

QUESTIONNAIRE FOR QUALIFICATION

INTERNATIONAL PHARMACEUTICAL BUSINESS

PARTNERS

Screening questionnaire for potential new customers

Dear interested party,

Thank you for your interest in a business partnership with our company. To ensure a successful and long-term collaboration, we ask that you complete this questionnaire fully and truthfully. This questionnaire serves to qualify potential business partners in accordance with regulatory requirements (EU GDP, GMP) and our internal compliance standards. The information provided will help us assess your suitability as a reliable partner.

IMPORTANT NOTE: This questionnaire does not constitute a binding offer or contract. We reserve the right to accept or reject applications at our sole discretion.

1. GENERAL COMPANY INFORMATION

1.1 Full company name:

1.2 Registered business address:

1.3 Country of business activity:

1.4 Year of establishment of the company:

1.5 Legal form of the company (e.g., LLC, Inc., Ltd.):

1.6 Commercial register number:

1.7 Value added tax identification number (VAT ID):

1.8 Company website:

1.9 Number of employees:

☐ 1-10 ☐ 11-50 ☐ 51-200 ☐ 201-500 ☐ >500

2. CONTACT INFORMATION

2.1 Name of the managing director/CEO:

2.2 Name of the primary contact person for this partnership:

2.3 Position/title of the contact person:

2.4 Email address of the contact person:

2.5 Telephone number (with country code):

3. BUSINESS ACTIVITIES & EXPERIENCE

3.1 Type of business activity:

☐ Pharmaceutical manufacturer

☐ Wholesaler/distributor

☐ Pharmacy chain

☐ Hospital/clinic

☐ Retail pharmacy

☐ Trading company

☐ Other: _____

3.2 How many years have you been in the pharmaceutical business?

3.3 In which countries are you currently active? (Please list all)

3.4 Which pharmaceutical product categories do you currently distribute/trade?

☐ Finished dosage forms (FDF)

☐ Active pharmaceutical ingredients (APIs)

☐ Sterile products

☐ Local anesthetics

- ☐ Veterinary products
- ☐ Dietary supplements
- ☐ Medical devices
- ☐ Other: _____

4. REGULATORY & QUALITY REQUIREMENTS

4.1 Do you have a valid wholesale license (GDP license)?

☐ Yes ☐ No

If yes, please attach a copy.

Issuing authority: _____

Valid until: _____

4.2 Do you have a manufacturing license?

☐ Yes ☐ No

If yes, please attach a copy.

4.3 Are you GDP-certified (Good Distribution Practice)?

☐ Yes ☐ No

If yes, please attach certificate.

4.4 Do you have a qualified person?

☐ Yes ☐ No

If yes, name and qualification: _____

4.5 Have you been inspected by an authority in the last 3 years?

☐ Yes ☐ No

If yes, when and with what result? _____

4.6 Have you had any regulatory violations, sanctions, or license revocations in the last 5 years?

☐ Yes ☐ No

If yes, please explain in detail: _____

4.7 Do you have a Quality Management System (QMS)?

☐ Yes ☐ No

5. FINANCIAL STABILITY**5.1 Annual revenue (last fiscal year):**

☐ < 500.000 EUR ☐ 500.000 - 2 Mio. EUR ☐ 2 - 10 Mio. EUR ☐ 10 - 50 Mio. EUR

5.2 Are you prepared to provide annual financial statements for the last 2 years?

☐ Yes ☐ No

5.3 Bank reference: Name and address of your main bank:**5.4 Do you have product liability insurance?**

☐ Yes ☐ No

If yes, amount of coverage: _____

5.5 Have you filed for bankruptcy in the last 3 years or are you currently in bankruptcy proceedings?

☐ Yes ☐ No

6. COMMITMENT & LONG-TERM COOPERATION

6.1 Why are you interested in working with our company?

6.2 Which specific products from our portfolio are you interested in?

6.3 What is your estimated annual order volume from us? (Quantities or sales volume)

6.4 Are you planning a long-term strategic partnership (>3 years)? ☐ Yes ☐ No

6.5 Are you willing to invest in marketing and sales activities for our products? ☐ Yes ☐ No

If yes, what activities are you planning? _____

6.6 Have you already developed a business plan or market strategy for our products? ☐

Yes ☐ No

If yes, please summarize or attach:

6.7 How many sales representatives do you have for the pharmaceutical sector?

6.8 Which other international pharmaceutical manufacturers do you already have long-term partnerships with (>3 years)?

7. BUSINESS REFERENCES

7.1 Please provide at least two business references:

(Name, company, contact details, duration of collaboration)

Reference 1:

Reference 2:

8. INFRASTRUCTURE & LOGISTICS

8.1 Do you have your own transport vehicles or do you work with logistics service providers?

8.2 Is your cold chain validated in accordance with GDP?

☐ Yes ☐ No

8.3 Do you have a system for tracing medicinal products (e.g., serialization)?

☐ Yes ☐ No

9. COMPLIANCE & LEGAL CONFORMITY

9.1 Have you ever traded in counterfeit or illegal medicines?

☐ Yes ☐ No

9.2 Have any criminal investigations been initiated against your company or its senior employees in the last 5 years?

☐ Yes ☐ No

If yes, please explain: _____

9.3 Do you have an anti-corruption and compliance policy?

☐ Yes ☐ No

9.4 Are you familiar with the EU GDP guidelines and national pharmaceutical laws?

☐ Yes ☐ No

10. ADDITIONAL DOCUMENTS

Please attach the following documents (if applicable):

- ☐ Copy of wholesale license / GDP certificate
- ☐ Copy of commercial register extract
- ☐ Company brochure or company profile
- ☐ Proof of product liability insurance
- ☐ Annual financial statements for the last 2 years (if ready for disclosure)
- ☐ Reference letters from existing partners
- ☐ Organisational chart of the company

DECLARATION AND SIGNATURE

I hereby confirm that all the information provided above is true and complete. I am aware that providing false information may result in the immediate termination of the business relationship and may have legal consequences.

Name of signatory: _____

Position/title: _____

Date: _____

Signature: _____

Company stamp:

DATA PROTECTION NOTICE

The data you provide will be used exclusively to assess your suitability as a business partner and will be treated confidentially in accordance with the EU General Data Protection Regulation (GDPR). Your data will not be passed on to third parties unless this is necessary to comply with regulatory requirements.

Export Service Inquiry Form

Pharmaceutical Registration and Regulatory Affairs Services

1. PACKAGE 1: Basic Documentation (CPP, GMP/GDP)

Do you need support for obtaining and preparing:

- ☐ CPP Certificate (Certificate of Pharmaceutical Product) – WHO
- ☐ RP Copy (Responsible Person)
- ☐ GMP Certificate (Good Manufacturing Practice)
- ☐ GDP Certificate (Good Distribution Practice)

Special Requirements/Notes:

2. PACKAGE 2: Translation and Certification

Do you need support for:

- ☐ Translation of pharmaceutical documentation
- ☐ Certification of documents by authorities
- ☐ Both (combined package)

Document Volume (please estimate)(for a product):

Approximate word count of documents to be translated/certified:

- ☐ Package 2

Language(s): _____

Certification required for:

- ☐ Notarial certification
- ☐ Official authority certification
- ☐ Apostille (Hague Convention)
- ☐ Other: _____

Notes:

3. PACKAGE 3: Dossier Update and Expert Reports

Do you need support for:

- ☐ CTD Module 1 Update (Administrative and Regional Data)
- ☐ Preparation of Quality Expert Reports
- ☐ Both (combined)

Timeline:

- ☐ Package 3 Standard:

Which modules need to be updated?

- ☐ Module 1 (Administrative Data)
- ☐ Module 2 (Summaries)
- ☐ Module 3 (Quality/CMC)
- ☐ Other: _____

Number of Expert Reports Required:

- ☐ 1 Report
- ☐ 2 Reports
- ☐ Other Number: _____

Project Complexity Level:

- ☐ Simple (Routine update, well-known active substance)
- ☐ Medium (New formulation, established market)
- ☐ Complex (New active substance, highly regulated markets)

4. PACKAGE 4: New Dossier Preparation

Do you need support for **COMPLETE NEW PREPARATION** of a pharmaceutical dossier?

Which configuration do you need?

- ☐ Package 4A

Dossier Update (Modules 1-3) + 1 Expert Report
For simple generics, well-known active substances

- ☐ Package 4B

Complete Dossier + 2 clinical/non clinical Reports + Basic Stability
For new formulations, established markets

Type of Pharmaceutical Product:

- ☐ Generic ☐ New Formulation ☐ New Active Substance ☐ Biologic ☐ Other:

Availability of Existing Data:

- ☐ Dossier available from another country (base data available)
- ☐ Only partial documentation available
- ☐ No documentation available (complete new preparation)

Target Market(s) for Dossier:

5. PACKAGE 5: Country-Specific Labels and Box Inserts

Do you need support for:

- ☐ Pharmaceutical Labels (outer label)
- ☐ Carton/Box design
- ☐ Both

Which configuration do you need?

- ☐ Package 5 Standard: 3,000 EUR (monolingual)

Required Languages:

Special Features:

- ☐ Standard labeling
- ☐ With serialization features (Track & Trace)
- ☐ With security features (e.g., hologram, anti-counterfeiting)
- ☐ Accessible design (Braille, large print)

6. ADDITIONAL INFORMATION

Total Budget Range (if available):

Current Status of the Product:

- ☐ Already registered in other markets → Which ones? _____
- ☐ Never registered → Complete new preparation required
- ☐ International registration planned → How many countries? _____

Timeline for this Project:

- ☐ Within 3 months
- ☐ Within 6 months
- ☐ Within 12 months
- ☐ Flexible planning

7. FINAL REMARKS**Special requirements or special features:**

Signature and Confirmation**Data Protection Declaration:**

I confirm that I have read and understood the data protection provisions and agree to the storage and processing of my data.

☐ Confirmation read and accepted

Signature of Applicant

Date

Contact Person (if different)