

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

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

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

If yes, what activities are you planning? _____

6.5 Have you already developed a business plan or market strategy for our products? Yes No

If yes, please summarize or attach:

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

6.7 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. Basic Documentation (CPP, GMP/GDP)

CPP Certificate (Certificate of Pharmaceutical Product)

Translation needed in _____

Apostille (Hague Convention)

legalized by embassy

Other: _____

Manufacturing license

copy/scan

legalized Copy

Translation needed in _____

Apostille (Hague Convention)

legalized by embassy

Other: _____

GMP Certificate (Good Manufacturing Practice)

copy/scan

legalized Copy

Translation needed in _____

Apostille (Hague Convention)

legalized by embassy

Other: _____

GMP Contract Manufacturing

- copy/scan
- legalized Copy
- Translation needed in _____
- Apostille (Hague Convention)
- legalized by embassy
- Other: _____

Manufacturing license Contract manufacturer

- copy/scan
- legalized Copy
- Translation needed in _____
- Apostille (Hague Convention)
- legalized by embassy
- Other: _____

GDP contract manufacturer

- copy/scan
- legalized Copy
- Translation needed in _____
- Apostille (Hague Convention)
- legalized by embassy
- Other: _____

GDP Certificate (Good Distribution Practice)

- legalized Copy
- copy/scan
- Translation needed in _____
- Apostille (Hague Convention)
- legalized by embassy
- Other: _____

Special Requirements/Notes:

2. Regulatory Documents

| | | | | | |
|---|--------------------------|----------------|--------------------------|----------------|--------------------------|
| Modul 1 | | Modul 2 | <input type="checkbox"/> | 3.2.P.4 | <input type="checkbox"/> |
| 1.0 Cover letter | <input type="checkbox"/> | 2.3.S | <input type="checkbox"/> | 3.2.P.5.1 | <input type="checkbox"/> |
| 1.1 Tracking Table | <input type="checkbox"/> | 2.3 P. | <input type="checkbox"/> | 3.2.P.5.2 | <input type="checkbox"/> |
| 1.2 Application Form | <input type="checkbox"/> | 2.4 | <input type="checkbox"/> | 3.2.P.5.3 | <input type="checkbox"/> |
| QP declaration | <input type="checkbox"/> | 2.5 | <input type="checkbox"/> | 3.2.P.5.4 | <input type="checkbox"/> |
| Elemental Impurities | <input type="checkbox"/> | Modul 3 | <input type="checkbox"/> | 3.2.P.5.5 | <input type="checkbox"/> |
| Nitrosamine | <input type="checkbox"/> | 3.2.S | <input type="checkbox"/> | 3.2.P.5.6 | <input type="checkbox"/> |
| 1.3.1 SmPC | <input type="checkbox"/> | 3.2.P.1 | <input type="checkbox"/> | 3.2.P.6 | <input type="checkbox"/> |
| 1.3.2 PIL | <input type="checkbox"/> | 3.2.P.2.1 | <input type="checkbox"/> | 3.2.P.7 | <input type="checkbox"/> |
| 1.3.3 Labelling | <input type="checkbox"/> | 3.2.P.2.2 | <input type="checkbox"/> | 3.2.P.8.1 | <input type="checkbox"/> |
| 1.3.4 Readability testing | <input type="checkbox"/> | 3.2.P.2.3 | <input type="checkbox"/> | 3.2.P.8.2 | <input type="checkbox"/> |
| 1.3.6 Braille | <input type="checkbox"/> | 3.2.P.2.4 | <input type="checkbox"/> | 3.2.P.8.3 | <input type="checkbox"/> |
| 1.4.1 Expert Quality | <input type="checkbox"/> | 3.2.P.2.5 | <input type="checkbox"/> | Modul 4 | <input type="checkbox"/> |
| 1.4.2 Expert Non-Cliniical | <input type="checkbox"/> | 3.2.P.2.6 | <input type="checkbox"/> | Modul 5 | <input type="checkbox"/> |
| 1.4.3 Expert Clinical | <input type="checkbox"/> | 3.2.P.3.1 | <input type="checkbox"/> | E-CTD | <input type="checkbox"/> |
| 1.5. Information on bibliografic/generic applications | <input type="checkbox"/> | 3.2.P.3.2 | <input type="checkbox"/> | | |
| 1.6 Environmental Risk Assessment | <input type="checkbox"/> | 3.2.P.3.3 | <input type="checkbox"/> | | |
| 1.8.1 Pharmakovigilance system | <input type="checkbox"/> | 3.2.P.3.4 | <input type="checkbox"/> | | |
| 1.8.2 Risk Management-Plan | <input type="checkbox"/> | 3.2.P.3.5 | <input type="checkbox"/> | | |

3. Country-Specific Labels and Box Inserts

- Primary packaging
 - Carton/Box
 - Package insert

 - Packaging in German
 - Packaging in other languages:
-

- printed Mockup must be approved by authority

Special Features:

- With serialization features (Track & Trace, security features)
- Accessible design (Braille, large print)

4. 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)