

A. General Information	
1. Company Information	
1.1 Company Address Information	
Name of company:	
Address, Postcode:	
Country:	
1.2 Address Information of Site of Interest	
Name of company (if different from above):	
Address, Postcode:	
Country:	
1.3 Contact Information (Please provide details of an available contact)	
Name:	
Position:	
Telephone number:	
Email address:	
1.4 Nature of operations (check all that apply)	
Manufacturing of materials supplied	Yes ☐ No ☐
Trading of materials supplied	Yes ☐ No ☐
If you do trading of materials, please add name & address of manufacturer:	
Service provider	Yes
If you are a service provider, please specify which service (s):	

2. Personnel			
2.1 PERSONNEL - ORGANISATION			
2.1.1	Please enclose a copy of your high-level organisational chart indicating key personnel.	Enclosed ☐ Ref:	N/A ☐
2.1.2	Total number of personnel at the site of interest (as referenced in 1.2):	FTE	
2.1.3	Number of employees in: • Management: • Operations: • Quality Assurance (QA): • Quality Control (QC): • R&D: • Maintenance: • Warehouse (if applicable):	FTE FTE FTE FTE FTE FTE FTE	
2.1.4	Are the responsibilities and tasks of all personnel defined in written job descriptions?	Yes ☐	No ☐
2.1.5	Is the Quality Unit independent from Operations?	Yes ☐	No ☐
2.1.6	Which department approves product release (if applicable)?		
2.2 PERSONNEL – TRAINING			
2.2.1	Is a written procedure for training of employees in place?	Yes ☐	No ☐
2.2.2	Are job-specific training requirements clearly defined?	Yes ☐	No ☐
2.2.3	Are training effectiveness and employee competency periodically assessed?	Yes ☐	No ☐
2.2.4	Is GMP training conducted on a regular basis and in sufficient frequency to assure that the employees remain familiar with current GMP requirements?	Yes ☐	No ☐ N/A ☐
2.2.5	Is all training documented?	Yes ☐	No ☐
COMMENTS:			

5. Quality Standards and Certifications			
5.1	Does your company have a quality management system in place	Yes ☐	No ☐
5.2	Do you hold certification(s) against any recognized quality standards by an accredited third-party body e.g. cGMP, ISO 9001, 14001 or 22000? If yes: specify and provide copies of certificates: Ref.:	Yes ☐	No ☐
5.3	Do you hold licences/registrations issued by any regulatory agency or body? If yes specify and provide copies: Ref.:	Yes ☐	No ☐
			N/A ☐
5.4	Has the company been subject to periodic audits by competent health authorities (e.g. EMA, MHRA, FDA...) or notified inspection bodies (ISO, etc...)? If yes, please provide details of the latest inspection date(s):	Yes ☐	No ☐
			N/A ☐
	Authority	Date	
5.5	If the answer to question 5.3 is yes, are there – at the time of completion of this questionnaire – any pending (unresolved) critical observations / warning letters resulting from these inspections?	Yes ☐	No ☐
			N/A ☐
5.6	Are any aspects of the manufacturing process or of the service provided subcontracted?	Yes ☐	No ☐
	If so, please provide detail:		N/A ☐
5.7	Are there Quality / Technical / Service Level Agreements held with these subcontractors?	Yes ☐	No ☐
			N/A ☐
COMMENTS:			

6. Quality Management Documentation

Do you have procedures that document how you perform the following activities:

If 'YES' please provide the document reference number / identification.

6.1	QUALITY SYSTEM				Comment
6.1.1	Quality Policy / Manual	Yes ☐	No ☐	N/A ☐	
6.1.3	Internal Audit / Self-Inspection Program	Yes ☐	No ☐	N/A ☐	
6.1.4	Supplier Evaluation / Qualification Program	Yes ☐	No ☐	N/A ☐	
6.1.6	Training Program	Yes ☐	No ☐	N/A ☐	
6.1.7	Change Control	Yes ☐	No ☐	N/A ☐	
6.1.8	Deviation / Investigation Reporting	Yes ☐	No ☐	N/A ☐	
6.1.9	Non-Conformance Reporting	Yes ☐	No ☐	N/A ☐	
6.1.10	Documentation Control	Yes ☐	No ☐	N/A ☐	
6.1.11	Do you have a recall system/procedure in place?	Yes ☐	No ☐	N/A ☐	
6.2	FACILITIES AND EQUIPMENT SYSTEM				
6.2.1	Pest Control Program	Yes ☐	No ☐	N/A ☐	
6.2.2	Preventive Maintenance Program	Yes ☐	No ☐	N/A ☐	
6.2.3	Calibration Program	Yes ☐	No ☐	N/A ☐	
6.2.3	Equipment & Instrument Qualification	Yes ☐	No ☐	N/A ☐	
6.2.4	Facility Cleaning / Sanitization	Yes ☐	No ☐	N/A ☐	

7. SOP System / Document Control

7.1	Are written procedures (SOPs) established for all quality related activities?	Yes ☐	No ☐
7.2	Are quality-related procedures approved by the Quality Unit?	Yes ☐	No ☐
7.3	Do you perform a periodic review of SOPs?	Yes ☐	No ☐
7.4	Are the issuance and distribution of SOPs controlled?	Yes ☐	No ☐
7.5	Is a system in place to assure that obsolete versions of quality relevant documents are withdrawn from use?	Yes ☐	No ☐
COMMENTS:			

8. Data Management and Data Integrity			
8.1 Optional sub-headline			
8.1.1	Is there a documented policy ensuring the integrity of data and its management within your organization?	Yes ☐ No ☐	
8.1.2	If the answer to 8.1.1 is yes, do you hold official certificates on these topics (e.g. ISO27001) ? If so, which ones?	Yes ☐ No ☐	N/A ☐
8.1.3	Do you have documented evidence (e. g. training records) showing that each staff member generating or manipulating critical data has been trained regarding the principles of Data Integrity?	Yes ☐ No ☐	
8.1.4	Do you have written procedures describing how and how long quality relevant data will be kept in archives before disposal (destruction)? If yes, what is your archiving period...: ... for paper data? ... for electronic data?	Yes ☐ No ☐	N/A ☐
8.1.5	Are your quality critical electronic systems protected against unauthorized access?	Yes ☐ No ☐	N/A ☐
8.1.6	Are your quality critical electronic systems subject to regular backup?	Yes ☐ No ☐	N/A ☐
8.1.7	Do you have specific procedures dealing with cyber security?	Yes ☐ No ☐	
8.1.8	If the answer to 8.1.7 is yes, do you hold any official certificates on this topic? If so, which ones?	Yes ☐ No ☐	N/A ☐
COMMENTS:			

9. Change Management

9.1	Is a written procedure/system for change control in place?	Yes ☐	No ☐	
9.2	Do you classify changes according to their impact on product quality (e.g. minor and major changes)?	Yes ☐	No ☐	N/A ☐
9.3	Are changes which have impact on the product quality approved by the Quality Unit?	Yes ☐	No ☐	N/A ☐
9.4	Do you assess (as part of the change request) whether customers need to be informed on major changes affecting product quality?	Yes ☐	No ☐	N/A ☐
9.5	Is a log maintained of changes to processes, materials, equipment and methods?	Yes ☐	No ☐	
9.6	Are you notified about changes from your suppliers / sub-contractors?	Yes ☐	No ☐	

COMMENTS:

10. Deviation Handling / OOS Handling

10.1	Is a written procedure/system for the handling of deviations and non-conformances in place?	Yes ☐	No ☐	
10.2	Are deviations from established procedures documented, investigated in a timely manner and filed by the Quality Unit?	Yes ☐	No ☐	
10.3	Do investigations of deviations consider the impact on product quality or the service delivered?	Yes ☐	No ☐	N/A ☐
10.4	Do investigations of deviations consider the impact on product quality of previous batches or previous services being delivered?	Yes ☐	No ☐	N/A ☐
10.5	Are the results of investigations reviewed and approved by the Quality Unit?	Yes ☐	No ☐	N/A ☐
10.6	Is a written procedure/system for investigating Out of specification results established?	Yes ☐	No ☐	N/A ☐
10.7	Does the OOS SOP comply with concepts / processes as defined in US-FDA OOS or MHRA Guidelines?	Yes ☐	No ☐	N/A ☐

COMMENTS:

11. Complaints / Recalls

11.1	Are complaints recorded and investigated according to a written procedure?	Yes ☐	No ☐
11.2	What is your time target for responding to complaints?		
11.3	Do you have a written procedure in place which defines the circumstances under which a recall or market withdrawal of a product should be considered?	Yes ☐	No ☐ N/A ☐
COMMENTS:			

12. Sub-contractor Qualification

12.1	Do you work with sub-contractors?	Yes ☐	No ☐
12.2	Is there a written contract in place between the sub-contractor and your company where all tasks, services and responsibilities are clearly defined?	Yes ☐	No ☐ N/A ☐
12.3	Is a written procedure for sub-contractor qualification in place?	Yes ☐	No ☐ N/A ☐
12.4	Is the sub-contractor qualification documented?	Yes ☐	No ☐ N/A ☐
12.5	Do you carry out periodical monitoring of sub-contractors?	Yes ☐	No ☐ N/A ☐
12.6	Does the procedure on sub -contractor qualification consider a re-qualification? If yes, what is your re-qualification period?	Yes ☐	No ☐ N/A ☐
12.7	Is ensured that you only use / order from approved sub-contractors?	Yes ☐	No ☐ N/A ☐
12.8	Is a system in place to assure that your sub-contractors notify you about significant changes?	Yes ☐	No ☐ N/A ☐
12.9	Are written specifications / quality requirements clearly defined for the products / services delivered from your sub-contractor?	Yes ☐	No ☐ N/A ☐
12.10	Is a system in place to assure that only current versions of specifications/quality requirements are used?	Yes ☐	No ☐ N/A ☐
COMMENTS:			

13. Internal Audits

13.1	Do you perform internal audits on a regular base?	Yes ☐	No ☐	
13.2	Are internal audits performed by the Quality Unit?	Yes ☐	No ☐	N/A ☐
13.3	Are audit findings documented?	Yes ☐	No ☐	N/A ☐
13.4	Are corrective actions defined and implemented in a timely manner?	Yes ☐	No ☐	N/A ☐

COMMENTS:

14. Business Continuity

14.1	Is a business continuity plan established? If yes, please answer the following questions:	Yes ☐	No ☐	
14.2	What elements are covered by your business continuity plan: • Purchasing/Supplier • Supply chain • Production • Facilities / Utilities • Quality (e.g. Back up of equipment) • SHE • Human Resources • IT • Finance • Natural disaster (e.g. flooding, earthquake) • Pandemics Please refer the document ID(s) here: _____	Yes ☐ Yes ☐ Yes ☐ Yes ☐ Yes ☐ Yes ☐ Yes ☐ Yes ☐ Yes ☐ Yes ☐ Yes ☐ Yes ☐	No ☐ No ☐ No ☐ No ☐ No ☐ No ☐ No ☐ No ☐ No ☐ No ☐ No ☐ No ☐	

COMMENTS:

15. Comments, References, Appendices

Please list all references and enclosures that you make to this questionnaire and specify the reference number given to each document. Use one list for all sections of the document and extend it if needed.

[illegible]

Completion Signatures

- Confirmation that enclosed information is correct and relevant to the product(s) in scope.
- You will inform us in case of any changes to the product status

Completed by:

Name (Print):

Position:

Signature:

Date:

Approved by (name of Quality representative):

Name (Print):

Position:

Signature:

Date: