GDP QUESTIONNAIRE

SYMBIO
FARMA BV

COMPANY INFORMATION

Company Name

Country

Headquarter Address

Number of Employees

Name of Contact Person

Email of Contact Person

Phone Number of Contact Person

RESPONSIBLE PERSON

Name of Responsible Person (RP)

Phone Number of Responsible Person (RP)

E-mail Address of Responsible Person (RP)

What Is the Educational Backround Of Responsible Person (RP)?

GDP QUESTIONNAIRE

LICENCE & AUTHORISATION

Are You In Possession of a Valid Wholesale Distribution Licence?

☐ Yes   ☐ No

If Yes, Number of The License

[   ]

Issued

[   ]

Valid

[   ]

Name of Warehouse(s)

[   ]

Warehouse(s) Address(es)

[   ]

Warehouse(s) Opening Days and Opening Hours

[   ]

Are You in Possession of a Valid Manufacterer Licence? (GMP License)

☐ Yes   ☐ No

If Yes, Number of the License

[   ]

Issued

[   ]

Valid

[   ]

Please Attach Copies of Valid Certifications (GMP, GDP, Controlled Drug License, ISO 9001, Other)

☐ GDP   ☐ GMP

☐ ISO 9001   ☐ CONTROLLED DRUG LICENSE

☐ Other

[   ]

Other Certification/ Accreditation/Registration/ Approval

☐ Yes   ☐ No

If Yes, Number of the Certificate

[   ]

Last Inspection from Your National Authorities (Month/Year)

[   ]

Will You Inform Us About Major Changes of Your Location of Storage, Activities or Licenses?

☐ Yes   ☐ No

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SOP

Do You Have Written Procedures (Sop) That Cover All Key Activities In Your Company?	☐ Yes	☐ No
Does SOPs Include		
Complaint Management	☐ Yes	☐ No
Identification and Preventation of Counterfeited Products	☐ Yes	☐ No
Supplier Approval	☐ Yes	☐ No

QUALITY MANAGEMENT SYSTEM

Do You Have a Quality System in Place?	☐ Yes	☐ No
Have You Done a Risk Assessment of Your Processes?	☐ Yes	☐ No
Is There a Process in Place for Capa?	☐ Yes	☐ No
Are There Process for Change Control?	☐ Yes	☐ No

TRAINING RECORDS

Do You Perform Initial and Regular Training of Your Staff Included in Storage, Handling and Transportation of Medicines?	☐ Yes	☐ No
Have You Got a Training Plan? Are The Trainings Documented?	☐ Yes	☐ No

SELF-INSPECTIONS

Do You Perform Regular Self-inspection?	☐ Yes	☐ No	
Frequency Of Regular Self-inspection?	☐ Quaterly	☐ Half a Year	☐ Yearly

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VALIDATIONS OF SUPPLIERS/CUSTOMERS

Do You Qualify Your Suppliers?
☐ Yes ☐ No

Does This Qualification Include Licenses Checking?
☐ Yes ☐ No

Does This Qualification Include The Audits?
☐ Yes ☐ No

Do You Maintain an Updated List of Your Approved Suppliers?
☐ Yes ☐ No

ORDERING

Do You Source Your Medicinal Products From Authorised Wholesalers?
☐ Yes ☐ No

Are The Products Supplied to Symbio Have Been Released By Manufacturers Within The EEA.
☐ Yes ☐ No

Do You Receive Products

For Sale Directly From The Manufacturers?
☐ Yes ☐ No

For Sale Directly From Other Domestic Suppliers?
☐ Yes ☐ No

For Sale Directly From From Outside Of EU?
☐ Yes ☐ No

RETURNS

Do You Have a Separate SOP For Accepting Returns
☐ Yes ☐ No

Does This SOP Include That the Returned Goods Need to Be Separated on Quarantine Area, They Must Be Checked and Approved By Responsible Person, Before They Can Be Put on Saleable Stock?
☐ Quaterly ☐ Half a Year ☐ Yearly

Is The Temeparture In The Quarantine Area Monitored?
☐ Yes ☐ No

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RECALLS

Can A Product Be Traced In Your System By Batch Number?	☐ Yes	☐ No
Will You Inform Us Directly In Case Of A Recall Or Any Other Quality Issues?	☐ Yes	☐ No

WAREHOUSE

Do You Have The Following Contols For The Stored Medicinal Products?

Temperature Control	☐ Yes	☐ No
Humidity Control	☐ Yes	☐ No
Pest Control	☐ Yes	☐ No
Regular Cleaning & Maintenence	☐ Yes	☐ No
Have You Got Temperature Controlled Storage Capacity?	☐ Yes	☐ No
Is The Warehouse Mapped for Seasonal Temperature Variance?	☐ Yes	☐ No

TRANSPORT

Do You Perform Transportation of Medicines With Your Own Vehicles?	☐ Yes	☐ No	☐ N/A
Are These Vehicles Qualified?	☐ Yes	☐ No	☐ N/A
Have You Got Temperature Controlled Vehicles?	☐ Yes	☐ No	☐ N/A
If You Do Not Perform Transportation of Medicines with Your Own Vehicles, Have You Got Quality Contracts with Your Subcontracted Transporters?	☐ Yes	☐ No	☐ N/A
Have You Got Temperature Controlled Vehicles?	☐ Yes	☐ No	☐ N/A

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Name	
Function at Your Company (Preferably QA Member)	
Signature and Stamp	
Date	

SYMBIO FARMA B.V. USE ONLY

Approval By RP (Signature)	
Date of Approval	