



**Your Global Full Services Partner  
in Life Science**



PHARMA ENGINEERING & PROCESS

CONSTRUCTION

QUALIFICATION, CSV

DIGITAL QUALITY & INNOVATION

ENERGY, WASTE & MAINTENANCE

TRAINING

SCIENTIFIC EVENTS

PROCESS & QUALITY

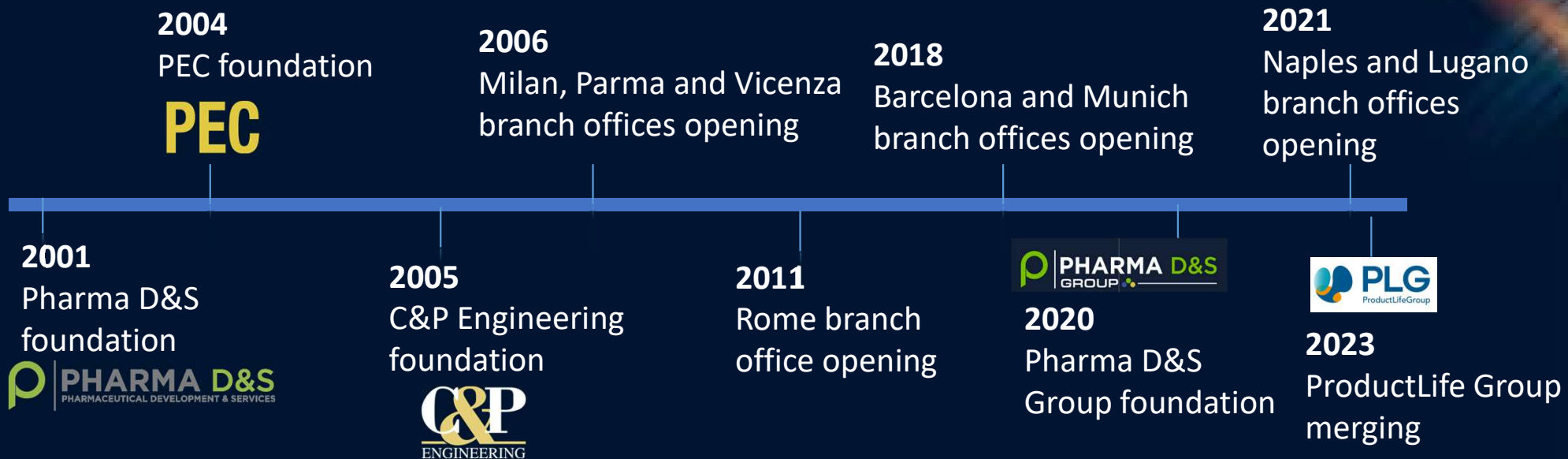
REGULATORY AFFAIRS

MEDICAL AFFAIRS

C.R.O.

PHARMACOVIGILANCE

Pharma D&S Group was born from a strategic decision. The aim was the creation of a company providing a complete range of services in the pharmaceutical and life sciences area.



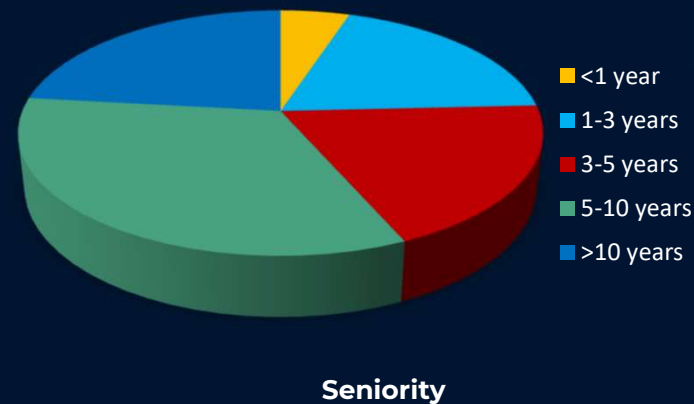
- MORE THAN 1000 CUSTOMERS
- FLORENCE, MILAN, ROME, NAPLES, BARCELONA, MUNICH, LUGANO
- 250 CONSULTANTS

- Seniority

- ❖ Corporate and International Managers from Pharma Firms
- ❖ Recently Graduates
- ❖ Technical and professional personnel

- 90% Graduates in Scientific learnings (CTF, Chemistry, Biotechnology, Pharmacy, Biology, Medicine, Engineering, Physics, etc.)

- 12% PhDs



INTRODUCTION

# ProductLife Group at a glance



**GLOBAL  
COVERAGE**

**1600+**  
EXPERTS  
worldwide

**30**  
YEARS of  
experience

**150**  
COUNTRIES  
covered

**600**  
CUSTOMERS

Large & Mid-size  
Biopharma,  
HealthTech  
organisations

by our experts or partners  
on 5 CONTINENTS

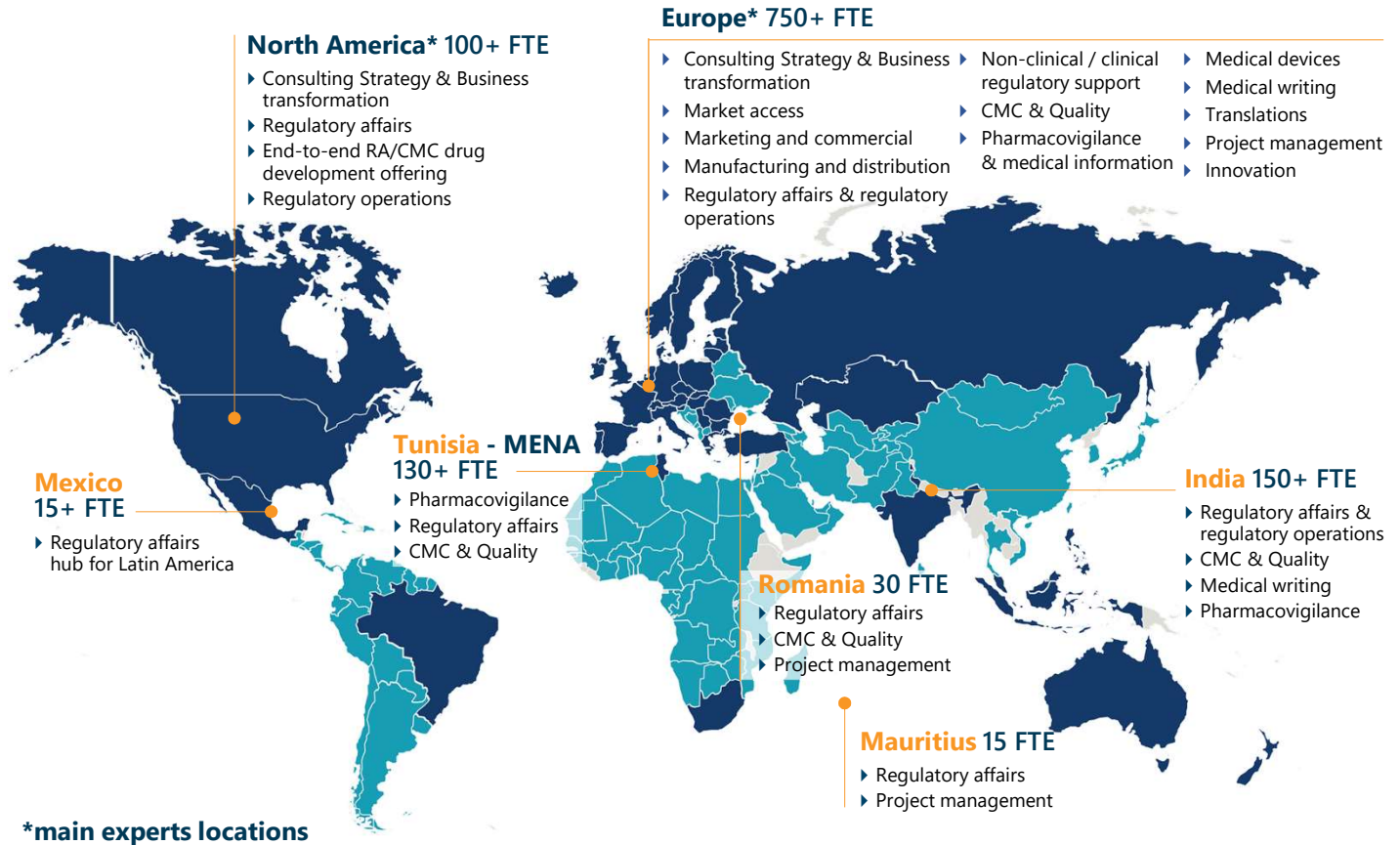
A PARTNER WHEN AND WHERE YOU NEED ONE  
**PLG, your worldwide partner**



PLG covers more than  
**50 countries** with its  
 own resources, and more than  
**150 countries**  
 with its global network  
 of qualified partners


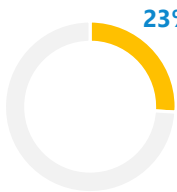


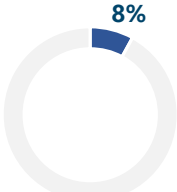


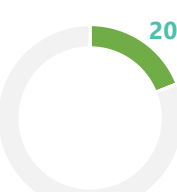

**5 right shoring sites**

Romania, Tunisia, India,  
 Mexico, Mauritius



## PLG CLIENT OVERVIEW


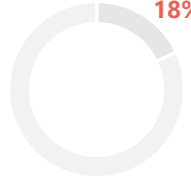


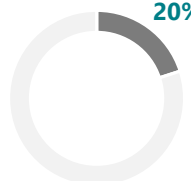


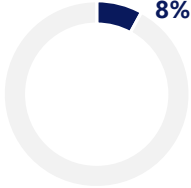

# Complementary lines of services

| BUSINESS UNIT  | DESCRIPTION   | 2022 VOLUME  | KEY CUSTOMERS   |
|--|---|--|---|
|  <p>Regulatory Affairs</p>       | <ul style="list-style-type: none"> <li>✓ Global <b>regulatory intelligence &amp; strategy</b></li> <li>✓ <b>Submission strategy &amp; dossier preparation</b> for new products or line extensions in multiple geographies</li> <li>✓ Global <b>geographic rollout &amp; lifecycle management at central and local levels</b> (incl. administrative, safety and CMC variations, renewals...)</li> <li>✓ <b>Local regulatory support</b> &amp; local agent</li> <li>✓ <b>Interaction with regulatory agencies</b> worldwide</li> <li>✓ <b>Artworks</b> reviews</li> <li>✓ Healthcare compliance</li> </ul>  |  <p>23%</p>   |    |
|  <p>Regulatory Operations</p>   | <ul style="list-style-type: none"> <li>✓ Preparation and publishing of <b>clinical trials applications (IND/CTA)</b></li> <li>✓ Electronic management of the assembly, compilation and publishing of <b>electronic regulatory submissions (eCTD)</b></li> <li>✓ <b>RIMS with RA &amp; PV integration</b> (IDMP, XEVMPD, DADI, LCM etc.)</li> <li>✓ <b>Pharma IT organization &amp; applications</b> set-up, support and maintenance</li> <li>✓ IT cloud for <b>dedicated EDMS/EQMS/PV systems</b></li> <li>✓ <b>Product labelling management</b>, Readability testing, Translations</li> </ul>  |  <p>8%</p>    |   |
|  <p>Safety &amp; Vigilance</p> | <ul style="list-style-type: none"> <li>✓ Full pre- and post-market <b>safety/vigilance consulting</b> services</li> <li>✓ <b>Case management</b></li> <li>✓ <b>Qualified person</b> for PV (QPPV, LQPPV, LSO)</li> <li>✓ <b>Medical literature monitoring</b> (local &amp; global)</li> <li>✓ Establishment, validation and management of <b>PV databases</b></li> <li>✓ <b>Medical Information</b></li> <li>✓ Development and implementation of <b>risk management strategies &amp; plans</b></li> <li>✓ <b>Medical writing</b>: periodic reports, clinical overviews, PSMF</li> <li>✓ Assistance with <b>audit/inspection preparation</b> and training</li> </ul> |  <p>20%</p> |  |



## PLG CLIENT OVERVIEW

# Complementary lines of services

| BUSINESS UNIT   | DESCRIPTION   | 2022 VOLUME   | KEY CUSTOMERS   |
|---|---|---|---|
|  <p>Product Development</p>                 | <ul style="list-style-type: none"> <li>✓ <b>Integrated CMC/RA-Q development</b></li> <li>✓ <b>Regulatory, nonclinical &amp; clinical development</b> strategy consulting &amp; operations support</li> <li>✓ <b>Medical writing:</b> IND/CTA, NDA/ANDA, BLA, eCTD modules 2.4-7, 4, 5, study reports</li> <li>✓ Focus on the <b>critical CMC issues</b></li> <li>✓ <b>Regulatory documents:</b> biowaivers, briefing packages, ERA, PDE, ODD, PIP, CCDS/CCSI</li> <li>✓ <b>Medical device</b> consulting</li> </ul>   |  <p>18%</p>  |    |
|  <p>Quality &amp; Compliance</p>           | <ul style="list-style-type: none"> <li>✓ <b>Quality systems consulting</b> and IT management</li> <li>✓ <b>Audits &amp; inspections</b> readiness</li> <li>✓ <b>Operational QA &amp; QC</b>, remediation plans</li> <li>✓ <b>Deviations/CAPAs/OOS</b></li> <li>✓ <b>QP batch release /certification EU</b> (clinical or commercial import/export)</li> <li>✓ Commissioning Qualification Validation (<b>CQV</b>)</li> <li>✓ Computer Systems Validation (<b>CSV</b>)</li> <li>✓ IT security and <b>data integrity</b></li> <li>✓ Medical device consulting</li> </ul> |  <p>20%</p>  |   |
|  <p>ProductLife Consulting</p> <p>PLG</p> | <ul style="list-style-type: none"> <li>✓ <b>Strategy &amp; top line improvement</b> (development of new activities, new products, footprint extension); Market access; <b>Business transformation</b>; <b>Digitalization</b> strategy and roadmap; <b>M&amp;A</b> and <b>Bottom-line</b> optimization</li> </ul>  |  <p>8%</p> |  |



# Engineering at the service of Pharmaceutical Industry

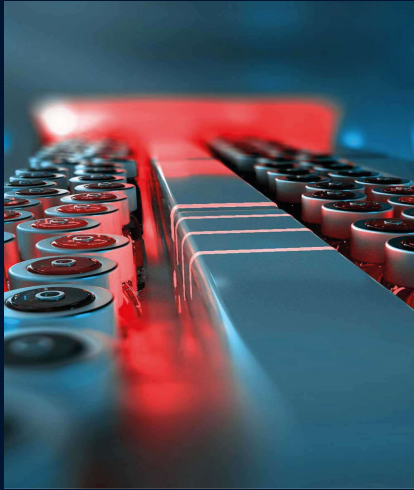
Since 2005, C&P Engineering has  
managed more than 2700 projects

**C&P**  
ENGINEERING





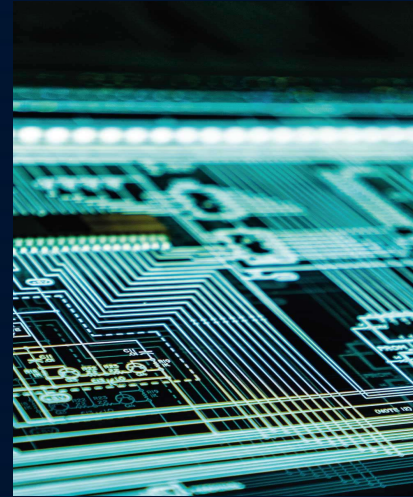
**C&P Engineering is a consulting and engineering services company operating in the sector of chemical-pharmaceutical, nutraceutical, biomedical, cosmetic industries and other sectors (microelectronics, aerospace and optics).**



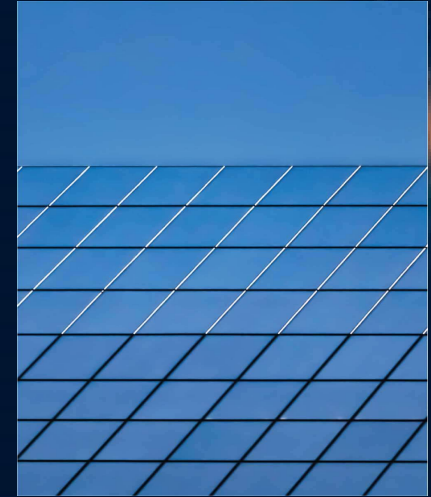
**PHARMA &  
PROCESS  
ENGINEERING**



**CONSTRUCTION**



**QUALIFICATION, CSV,  
DIGITAL QUALITY &  
INNOVATION**




**ENERGY, WASTE &  
MAINTENANCE**





# Pharma & Process Engineering

A close-up photograph of a computer keyboard, with the keys illuminated by a strong red light from the left, creating a dramatic, low-key effect. The background is dark and out of focus.

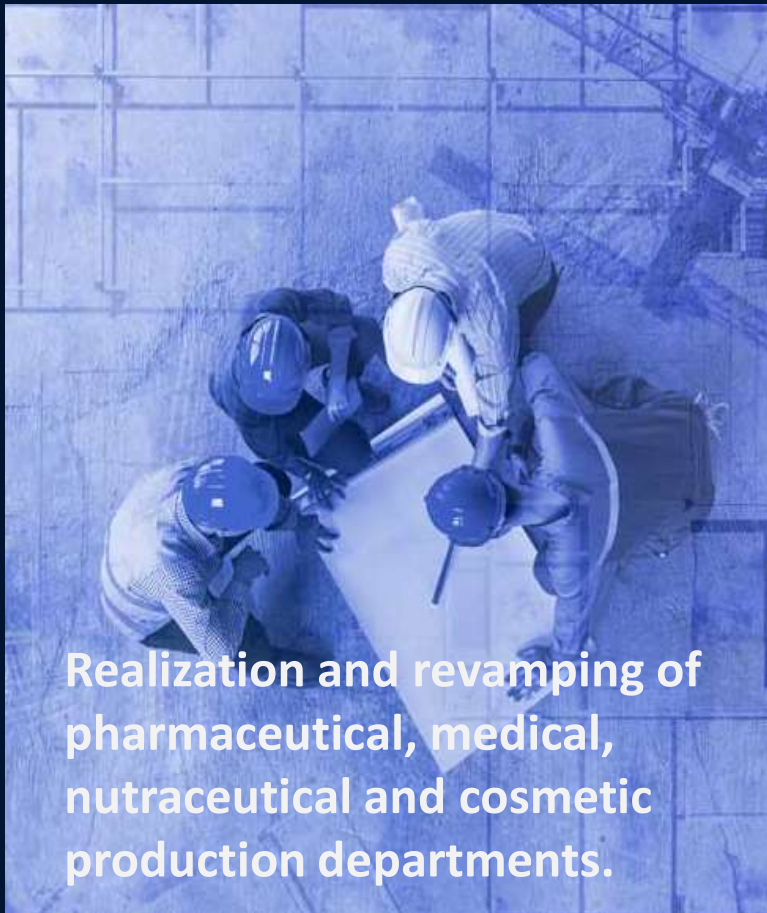
**Pharmaceutical and process engineering in the chemical-pharmaceutical, nutraceutical, medical, cosmetics, electronics, fine mechanics and food sectors**

## PHARMA & PROCESS ENGINEERING

- Management consulting
- Preliminary Project Assessment and Feasibility Study
- CONCEPTUAL DESIGN
- Development of User Requirements (URS) and definition of project specifications (Functional and Technical Specifications)
- Basic and Detailed Design (also with design by cost mode).
- Assistance in the definition phase of new machine and plant investments
- Project management, construction management and site assistance
- Pre- and post-inspection GMP adjustments



# Construction



**Realization and revamping of pharmaceutical, medical, nutraceutical and cosmetic production departments.**

## **CONTROLLED CONTAMINATION ENVIRONMENTS.**

- Clean rooms and confined areas
- Particle control and biological containment environments
- Laminar flow hoods
- RABS, Glove Boxes, Isolators, VHP and LAF material passes

## **SERVICE INSTALLATIONS**

- Water and thermal installations
- Air treatment installations (HVAC)
- Electrical installations
- Suction and abatement systems
- Water treatment plants for special use: PW, WFI , PS
- Technological gas production and distribution plants
- Other special installations

## **CIVIL WORKS**

- Functional structures or buildings for the construction of Production Plants.
- Pharmaceutical infrastructures (false ceilings, cladding, walls)

# Qualification

**Documented verification according to the Qualification and Validation process of equipment, utilities and production lines.**



## QUALIFICATION ACTIVITIES

- Technical definition and execution of qualification/validation protocols DQ, IQ, OQ and PQ
- Validation Master Plan
- Commissioning activities, Factory Acceptance Test (FAT) and Site Acceptance Test (SAT)
- HVAC and Utilities (PW, WFI, PS), Process Equipment Qualification & Thermal Mapping
- Execution of calibration programs
- Quality Risk Management, GMP Reviews, Risk Analysis and definition of adaptation plans
- Drafting of supporting standard operating procedures (SOPs), work instructions and guidelines





# Computerized System Validation

Documented verification according to the Qualification and Validation process and process digitalization development.

- SW Validation (Management Systems; Production Control Systems and Laboratory Systems)
- Compliance Assessment & Remediation Plan
- Data Integrity Solutions
- Assessment & Qualification of IT Infrastructures.
- IT Quality System Development.
  - SOPs writing
  - Quality Agreement definition
  - Audit Trail Review strategy
  - Customize Validation Strategy
  - IT Audit
- Training



# Digital Quality & Innovation

## DIGITAL CONSULTANCY

- Merge & Acquisition
- Process reengineering
- Digital strategy
- Digital Auditing
- Partners and Solutions selection (Software, Cloud, Cybersecurity)

## DIGITAL PROJECT

- Project Management
- Solution development
- Solution reengineering
- Project IT support

## DIGITAL SUPPORT

- Application Maintenance
- Infrastructure monitoring & control



## PHARMA 4.0™

- Business Intelligence & Big Data
- Artificial Intelligence
- Augmented & Virtual Reality
- IoT





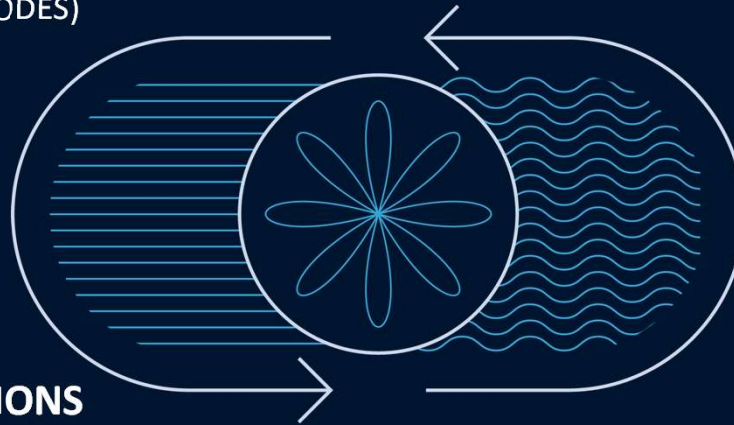
# Energy, Waste & Maintenance

## WASTE AND WASTEWATER OPTIMISATION AND MANAGEMENT

- Revision of waste classification (EWC CODES)
- Evaluation of management methods
- Separate collection organization
- Disposal optimization
- Wastewater disposal studies

## ENERGY AND TELECOMMUNICATIONS CONTRACT MANAGEMENT

- Cost positioning analysis
- Research of the best market options
- Assistance with tenders and contracts
- Monitoring of consumption and costs
- Simulation of cogeneration effects on costs
- Evaluation of connection methods



## ENERGY USE OPTIMISATION

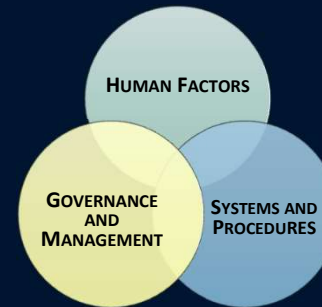
- Energy audits
- Study of customized solutions
- Study of cogeneration plants
- Implementation of eco-friendly systems

## MAINTENANCE MANAGEMENT

- Definition of maintenance programs
- External management of programs
- Optimization of maintenance activities
- Contract definition assistance
- Support in drafting and revising Work Instructions

## *Why choosing Pharma D&S Group:*

- FOCUS ON LIFE SCIENCES
- MORE THAN 20 YEARS EXPERIENCE
- HIGH SENIORITY
- INTERNATIONAL EXPERTISE
- CUSTOMIZE APPROACH





# Main Customers



intercos





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[www.pharmades.it/pharma-ds-group](http://www.pharmades.it/pharma-ds-group)

