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GMP Series

GMP Supplier Assessment Questionnaire for APIs and Excipients

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Information for Completion Instructions

This questionnaire consists of
Part 1: Preliminary information about supplier and manufacturer
Parts 2 to 8: detailed information about manufacturer

The information gathered will provide documentation for our files to support the supplier qualification process within Maas & Peither Pharma GmbH in order to choose a supplier for active pharmaceutical ingredients or excipients.

Please take your time to review and answer the questions as accurately as possible directly on the form.

Please indicate the questions not applicable to you with “n/a” (not applicable). If the answer to a question can best be addressed by providing copies of documents, please respond to the question by referencing and including the return package.

Please return a copy (as pdf) of the completed and signed questionnaire to surname.name@maas-peither-pharma.de Of course, all information in this regard will be treated confidentially

Thank you in advance for your assistance. if you have any questions, please contact me at phone number: + 49 (0)60 – 1234 - 567

2.2 Quality Requirements

Does the company have a Quality Management System?	☐ yes ☐ no
Are sub-suppliers included in the Quality Management System?	☐ yes ☐ no
Do you produce complying with special regulations (e.g. EU-GMP-Guide Part II, IPEC)?	
Are you complying with the EU-GMP standard?	☐ yes ☐ no
Do you have a currently valid GMP certificate? If yes, please attach a copy	☐ yes ☐ no ☐ n.a.
Is there any supervisory authority?	☐ yes ☐ no ☐ n.a.
Is there any local supervisory authority? <Name of the authority>	
Date of the latest inspection: …	
Do you have a written confirmation for the product in question?	☐ yes ☐ no ☐ n.a., GMP-standards are comparable according to listing of third countries (see O.J. of the EU) or production within EU or EEA
Is a certificate according EN/ISO 9001 available for the manufacturing site? If yes, please attach a copy.	☐ yes ☐ no ☐ n.a.
Have you been inspected by other local and foreign authorities in the last five years? If yes, please specify which authorities.	☐ yes ☐ no
If yes, please attach a copy of the latest GMP certificate thereof.	

4 Premises and Equipment

Are your manufacturing areas	
Dedicated ☐	Multi-purpose ☐
Please describe the air handling system (heating, ventilation, air conditioning) in the production area.	
Are there written procedures in place for:	
• Pest control	☐ yes ☐ no
• Room qualification	☐ yes ☐ no ☐ n.a.
• Room cleaning/-disinfection	☐ yes ☐ no
Is there a microbiological monitoring program for the production area in place?	☐ yes ☐ no
Is a hygiene/sanitation program available?	☐ yes ☐ no
Are there written procedures for:	
• qualification of equipment	☐ yes ☐ no ☐ n.a.
• calibration of equipment	☐ yes ☐ no
• maintenance of equipment	☐ yes ☐ no
• inspection of measuring and testing equipment	☐ yes ☐ no
• cleaning (between two batches of the same product, between different products)	☐ yes ☐ no

If yes, please list the subcontractors and the provided services.	
Are the contract laboratories qualified?	☐ yes ☐ no
Is microbiological monitoring performed on a regular basis?	☐ yes ☐ no ☐ n.a
If yes, on which materials (e.g. raw material, finished product, water)?	
Are any parts of the microbiological activities subcontracted?	☐ yes ☐ no ☐ n.a
If yes, please list the subcontractors and the provided services.	
Are the contract laboratories qualified?	☐ yes ☐ no