Agenda

Company Profile

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Established in 1984, Euticals is a Chemical Company focused on the development and manufacturing of Active Pharmaceutical Ingredients (APIs), Customs Synthesis products and Fine Chemicals.

Euticals is a privately owned company controlled by Private Financial Investors.
Historical Milestones

- **1984**: Our Start
  - EUTICALS
    - Prime European Therapeutics SpA
    - Spin-off of Istituto Chemioterapico Italiano

- **1995**: ACQUISITION
  - Acquisition by Carinelli Family

- **2001**: ACQUISITION
  - Acquisition of Prochisa SpA
    - Norpharma’s Rozzano plant

- **2002**: ACQUISITION
  - Pro. Bio.Sint. SpA
Today Euticals Group is one of the leading players in the Pharmaceutical & Fine Chemicals Industry with a global scale production and diversified manufacturing plants.
Products and Services

Our Offer

API MANUFACTURING
Extensive product portfolio with more than 200 APIs covering multiple therapeutic areas

CUSTOM SYNTHESIS
Euticals has the skill and experience to meet a wide range of outsourcing needs including: process development, scale-up, validation, and rapid volume escalation

CONTRACT MANUFACTURING
Supporting our customers from non-GMP to full cGMP synthesis and chemical manufacturing services, from production of early stage clinical trial materials to post-launch commercial manufacturing

FINE CHEMICALS
Broad technological expertise including: boronic acids, prostaglandin precursors, organometallics, cross couplings, enzymatic chemistry and high performance reagents
Key Figures

Turnover by Business Offering

- APIs and Intermediates: 64%
- Custom Synthesis: 7%
- Contract Manufacturing: 13%
- Fine Chemicals: 16%

(*) - 2015 data
Key Figures

Turnover by Area

- US & Canada: 25%
- LATAM: 6%
- TOP 5 EU: 21%
- Rest of EU: 22%
- MENA: 2%
- India: 8%
- China: 3%
- Japan: 3%
- Rest of World: 10%
- Rest of World: 22%

(*) - 2015 data
# Key Technologies

<table>
<thead>
<tr>
<th>Monobactams</th>
<th>Sterile APIs</th>
<th>Fermentation</th>
<th>Controlled Substances (US)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturer of Aztreonam, both Oral APIs and Sterile</td>
<td>Dedicated plant</td>
<td>Ergots Alkaloids and Immunosuppressant</td>
<td>4 DEA manufacturing areas for total capacity of 180 m³</td>
</tr>
<tr>
<td>Dedicated plant</td>
<td>Sterilization via aseptic filtration and crystallization</td>
<td>Absorption/Silica Gel/Ion Exchange Chromatography</td>
<td>Research and export registration for schedules I, II and V</td>
</tr>
<tr>
<td>Involved in new Monobactams developments</td>
<td></td>
<td></td>
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</table>

<table>
<thead>
<tr>
<th>Organometallics</th>
<th>Heterocycles</th>
<th>Enzymatic Chemistry</th>
<th>Other Capabilities</th>
</tr>
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<tbody>
<tr>
<td>Lithiation</td>
<td>Nicotinic Acid derivatives</td>
<td>Lipase applications</td>
<td>Cryogenic Chemistry</td>
</tr>
<tr>
<td>Boronic Acids</td>
<td>Piperazines</td>
<td>Chiral Cyclopentenol acetates</td>
<td>Hydrogenation</td>
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<tr>
<td>Tri-F Methyl Pyridines</td>
<td>Naphthyridines</td>
<td>Alcohol Dehydrogenase (ADH) applications</td>
<td>Steroids</td>
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<tr>
<td>Grignard</td>
<td>Furans</td>
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<td>Curares</td>
</tr>
<tr>
<td>X-Coupling</td>
<td>Indoles</td>
<td></td>
<td>Preparative HPLC purifications stationery phases</td>
</tr>
<tr>
<td>C-O Couplings</td>
<td>Triazoles</td>
<td></td>
<td>Green Chemistry</td>
</tr>
<tr>
<td></td>
<td>Pyrimidine</td>
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<td>(Amides preparation)</td>
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</tbody>
</table>

- 4 DEA manufacturing areas for total capacity of 180 m³
- Research and export registration for schedules I, II and V
- Cryogenic Chemistry
- Hydrogenation
- Steroids
- Curares
- Preparative HPLC purifications stationery phases
- Green Chemistry (Amides preparation)
Euticals R&D

Our Strong Scientific Expertise Network

5 Internal Centers
Crossed functions and multidisciplinary approach

1 Affiliate Center
State of the Art analysis research center

International Partnership
Collaboration with international CRO

Universities
Looking for Innovation

Services & Support:

• Project feasibility, Definition of New Synthetic Routes

• Development and Optimization of chemical Processes for New Generic API or NCE for Phase I – II – III devoted to Clinical Trials

• Scale-up

• Analytical Methods Development and Validation

• Isolation and Characterization of impurities

• Regulatory Support
R&D Centers

5 Internal + 1 Affiliate Development Centers

Total **61 highly skilled chemists** are focused on:
- API development
- Analytical development
- Process development and scale-up
- Process stewardship & improvement

<table>
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<tr>
<th>Country</th>
<th>Chemical Lab</th>
<th>Analytical Lab</th>
<th>TOTAL</th>
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<td>USA</td>
<td>6</td>
<td>3</td>
<td>9</td>
</tr>
<tr>
<td>France</td>
<td>4</td>
<td>2</td>
<td>6</td>
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<tr>
<td>Germany</td>
<td>17</td>
<td>xx</td>
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<tr>
<td>Italy</td>
<td>15</td>
<td>14</td>
<td>29</td>
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<tr>
<td>TOTAL</td>
<td>42</td>
<td>19</td>
<td>61</td>
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(xx) – Not accounted as R&D FTE
Chorisis is a Contract Research Organization, founded in 1986, owned entirely by Euticals, as separate legal entity, since July 2013. Mission: supply development and optimization analytical, preparative and industrial purification service. Chorisis is located in Insubrias Bio Park of Gerenzano (formerly Dow-Lepetit Research Center).
Euticals Manufacturing Sites

cGMP Plants:

- USA
- France
- Italy
France

TONNEINS
2015: ANSM
2014: FDA
ISO 9001, 14001, 18001
Aseptic Filtration & Crystallization

BON-ENCONTRE
2014: FDA
2013: ANSM
ISO 9001, 14001, 18001
Organometallic & Cryogenic Chemistry

Last inspection dates
See details on ppt plants
Frankfurt

Frankfurt
2015: ISO 50001
2014: ISO 9001
Boronic Acids & T3P® Reagent

Last inspection dates
See details on ppt plants
Springfield
2014: FDA
(since) 2005: DEA License
Distillation Large Volumes
QA & QC

**Italy**
- **QA**: 19, GMP and Qualification Compliance
- **QC**: 52, Chemical, Microbiological and Fermentation Analysis

**Germany**
- **QA**: 1, ISO Certification and HSE
- **QC**: 0, Outsourced

**USA**
- **QA**: 3, GMP and Qualification Compliance
- **QC**: 8, HPLC, UPLC and GC

**France**
- **QA**: 4, Sterile Manufacture and ISO Certification
- **QC**: 13, HPLC, GC, Titration, Endotoxins, Particle Counting, Microbial and Sterility tests

**Overall**
- Quality Assurance: 27
- Quality Control: 73
- Total: 100
DMF Statistics & CEP

More than 90 Customers Audits per year
8 Customers Audits every month
(on average at our facilities)
Euticals has exemplary commitment to quality. Our multiple cGMP facilities across Europe and the USA are audited by all relevant regulatory authorities and by our customers on a regular basis with excellent track record and no critical observations.
## EDQM- Certificate of Suitability (CEP)

<table>
<thead>
<tr>
<th>PRODUCT</th>
<th>Rozzano – Q.de S.</th>
<th>Origgio</th>
<th>Varese</th>
<th>Lodi</th>
<th>Bon-Encontre</th>
<th>CEP NUMBER</th>
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<tr>
<td>Niflumic Acid</td>
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<td>Hydroxyurea</td>
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<td>Chlortalidone Unmilled, Milled, Micronized</td>
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<td>R1-CEP 2001-020</td>
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<td>Ticlopidine Hydrochloride</td>
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<td>Bromocriptine Mesylate</td>
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<tr>
<td>Cytarabine</td>
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<tr>
<td>Fludarabine Phosphate</td>
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<td>✔</td>
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<td>R1-CEP 2009-282</td>
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</tbody>
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Sustainable Facilities

Italian Safety Regulations (D.Lgs. 81/08)

Risk of Explosion (99/92/EC, [ATEX 137], 94/9/EC [ATEX 100], DSEAR2002 and COMAH. Regulations 1999 and updating)

Pressure Equipment (PED 97/23/EC and ASME)

Environment Protection (European Directive 96/61/CE, D.Lgs.59 /05, D.Lgs. 152/06, Clean Air and Water Act, NPDES and POTW)

Big and Relevant Risk (D. Lgs. 334/99 and updating)

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