NET-PHARMA GLOBAL 360

Build the future

Barcelona – EU Facilities

July 2025

NET-PHARMA delivers GMP compliant solutions for pharma & healthcare — from concept to commissioning.

Your vision, our execution—built to spec, built to last

EXPERTISE BACKGROUND

Net-Pharma is a privately owned group of companies providing international industrial solutions. We have more than 300 employees and we are in 72 countries spanning around world. We deliver high quality, tailor-made solutions in engineering operations, process technologies, regulatory and technical services.

COMERCIAL PHARMACEUTICAL PRODUCTS

+20

INDUSTRIAL ENGINEER

+70

IT / SOFTWARE ENGINEER

+80

REGULATORY (RA, GDP, GxP, CSV)

+70

FIELD TECHNICIAN

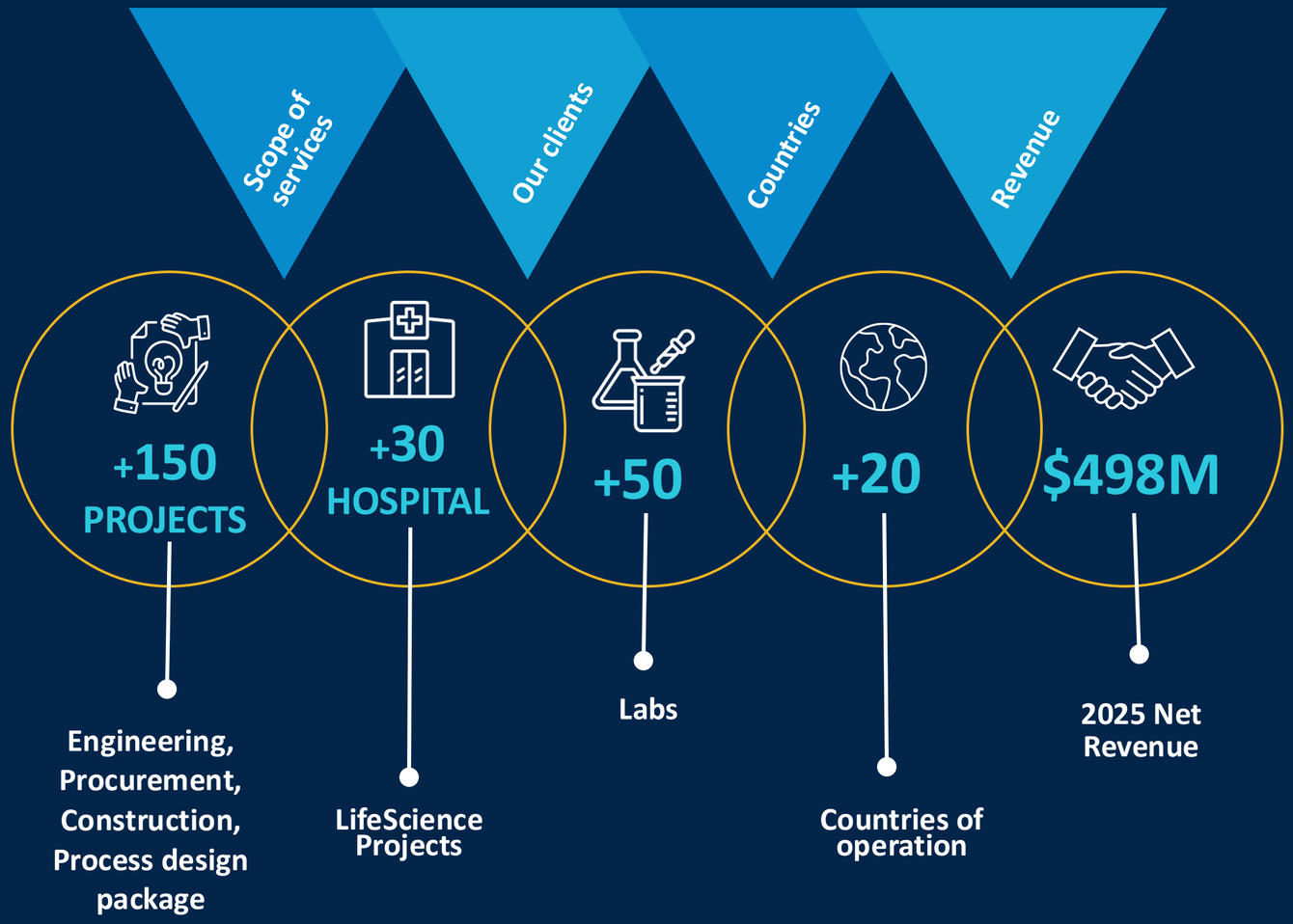
+160

NET-PHARMA

NET-PHARMA AT A GLANCE

We provide specialized services and strategic consulting in industrialization projects for high-tech product development. Your trusted partner from R&D to market launch

NET-PHARMA GLOBAL PROJECTS



NET-PHARMA

SCOPE OF SUPPLY

ORAL SOLID DOSAGE (OSD) PLANTS

Tablets, Capsules, Powders, Coated tablets

NON-STERILE LIQUID PLANTS

Syrups, Oral solutions, Suspensions, Non-sterile eye drops

STERILE LIQUID PLANTS

Injectables, Ampoules, Vials, Pre-filled syringes, Sterile eye drops

LYOPHILISED PRODUCT PLANTS

Freeze-dried injectables, Lyophilised vaccines, Lyophilised antibiotics

BIOTECH PLANTS (BIOLOGICS)

Monoclonal antibodies (mAbs), Recombinant proteins, Vaccines, Advanced Therapy Medicinal Products (ATMPs)

INDUSTRIAL RADIOPHARMACEUTICAL PLANTS

FDG (Fluorodeoxyglucose), Ga-68 compounds, Lu-177 radio-labelled products, Other nuclear medicine radiopharmaceuticals

HPAPI / CYTOTOXIC / HORMONAL PLANTS

Chemotherapy drugs, Immunosuppressants, Hormonal drugs, High-potency APIs

SEMI-SOLID AND TOPICAL PLANTS

Creams, Ointments, Gels, Emulsions

ACTIVE PHARMACEUTI-CAL INGREDIENT (API) PLANTS

Synthetic APIs, Biotech APIs, Intermediates for final drug production

COMBINATION PRODUCT / DRUG–DEVICE PLANTS

Inhalers, Pre-filled syringes, Drug-eluting, stents or implants, Combination delivery devices

HOSPITAL COMPOUNDING PHARMACIES

Total Parenteral Nutrition (TPN), Cytotoxic preparations, Radiopharmaceuticals (on-demand), Personalised ATMPs, Sterile magistral preparations

FULL HOSPITALS (AS ENGINEERED FACILITIES)

Surgical medications, Diagnostic and radiology drugs, In-house compounded medicines, Sterile supply for hospital use, Emergency and ICU-specific therapies

PHARMACEUTICAL DISTRIBUTION CENTRES

Finished pharmaceutical products, Clinical trial materials, Temperature-sensitive drugs, Controlled substances, APIs and intermediates for manufacturing

NET-PHARMA

TAILORED FINANCING SOLUTIONS

SOURCES OF FUNDS

- Traditional Finance
  - Banks
  - Multilateral banks
- Concessional credits
- Family offices
- Investors
- EU Global Project Finance
- Green funds

PPP / PFI / PF

- Public Private Partnerships (PPP)
  - Payment mechanisms
  - Availability & demand risks allocation
- Private Finance Initiative (PFI)
- Project Finance
- Main models (BOT, BOOT, DBFO)

SUPPORT THROUGH EXPORT CREDIT AGENCIES (ECAS)

- Coverage of up to 85% of the total project value
- Repayment terms of 5 to 10 years, tailored to each client and project

COMPETITIVE INTEREST RATES

- More attractive than traditional bank financing
- Available in multiple currencies (€, USD, etc.)

FLEXIBLE AND PROGRESSIVE DISBURSEMENT

- Payments aligned with project milestones (no large upfront cash needs)
- Possibility of a grace period until commissioning

"We finance your growth, not just your project"

NET-PHARMA

NET-PHARMA
360° PROJECTS

PROJECT MANAGEMENT & MONITORING

0 FUNCTIONAL PLANS AND FEASIBILITY STUDIES

1 PHARMACEUTICAL TECH TRANSFER

2 . I PLANT & PROCESS ENGINEERING

2 . II INDUSTRY 4.0 & CYBERSECURITY

3 . I CONSTRUCTION & EQUIPMENT

3 . II CONSTRUCTION, EQUIPMENT. INDUSTRY 4.0

4 PHARMACEUTICAL QUALITY SYSTEM

5 GALENIC DEVELOPMENT

6 REGULATORY AFFAIRS

7 LEGAL SUPPORT

8 LABORATORY CONTROL

9 MANAGEMENT SUPPORT & TRAINING

10 ENSURING SAFETY PRODUCT . I

10 . EU COMPLIANCE U-GMP / FDA | OUR SERVICES

11 MARKET ACCESS

12 LOGISTICS AND DISTRIBUTION

At Net-Pharma, we develop your pharmaceutical and healthcare project from initial design to full implementation & development.
We bring your product to market.

360° service

PROJECT MANAGEMENT & MONITORING

We provide strategic project management and monitoring services tailored to the needs of lifescience and healthcare projects. Our role goes beyond coordination: we offer a neutral and structured approach to both management and monitoring, ensuring that projects remain aligned, transparent, and successful across all stakeholders.

PROJECT MANAGEMENT

Project Governance & Oversight	• Structured supervision across all project stages, from conceptual design to commissioning
Stakeholder Coordination	• Interface with authorities, contractors, suppliers, and technical partners
Timeline, Budget & Risk Control	• Monitoring and mitigation plans tailored to construction, equipment and operations
Standardised PM Methodology	• Implementation of processes, tools, documentation and reporting aligned with best practices
Conflict Prevention & Resolution	• Ensuring transparency and alignment through neutral oversight

PROJECT MONITORING

Independent Oversight	• Regular and structured review of project execution to ensure adherence to scope, timeline and budget
Milestone Tracking	• Monitoring completion of key deliverables and contractual obligations
Budget Verification	• Cross-checking budget execution against financial planning and funding disbursement schedules
Risk & Deviation Alerts	• Early identification and reporting of delays, budget overruns or deviations in implementation
Performance Reporting	• Periodic reports with objective data on project progress, risks and corrective actions

NET-PHARMA

0. FEASIBILITY STUDIES AND FUNCTIONAL PLANS

Ensuring project feasibility and functional coherence from day one

FEASIBILITY STUIDIES

- Comprehensive assessment of technical, clinical, regulatory, and financial feasibility
- Market and institutional context analysis
- Definition of scalable, sustainable, and regionally adapted healthcare solutions
- Investment sizing and CAPEX/OPEX structure aligned with international standards

FUNCTIONAL PLANS

- Definition of portfolio and project flows
- Operational layout validation aligned with project requirements
- Equipment needs and integration with workflows
- Alignment between architecture, engineering, electromechanicals, equipment, operation, and regulatory frameworks

AGGREGATED VALUE

- Guarantees a cohesive path from project concept to execution
- De-risking of investment through integrated planning
- Ensures medical-operational coherence for facility performance

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1. PHARMACEUTICAL TECH TRANSFER

We consolidate commercial development and internationalisation through business models based on solid and strategic alliances with different international partners, offering licensing and/or distribution agreements with third party pharmaceutical companies.

- Dossier - MA search at a global level
- Dossier Strategy and Registration - MA at global level
- Laboratory handbook analysis as a complement

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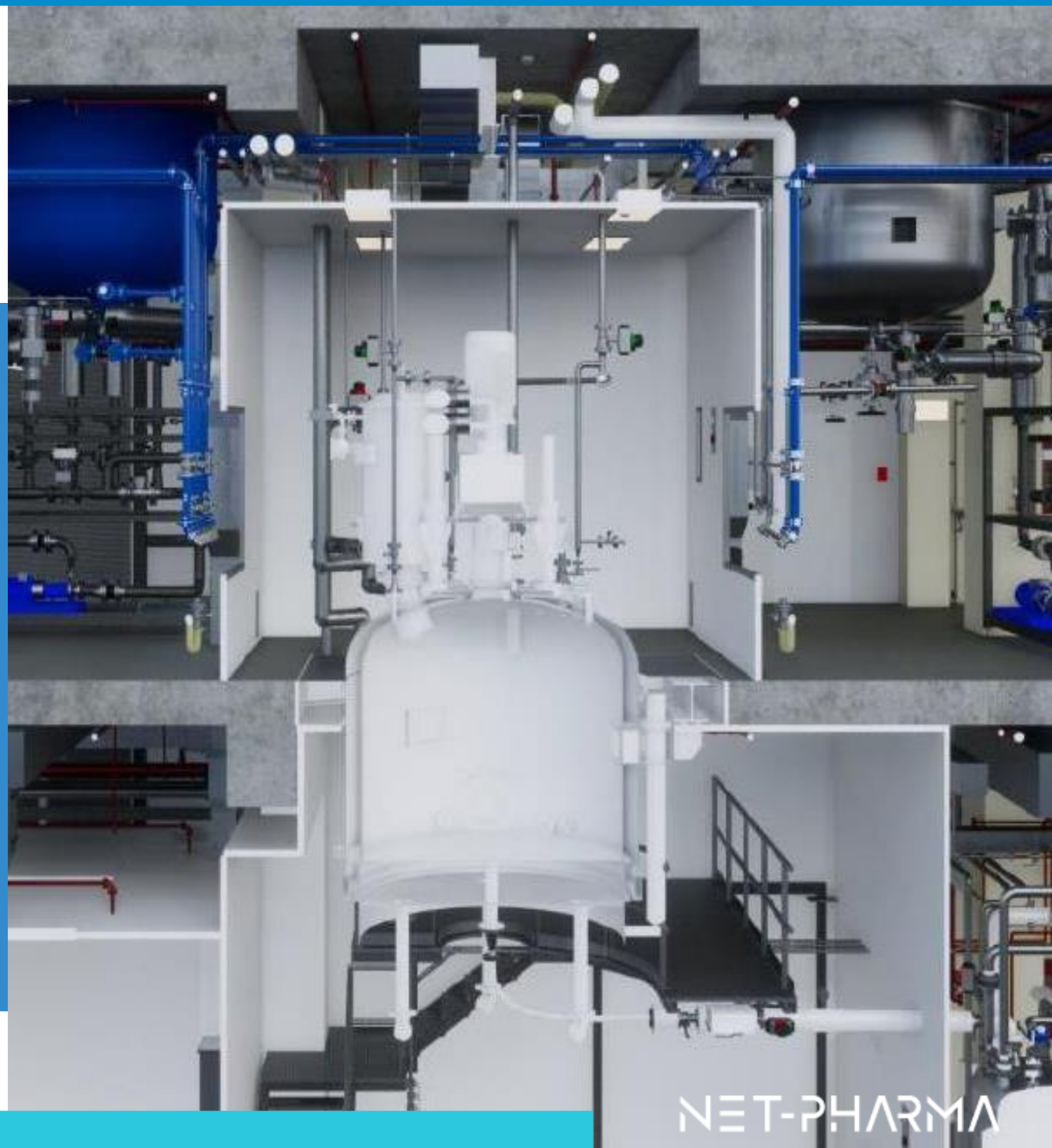
2.I
PLANT & PROCESS ENGINEERING

- Pre-Engineering
- Product study consultancy
- Production strategy
- Viability study
- Concept design, Basic design ,Detail design
- Capacity Study
- Process design & GMP Utilities Equipment selection HVAC & Utilities
- Control & Automatisation
- BIM development
- Project Management
- Pharmaceutical Distribution Centres (GxP- compliant Warehouses)



2.II INDUSTRY 4.0 & CYBERSECURITY

FACTORY AUTOMATION

- Implementation of SCADA, PLC, and DCS systems.
- Integration with GxP-compliant control systems.
- Centralised supervision of production and utilities.

DIGITAL OPERATIONS

- Paperless strategy and implementation of MES, EBR, LIMS, and Digital Logbook.
- Real-time integration between factory and business level (ERP).
- Data qualification aligned with compliance standards.

MANUFACTURING IT

- Support on manufacturing IT infrastructures.
- Lifecycle management.
- ITIL-based service delivery with audit readiness.

CYBERSECURITY

- OT Governance to align cybersecurity with operational and compliance objectives.
- Implementation of secure architectures.
- Support for NIS2 compliance: risk analysis, roadmap definition and implementation.
- Secure architecture and lifecycle cyber protection.

DATA & INDUSTRIAL AI

- Centralisation of industrial data to enable data analytics and AI: OEE, Energy management, preventive and predictive maintenance, bottleneck analysis, Golden Batch, etc.
- Enabling AI in industrial environment through trusted, contextualised and compliant data sources.
- Intelligent assistants supporting plant documentation and reporting.

3.I
PLANT & EQUIPMENT CONSTRUCTION

Equipment portfolio in our core competences

1. PLANT-WIDE AUTOMATION & CONTROL SYSTEMS

2. CONTAINMENT & AIR QUALITY

- CLEAN ROOM A (GRADE A,B,C,D)
- MODULAR PANELS AND CLEANABLE ENCLOSURES
- HVAC SYSTEMS WITH PRESSURE, TEMP & HUMIDITY CONTROL
- HEPA FILTERS
- PASS-THROUGH HATCH (UV OR H2O2 DECON)

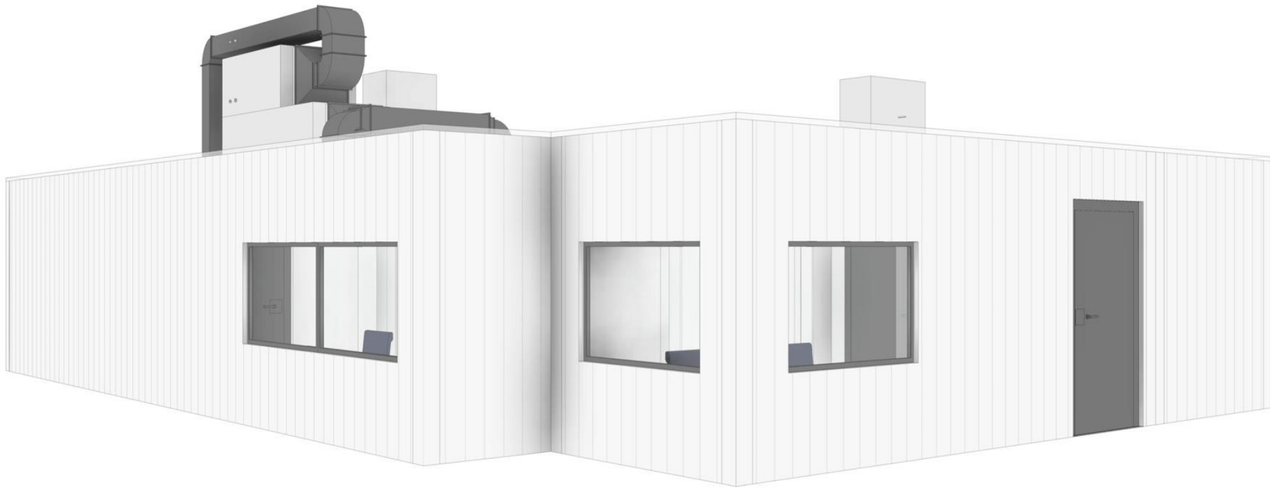
3. ASEPTIC PROCESSING

- REACTORS & BIOREACTORS (STERILE FINISH)
- CIP/SIP SYSTEMS
- PROCESS SKIDS
- STORAGE TANKS
- PW
- WFI
- CLEAN STEAM
- VHP (H2O2 VAPOR)
- PHARMACEUTICAL GRADE GASES
- AUTOCLAVES

4. FILL AND FINISH (PHARMA & RADIOPHARMA)

- ASEPTIC FILLING LINES (VIALS, SYRINGES, CARTRIDGES, EYEDROPS)
- ISOLATOR & RABs
- VISUAL INSPECTION
- FREEZE DRYERS WITH AUTOMATIC & SEMIAUTOMATOC LOADER
- FREEZE DRYER

3.II
PLANT CONSTRUCTION, EQUIPMENT, INDUSTRY 4.0



Modular systems designed within standard or customised containers to house critical processes in a controlled and regulated environment.

MAIN FEATURES

1. Designed to comply with GMP regulations and ISO standards
2. Plug & Play design. Quick and easy installation
3. Can be ideal for phased global expansion
4. Customisable according to the type of process: gene therapies, cell therapies, tissue engineering, hospital use, etc.
5. Portability and mobility. Can be relocated to different sites.

DISTINCTIVE ADVANTAGES

- **SCALABILITY**: Allows the addition of modules as needed to increase production capacity.
- **CLONABILITY**: Prefabrication and project standardisation enable faster execution of expansions.
- **TIME REDUCTION**: Traditional infrastructure construction can take a long time. Containerised systems can be operational within weeks or months.
- **PORTABILITY**: Their transportable design allows for relocation or the setup of multiple containerised units to bring production closer to the patient.
- **INCREASED RETURN ON INVESTMENT:** Maximised ROI thanks to rapid installation and scalability.

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4. PHARMACEUTICAL QUALITY SYSTEM

QUALITY SYSTEM

- Quality Management Systems implementation
- Technical Writing Documentation

RISK ANALYSIS EXPERTS

- Prevention of Cross Contamination
- Management of excipients and their suppliers
- Re-qualification activities
- Customised based on customer needs

IMPLEMENTATION OF ANNEX I CHANGES

- Control Contamination Strategy
- Assessment of compliance with the new Appendix 1
- Clean room cleaning validation

CROSS CONTAMINATION

- Toxicological evaluation of all APIs
- Risk Analysis for the prevention of Cross Contamination
- Preparation Cleaning Validation Master Plan
- Environmental verification/monitoring
- NPI assessments and organisational changes

VALIDATION SUPPORT

- Execution completion and support
- Preparation of:
    - Validation Master Plan
    - Process Validation Protocols / Reports
    - Cleaning Validation Assessments/ Cleaning Validation Protocols / Reports

5. GALENIC DEVELOPMENT

- We provide customised galenic development services aligned with our customers' specific requirements and the unique needs of each product.
- Our team of formulation experts works in collaboration with our customers to create tailor-made solutions that meet the highest quality standards and regulations.
- Our portfolio includes a wide variety of formats, such as solutions, suspensions, creams, ointments and transdermal patches.
- We comply with international regulations and standards, guided by authoritative benchmarks such as the European Pharmacopoeia, the United States Pharmacopeia (USP) and the International Conference on Harmonisation (ICH).
- And providing support in the transfer to production.

6. REGULATORY AFFAIRS

The appropriate regulatory strategy will allow the smoothest pathway for marketing your product.

PRODUCT DEVELOPMENT

PRESENTATION

POST COMMERCIALISATION

BEFORE THE PRESENTATION

- Roadmap and GAP analysis: Registration strategy: type of procedure, national regulations, legal basis, etc
- Scientific advice and pre-submission meetings
- Risk analysis/Scientific evaluation
- Medical/technical writing and support CMC
- Project management
- Regulatory Intelligence

REGULATORY AFFAIRS OPERATIONS

- During the preparation of the presentation of the Dossier
- Comprehensive due diligence and file Audit
- Design of the regulatory strategy (including the legal basis) and calculation of the rate
- Module 1 Documents: Readability Test, Bridge Reports, Environmental Risk Assessment and Product Information
- PhV services: QPPV, local contact in Spain

- From submission to obtaining authorisation
- Presentation and management of the procedure: NP, DCP, MRP, CP EU and FDA
- Data integrity: dossier compilation and e-CTD publication
- Act as a liaison and contact between companies and regulatory agencies
- National phases

POST COMMERCIALISATION

- Product release
- Product life cycle management: variations, renewals, marketing authorisation holder transfers and regulatory commitments
- Audits related to the acquisition of portfolios
- Regulatory Compliance and Quality Assurance

NET-PHARMA

7. LEGAL SUPPORT

1. BUSINESS STRUCTURING

Design the proper corporate structure (subsidiary, joint venture, permanent establishment, branch, representative office) to conduct the business, considering both (i) corporate governance & responsibilities and (ii) tax implications on the income generation and its repatriation. In the event of acquiring an existing local company to facilitate the landing of the Company, M&A legal and tax assistance would be required.

2. REGULATORY FRAMEWORK AND LICENCES

The life-sciences sector is highly regulated. Thus it is essential to acknowledge the local features regarding:

a. The manufacture, import, distribution and sale of medicines.
b. The permits from the health authority, product registrations, and authorisations for the import/export of pharmaceuticals.
c. Compliance with good practices of the life-sciences sector.

3. INTELLECTUAL PROPERTY

Covering both patents and trademarks and data protection regulations (clinical trials, etc.).

4. CONTRACTS

Assistance on the design of the (i) distribution and supply contracts, (ii) confidentiality and non-compete agreements, (iii) the framework contracts regulating the activity with clients and suppliers and (iv) to understand the general system of responsibility (both civil and criminal).

5. REGULATORY AND ETHICAL COMPLIANCE

This covers the advertising and promotion framework as well as the Pharmacovigilance local canvas.

6. TAXATION

The evaluation of the tax impacts of the business is crucial to understand the future performance of the business. Several issues should be analysed in this regard:

a. Corporate structure: Evaluate the best legal form for your company (subsidiary, branch, joint venture, etc.) according to local legislation and international treaties (for the repatriation of income).
b. Local taxes: Both direct (Corporate Income Tax) and indirect (VAT, import duties, etc.) and the requirements for filing and payment.
c. Transfer pricing regulations: If your company is part of an international group, you must comply with transfer pricing regulations for transactions between related companies.
d. Tax incentives: Investigate whether there are any tax incentives or exemptions for the pharmaceutical industry or for foreign investment, such as, for example, the Research and Development CIT credit.

7. INTERNATIONAL TRADE

a. Import/export regulations: Consider restrictions, tariffs, and labelling requirements for pharmaceutical products.
b. International treaties: Analyse whether there are free trade agreements or bilateral agreements that may affect your business.

8. CONTRACTS

To ensure compliance with local labour laws, including work permits for foreign employees and regulations regarding health professionals.

NET-PHARMA

8. LABORATORY CONTROL

We have our own Laboratory, approved EU GMP and FDA, and the following are the main services:

- Physicochemical Laboratory
- Microbiological Laboratory
- Extractables and Leachables Studies
- Nitrosamines and Mutagenic Impurities Analysis
- Galenic Development and Lyophilisation Studies
- Analytical Method Development
- Validation and Transfer of Analytical Methods
- Sample Storage for Stability
- Bath Analysis and Release (also as EU Releaser)
- Analytical Consultancy

And from the quality assurance side, by performing Ad-hoc GXP Audits.

NET-PHARMA

9. MANAGEMENT SUPPORT & TRAINING

NET-PHARMA TALENT

We offer customised training and interim solutions to cover unmet needs of different business lines (medicines, APIs, quality, biosafety, etc.) and focused diverse professional profiles in the Life Sciences sector.

From implementation to local readiness: preparing teams for sustainable handover of medical and pharmaceutical infrastructure

BUSINESS CASE & OPERATIONAL SUPPORT

- Business Case (medical service definition, P&L account, FCF, among others)
- On-site implementation planning and operationalisation
- Risk management and contingency plans
- Brothership with Spanish Hospital (Clinical sessions, among others)

TEAM CONSOLIDATION & TRAINING

- Staff recruitment, onboarding and upskilling
- Technical, clinical, and administrative continuous training programs
- Deployment of local operational teams

TOOLS ADOPTION & SYSTEM INTEGRATION

- Implementation of standardised management tools
- Process optimisation and documentation
- KPI systems, performance tracking and continuous improvement
- Support in the adoption of ERP / HIS / maintenance systems

KNOWLEDGE TRANSFER & EXIT STRATEGY

- Structured handover and local ownership planning
- Operational manuals, Standard Operating Procedures, and escalation protocols
- Support lines and remote assistance post-transition

10.I
ENSURING SAFETY

The patient is always in our radar

PHARMACOVIGILANCE SUPPORT PRE AND POST-MARKETING

- Support on the creation of new PhV system for the company or use the Qualipharma PhV system
- EU QPPV/Deputy and local contact roles
- Global and local literature monitoring
- xEVMPD and case management
- Preparation of periodic reports
- Preparation of Risk Management Plans
- Maintenance of the PhV system
- Quality and Compliance management

TOXICOLOGY SUPPORT

- GAP analysis of available toxicological documentation.
- Ingredient safety assessments.
- Review of limits for impurities, residual solvents and contaminants
- Bibliographical support on safety justification (Non-Clinical part).
- Preparation of environmental and toxicological risk assessments.
- Support on analytical tests, if needed.

NET-PHARMA

10.II COMPLIANCE EU-GMP / FDA

PRE-APPROVAL INSPECTION PROGRAMME

- Objective 1:
  - Investigations/Trends
  - Material Handling
  - Contamination
  - Procedures
  - Process feasibility
- Objective 2: Conformance to Application
- Objective 3: Data integrity

GAP ASSESSMENT EU-GMP / FDA COMPLIANCE

- According to FDA Chapter 46: Compliance Programme 7346.832: Pre-Approval Inspections/Investigations. Part III – Inspectional or to EU-GMP
- The methodology for conducting the GAP Assessment will consist of an on-site inspection:
  - Facilities
  - Validations
  - Procedures and records
  - Documentation

REMEDIATION PLAN

- Creation of the Remediation Plan
  - Dates
  - Resources
  - Objectives
- Creation or modification of SOPs/records/documentation
- Amend or attach supporting documentation in validations, records of non-conformities, deviations and change controls, OOS/OOT
- Identify and contact external suppliers approved by FDA to carry out or complete microbiological packaging or gap-identified validations

MANAGEMENT BEFORE AND DURING HEALTH AUTHORITIES INSPECTION

- Rules and behaviour retraining in inspections. Training in the subjective management of audits
- Visit(s) to the plant, to identify “last minute” gaps and behaviour or inappropriate practices
- Formation of the Audit management process. Identification of roles and responsibilities
- Staging management “War” room and strategic room SME preparation

11. EXPORT MARKET ACCESS

The market access process for new medicines refers to the set of stages and procedures that allow a pharmaceutical product, after development and regulatory approval, to reach patients. This process not only involves marketing authorisation but also price negotiation, reimbursement decisions, inclusion in healthcare systems, and actual availability to users.

STRATEGIC APROACH

- Marketing authorisation for a drug is granted by the regulatory authority (EMA, FDA, etc.), provided that the new product has more benefits than risks.
- Following this authorisation, each country decides whether to finance the drug with public funds, assessing the incremental benefit of the drug over existing ones and its cost-effectiveness.
- Therefore, in parallel with the regulatory process, a market access strategy is being prepared in each of the countries where the new drug is to be introduced.
- This strategy must take into account the drug's indication, the size of the target population, the price and the conditions of administration.

PRICE AND REEMBURSMENT PROCESS

- To this end, a value dossier is prepared to accompany the price and reimbursement application, the content and scope of which varies from country to country.
- In addition, a cost-effectiveness or cost-utility model is prepared in accordance with each country's methodological guidelines.
- Finally, the budget impact is prepared, summarising the cost (or savings) to be borne by the healthcare system with the introduction of the new drug

- If both are positive, the price and the budgetary impact for the country are negotiated. After this negotiation, the drug can be marketed.
- Each country has its own process and there are even cases where one country entrusts both authorisation and price and reimbursement to the decision of another country.
- Detailed knowledge of the processes and systems allows access to the market at the right price at the right.

NEGOTIATION

- After submission, the negotiation process with the healthcare system begins, during which the terms of access are agreed upon: the final price, the number of packages or the maximum total sales per year, and the different types of shared agreements that may exist to reduce uncertainties (pay-for-performance models or financial risk minimisation agreements).

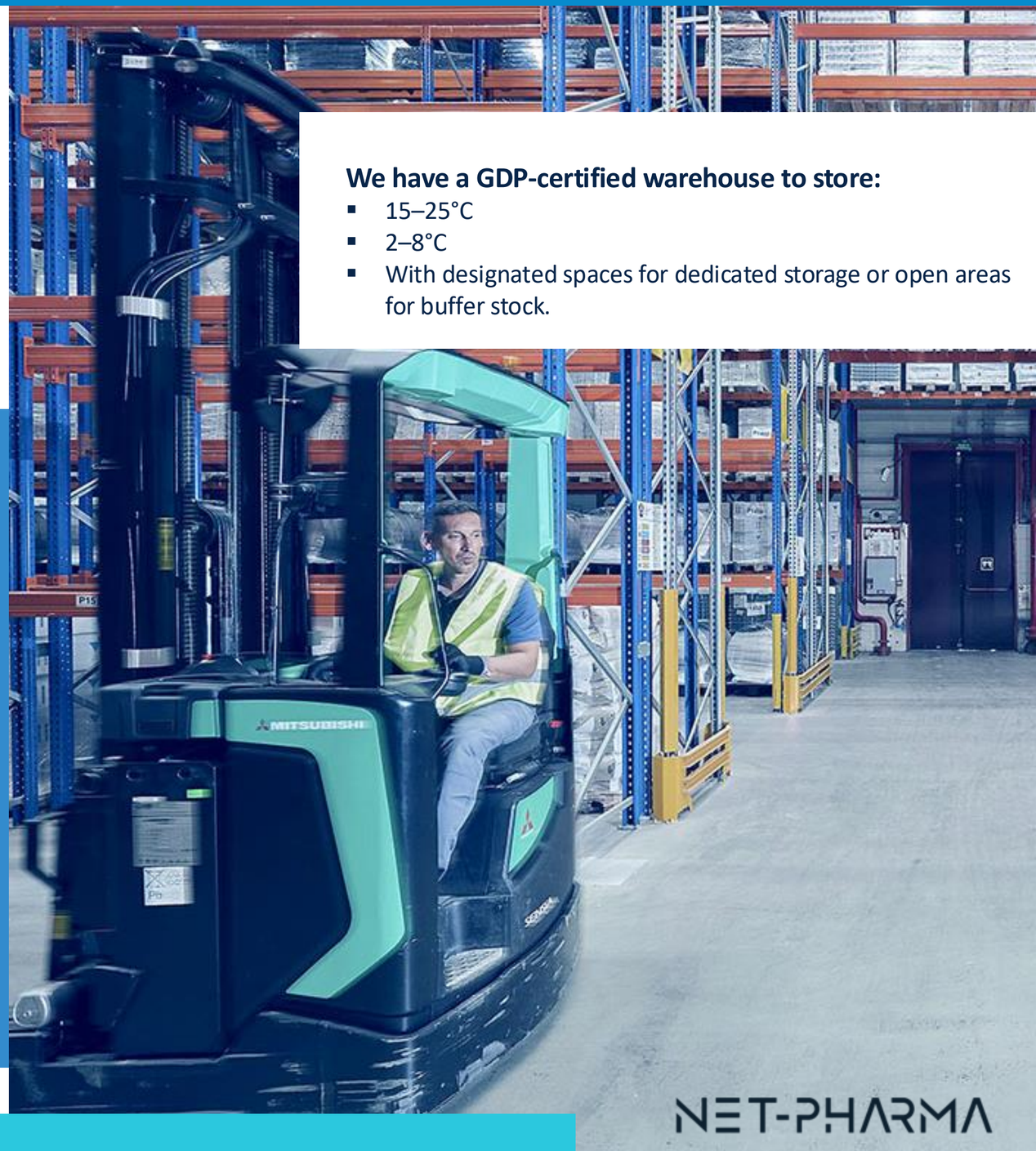
THE MARKET ACCESS PROCESS FOR NEW MEDICINES IS COMPLEX AND REGULATED DIFFERENTLY ON EACH CONTINENT, WHICH IMPACTS THE SPEED, EQUITY, AND AVAILABILITY OF MEDICINES FOR PATIENTS.

NET-PHARMA

12. LOGISTICS AND DISTRIBUTION

Offering services as a contract warehouse.

- We organise storage according to the specifications of the manufacturer, customer or goods, giving them personalised treatment. We develop activities related to the storage and conservation of medicines, always guaranteeing storage conditions in a GDP environment.
- And also we offer services are provided as an Importing Laboratory. Offering an integral service in such a way that we take care of storage, sampling, analysis, release and distribution of the batches, ensuring the correct storage conditions at all times.
- We consider Customs issues, helping partners to speed up customs clearance to make transport procedure as quick and efficient as possible, considering our facilities are authorised by AEMPS.



We have a GDP-certified warehouse to store:

- 15–25°C
- 2–8°C
- With designated spaces for dedicated storage or open areas for buffer stock.

NET-PHARMA

Success Stories

Madrid - EU Headquarters

HOSPITAL de Sampaka (Equatorial Guinea)

As a life sciences innovation ecosystem, Net-Pharma considers this project a benchmark in technology transfer, regional scalability and international collaboration. The initiative stands out for:

- Alignment with UN Sustainable Development Goal 3 (Good Health and Well-being)
- Smart application of medical technologies in resource-constrained environments
- Optimised local logistics through a dedicated distribution warehouse

This project reinforces Net-Pharma's mission to foster public-private partnerships and deliver sustainable, integrated healthcare solutions in emerging markets.

I. MAINTENANCE AND REHABILITATION PHASE

- Supply of original spare parts for the refurbishment of existing equipment.
- Optimisation of critical medical devices to ensure safety and optimal performance.

II. NEW EQUIPMENT INSTALLATION PHASE

- Medical gas generation plant to support operating rooms and intensive care units.
- Advanced anaesthesia machines, ventilators, X-ray systems and surgical equipment.
- Deployment of medical technologies to enhance diagnostics and complex interventions.

NET-PHARMA

IMEXPHARM in Vietnam

It coordinates the activities of the companies within the Hub, supplies APIs to Vietnam for product development, and represents the Vietnamese client in Europe to support customer acquisition across European and global markets.

I. REGULATORY & PV

- Design of the regulatory strategy
- Update of dossiers for submission to the EMA in compliance with current regulatory requirements.
- Pharmacovigilance support, ensuring compliance with European regulations.

II. QUALITY COMPLIANCE & SYSTEM

- GMP Audit and GAP Analysis
- Data Integrity Evaluation
- Facilities, Utilities & Equipment Qualification and Validation
- Implementation of the Pharmaceutical Quality System (PQS)
- Annex 1 Alignment, with Remediation and Action Planning.

III. POST COMMERCIALISATION

- Act as the TAC in Europe for the client's various registrations.
- Serves as the importing laboratory in Europe.
- Pharmacovigilance of Vietnamese products for three countries: Portugal, Spain, and Hungary.
- Continuous Training in Good Manufacturing Practices (GMP) and Audit Readiness

VIVUNT in Spain

Comprehensive Strategy Development for the Establishment of a Lyophilised Injectables Manufacturing Plant in Spain for a Non-EU Pharmaceutical Company

Includes the design and execution of the commercial strategy, product development, regulatory planning, equipment procurement, engineering, construction, quality, qualification and validation of the facility, along with support in communications with European regulatory authorities.

I. COMMERCIAL, PRODUCT DEVELOPMENT & REGULATORY	II. DESIGN & CONSTRUCTION	III. QUALITY COMPLIANCE, SYSTEM & TRAINING
▪ Commercial strategy for EU entry ▪ Development of four lyophilised products ▪ Regulatory strategy, roadmap and submission planning ▪ API and excipient sourcing evaluation ▪ Toxicological assessment of selected APIs ▪ Liaison with European regulatory authorities	▪ Conceptual and detailed engineering design ▪ Selection and procurement of process equipment ▪ Construction and coordination of cleanrooms and critical systems (HVAC, PW, WFI, gases) ▪ Commissioning and startup of cleanrooms and GMP utilities	▪ Definition of URS and GMP-compliant design ▪ Qualification of equipment, critical, systems and utilities ▪ Validation master plan and risk-based approach ▪ Compliance oversight and inspection readiness ▪ Implementation of the GMP Quality System

NET-PHARMA

NEOM HOSPITAL in Saudi Arabia

SERVICES:

- Project monitoring
- Medical concept
- Medical and non-medical equipment plan
- Support to the architecture and engineering team for the development of technical projects (RIBA 0-4)

NET-PHARMA

AXA Diagnostic Centres in Spain, Egypt and Nigeria

SERVICES:

- Project management
- Medical concept
- Medical and non-medical equipment plan
- Support to the architecture and engineering team for the development of technical projects (RIBA 0-4).
- Strategic approach to procurement
- Market study and research to identify assets to be acquired
- Medical due diligence
- Assistance to procurement negotiations

NET-PHARMA

NET-PHARMA

Our NetWork is our NetWorth

NET-PHARMA HUB

Head Quarters

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July 2025