	Questioning Company	Answering Company
Company	Sample Company	
Name	Max Mustermann	
Email	info@mustermann.com	
Tel.	1234987654	

No.	Question	Answer
1	Has the company a certificate of GMP?	○ Yes ○ No
2	Is the manufacturing plant FDA approved?	○ Yes ○ No
3	Is the manufacturing plant EMEA approved?	○ Yes ○ No
4	Is there a organization chart?	○ Yes ○ No
5	Is the pharmacist in charge present?	☐ Yes ☐ No ☐ NA
6	Environmental protection?	○ Yes ○ No
7	Facilities safety (Fire Brigade)?	○ Yes ○ No
8	What is the surface of the land?	
9	What is the total built arena?	
10	Is there a restaurant / cafeteria in the premises of the company?	
11	Are all products duly registered at the proper National Sanitary Entity?	
12	Does the company import starting materials?	○ Yes ○ No
13	Does the company import intermediate products?	○ Yes ○ No
14	Does the company import bulk products?	○ Yes ○ No
15	Does the company import finished products?	○ Yes ○ No

No.	Question	Answer
16	Did the company a list of imported products (intermediate, bulk, finished) ?	○ Yes ○ No
17	Does the company export finished products?	○ Yes ○ No
18	Does the company perform activities related to other categories of products subject to an e.g. authorization from the appropriate Sanitary Entity?	
19	Is there any company that carries out any sort of activities for you?	○ Yes ○ No
20	What are these activities?	
21	Can you give information about the production capability and the batch size?	
22	Packing size	
23	Delivery time	
24	Numbers of employees / Administrative	
25	Numbers of employees / Production	
26	Numbers of employees / Quality	
27	Numbers of employees / Research and Development	
28	Numbers of employees / Industrial Maintenance	
29	Numbers of employees / others	
30	Numbers of employees / Total	
31	How is the percentage of employees in your Quality Organization to totol employees?	
32	Is there a function description?	○ Yes ○ No
33	Are the responsibilities of each activity defined clearly?	○ Yes ○ No
34	Does the Technical Liable work full time?	○ Yes ○ No
35	What are the main products of the company?	
36	Which manufacturing processes are carried out at your site?	
37	Are there registered drug master files (DMF)	○ Yes ○ No

No.	Question	Answer
38	Do you have Certificates of Suitability to the Monograph of the European Pharmacopoeia (CoS) for your products mentioned on the front page?	○ Yes ○ No
39	Are your products listed on the front page conform to a monograph of a pharmacopoeia?	○ Yes ○ No
40	To which pharmacopoeia monograph the products listed on the front page are conform?	
41	Do you have TSE Certificates of Suitability to the Monograph of the European Pharmacopoeia (CoS) for your products mentioned on the front page, if applicable?	
42	If available, please attach a copy of process flow charts	
43	Do you use subcontractors for particular manufacturing steps?	
44	Is your company member of an association pertaining to manufacturing of raw materials for the pharmaceutical industry, e.g. IPEC (International Pharmaceutical Excipients Council), APIC (Active Pharmaceutical Ingredients Manufacturers)?	○ Yes ○ No
45	Do you claim that your procedures are in accordance with GMP?	
46	Which production step is compliant to the GMP regulations?	
47	Has your company already been inspected by the local or a foreign authority regarding compliance with the European Guide to Good Manufacturing Practises (EG-GMP), or the WHO Guide to Good Manufacturing Practices (WHO-GMP)?	○ Yes ○ No
48	Is your company in the possession of a GMP certificate?	○ Yes ○ No
49	Has your company already been inspected by the Food & Drug Administration / USA (FDA)?	○ Yes ○ No
50	Has your company already been inspected by customers?	○ Yes ○ No
51	How many inspections by customers does your company undergo per year in average?	
52	How is the share of pharmaceutical customers auditing your company?	
53	Please enclose an organisational chart that provides the communication pathways and responsibilities in your company?	
54	Written job descriptions are available?	○ Yes ○ No
55	Which department is responsible for testing / release of starting materials?	
56	Which department is responsible for testing / release of bulk (if applicable)?	
57	Which department is responsible for testing / release of finished products?	
58	Which department is responsible for in-process controls during production?	

No.	Question	Answer
59	Do you have written procedures for In-Process Controls (IPC)?	○ Yes ○ No
60	Are the results of In-Process Controls documented and archived?	○ Yes ○ No
61	Do you have a written procedure for recovering solvents?	○ Yes ○ No
62	Do you have a written specification for recovered solvents?	○ Yes ○ No
63	Are recovered solvents analyzed according to written analytical instructions?	○ Yes ○ No
64	In which department are employees regularly trained in GMP-topics, such as hygiene, cleanliness of facilities and equipment, adherence to procedures to ensure integrity of product, danger of intermixture and cross contamination?	
65	Do you have an established training system that ensures that all employees are trained in periodical intervals in the GMP topics relevant for their duties?	○ Yes ○ No
66	Is your GMP-training documented?	○ Yes ○ No
67	Is there a training programm for new employees?	○ Yes ○ No
68	Is the training documented?	○ Yes ○ No
69	Are there regular health examinations of the employees working in the production and quality control (sampling) departments?	○ Yes ○ No
70	Are non pharmaceutical products manufactured within the same premises?	
71	Do you manufacture different grades of the same product (e.g. pharmaceutical grade and technical grade)?	○ Yes ○ No
72	Do you manufacture different grades of the same product (e.g. pharmaceutical grade and technical grade) with the same equipment?	○ Yes ○ No
73	Are production, storage and quality control facilities all located on one production site?	○ Yes ○ No
74	Is the handling of exposed product carried out under clean room conditions?	○ Yes ○ No
75	For which parameters have you implemented a documented monitoring in your production areas?	
76	Do you handle exposed products in the open air?	○ Yes ○ No
77	Do you have changing / toilet / refreshment facilities physically separated from production / storage areas?	○ Yes ○ No

No.	Question	Answer
78	Do you have a written general housekeeping procedure?	○ Yes ○ No
79	Is access to the storage areas possible only for authorised personnel?	○ Yes ○ No
80	Are there written procedures for cleaning and hygiene of the storage area?	○ Yes ○ No
81	Do you have a hygiene/sanitation program that covering rooms, staff and eqiupment?	○ Yes ○ No
82	Are all cleaning measures documented?	○ Yes ○ No
83	Do you have written cleaning procedures?	○ Yes ○ No
84	Are measures taken for pest control of storage and production areas?	
85	Are taken measures for pest control of storage and production areas effectiveness monitored?	○ Yes ○ No
86	Where is the sampling of starting materials done?	
87	Is sampling carried out according to a written sampling plan?	○ Yes ○ No
88	Is the sampling of materials/products documented?	○ Yes ○ No
89	Do you have a system to check incoming materials prior to their use?	○ Yes ○ No
90	Is the approval or rejection of incoming materials documented?	○ Yes ○ No
91	How is the procedure for products to ensure their respective status (e.g.quarantine-released-rejected)?	
92	Are starting materials, packaging materials and finished products within the storage area marked at the container respectively pallet with status labels?	
93	Who is carrying out the actual labelling of the container / pallet of the starting materials, packaging materials and finished products within the storage area marked at the container respectively pallet with status labels?	
94	Are there dedicated storage areas for rejected materials / products?	○ Yes ○ No
95	Do you investigate the reason for rejected materials?	○ Yes ○ No
96	Is the storage administration system computerised?	○ Yes ○ No
97	Has the computerised storage administration system been validated?	○ Yes ○ No

No.	Question	Answer
98	How can be guaranteed that materials / products are used / despatched according to the first-in-first-out principle?	
99	How is guaranteed that only products are despatched which are released by the quality control department?	
100	Do you have a seperate weighting area?	○ Yes ○ No
101	Do you have suitable material storage and personnel locker in the finishing area?	○ Yes ○ No
102	Do you deliver with your own means of transport?	○ Yes ○ No
103	Do you exercise control on the transport used?	○ Yes ○ No
104	Written procedures are used for?	
105	Do you perform microbiological monitoring?	
106	Is the access to the manufacturing areas regulated e. g. via access authorisation cards?	○ Yes ○ No
107	Are there written procedures for cleaning and hygiene in the manufacturing area?	○ Yes ○ No
108	Are records kept of room cleaning?	○ Yes ○ No
109	Are there written procedures stating which principle hygiene measures are taken before entering the manufacturing areas?	○ Yes ○ No
110	How is the term batch / lot no. defined?	
111	Please explain your batch numbering system?	
112	How high is the usual amount of a batch / lot?	
113	Do you manufacture according to a written and specific procedure for each product?	○ Yes ○ No
114	Are these procedures agreed by an independent Quality Assurance / Quality Control Department?	○ Yes ○ No
115	Do you establish and keep records for each batch produced, giving a complete account of the manufacturing history?	
116	Are these records formally checked by the Quality Assurance / Quality Control Department?	○ Yes ○ No
117	Do you have a system of equipment and line clearance?	○ Yes ○ No

No.	Question	Answer
118	Do you maintain batch integrity during manufacturing?	○ Yes ○ No
119	Do you maintain batch integrity during packaging?	○ Yes ○ No
120	Do you keep batch integrity during storage?	○ Yes ○ No
121	Do you have a yield reconciliation system (input / output balance)?	○ Yes ○ No
122	Do you rework or reprocess batches / lots, which are out of specification?	○ Yes ○ No
123	Are reworks of the rejected batches / lots documented?	○ Yes ○ No
124	How is the packaging performed?	
125	If the packaging is performed in a subsequent stage, is the dispensing and / or subdivision performed according to GMP rules?	○ Yes ○ No
126	Are you prepared to meet packaging and labeling requirements of your customers?	○ Yes ○ No
127	Do you guarantee absence of inter-reaction between product and container?	○ Yes ○ No
128	Are lubricants and/or oils that may come in contact with products, certified as food grade?	○ Yes ○ No
129	How is it ensured that the original seal of containers is intact and not opened during transport?	
130	What doese the labeling indicate?	
131	Are re-usable containers used?	
132	Is there a reconciliation of the amount of printed packaging materials used (folding carton, product insert, patient brochure, label) after completion of the packaging order?	○ Yes ○ No
133	What action is taken with surplus, unprocessed printed packaging materials after completion of packaging order?	
134	Are raw materials of animal origin processed anywhere in your company?	○ Yes ○ No
135	Is validation data for all critical production steps available?	○ Yes ○ No
136	Are there written procedures for the calibration and equipment monitoring of analytical equipment?	○ Yes ○ No
137	Is the status of the analytical equipment (e.g. released, rejected, to be calibrated) clearly identifiably labeled?	○ Yes ○ No

No.	Question	Answer
138	Are there regular checks and respectively calibration / adjustments of control instruments that are used in the analytical laboratory?	○ Yes ○ No
139	Are records kept of this monitoring?	○ Yes ○ No
140	Do you have a documeted Preventative Maintenance Program that includes the associated records for equipment used in the control, weighting, measuring, monitoring and testing of products?	○ Yes ○ No
141	Are valid specifications and test procedures available for all starting materials (raw and packaging materials)?	○ Yes ○ No
142	Is each container of delivered starting materials (raw materials, packaging materials, solvents) sampled for identity testing?	
143	Is the manufacturer / supplier requested to provide certificates of analysis for each raw material delivery?	○ Yes ○ No
144	Do you assign expiration dates to your starting materials, when appropriate?	○ Yes ○ No
145	Do you have a system for checking expiration dates of starting materials before use?	
146	Is each parameter of the specification tested on every batch of finished product?	○ Yes ○ No
147	In which way are laboratory results and analytical raw data documented?	
148	How long is the archiving period of documentations on control tests and analytical raw data?	
149	How long is the archiving period of batch related manufacturing documentation?	
150	How long is the archiving period of retain samples for: Raw materials used?	
151	How long is the archiving period of retain samples for: Finished products manufactured?	
152	Do you have an On-Going Testing Program that establishes and monitors the stability or shelf-life characteristics of products to support the expiry date?	○ Yes ○ No
153	Is Quality Assurance organised in your company as an independent department?	○ Yes ○ No
154	Do you have a documented system to handle complaints?	○ Yes ○ No
155	Do you have a documented system to handle recall procedures?	○ Yes ○ No
156	Does the Quality Assurance Department participate in necessary follow-up procedures caused by customer complaints?	○ Yes ○ No
157	Are records kept of these performed follow-up procedures?	○ Yes ○ No

No.	Question	Answer
158	Do you have a document system for tracking Corrective and Preventative Actions (CAPA)?	○ Yes ○ No
159	Does your company purchase raw materials only from approved suppliers?	○ Yes ○ No
160	Do you carry out regular supplier inspections or audits of your packaging and raw material suppliers in order to qualify them as reliable suppliers?	
161	Do you keep a list of released manufacturers and suppliers of packaging materials, active pharmaceutical ingredients and recipients which is binding for the Purchasing Department?	○ Yes ○ No
162	Do you have an established, formally documented change control system for planned changes of manufacturing and test procedures, machines and equipment, premises or service and technical equipment?	○ Yes ○ No
163	Which departments are in principle involved in the decision and approval of changes?	
164	Is a change control system established to ensure that changes in production processes, analytical procedures and equipment are carried out in a controlled and documented manner?	○ Yes ○ No
165	Do you provide notification to us on a timely manner and each time, when a process, equipment or analytical method change, affecting the regulatory status (e.g. CEP, Quality Agreement), is made?	○ Yes ○ No
166	Do you notify your customer without being asked in case of changes of product specifications or test procedures that could influence the quality of the product manufactured?	
167	How are GMP-related documents (e.g. SOPs, test procedures, specifications, manufacturing procedures, etc.) written and managed in your company?	
168	What measurements are taken to ensure that outdated versions of documents are exchanged and destroyed?	
169	Are working procedures and regulations, as SOPs regularly checked and if necessary updated by the relevant departments?	○ Yes ○ No
170	Is the entirety of quality assurance measures in your company described in a quality manual?	○ Yes ○ No
171	Do you have an established self-inspection system in your company to monitor the use, adherence and effectiveness of your quality management system?	○ Yes ○ No
172	Which areas of your company are regularly subject to self-inspections?	
173	Are these self-inspection carried out on the basis of a yearly drawn up inspection plan?	○ Yes ○ No
174	Do you have an established system for monitoring arising follow-up activities?	○ Yes ○ No
175	Is Quality Control independent from production?	○ Yes ○ No
176	Is Quality Assurance independent from production?	○ Yes ○ No
177	Will your company give its consent for a customer audit on site?	○ Yes ○ No

No.	Question	Answer
178	Does your company perform on regular time intervals self-inspections (internal audits) and are records kept of such inspection?	○ Yes ○ No
179	Are employees and operators trained regularly?	○ Yes ○ No
180	How frequently is employees and operators training conducted for work duties?	
181	Do you have a written GMP training program?	○ Yes ○ No
182	For whom is the GMP training program and how frequently is it performed?	
183	How is the training performed at your site?	
184	Are records of training maintained?	○ Yes ○ No
185	Does your company maintain a Master Record System (MRS)?	○ Yes ○ No
186	Are batch records checked for compliance with the valid master record and assigned a unique batch number acc. Master Record System (MRS)?	
187	After completion of the batch, is the record checked for completion of all required recordings?	○ Yes ○ No
188	Do batch records permit exact traceability of raw materials, production steps, in-process-controls and yields?	○ Yes ○ No
189	Who is checking the record for completion of all required recordings after completion of the batch?	
190	Do written procedures exist for dealing with Out-of-Specification test results?	○ Yes ○ No
191	Do written procedures exist for dealing with deviations (production and QC) including documentation?	○ Yes ○ No
192	Is a Certificate of Suitability (CEP) available?	○ Yes ○ No
193	Is the manufacturing / filling facility / equipment used exclusively for the product being subject of this questionnaire?	○ Yes ○ No
194	What substances are also used in the manufacturing / filling facility / equipment beside the product being subject of this questionnaire?	
195	If substances are also used in the manufacturing / filling facility / equipment beside the product being subject of this questionnaire which measures have been taken for preventing cross-contamination, mix ups or incorrect labelling?	
196	Are sensitizing antibiotics (e.g. beta-lactam antibiotics) produced on the same facility/equipment or in close proximity to it?	○ Yes ○ No
197	Which other types of products (apart from the product being subject of this questionnaire) are processed/ handled at the manufacturing-site?	

No.	Question	Answer
198	Is repacking or relabeling performed after it left the production-area?	○ Yes ○ No
199	In case of changes of the manufacturing process: Does your company send information to its customers, even if not asked for or agreed on?	○ Yes ○ No
200	Is critical production and filling equipment qualified?	○ Yes ○ No
201	Is the manufacturing process validated?	
202	What are the recommended storage conditions of the product being subject of this questionnaire?	
203	What is the period of shelf-life for the product being subject of this questionnaire?	
204	Can you supply a Safety Data Sheet (SDS) for the product, which is subject of this questionnaire? Please mention and attach a copy of each SDS	
205	Does your company have a documented system for food safety?	○ Yes ○ No
206	Do you use any allergens (e.g. gluten, peanut oil, starch, sodium, lactose, etc.) during manufacturing or processing the products?	○ Yes ○ No
207	Are contaminations of the product possible with the following impurities? Herbicides; Pesticides; Alfatoxine; Residuals fumigants; Ethylenoxide; Residual Solvents; Radioactivity; Metal catalyst?	☐ Yes ☐ No ☐ N/A
208	Is safety and environmental protection an objective of your company?	○ Yes ○ No
209	Do you have a certificate of ISO 14001?	○ Yes ○ No
210	Are you certificate according EMAS?	○ Yes ○ No
211	Do you manage your facility corresponding to official permissions and valid legal regulations?	○ Yes ○ No
212	Do you train your employees regulary in relevant safety and environment topics?	○ Yes ○ No
213	Do you take back packaging materias from your customers, or do you participate at a recycling system which collects packaging materials from your customers	○ Yes ○ No
214	Do you have an alarm and hazardous plan available, which is regulary trained with task forces?	