



CORPORATE PRESENTATION

March 2021

MADE WITH CARE



CORPORATE PRESENTATION



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1

ABOUT MEDICHEM





Independently owned **API and FDF Developer** and **Manufacturer**

Proven track record with **FDA** and the **main International Regulatory Agencies**

Committed to **On-Time Delivery** and **Outstanding Quality**

Supports Customers to help them achieve their **Goals**

1972

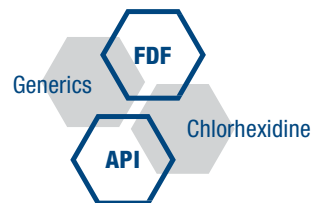


OFFICES
R&D /MANUFACTURING

- › Spain
- › Malta
- › USA
- › China
- › Spain
- › Malta



VERTICAL INTEGRATION



2 INDEPENDENT BUSINESS UNITS



BEYOND OUR CORE BUSINESS

- › HPAPI
- › Intermediates
- › Contract Services
- › Patent friendly-environment



UNPARALLELED REGULATORY INSPECTIONS RECORD



GOOD MANUFACTURING PRACTICE

ALMOST
50 YEARS

OF WORLDWIDE EXPERIENCE AND RELIABILITY!

Reliable

“Our dedicated team pays special attention...”



**MADE
WITH
CARE**

Customer Oriented

...during each interaction with the Customer.”



Quality-driven

.... to every step of development and manufacturing ...



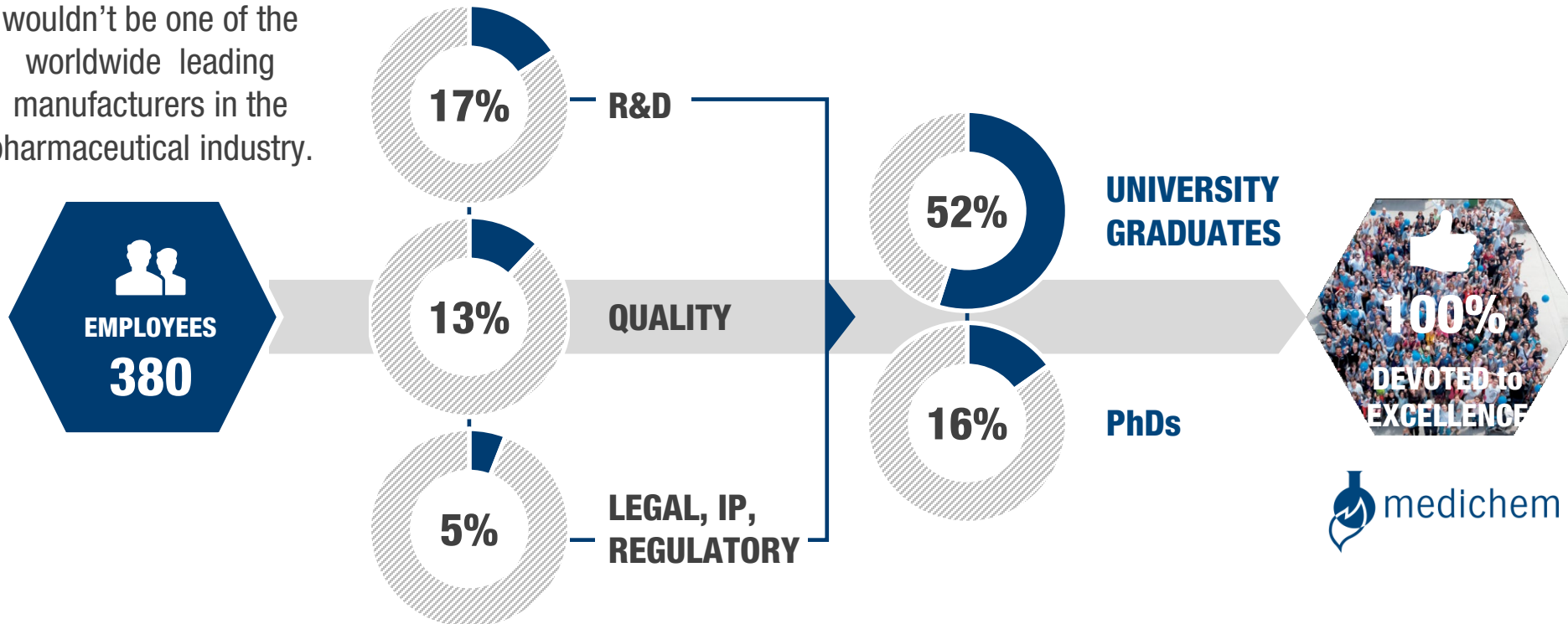
2

MEDICHEM CARES



Our Greatest Asset

Without the commitment of our 380 employees around the world, Medichem wouldn't be one of the worldwide leading manufacturers in the pharmaceutical industry.



Promoting productive relationships in Medichem based on respect

Respect



Bringing out the best in our work, generating trust in others

Trust and Responsibility



Teamwork

Working together in a cohesive way towards a common goal



Communication & Transparency

Always encouraging our colleagues' participation, being honest.

Continuous Change

Building opportunities to do things more efficiently

At Medichem, we are committed to being a caring citizen in the communities where we live and work.

We are passionate about improving the quality of life around us.



Medichem is actively engaged in managing and controlling the impact of pharmaceuticals in the environment.

Environmental Management: ISO 14001

- › Medichem was first certified according to ISO 14001 in 2001.
- › Since then it has been subject to annual follow-up audits and to re-certification every three years.
- › Medichem is certified by the Spanish Association for Standardization and Certification, AENOR.



Medichem is certified
by SGS.
The current certificate
is dated July 2019.



Medichem is member of the AMR via the representation of Medicines for Europe

(European Generic Association).



The AMR Industry Alliance brings together biotech, diagnostics, generics and research-based pharmaceutical companies, to drive and measure industry progress to curb antimicrobial resistance.

3

OUR PRODUCTS



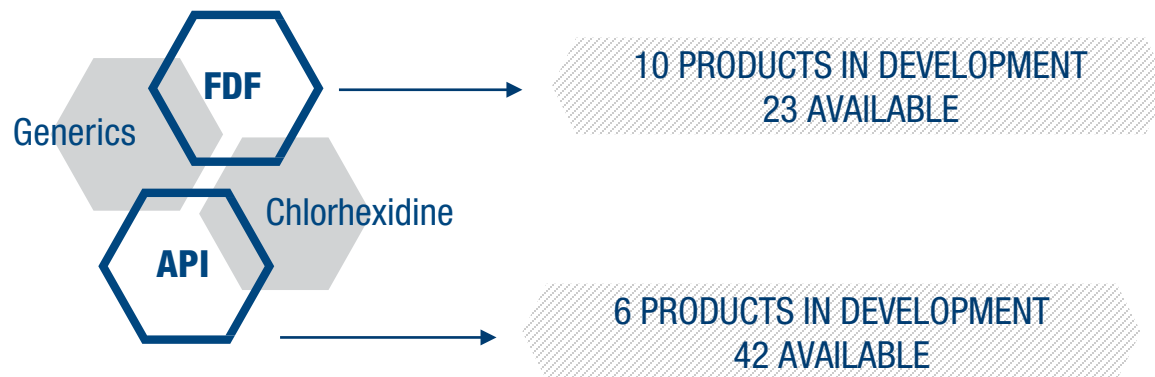
INTRODUCTION TO OUR RANGE OF PRODUCTS



**2 INDEPENDENT
BUSINESS UNITS**



**VERTICAL
INTEGRATION**

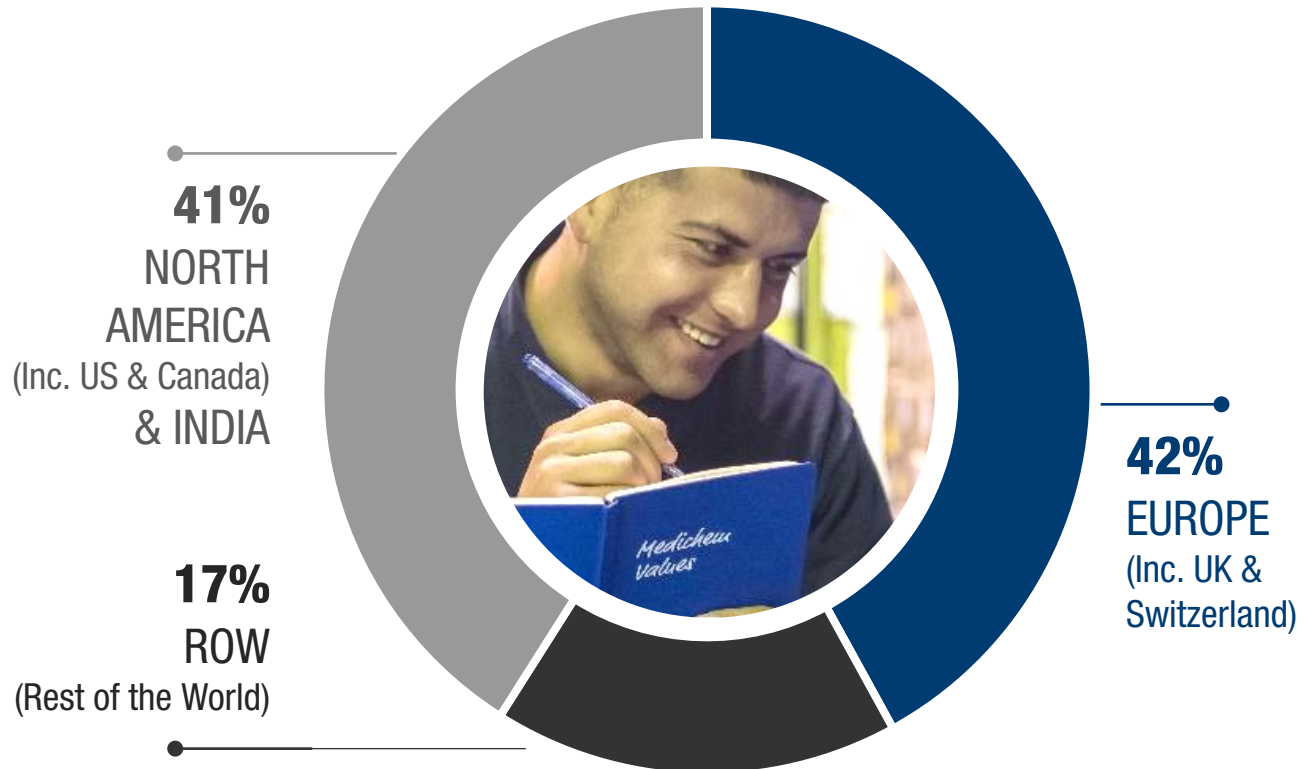




Sales in 2020:

€ 114 M

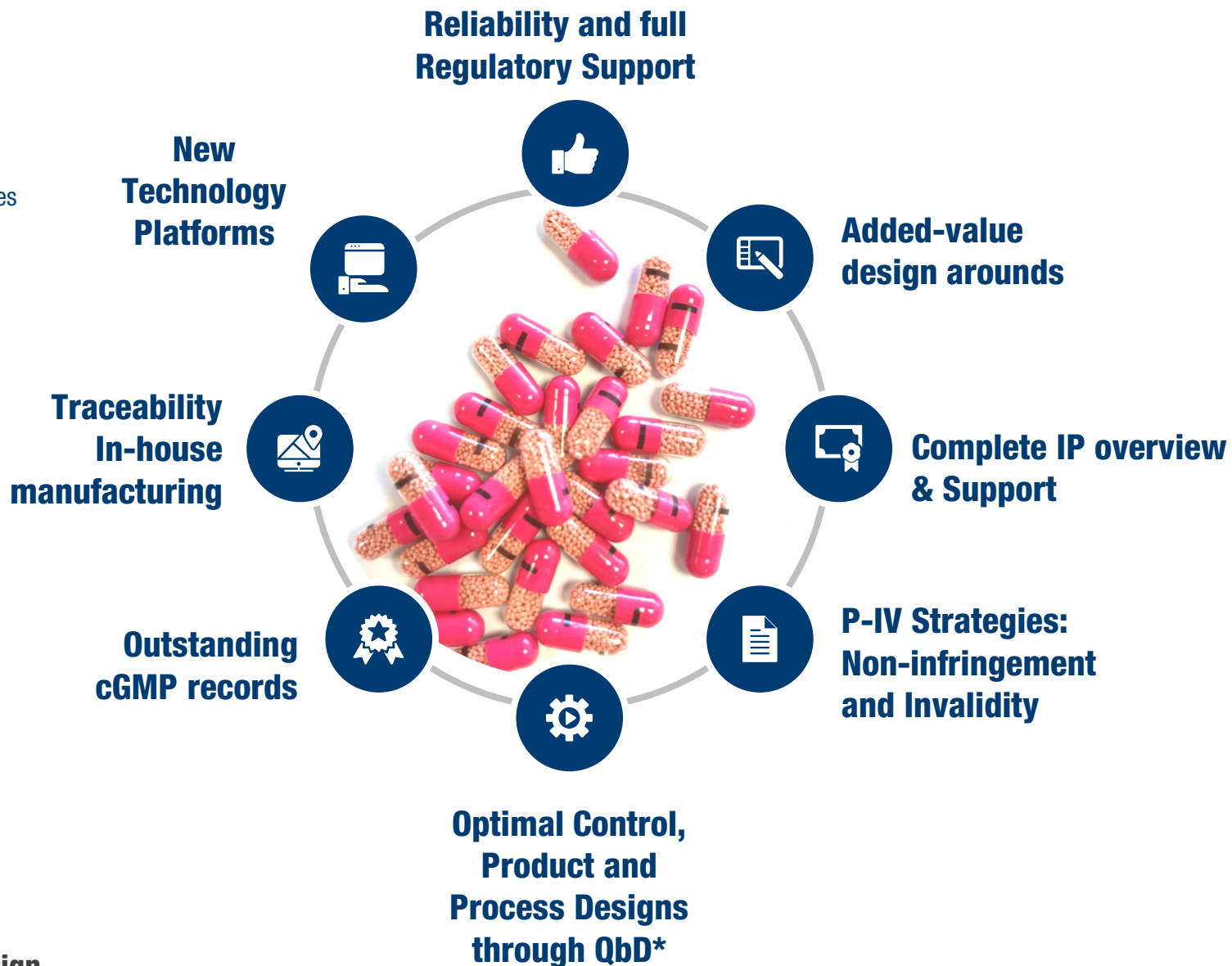
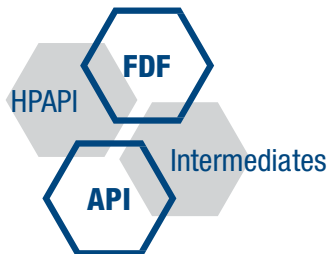
\$ 131 M



3.1

**ADDED-
VALUE
GENERICS**





*QbD: Quality by Design



SOLID ORAL DOSAGE FORMS

- › Capsules
- › Tablets
- › Film-coated tablets



STERILE FORMS

- › Powder for solution for injection or infusion
- › Solution for inhalation, injection or infusion



SOLUTIONS

- › Oral Solution in bottle

DIFFERENT TECHNOLOGIES ARE AVAILABLE FOR THE ABOVE FORMS:



- › PELLETS BY LAYERING



- › HOT MELT EXTRUSION



- › PELLETS BY EXTRUSION-SPHERONIZATION



- › LYOPHILISATION (FREEZE DRYING)



- › WET OR DRY GRANULATION

OUR FDF IN NUMBERS

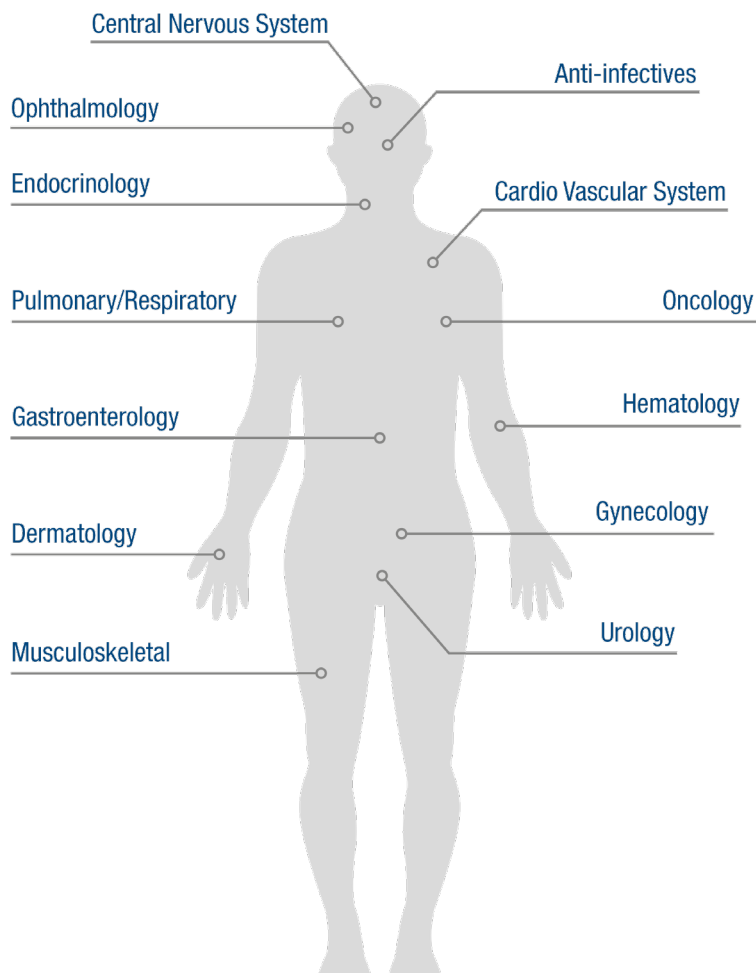
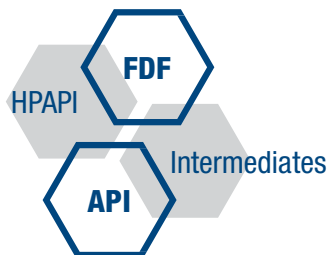
3 ANDAs approved by FDA

3 ANDAs filed at FDA

8 FDFs available

5 FDFs in pipeline

845 EU marketing authorizations



- Allergic conjunctivitis
- Anaesthesia
- Analgesic
- Anemia
- Antibiotic
- Anticoagulant
- Antidepressant
- Antifungal
- Antipsychotic
- Antithrombotic
- Arrhythmias
- Benign prostatic hyperplasia
- Carcinoma and sarcoma
- Chronic obstructive pulmonary disease (COPD)
- Constipation
- Fibrosis
- Glaucoma
- Hyperkalemia
- Hyperparathyroidis
- Hyperphosphatemia
- Hypertension
- Impetigo
- Insomnia
- Lymphoblastic leukemia and lymphoma
- Myeloma
- Myocardial perfusion imaging
- Narcolepsy
- Neuralgia, Epilepsy, or Bipolar Disorder
- Opioid withdrawal
- Osteoporosis
- Overactive bladder
- Parkinson's disease
- Rosacea
- Sclerosis (multiple and amyotrophic lateral)
- Seizures associated with LGS
- Sedation
- Skeletal muscle spasms
- Smoking cessation
- Thrombocytopenia
- Tumors
- Type 2 Diabetes
- Viral infections

3.2

CHLORHEXIDINE & ANTISEPTICS



CHLORHEXIDINE



1985

+30 Years of Experience



+250

Customers



+50 Countries served



Double-digit growth



Independent Business Unit



Worldwide Key Player



UNPARALLELED REGULATORY INSPECTIONS RECORD

 Successfully inspected since 1985

 cGMP Company since 1985

 ISO 14001 certified since 2001

 Successfully inspected since 2009

EDGE PERFORMANCE PRODUCTS

Chlorhexidine is widely used as active pharmaceutical ingredient, disinfectant, antiseptic, preservative or excipient.

AN EXTREMELY VERSATILE AND EFFECTIVE PRODUCT

BROAD SPECTRUM EFFICACY
(bacteria's, viruses and fungi)

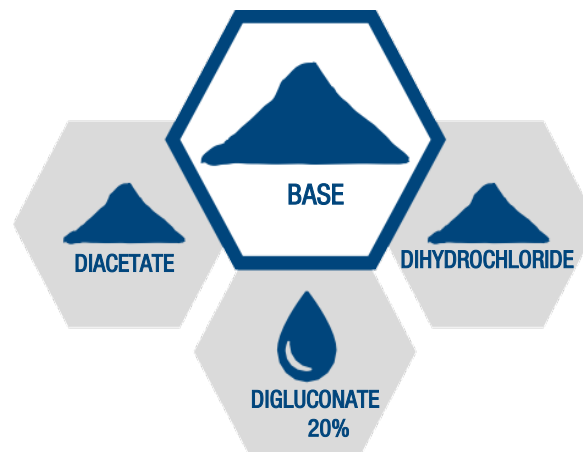
LOWER IMPURITY PROFILE

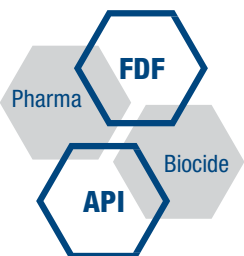
SAFETY-PROFILE ON THE SKIN

LOW IRRITATION

CHLORHEXIDINE API AN EXTENSIVE PORTFOLIO

4 active own-manufactured ingredients





PHARMA

0.5% solution
70% alcoholic
Transparent or colored solutions



BIOCIDE

0.5% and 2% solutions
Aqueous, transparent or colored alcohol solutions

4% scrub
2% wipes
Aqueous or alcoholic

Broad regulatory expertise

CHLORHEXIDINE	CEP	DMF EU	DMF US	DMF CANADA	DMF TAIWAN	BPR	REACH	COSMETIC REG.	HALAL
BASE			•				•		
DIACETATE	•	•	•	•			Exempt		•
DIGLUCONATE 20% SOLUTION	•		•	•	•	Listed in BPR PT1, PT2, PT3	•	•	•
DIHYDROCHLORIDE	•	•	•				•	•	•



- Biocidal active ingredient for PT1, PT2 and PT3 (BPR)
- Listed as Active Substance Supplier in accordance with art. 95

A WIDE RANGE OF APPLICATIONS



PHARMA



BIOCIDE



ORAL CARE



COSMETICS



VETERINARY



INDUSTRIAL

4

OUR EXPERTISE



1

Contributing to the success of our partners

2

Full IP support and IP opportunities

3

Vertically Integrated Manufacturing

4

Outstanding Regulatory support

5

Agile Contract & Customer Services

6

Successful partnerships

R&D, the basis of Medichem's strategy and success

Our highly-qualified personnel engages daily in technically challenging projects:

10%

Company turnover dedicated to R&D

UNIQUE

Added-value products, combined with new technology platforms

QUALITY

Meet all regulatory requirements, to the highest EU & USA standards of quality

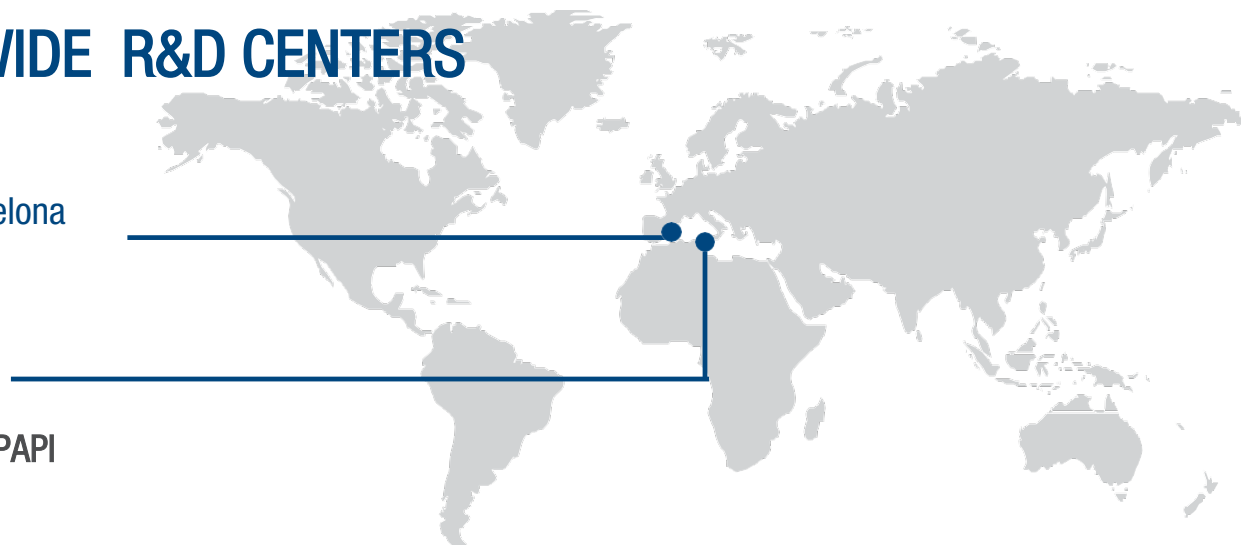
WORLDWIDE R&D CENTERS

SPAIN

Celrà and Barcelona
API and FDF

MALTA

Hal Far
API, FDF and HPAPI



Intellectual Property

- › Accurate freedom to operate evaluation
- › Designing the smartest IP strategy for our clients
- › Protecting Medichem's innovative developments that provide competitive advantages
- › CMO services



1

2 strategic facilities in Malta

- › Unique patent situation
- › Medichem offers its clients:
 - › An Early Launch in countries with no patent protection
 - › A Launch on Day-1 in countries with patent protection



SPAIN Celrà

- API and Chlorhexidine (25,000 m²)

MALTA Hal Far

- API and HPAPI (8,800 m²)
- FDF (6,600 m²)



VIM'S BENEFITS

API

LONG-TERM
WORLDWIDE
EXPERIENCE



Single
Analytical
Transfer

Complete
Regulatory
& IP support

Quality
Assurance &
Reliability

Smooth
Customer
Experience

FDF

FIRST TO
MARKET

Our primary goals when managing multi-purpose production lines:



To manufacture to the **highest quality standards** of the pharmaceutical industry



To ensure a **timely delivery** to our clients



To maintain a **safe workplace** for our team



SAFETY PLAN

HAZOP studies

First Aid and Fire Fighting

Emergency Plan

Regular drills

Periodical medical examination

Included in the Process Design





API

- API development
- High volume production
- Flow chemistry
- Hydrogenation – Biazzi®, 10 bar

FDI

- 505(b)2 development
- Development and industrialization of injectables
- Development of Tablets, Capsules and Pellets

HPAPI



- API development
- IP and early launch opportunities
- Chromatographic purification at industrial scale
- Nanofiltration (lab and industrial scale)

- Development and industrialization of IR and XR release solid oral forms, Tablets, Capsules and Pellets
- 505(b)2 manufacturing
- Dry and Wet Granulation, Film Coating, Hot Melt Extrusion, packaging for both Blisters and Bottles, Serialization
- Contract manufacturing

- Dedicated facility
- Latest total containment technology with OEL, Occupation Exposure Limit, down to 40ng/m³

LONG-STANDING EXPERTISE

900

MARKETING AUTHORIZATIONS

415

DMFs

100

ACTIVE ANDAs WITH OUR APIs

17

CERTIFICATES OF SUITABILITY

3

ANDAs APPROVED AT FDA

...submitted to date to Regulatory Agencies around the globe

API Celrà - ES



Spanish Medicines Agency (AEMPS)
Since 2008



Generalitat de Catalunya

Catalunya GMP Plant Inspection
Since 2014
R&D hubs in Barcelona & Celrà



FDA inspected since 1985.
No form 483 since 1999



ISO 14001 certified since 2001



Korean FDA (MFDS) since 2012



PMDA approved plants since 2009



Halal Inspection Since 2016

API+FDf Hal Far - Malta



US FDA inspected since 2007 (API), since 2017 (FDf)
No form 483 since 2012 (API)



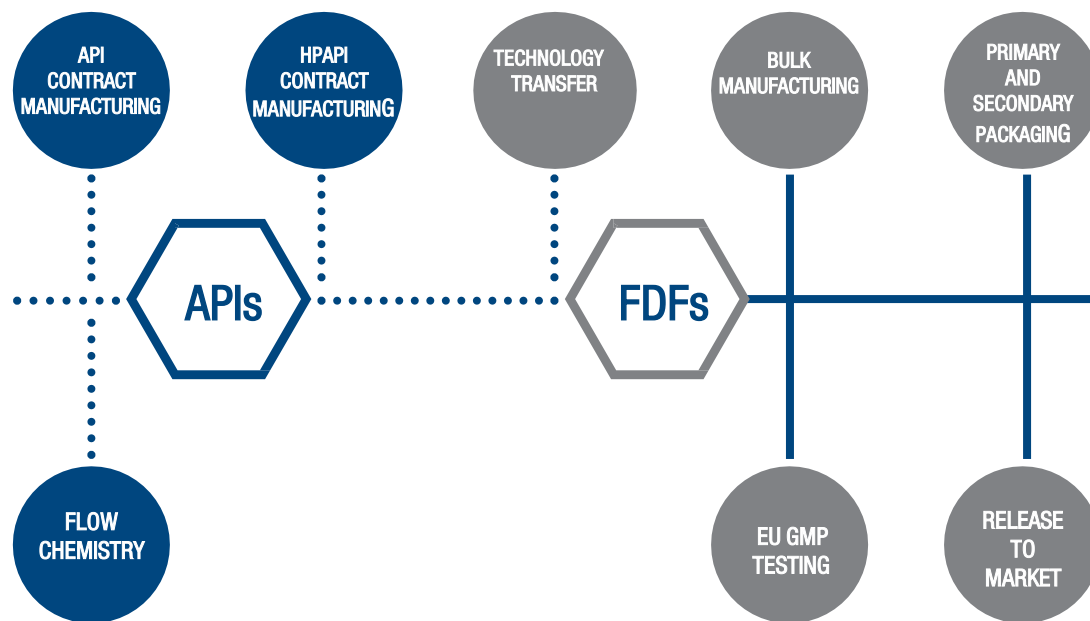
EU GMP certification by Malta Medicines Authority since 2007 (API) since 2006 (FDf)



ISO 14001 certified since 2009 (API)



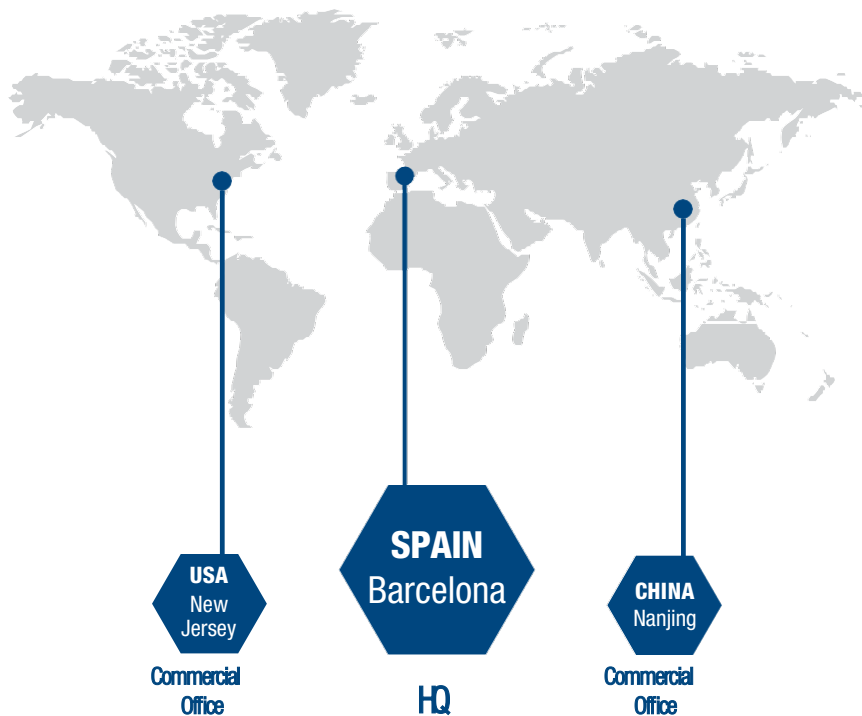
Tailor-made solutions



Medichem offers a wide range of contract services:

The strategic planning and location in Malta of Medichem and Combino Pharm allow the launch of our 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.



A solid base of international clients

Delivering products to more than 70 countries,
including the United States and within Europe,

Consolidated alliances with strategic partners for decades

Customer Story – Novartis

“As a customer of Medichem, I have found their core strength to be a clear sense of customer focus, with quality, safety and supply being at the forefront of any conversations that are held between the teams.

Medichem have always provided innovate and flexible solutions to ensure consistent product supply with exceptional delivery service. The global scope of Medichem’s operations have ensured RA support for key markets for Novartis.”

Customer Story – SK Pharma

“It is always a pleasure working with Medichem. Commitment of their employees is something that really infuses security in every business opportunity. Medichem always guarantees the high level of quality and all needed documentation for each product, which is more than important. We are glad that this partnership has helped us expand our portfolio.”

Customer Story – Azelis

“We really appreciate the speed and depth of support we receive from Medichem. The products are of high quality and are accompanied by a high level of documentation.

The people are friendly and interested in the detail of our business. They treat small and large requests with the same commitment.”

Partner Story – Neochemical

“Medichem has been a reliable partner since 2016. This partnership helped us increase our product range in a very short period of time and reach new markets through alternative product applications.

This fundamental alliance allowed us to reduce the start-up time and consequently reallocate resources in alternative projects.”

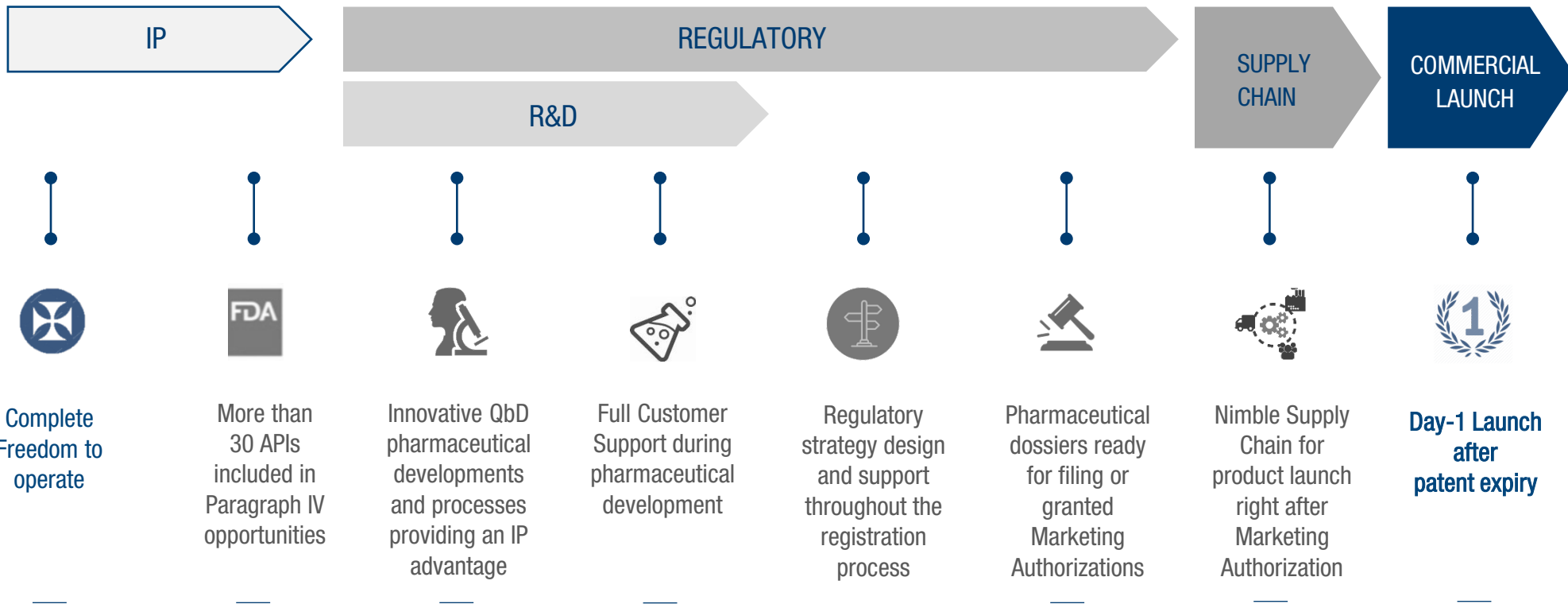
5

SYNOPSIS





THE VALUE OF HAVING OUR PARTNER'S SUCCESS AS A GOAL



THANK
YOU