NET-PHARMA

EMPOWERING FOREIGN COMPANIES TO THRIVE IN IBERIA

Build the future

Barcelona – EU Facilities

July 2025

NET-PHARMA. One Platform. Every Solution. Total Market Access.

Where international strategy meets local implementation

EXPAND SMARTER. LAND STRONGER

How can I enter the Iberian market safely and compliantly, avoiding legal and regulatory pitfalls from day one?

Not only do we have the answers...

How do I build the right local team, find the ideal partners and set up operations that truly connect with Spanish and Portuguese customers?

...we deliver solutions that move your business forward.

NET-PHARMA

OUR VALUE PROPOSITION

"Integrated solutions for commercial success in Iberia"

1. GAP ANALYSIS
2. ROADMAP
3. FACILITIES WORKING OFFICES
4. LEGAL SUPPORT
5. REGULATORY AFFAIRS
6. MANAGEMENT SUPPORT & TRAINING
7. MARKET ACCESS
8. SALES & DISTRIBUTION

At Net-Pharma, we guide your access to market, ensuring an efficient and impactful entry in Iberia.
We don't just launch your product — we establish your company successfully in Spain and Portugal.

"Your one-stop partner for business expansion"

- 360º Commercial landing service

NET-PHARMA

1. GAP ANALYSIS

A GAP analysis is a fundamental strategic exercise that pinpoints the disparity between your current operational state and your desired future state. In the context of commercial expansion, it meticulously identifies what's missing or requires enhancement to ensure a triumphant market entry or product introduction.

In a commercial landing context, a GAP analysis typically involves:

- **Assessing current capabilities:**

This includes a thorough evaluation of existing marketing infrastructure, sales channels, distribution networks and internal compliance protocols.

- **Comparing them to market requirements:**

This step involves benchmarking your current state against the specific demands of the target market or the evolving expectations of potential customers.

- **Identifying gaps:**

Through this comparison, you identify critical deficiencies in resources, operational processes, or specialised knowledge required for success.

- **Prioritising actions:**

The final stage involves ranking the identified gaps by urgency and impact, enabling a focused approach to bridge these deficiencies effectively.

2. ROADMAP

After completing a thorough GAP analysis, the next key step is to create a **Roadmap.** A strategic and detailed action plan. This roadmap outlines the step-by-step actions and specific timelines needed to close the identified gaps and achieve successful market entry or product launch. It translates challenges into clear, actionable objectives to guide your progress.

1

Key Milestones

Define critical checkpoints such as product localisation, establishing local operational presence, hiring local staff and securing necessary regulatory approvals.

2

Timeline & Phases

Outline a clear schedule for each phase of the launch, breaking down the entire process into manageable, time-bound segments.

3

Required Resources

Detail the allocation of essential resources, including financial budgets, human capital, necessary technological infrastructure, and strategic partnerships.

4

Assessing current capabilities

This includes a thorough evaluation of existing marketing infrastructure, sales channels, distribution networks and internal compliance protocols.

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3. FACILITIES WORKING OFFICES

MADRID
(Alcobendas)

NET-PHARMA HUB MADRID

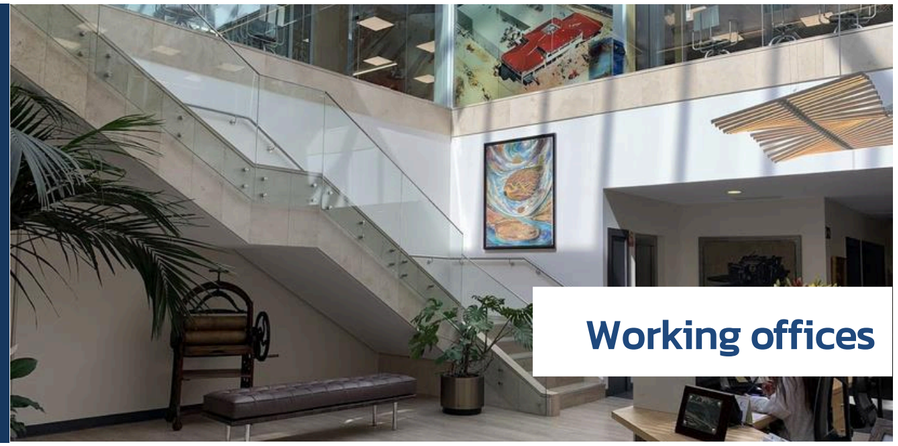
BARCELONA
(Sant Quirze del Vallès)

NET-PHARMA HUB BARCELONA

NET-PHARMA

3. FACILITIES WORKING OFFICES

5,000 m²



Working offices

3,000 m²

Storage

500 m²

GMP Laboratory

150 attendees

Conference Room

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4. LEGAL SUPPORT

1.BUSINESS STRUCTURING

Design the appropriate corporate structure (subsidiary, joint venture, branch, M&A etc.) to operate locally, considering corporate governance, responsibilities, and tax implications on income and repatriation.

2. REGULATORY FRAMEWORK AND LICENCES

- Regulation of the manufacture, import, distribution, and sale of medicines.
- Health authority permits, product registrations and import/export authorisations. Compliance with life-sciences good practices.

3. INTELLECTUAL PROPERTY

Covers patents, trademarks and data protection (e.g., clinical trials).

4. CONTRACTS

Given the sector's high regulation, it is essential to consider local specificities in distribution, supply, confidentiality, non-compete and framework agreements with clients and suppliers, as well as liability (civil and criminal).

5. REGULATORY AND ETHICAL COMPLIANCE

Covers the framework for advertising, promotion and local Pharmacovigilance requirements.

6. TAXATION

Considering local laws and international treaties for income repatriation.

- Local taxes
- Transfer pricing
- Tax incentives

7. INTERNATIONAL TRADE

- Import/export
- Treaties: Analyse trade agreements impacting your business.
- Labour compliance

8. CONTRACTS

Evaluate tax impacts on business performance and analyse related issues carefully.

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5. 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

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6. 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
- Connection with Spanish Hospitals (Clinical sessions, among others)

TEAM CONSOLIDATION & TRAINING

- Staff recruitment, onboarding and upskilling
- Technical, clinical, and administrative continuous training programmes
- 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

7. 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 medication 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 medication 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 medication is to be introduced.
- This strategy must take into account the medication'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 medication

- 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 time.

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.

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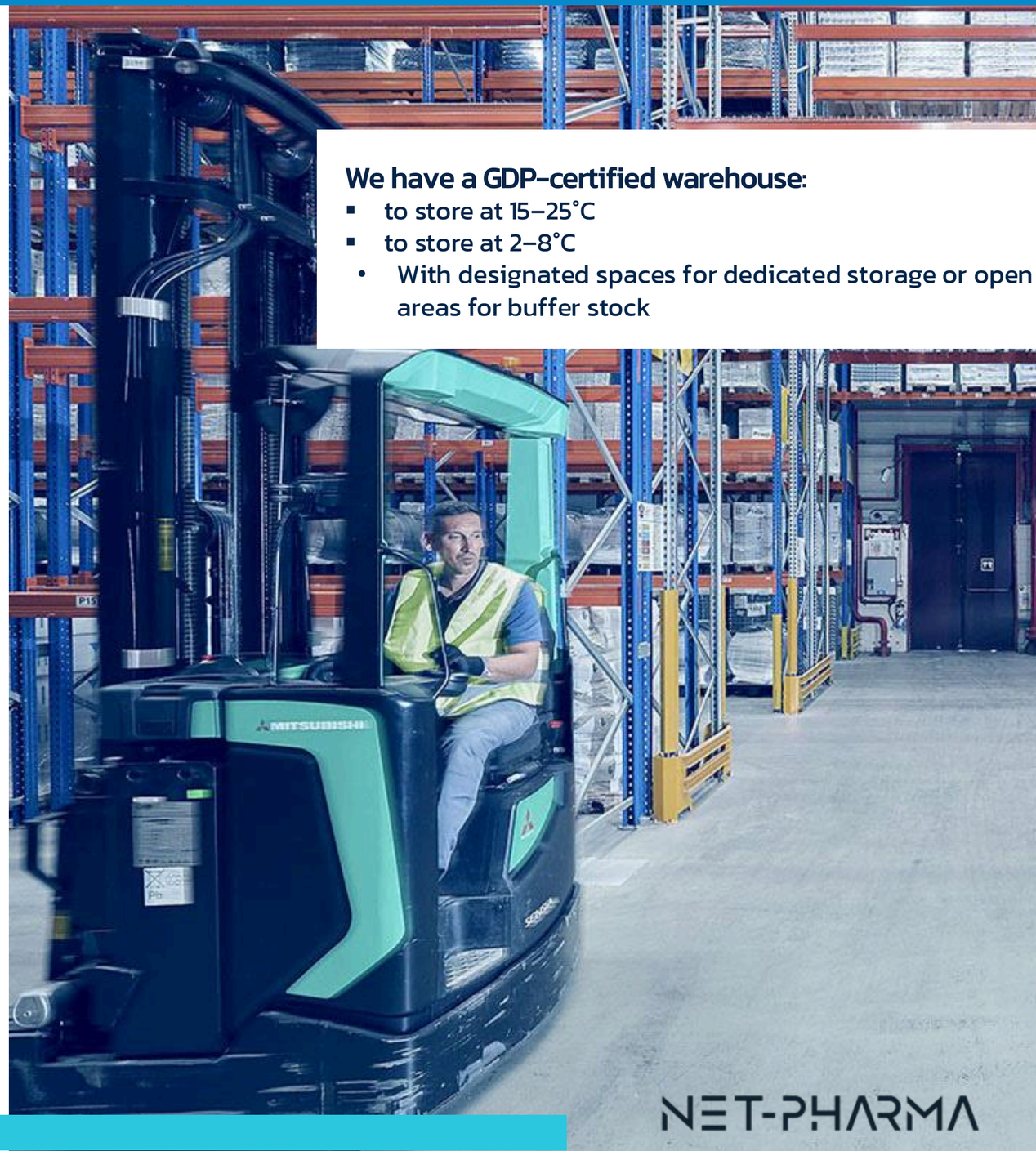
8. SALES AND DISTRIBUTION

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. We also offer services which 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 at 15–25°C
- to store at 2–8°C
- With designated spaces for dedicated storage or open areas for buffer stock

NET-PHARMA

COMPANIES WE'VE ALREADY LANDED IN IBERIA

Endress+Hauser

BWT
BEST WATER TECHNOLOGY

CHC LAB
International

camfil

NETZSCH
Proven Excellence.

Alpen Pharma
Alpen Pharma Group

AG Solution
Process Automation & Industrial ICT

TYTESA
Energía y Automatización

QUANT™

verifarma

NET-PHARMA

OUR NETWORK IS OUR NET WORTH

NET-PHARMA HUB

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