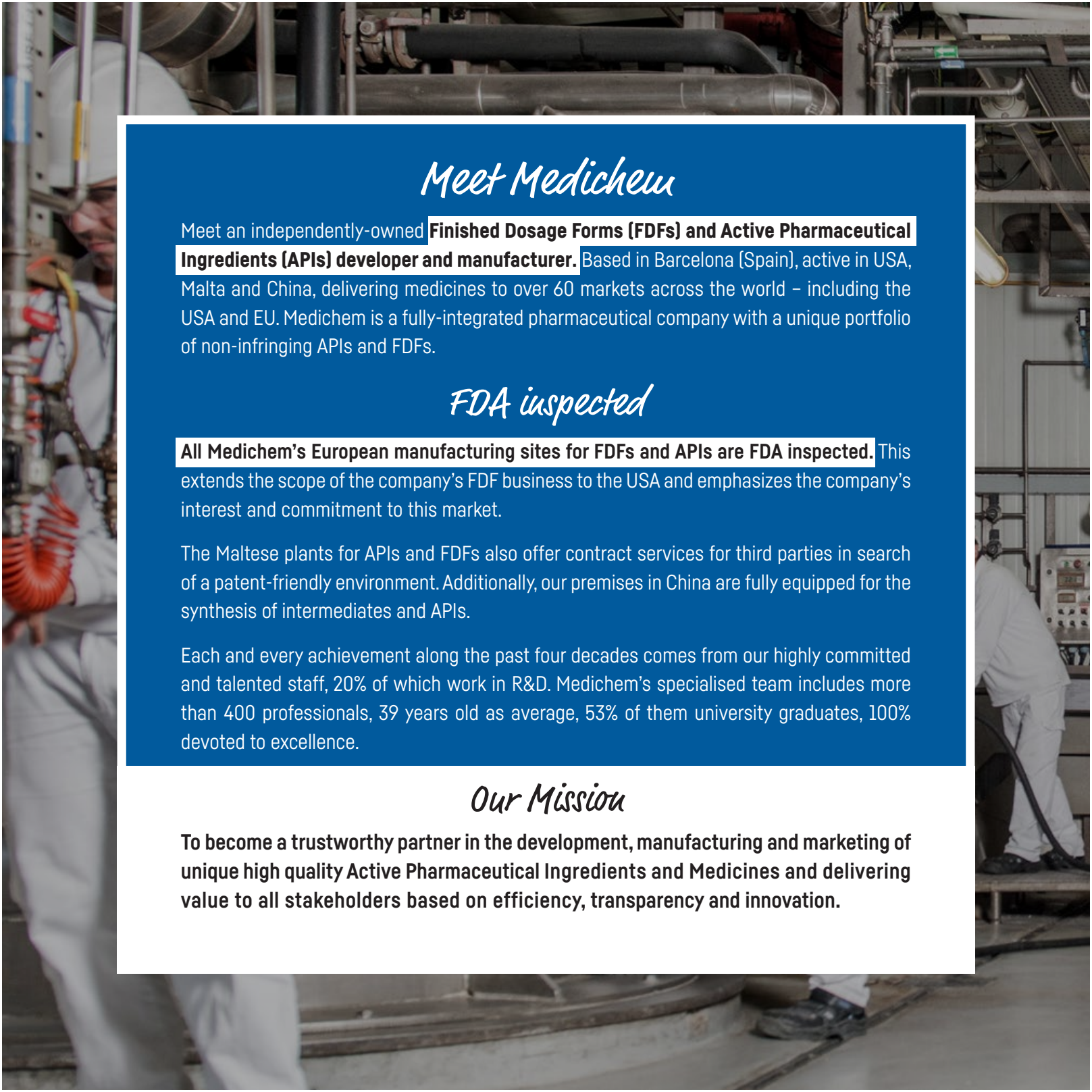

medichem
Who we are
Let's work together on achieving your unique goals.
Unique³
Unique Products
Unique Customers
Unique Team
OCT 2017



Meet Medichem

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

FDA inspected

All Medichem's European manufacturing sites for FDFs and APIs are FDA inspected. This extends the scope of the company's FDF business to the USA and emphasizes the company's interest and commitment to this market.

The Maltese plants for APIs and FDFs 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

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 FDFs & APIs
CHLORHEXIDINE
CONTRACT SERVICES

WHAT WE DO

Generic FDFs & APIs

Medichem develops and manufactures non-infringing cGMP Active Pharmaceutical Ingredients, 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 70 products in 15 different therapeutic areas: Cardiovascular, Central Nervous System, Dermatology, Ophthalmology, Endocrinology, Anti-infectives, Gastroenterology, among others.

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

- CARDIOVASCULAR
- CENTRAL NERVOUS SYSTEM
- DERMATOLOGY
- OPHTHALMOLOGY
- ENDOCRINOLOGY
- ANTI-INFECTIVES
- GASTROENTEROLOGY

WHAT WE DO

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.

Chlorhexidine salts are registered as pharmaceutical active ingredient in several countries. Medichem has also notified chlorhexidine digluconate as a biocidal active ingredient for product-types 1, 2 and 3 and is therefore included in the list of active substances and suppliers according to Article 95 of the EU Biocidal Products Regulation (BPR). Medichem is also compliant with regulation 1907/2006/EC (REACH) for chlorhexidine salts.

CHLORHEXIDINE FORMULATIONS:

Medichem has 2 products already on the market:

- **CHG Aqueous solution 2%**
- **CHG Alcoholic coloured solution 2%**

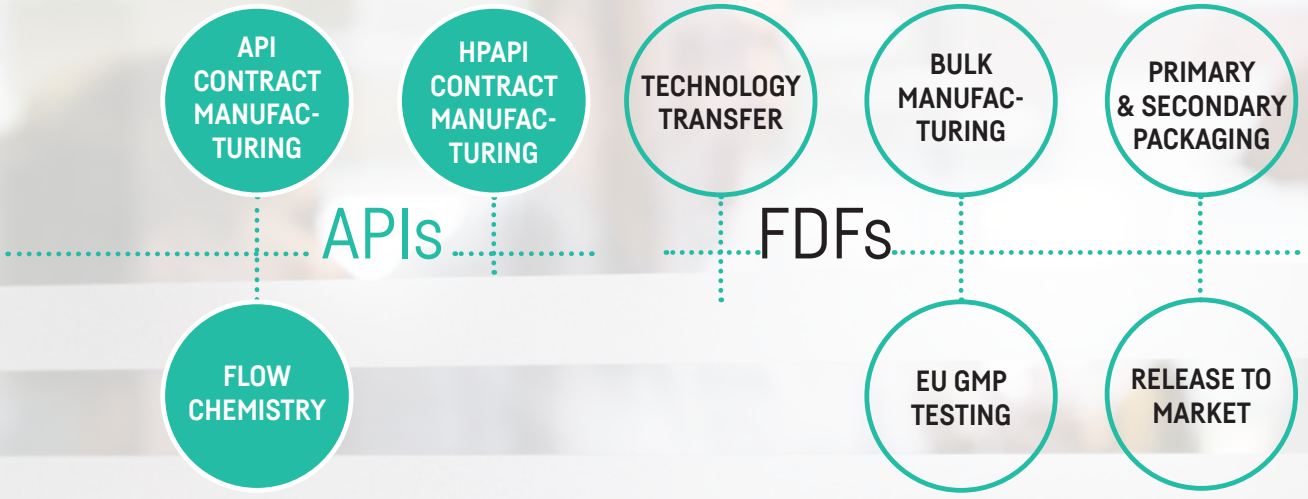
And we expect the authorization of:

- **CHG Aqueous solution 0.5%**
- **CHG Alcoholic solution 0.5% and 2%**
- **CHG Alcoholic coloured solution 0.5%**

Furthermore we have other products under development. Our aim is to have a broad range of chlorhexidine formulations in the market which will be available for licensing.

WHAT WE DO

Contract Services



We're here to help

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.

WHERE WE ARE

Our sites

Global reach

OUR MANUFACTURING SITES

SPAIN [CELRÀ]

APIs and Chlorhexidine [25.000 m^2]

MALTA [HAL FAR]

APIs [8.800 m^2] and oral finished dosage forms [6.600 m^2]

CHINA [ANHUI]

APIs intermediates and Chlorhexidine [55.000 m^2]

OUR 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 COMMERCIAL OFFICES

SPAIN [BARCELONA]

USA [NEW JERSEY]

CHINA [NANJING]

HOW MUCH WE PRODUCE

Our capacities

API Capacity

SPAIN

- GLASS LINED: 60 m^3, 20 reactors
- STAINLESS STEEL: 70 m^3, 20 reactors
- TANK FARM: 600 m^3

MALTA

- GLASS LINED: 7 m^3, 4 reactors
- STAINLESS STEEL: 4 m^3, 3 reactors
- TANK FARM: 40 m^3

CHINA

- GLASS LINED: 149 m^3, 69 reactors
- TANK FARM: 160 m^3

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
- Nanofiltration

HPAPI Capacity

MALTA

- Class 4: OEL down to 40 ng/m^3
- Reactors: 2 x 15 lt
- Nutsche Filter, Dryer, Mill and Micronizer.

WHO WE ARE

Our team, your team

EMPLOYEES	AVERAGE AGE	UNIVERSITY LEVEL
450	39	53%

PhDs	R&D TEAM	QUALITY TEAM
7%	20%	14%

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 450 people carrying on with their work in Spain, Malta, USA and China, with partners across the world.

WHERE WE WORK

Business Development

Coming Together

Medichem has a solid base of international customers and delivers products to more than 60 countries in the United States, Europe and others.

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!

HOW WE INNOVATE

Innovation moves us

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.

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.

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

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.

REGULATORY AFFAIRS

Setting the bar higher

MEDICHEM ADDS UP TO OVER 810 MARKETING AUTHORISATIONS, OVER **300** DMFs AND **15** CERTIFICATES OF SUITABILITY FOR APIs SUBMITTED TO REGULATORY AGENCIES AROUND THE GLOBE.

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 the USA.

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.

OUR HISTORY

Over 40 years of success

Medichem consolidated its business model from 1972 to 1985. That year, a generic company won the first "Paragraph IV" patent certification by the USA regulator the 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.

1985-2004

- Medichem: 1st FDA audit and growth of the US market
- Combino Pharm: Launch of hospital B2C generic division in Spain

2005-11

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

2012-14

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

2015-16

- Combino Pharm: Divestment of B2C hospital business in Spain and Portugal
- Internal restructuring merging the Spanish entities Medichem and Combino Pharm

2016-17

- First ANDA submitted fully developed by Medichem and manufactured by Combino Pharm Malta
- 1st FDA Audit Combino Pharm Malta plant
- Start of operations Medichem USA affiliate

CONTACT US

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