	Questioning Company	Answering Company
Company	Sample Company	
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No.	Question	Answer
1	Which Quality Management systems are operative at your company? Please attach a copy of each certificate.	
2	Is your company certified according to DIN EN ISO or other standards? Please mention and attach a copy of each certificate	
3	Is there a organization chart?	○ Yes ○ No
4	What is the surface of the land?	
5	What is the total built arena?	
6	How many buildings are there in the project?	
7	Is there a restaurant / cafeteria in the premises of the company?	
8	Is there any company that carries out any sort of activities for you?	○ Yes ○ No
9	What are these activities?	
10	Delivery time	
11	Numbers of employees / Administrative	
12	Numbers of employees / Production	
13	Numbers of employees / Quality	
14	Numbers of employees / Research and Development	
15	Numbers of employees / Industrial Maintenance	
16	Numbers of employees / others	
17	Numbers of employees / Total	
18	How is the percentage of employees in your Quality Organization to totol employees?	

No.	Question	Answer
19	Is there a function description?	○ Yes ○ No
20	Are the responsibilities of each activity defined clearly?	○ Yes ○ No
21	Does the Technical Liable work full time?	○ Yes ○ No
22	What are the main products of the company?	
23	If available, please attach a copy of process flow charts	
24	Do you use subcontractors for particular manufacturing steps?	
25	Has your company already been inspected by customers?	○ Yes ○ No
26	How many inspections by customers does your company undergo per year in average?	
27	Please enclose an organisational chart that provides the communication pathways and responsibilities in your company?	
28	Written job descriptions are available?	○ Yes ○ No
29	Which department is responsible for testing / release of starting materials?	
30	Which department is responsible for testing / release of bulk (if applicable)?	
31	Which department is responsible for testing / release of finished products?	
32	Which department is responsible for in-process controls during production?	
33	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?	
34	Is there a general training programm for the staffs?	○ Yes ○ No
35	Is there a training programm for new employees?	○ Yes ○ No
36	Is the training documented?	○ Yes ○ No
37	Are production, storage and quality control facilities all located on one production site?	○ Yes ○ No
38	Is the handling of exposed product carried out under clean room conditions?	○ Yes ○ No
39	For which parameters have you implemented a documented monitoring in your production areas?	

No.	Question	Answer
40	Do you handle exposed products in the open air?	○ Yes ○ No
41	Do you have changing / toilet / refreshment facilities physically separated from production / storage areas?	○ Yes ○ No
42	Do you have a written general housekeeping procedure?	○ Yes ○ No
43	Is access to the storage areas possible only for authorised personnel?	○ Yes ○ No
44	Are there written procedures for cleaning and hygiene of the storage area?	○ Yes ○ No
45	Are measures taken for pest control of storage and production areas?	
46	Are taken measures for pest control of storage and production areas effectiveness monitored?	○ Yes ○ No
47	Where is the sampling of starting materials done?	
48	Is sampling carried out according to a written sampling plan?	○ Yes ○ No
49	Do you have a system to check incoming materials prior to their use?	○ Yes ○ No
50	Is the approval or rejection of incoming materials documented?	○ Yes ○ No
51	Are starting materials, packaging materials and finished products within the storage area marked at the container respectively pallet with status labels?	
52	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?	
53	Are there dedicated storage areas for rejected materials / products?	○ Yes ○ No
54	Do you investigate the reason for rejected materials?	○ Yes ○ No
55	Is the storage administration system computerised?	○ Yes ○ No
56	Has the computerised storage administration system been validated?	○ Yes ○ No
57	How can be guaranteed that materials / products are used / despatched according to the first-in-first-out principle?	
58	How is guaranteed that only products are despatched which are released by the quality control department?	
59	Do you deliver with your own means of transport?	○ Yes ○ No

No.	Question	Answer
60	Do you exercise control on the transport used?	○ Yes ○ No
61	Written procedures are used for?	
62	Is the access to the manufacturing areas regulated e. g. via access authorisation cards?	○ Yes ○ No
63	Are there written procedures for cleaning and hygiene in the manufacturing area?	○ Yes ○ No
64	Are records kept of room cleaning?	○ Yes ○ No
65	Are there written procedures stating which principle hygiene measures are taken before entering the manufacturing areas?	○ Yes ○ No
66	How is the term batch / lot no. defined?	
67	Please explain your batch numbering system?	
68	How high is the usual amount of a batch / lot?	
69	Do you manufacture according to a written and specific procedure for each product?	○ Yes ○ No
70	Are these procedures agreed by an independent Quality Assurance / Quality Control Department?	○ Yes ○ No
71	Do you establish and keep records for each batch produced, giving a complete account of the manufacturing history?	
72	Are these records formally checked by the Quality Assurance / Quality Control Department?	○ Yes ○ No
73	Do you have a system of equipment and line clearance?	○ Yes ○ No
74	Do you maintain batch integrity during manufacturing?	○ Yes ○ No
75	Do you maintain batch integrity during packaging?	○ Yes ○ No
76	Do you keep batch integrity during storage?	○ Yes ○ No
77	Do you have a yield reconciliation system (input / output balance)?	○ Yes ○ No
78	Do you rework or reprocess batches / lots, which are out of specification?	○ Yes ○ No
79	Are reworks of the rejected batches / lots documented?	○ Yes ○ No

No.	Question	Answer
80	How is the packaging performed?	
81	If the packaging is performed in a subsequent stage, is the dispensing and / or subdivision performed according to GMP rules?	○ Yes ○ No
82	Are you prepared to meet packaging and labeling requirements of your customers?	○ Yes ○ No
83	Do you guarantee absence of inter-reaction between product and container?	○ Yes ○ No
84	What doese the labeling indicate?	
85	Are re-usable containers used?	
86	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
87	What action is taken with surplus, unprocessed printed packaging materials after completion of packaging order?	
88	Are raw materials of animal origin processed anywhere in your company?	○ Yes ○ No
89	Is validation data for all critical production steps available?	○ Yes ○ No
90	Are there written procedures for the calibration and equipment monitoring of analytical equipment?	○ Yes ○ No
91	Is the status of the analytical equipment (e.g. released, rejected, to be calibrated) clearly identifiably labeled?	○ Yes ○ No
92	Are there regular checks and respectively calibration / adjustments of control instruments that are used in the analytical laboratory?	○ Yes ○ No
93	Are records kept of this monitoring?	○ Yes ○ No
94	Are valid specifications and test procedures available for all starting materials (raw and packaging materials)?	○ Yes ○ No
95	Is each container of delivered starting materials (raw materials, packaging materials, solvents) sampled for identity testing?	
96	Is the manufacturer / supplier requested to provide certificates of analysis for each raw material delivery?	○ Yes ○ No
97	Do you assign expiration dates to your starting materials, when appropriate?	○ Yes ○ No
98	Do you have a system for checking expiration dates of starting materials before use?	
99	Is each parameter of the specification tested on every batch of finished product?	○ Yes ○ No

No.	Question	Answer
100	In which way are laboratory results and analytical raw data documented?	
101	How long is the archiving period of documentations on control tests and analytical raw data?	
102	How long is the archiving period of batch related manufacturing documentation?	
103	How long is the archiving period of retain samples for: Raw materials used?	
104	How long is the archiving period of retain samples for: Finished products manufactured?	
105	Is Quality Assurance organised in your company as an independent department?	○ Yes ○ No
106	Do you have a documented system to handle complaints?	○ Yes ○ No
107	Do you have a documented system to handle recall procedures?	○ Yes ○ No
108	Does the Quality Assurance Department participate in necessary follow-up procedures caused by customer complaints?	○ Yes ○ No
109	Are records kept of these performed follow-up procedures?	○ Yes ○ No
110	Does your company purchase raw materials only from approved suppliers?	○ Yes ○ No
111	Do you carry out regular supplier inspections or audits of your packaging and raw material suppliers in order to qualify them as reliable suppliers?	
112	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
113	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
114	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
115	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
116	What measurements are taken to ensure that outdated versions of documents are exchanged and destroyed?	
117	Are working procedures and regulations, as SOPs regularly checked and if necessary updated by the relevant departments?	○ Yes ○ No
118	Is the entirety of quality assurance measures in your company described in a quality manual?	○ Yes ○ No
119	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

No.	Question	Answer
120	Which areas of your company are regularly subject to self-inspections?	
121	Are these self-inspection carried out on the basis of a yearly drawn up inspection plan?	○ Yes ○ No
122	Do you have an established system for monitoring arising follow-up activities?	○ Yes ○ No
123	Is Quality Control independent from production?	○ Yes ○ No
124	Is Quality Assurance independent from production?	○ Yes ○ No
125	Will your company give its consent for a customer audit on site?	○ Yes ○ No
126	Does your company perform on regular time intervals self-inspections (internal audits) and are records kept of such inspection?	○ Yes ○ No
127	Are employees and operators trained regularly?	○ Yes ○ No
128	How frequently is employees and operators training conducted for work duties?	
129	Do you have a written GMP training program?	○ Yes ○ No
130	For whom is the GMP training program and how frequently is it performed?	
131	How is the training performed at your site?	
132	Are records of training maintained?	○ Yes ○ No
133	Does your company maintain a Master Record System (MRS)?	○ Yes ○ No
134	Are batch records checked for compliance with the valid master record and assigned a unique batch number acc. Master Record System (MRS)?	
135	After completion of the batch, is the record checked for completion of all required recordings?	○ Yes ○ No
136	Who is checking the record for completion of all required recordings after completion of the batch?	
137	Do written procedures exist for dealing with Out-of-Specification test results?	○ Yes ○ No
138	Do written procedures exist for dealing with deviations (production and QC) including documentation?	○ Yes ○ No
139	Is a Certificate of Suitability (CEP) available?	○ Yes ○ No

No.	Question	Answer
140	Is the manufacturing / filling facility / equipment used exclusively for the product being subject of this questionnaire?	○ Yes ○ No
141	What substances are also used in the manufacturing / filling facility / equipment beside the product being subject of this questionnaire?	
142	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?	
143	Are sensitizing antibiotics (e.g. beta-lactam antibiotics) produced on the same facility/equipment or in close proximity to it?	○ Yes ○ No
144	Which other types of products (apart from the product being subject of this questionnaire) are processed/ handled at the manufacturing-site?	
145	Is repacking or relabeling performed after it left the production-area?	○ Yes ○ No
146	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
147	Is critical production and filling equipment qualified?	○ Yes ○ No
148	Is the manufacturing process validated?	
149	What are the recommended storage conditions of the product being subject of this questionnaire?	
150	What is the period of shelf-life for the product being subject of this questionnaire?	
151	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	
152	Does your company have a documented system for food safety?	○ Yes ○ No
153	Are your computerised systems provided with access authorisation?	○ Yes ○ No
154	Are access and changes constantly logged (audit trail)?	○ Yes ○ No
155	Is the security of the archived data tested?	○ Yes ○ No
156	Do you use electronic signatures in your computerised systems?	○ Yes ○ No
157	Is safety and environmental protection an objective of your company?	○ Yes ○ No
158	Do you have a certificate of ISO 14001?	○ Yes ○ No
159	Are you certificate according EMAS?	○ Yes ○ No

No.	Question	Answer
160	Do you manage your facility corresponding to official permissions and valid legal regulations?	○ Yes ○ No
161	Do you train your employees regulary in relevant safety and environment topics?	○ Yes ○ No
162	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
163	Do you have an alarm and hazardous plan available, which is regulary trained with task forces?	