	Questioning Company	Answering Company
Company	Sample Company	
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No.	Question	Answer
1	Is there a organization chart?	○ Yes ○ No
2	What is the surface of the land?	
3	What is the total built arena?	
4	Is there a restaurant / cafeteria in the premises of the company?	
5	Is there any company that carries out any sort of activities for you?	○ Yes ○ No
6	What are these activities?	
7	Numbers of employees / Administrative	
8	Numbers of employees / Production	
9	Numbers of employees / Quality	
10	Numbers of employees / Research and Development	
11	Numbers of employees / Industrial Maintenance	
12	Numbers of employees / others	
13	Numbers of employees / Total	
14	How is the percentage of employees in your Quality Organization to totol employees?	
15	Is there a function description?	○ Yes ○ No
16	Are the responsibilities of each activity defined clearly?	○ Yes ○ No
17	If available, please attach a copy of process flow charts	
18	Do you use subcontractors for particular manufacturing steps?	

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19	Has your company already been inspected by customers?	○ Yes ○ No
20	How many inspections by customers does your company undergo per year in average?	
21	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?	
22	Is there a general training programm for the staffs?	○ Yes ○ No
23	Are production, storage and quality control facilities all located on one production site?	○ Yes ○ No
24	Is the handling of exposed product carried out under clean room conditions?	○ Yes ○ No
25	For which parameters have you implemented a documented monitoring in your production areas?	
26	Do you handle exposed products in the open air?	○ Yes ○ No
27	Do you have changing / toilet / refreshment facilities physically separated from production / storage areas?	○ Yes ○ No
28	Do you have a written general housekeeping procedure?	○ Yes ○ No
29	Is access to the storage areas possible only for authorised personnel?	○ Yes ○ No
30	Are there written procedures for cleaning and hygiene of the storage area?	○ Yes ○ No
31	Are measures taken for pest control of storage and production areas?	
32	Are taken measures for pest control of storage and production areas effectiveness monitored?	○ Yes ○ No
33	Where is the sampling of starting materials done?	
34	Is sampling carried out according to a written sampling plan?	○ Yes ○ No
35	Are starting materials, packaging materials and finished products within the storage area marked at the container respectively pallet with status labels?	
36	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?	
37	Are there dedicated storage areas for rejected materials / products?	○ Yes ○ No
38	Is the storage administration system computerised?	○ Yes ○ No

No.	Question	Answer
39	Has the computerised storage administration system been validated?	○ Yes ○ No
40	How can be guaranteed that materials / products are used / despatched according to the first-in-first-out principle?	
41	How is guaranteed that only products are despatched which are released by the quality control department?	
42	Do you deliver with your own means of transport?	○ Yes ○ No
43	Do you exercise control on the transport used?	○ Yes ○ No
44	Written procedures are used for?	
45	Are the cleaning procedures validated to guarantee that limits for remaining levels of residues on the equipment surfaces after cleaning are regularly kept?	○ Yes ○ No
46	Records are kept of?	
47	Does your company have a water treatment system?	
48	Is the water used in production or for cleaning purposes subject to regularly chemical monitoring?	○ Yes ○ No
49	Is the water used in production or for cleaning purposes subject to regularly microbiological monitoring?	
50	Are there written procedures for cleaning and hygiene in the manufacturing area?	○ Yes ○ No
51	Are records kept of room cleaning?	○ Yes ○ No
52	Are there written procedures stating which principle hygiene measures are taken before entering the manufacturing areas?	○ Yes ○ No
53	How is the term batch / lot no. defined?	
54	Please explain your batch numbering system?	
55	How high is the usual amount of a batch / lot?	
56	Do you manufacture according to a written and specific procedure for each product?	○ Yes ○ No
57	Are these procedures agreed by an independent Quality Assurance / Quality Control Department?	○ Yes ○ No
58	Do you establish and keep records for each batch produced, giving a complete account of the manufacturing history?	
59	Are these records formally checked by the Quality Assurance / Quality Control Department?	○ Yes ○ No

No.	Question	Answer
60	Do you have a system of equipment and line clearance?	○ Yes ○ No
61	Do you maintain batch integrity during manufacturing?	○ Yes ○ No
62	Do you maintain batch integrity during packaging?	○ Yes ○ No
63	Do you keep batch integrity during storage?	○ Yes ○ No
64	Do you have a yield reconciliation system (input / output balance)?	○ Yes ○ No
65	Do you rework or reprocess batches / lots, which are out of specification?	○ Yes ○ No
66	Are reworks of the rejected batches / lots documented?	○ Yes ○ No
67	How is the packaging performed?	
68	If the packaging is performed in a subsequent stage, is the dispensing and / or subdivision performed according to GMP rules?	○ Yes ○ No
69	Are you prepared to meet packaging and labeling requirements of your customers?	○ Yes ○ No
70	Do you guarantee absence of inter-reaction between product and container?	○ Yes ○ No
71	What doese the labeling indicate?	
72	Are re-usable containers used?	
73	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
74	What action is taken with surplus, unprocessed printed packaging materials after completion of packaging order?	
75	Are raw materials of animal origin processed anywhere in your company?	○ Yes ○ No
76	Is validation data for all critical production steps available?	○ Yes ○ No
77	Are there written procedures for the calibration and equipment monitoring of analytical equipment?	○ Yes ○ No
78	Is the status of the analytical equipment (e.g. released, rejected, to be calibrated) clearly identifiably labeled?	○ Yes ○ No

No.	Question	Answer
79	Are there regular checks and respectively calibration / adjustments of control instruments that are used in the analytical laboratory?	○ Yes ○ No
80	Are records kept of this monitoring?	○ Yes ○ No
81	Are valid specifications and test procedures available for all starting materials (raw and packaging materials)?	○ Yes ○ No
82	Is each container of delivered starting materials (raw materials, packaging materials, solvents) sampled for identity testing?	
83	Is the manufacturer / supplier requested to provide certificates of analysis for each raw material delivery?	○ Yes ○ No
84	Do you assign expiration dates to your starting materials, when appropriate?	○ Yes ○ No
85	Do you have a system for checking expiration dates of starting materials before use?	
86	Is each parameter of the specification tested on every batch of finished product?	○ Yes ○ No
87	In which way are laboratory results and analytical raw data documented?	
88	How long is the archiving period of documentations on control tests and analytical raw data?	
89	How long is the archiving period of batch related manufacturing documentation?	
90	How long is the archiving period of retain samples for: Raw materials used?	
91	How long is the archiving period of retain samples for: Finished products manufactured?	
92	Is Quality Assurance organised in your company as an independent department?	○ Yes ○ No
93	Do you have a documented system to handle complaints?	○ Yes ○ No
94	Do you have a documented system to handle recall procedures?	○ Yes ○ No
95	Does the Quality Assurance Department participate in necessary follow-up procedures caused by customer complaints?	○ Yes ○ No
96	Are records kept of these performed follow-up procedures?	○ Yes ○ No
97	Does your company purchase raw materials only from approved suppliers?	○ Yes ○ No
98	Do you carry out regular supplier inspections or audits of your packaging and raw material suppliers in order to qualify them as reliable suppliers?	

No.	Question	Answer
99	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
100	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