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 execution

EXPAND SMARTER. LAND STRONGER

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

We don't just 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.

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 LIFESCIENCES HUB

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 specialized knowledge required for success.

PRIORITIZING 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 localization, 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

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4. FACILITIES WORKING OFFICES

5.000 m²

Working offices

3.000 m²

Storage

500 m²

GMP Laboratory

150 attendees

Conference Room

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2. LEGAL SUPPORT

1. **BUSINESS STRUCTURING**

Design the appropriate corporate structure (subsidiary, joint venture, branch, etc.) to operate locally, considering corporate governance, responsibilities, and tax implications on income and repatriation. If acquiring a local company, M&A legal and tax support would be needed.

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

Corporate structure: Define the optimal legal form (subsidiary, branch, joint venture) considering local laws and international treaties for income repatriation.

- Local taxes: Includes Corporate Income Tax, VAT, import duties, and filing obligations.
- Transfer pricing: Ensure compliance for intra-group transactions.
- Tax incentives: Check for benefits or exemptions (e.g., R&D credits) for the pharma sector or foreign investment.

7. **INTERNATIONAL TRADE**

- Import/export: Assess restrictions, tariffs, and labelling rules for pharmaceuticals.
- Treaties: Analyse trade agreements impacting your business.
- Labour compliance: Ensure adherence to local employment laws, work permits, and health professional regulations.

1. **CONTRACTS**

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

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6. REGULATORY AFFAIRS

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

PRODUCT DEVELOPMENT

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

PRESENTATION

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

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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7. 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

5. 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 is granted by agencies such as EMA or FDA if the drug demonstrates a positive benefit-risk balance.
- After approval, each country independently decides on public reimbursement, evaluating:
  1. Incremental clinical benefit compared to existing treatments
  2. Cost-effectiveness

In parallel with the regulatory process, a market access strategy must be developed in each target country.

- This strategy should consider:
- The drug's indication
- Size of the target population
- Price positioning
- Conditions of administration

ACCESS TO ECOSYSTEM

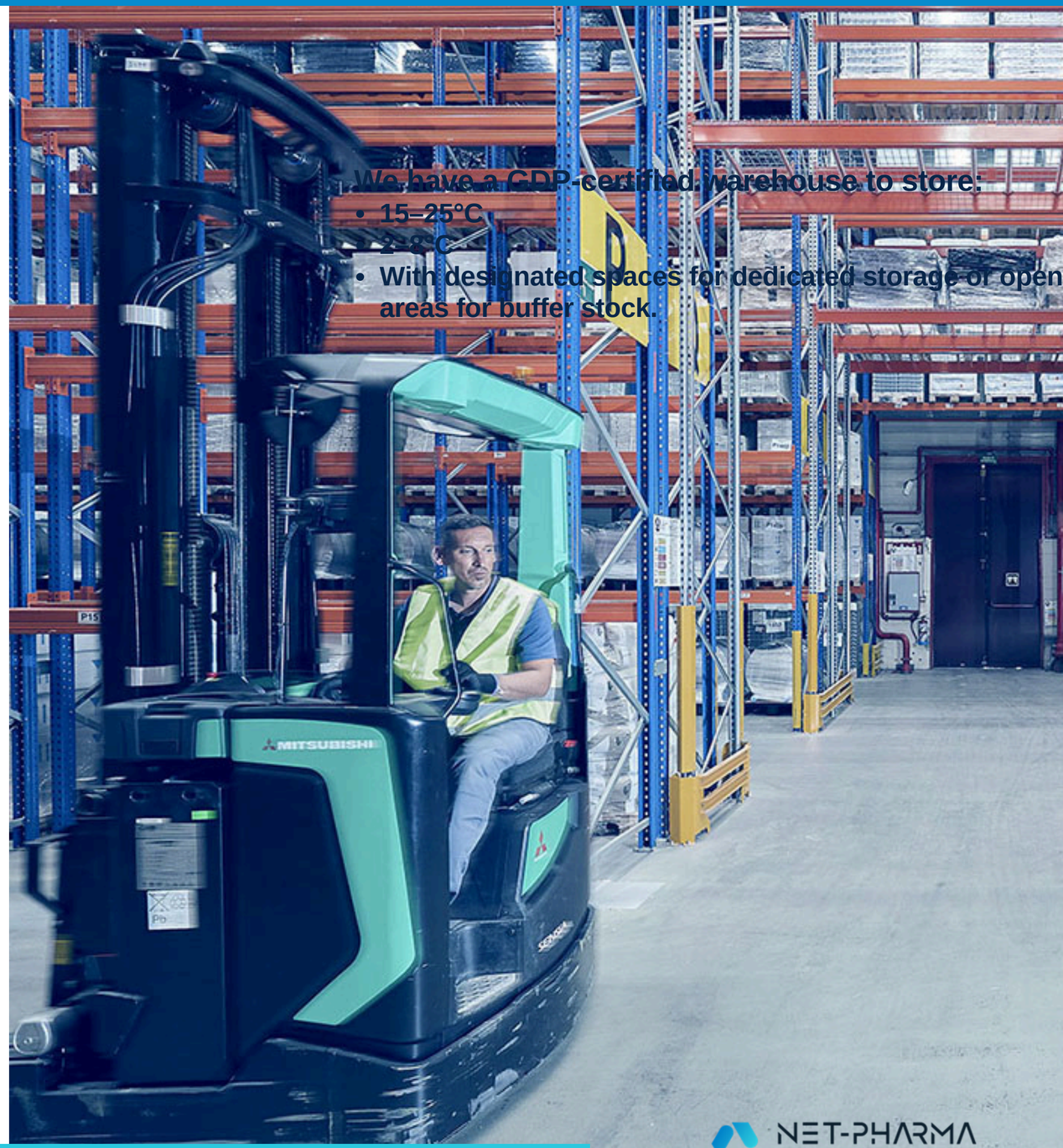
- **Strategic connections** with institutions, clusters & industry leaders
- **Presence at major trade shows** (CPHI, FARMAFORUM, BIOSPAIN, EXPOQUIMIA…)
- Exclusive networking events with top decision-makers
- **360º visibility** through our digital channels & media team
- **Talent attraction & tailored training programs**

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.

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.
- 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.



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MEMBERS ALREADY LANDED IN IBERIA

Endress+Hauser

CHC LAB International

BWT BEST WATER TECHNOLOGY

NETZSCH Proven Excellence.

Alpen Pharma Alpen Pharma Group

AG Solution Process Automation & Industrial ICT

QUANT™

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NET-PHARMA

Our NetWork is our NetWorth

NET-PHARMA HUB

Head Quarters
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