

REIG JOFRE CDMO SERVICES

REIG JOFRE is a **best-in-class provider of contract development and manufacturing solutions**. Founded in **1929**, Reig Jofre combines **tradition, science, technology**, and **innovation** with a strong **industrial culture**. We focus on the development, manufacturing, and marketing of pharmaceutical products and food supplements, with extensive knowledge and experience in essential medicines, specific antibiotics, small molecules, and biological products, including vaccines and advanced therapies.


BARCELONA PLANT

RJ Barcelona is a leading pharmaceutical manufacturing facility located in Sant Joan Despí, Barcelona, Spain. Our plant **specializes in producing a wide range of injectable products**, including freeze-dried and liquid vials, along with non-sterile liquid products.

FACILITIES & CAPABILITIES

 **Plant Size:** 27,000 m²

 **Employees:** 400

 **Capacity:** 40 million units annually

 **Sterile manufacturing:**

- 3 complete aseptic filling lines (one of them with isolator technology)
- 6 freeze-drying equipments (total surface 198 m²)
- Secondary packaging (including serialization and aggregation)



DEVELOPMENT & MANUFACTURING CENTERS



CONTACT US

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Please refer to "Services" page on
www.reigjofre.com

For direct request regarding CDMO Projects,
please write to cdmorj@reigjofre.com



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more information on
REIG JOFRE CDMO.

REIG  JOFRE



**REIG JOFRE BARCELONA
MANUFACTURING PLANT**

CDMO Services

TECHNOLOGIES AND SERVICES

OUR TECHNOLOGIES

- Compounding by means of Single Use Systems (Pall Corp.)
- Liquid vials & freeze-dried vials
- Non-sterile liquids
- Lyophilization process: automatic loading and unloading system to 54 sqm freeze driers (18 shelves) & 1000 kg ice
- Formats: for liquid & freeze-dried vials from 2R up to 50R + special format 'Easy Lyo' for 20 ml freeze-dried vial



OUR SERVICES

- **Pharmaceutical Development:**
 - Formulation
 - Manufacturing Process
 - Analytical Development
 - Clinical Trial Supply
 - Stability package
- **Manufacturing and Packaging:**
 - Manufacturing of injectable solutions and sterile freeze-dried products
 - Primary and secondary packaging
 - Associated analytical and support services
- **Support Services:**
 - QP Release
 - CMC and regulatory support in IMPD applications
 - CMC and regulatory support in NDA, eCTD applications
 - Support in Health Authorities audits
- **Recognized Expertise Center on Freeze-drying processes**

CERTIFICATIONS AND COMPLIANCE

CERTIFICATIONS

- EU-GMP certified by the Spanish Medicines Agency (AEMPS)
- ANVISA, PMDA (Japan), MFDS (South Korea), National GMP certifications for various countries
- ISO 9001 & CE certified facilities

QUALITY CONTROL / QUALITY ASSURANCE

- Regular inspections and rigorous testing to ensure product safety and efficacy including microbiological, chromatographic, physicochemical and Biotechnology testing
- Compliance with recent Eu-GMP Annex I (August 2023)

CDMO

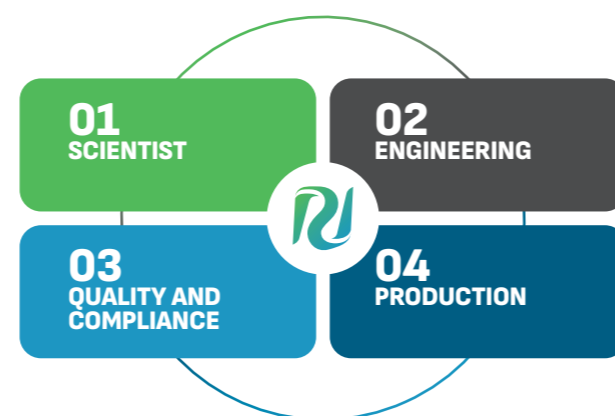


TARGET PRODUCT PROFILE - BASE LINE ASSESSMENT - PROJECT PLAN

CMC AND REGULATORY SUPPORT

STRINGENT cGMP STANDARDS AND QP RELEASE

TEAM



01. SCIENTIST

- Formulation
- Process set-up and characterization
- Analytics
- Collaboration with research centers

02. ENGINEERING

- Manufacturing Process
- Facilities
- Logistics

03. QUALITY AND COMPLIANCE

- Quality Assurance
- Regulatory
- Safety

04. PRODUCTION

- Technology Transfer
- Production

PROJECT PLAN

BASE LINE ASSESSMENT →

→ Target Product Profile (TPP)

RISK ASSESSMENT →

- Composition
- Manufacturing process
- Analytics
- Safety
- Logistics

PROJECT PLAN

- Actual processes
- Facilities/equipment
- Materials
- Training
- Certification

DRUG DISCOVERY

PRE-CLINICAL

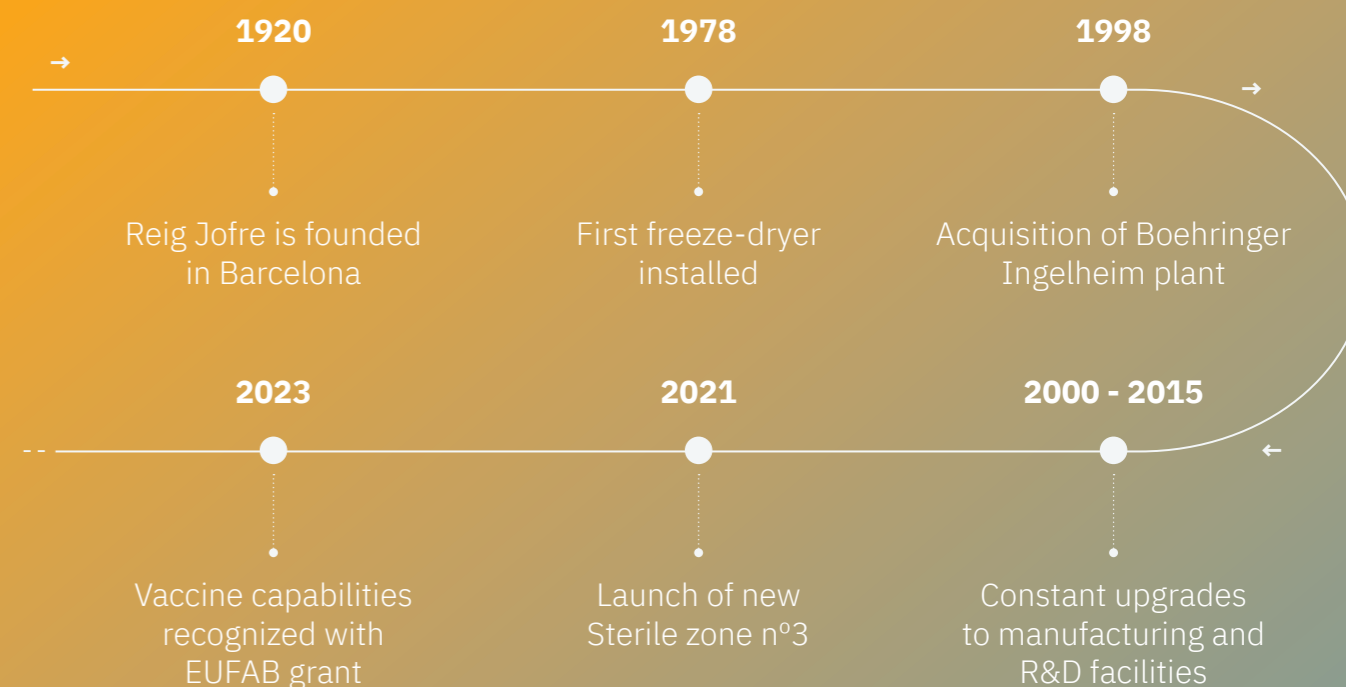
CLINICAL STUDIES

GMP MANUFACTURING

COMMERCIALIZATION

INCREMENTAL CMC

KEY MILESTONES:



WHY CDMO REIG JOFRE?



EXCELLENCE IN PRODUCT QUALITY: extensive knowledge & advanced freeze-drying technology, complying with the latest stringent regulatory standards.



CUTTING-EDGE TECHNOLOGY: state-of-the-art equipment at the service of the client to provide the best solutions.



FLEXIBILITY IN PLANNING: we adapt to your needs with flexible and efficient planning.



COMPREHENSIVE PROJECT MANAGEMENT: we listen and work closely with you to ensure your project's success.



PERSONALIZED AND HUMAN SERVICE: a close and tailored approach to meet your needs and expectations.



SMOOTH & CONTINUOUS DEVELOPMENT TO PRODUCTION: comprehensive capabilities ensuring a seamless progression from early phase to commercial scale.



EUROPEAN MEDICINES AGENCY



식품의약품안전처



ANVISA

RJ BARCELONA LABORATORIES

- 1,000 m²
- Space dedicated to biotechnological, microbiological, chromatographic and physicochemical analysis
- Equipped to carry out all type of tests related to QC testing of small molecules and biologics
- BSL2 certified rooms for cell culture and virus/bacteria
- Climatic chambers:
 - 25oC ± 2oC, 60% ± 5% RH
 - 30oC ± 2oC, 65% ± 5% RH
 - 30oC ± 2oC, 75% ± 5% RH
 - 40oC ± 2oC, 75% ± 5% RH