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?

Article Number	Product	Quantity/single Units	Quantity/ selling Box

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

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)