

# Export Service Inquiry Form

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PREISMUSTER

## 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:**

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## 2. Regulatory Documents

Do you need support for obtaining and preparing:

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-Clinical	<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 bibliographic/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 Pharmacovigilance 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:

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☐ 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

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Signature of Applicant

Date

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Contact Person (if different)