









FOCUS ON THE CUSTOM MANUFACTURING









- MOEHS HISTORY
- PHILOSOPHY
- CAPABILITY & REGULATORY AFFAIRS
- HOW WE WORK
- OUR COMMITMENT WITH SAFETY AND ENVIRONENT
- POWERFUL REGULATORY SKILLS
- WHY US?
- SOCIAL MEDIA



## MOEHS HISTORY



#### MOEHS HISTORY



1962

MOEHS was founded in Barcelona by Mr. Melchor Mallasen Ornat, hence the name of the company Mallasen Ornat and Sons. MOEHS was commercially established as a fine chemical manufacturer for the Pharmaceutical Industry.

#### Currently

MOEHS IBERICA is the headquarters of the MOEHS group. It performs corresponding services for each of its subsidiaries and for the group as whole.

Its R&D Building houses a laboratory and plant dedicated to the production of small quantities of so called Highly Active Potent Ingredients or any other Ingredients for the Pharmaceutical Industry.





**SANOFI (1980)** 



PMC (1995)



MOEHS CANTABRA (2000)



**COPRIMA (2005)** 

MOEHS (1962)



**BENECHIM (2008)** 



C.F. BERG (2009)



**MOEHS BCN (2013)** 



ZETA PHARM. (2019)

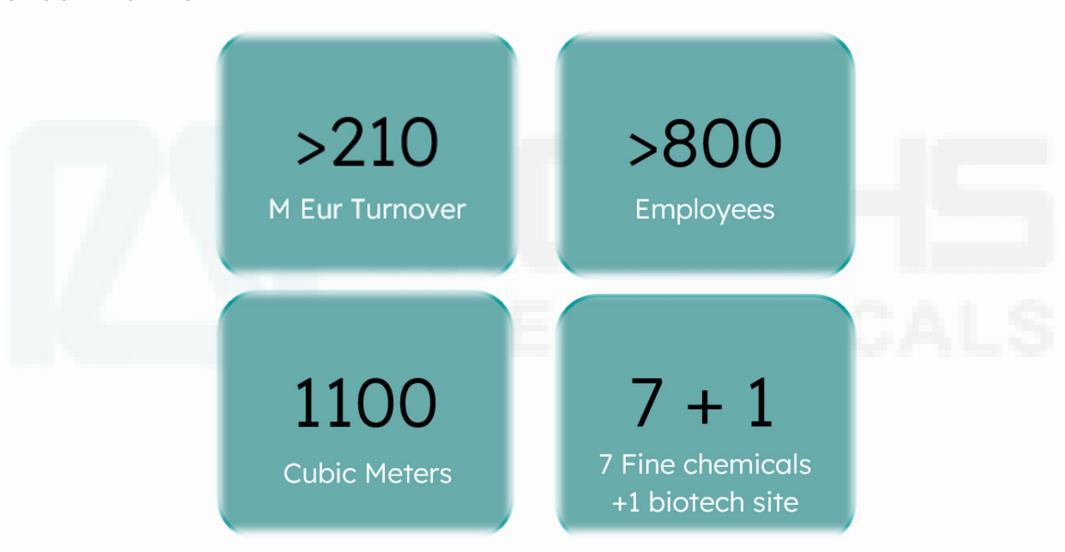


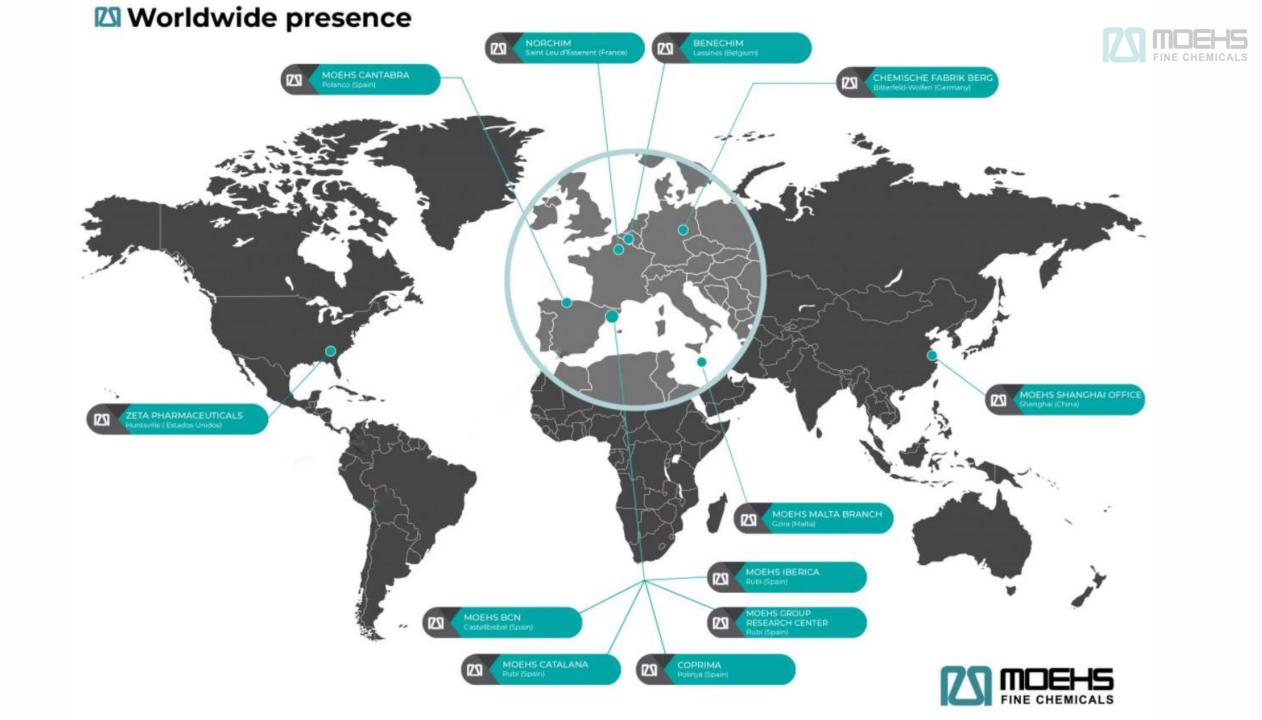
MOEHS IBERICA (CURRENTLY)

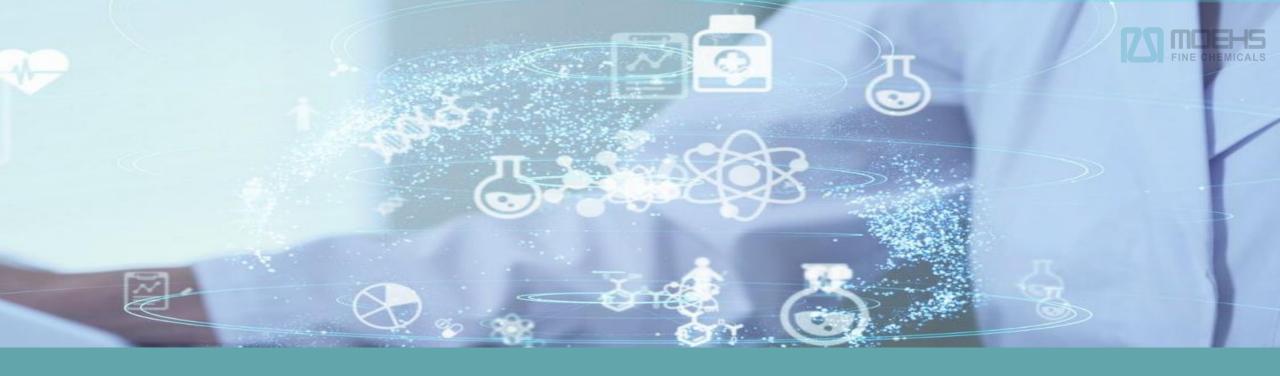
### MOEHS HISTORY



#### MOEHS GROUP HIGHLIGHT







# PHYLOSOPHY



#### **PHYLOSOPHY**





# Quality of products and services

which develops trust from our customers, keeping their loyalty and establishing long-term partnerships.





# Guarantee of flexibility and reliability

being proactive to the needs of our clients.

# Cost optimization

a direct result of our strategy on activities such as development, competitiveness and investments on equipment.

### **PHYLOSOPHY**



#### **CONTINUOUS COST OPTIMIZATION**

- Cost improvement due to industrial knowledge and experience in the market.
- Use of maximum productive capacity.
- Continuous optimization of the supply chain associated with the manufacturing process.

#### **PROACTIVITY**

- Flexibility in logistics.
- "Customization" of a compound according to the client's needs.
- Prospecting and selection of suppliers.

#### **RIGOR**

- Supply guarantee.
- Use of maximum productive capacity.
- Minimization of risks through close communication with the client.
- Complete documentary support that covers the client's needs.
- Policy backed by compliance with GPM regulations, FDA inspections and numerous audits of our clients.
- Environmental policy.

#### RELIABILITY

- Complete monitoring of the supply chain.
- Continuous analysis of the factors of the production process.
- Transparency and objectivity in the information towards our clients.







ICH Q7 Compliance - All sites are regularly audited by health authorities as well as customers



### MOEHS CATALANA



**CAPABILITY** 

Centrifuges Capacity Reactor Special Dryers Others Temperature Pressure Range range (bars) operations Tray Blenders, Sievers, pin & GL: 0.6.. 16m3 Hydrogenation Nutsche Filters hammer & jet mills SS: 2.. 10m3 -20 to 250°C 430m3 -1 to +20Jet Mill

REGULATORY AFFAIRS FDA Inspected since

Other inspections

Activity

1984

AEMPS-Spain (Sep 2020), K-FDA, Japanese Accreditation, Russian H.A. (July 2017)

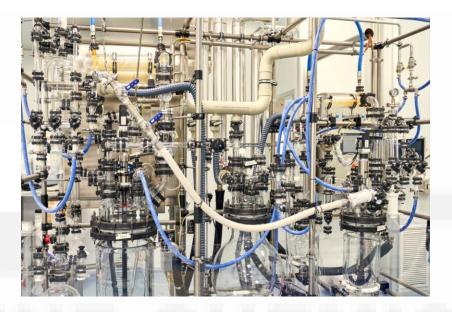
Generics / CM



ICH Q7 Compliance - All sites are regularly audited by health authorities as well as customers



#### **NORCHIM**



**CAPABILITY** 

Capacity Centrifuges Others Reactor Temperature Pressure Special Dryers Range range (bars) operations Paddle Hydrogenation GL: 0,1.. 2,5m3 Blenders Tray and 25m3 SS: 60 I .. 4m3 -60 to 170°C NMR studies Up to 20 Sievers Bicone

REGULATORY AFFAIRS FDA Inspected since

1989

Other inspections

Activity

AFSSAPS-France (Dec 2018), Japanese Accreditation

Process Research / CM



ICH Q7 Compliance - All sites are regularly audited by health authorities as well as customers



### **COPRIMA**



**CAPABILITY** 

Capacity Reactor Tempe Range

Temperature Pressure Range range (bars) Special operations

Centrifuges

Dryers

Others

GL: 3.. 11m3 72m3 SS: 3.. 10m3

-15 to 150°C

-1 to + 1

Jet Mill

SS SS automatic Fluid bed Paddle Bicone

Blenders, Sievers, pin & hammer & jet mills

FDA Inspected since

2001

Other inspections

Activity

REGULATORY AFFAIRS

AEMPS-Spain (Dec 2018), Cofepris, Japanese
Accreditation

Generics



ICH Q7 Compliance - All sites are regularly audited by health authorities as well as customers



### C.F. BERG



CAPABILITY

Capacity Reactor

Temperature

Pressure range (bars)

Special operations

**Dryers** 

Others

GL/SS 0.6.. 6m3 50m3

-10 to 150°C

Range

Up to 10

SS Hastelloy

Centrifuges

Paddle Tray and Bicone

Blenders Sievers

FDA Inspected since

2002

Other inspections

Jet Mill

Activity

REGULATORY **AFFAIRS** 

BfArM-Germany (Dec 2017), K-FDA, Japanese Accreditation

Generics / CM



ICH Q7 Compliance - All sites are regularly audited by health authorities as well as customers



## **MOEHS CANTABRA**



**CAPABILITY** 

Capacity Reactor Temperature Range

Pressure range (bars)

Special operations Centrifuges

Others Dryers

GL: 4... 10m3 SS: 4., 16m3 368m3

-15 to 150°C

-1 to +6

SS automatic

Fluid bed Paddle, Bicone Blenders, Sievers, pin & hammer & jet mills Spray drier

FDA Inspected since

Other inspections

Activity

Generics / CM

REGULATORY **AFFAIRS** 

AEMPS-Spain (Jan 2021), TGA, Japanese Accreditation

2010



ICH Q7 Compliance - All sites are regularly audited by health authorities as well as customers



### BENECHIM



**CAPABILITY** 

Capacity Reactor
3 x 30 l glass

Temperature Range

-70 to 120°C

Pressure range (bars)

-1 to +1.5

Special operations GMP Kilolab

HPAPIs unit

SS

Centrifuges

Nutsche Filter

Dryers

Others

Tray Sievers Mill

APABILITY 100m3

FDA Inspected since

2013

Other inspections

Activity

REGULATORY AFFAIRS

AFMPS-Belgium (Jan 2021), Japanese Accreditation

Generics / CM



ICH Q7 Compliance - All sites are regularly audited by health authorities as well as customers



## MOEHS BCN



**CAPABILITY** 

Capacity Reactor Temperature
Range

GL: 4.. 8m3
200m3 SS: 4.. 10m3 -14 to 120°C

Temperature Pressure Range range (bars)

-1 to +6

Special
) operations

Centrifuges

Dryers

Others

SS automatic

Bicone

Blenders, Sievers pin, Mills...

FDA Inspected since

Other inspections

Activity

REGULATORY AFFAIRS

AEMPS-Spain (March 2019), Japanese Accreditation

Generics / CM











#### **MGRC**

- From few ml to 30 L
- Full GMP if needed.

#### PILOT PLANT

- GL and SS reactors from 500 L to 3,000L
- Full GMP.

#### **INDUSTRIAL**

- Site assignment based on multifactorial imputs.
- Streamline Transfermonitored by MGRC team
- Dual Site strategy upon
   Market Conditions.



#### MGRC (MOEHS GROUP RESEARCH CENTER)



**CAPABILITY** 

Centrifuges Capacity Reactor Temperature Pressure Special Dryers Others Range range (bars) operations Fluid bed Hydrogenation SS, Uranus alloys, GL: 0,8.. 10m3 Blenders Paddle Hydrogenation SS: 2.. 12m3 Nutsche Filters 175m3 -10 to 180°C Sievers... -1 to +40Bicone catalysis

#### REGULATORY AFFAIRS



FDA Inspected since

AEMPS-Spain (Dec 2020)

Other inspections

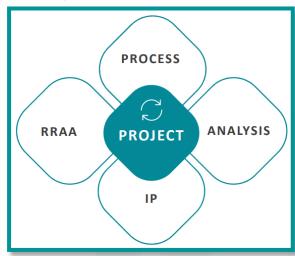
Activity

Development Generics / CM

ICH Q7 Compliance - All sites are regularly audited by health authorities as well as customers



#### MGRC (MOEHS GROUP RESEARCH CENTER)



Analytical & Process.

Development following Quality by Design (QbD) strategies.

Expertise in Control Strategy to support process registration and validation.

Controlled Substances Handling.

#### **CAPABILITIES**

- KiloLab: from 1L to 30L
- Hydrogenation: from 100ml to 2L, and up to 60Bar.
- Cryogenic reactions: from 100ml to 30L, -70° C to 185° C.
- HPAPIs: development and kilolab facility.

#### **TEAM**

Highly qualified personnel. 50 chemists in 2023. Capability for up to 70.

#### SPACE

Current lab around 600m2. MGRC is more than 2000m2.





## **OUR COMMITMENT WITH SAFETY AND**







Supports and follows the recommendations of the principles of responsibility of the PSCI.

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Assessment and control of the various emission sources in collaboration with local authorities

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Park of tanks for solvents, with P-N2 valves.

Alkaline and acid scrubbers for cleaning gases emitted into the atmosphere.

Warehouse for flammable solvents in drums.

Warehouse for flammable solvents in drums.

Wastewater treatment plants.

Process safety studies applied to the entire production process (DCS, ARC, RC1, risk analysis...)

Continuous training in Health and Safety.



Pioneers in Spain in the implementation of a waste management program.



## POWERFUL REGULATORY SKILLS



### POWERFUL REGULATORY SKILLS



Major Monograph compilation. Compliance to USP, EP, JP, ND. More than 30 CEPs issued. 29 USDMF filed at FDA. 10 JDMF filed at PMDA.

SHE beyond legally required

Audited by PSCI members.







# WHY US?







#### RELIABLE CDMO

Linearity of the Project: From PoC till Industrial.
Robust Process design.
Novelty IP Identification.

#### GROWTH BASED ON COLLABORATIVE RISK AND COST-SHARING APPROACH

Willingness of Co-Investment with Co-Marketing opportunities. Maximalize Development pipeline with no fixed Assets. Reduction on Development timelines.

#### PROVEN & SELECTED SUPPLIER

Expertise. Reliability. Reactivity. COGS effectiveness

#### FULL ADAPTATION UPON NEEDS

Short-term Capability at disposal Enlargement of existint Units.
Adaptability/Modulation of installations & technical requirements.







## **SOCIAL MEDIA**

#### **KEEP IN TOUCH**





















## THANK YOU SO MUCH.

