

C. Manufacturer Questionnaire

1. Manufacturer Details

1.1 Company Address Information

Name of company:

Site address:

Postcode:

Country:

Website:

1.2 Contact Information (Please provide details of an available contact)

This information should be filled into the General Questionnaire.

1.3 Product Information (List of materials covered by this questionnaire)

Material Name	Dedicated equipment	
	Yes ☐	No ☐
	Yes ☐	No ☐
	Yes ☐	No ☐
	Yes ☐	No ☐
	Yes ☐	No ☐
	Yes ☐	No ☐
	Yes ☐	No ☐

Please add list of all materials as appendix if required

1.4 Outsourcing / Third Party Involvement

Are any activities related to manufacturing or testing of the above product(s) outsourced to third parties? If yes, specify below or in a separate annex.

Yes ☐ No ☐

COMMENTS:

PRELIMINARY COMMENT:

Critical raw materials, including registered starting materials, are generally not subject to GMP requirements, which typically apply from the first registered intermediate onwards.

However, many suppliers of critical raw materials maintain quality systems and controls that incorporate principles aligned with, or inspired by, GMP practices. This questionnaire therefore includes not only questions covering essential requirements for the supply of critical raw materials but also additional questions intended to assess the implementation of certain GMP practices.

Responses to these questions may be considered as a positive differentiating factor during the evaluation and selection of suppliers, as they can provide additional confidence in the supplier's ability to consistently deliver materials of the required quality.

2. Quality Management		
2.1 QUALITY UNIT - RESPONSIBILITIES		
2.1.1	Is/(Are) the Quality Unit(s) independent from Operations?	Yes ☐ No ☐
	Is/(Are) the Quality Unit(s) responsible for:	
2.1.2	Review and approval of all appropriate quality related documents?	Yes ☐ No ☐
2.1.3	Review and approval of manufacturing records?	Yes ☐ No ☐
2.1.4	Release of material?	Yes ☐ No ☐
2.1.5	Review and approval of changes?	Yes ☐ No ☐
2.1.6	Approval of (new) suppliers / service providers of quality critical materials and services?	Yes ☐ No ☐
2.1.7	Performance, documentation and follow-up on Self-Inspections?	Yes ☐ No ☐
	If your answer is "No" on any of the questions above, please explain in the "Comments" section below:	
COMMENTS:		
2.2 QUALIFICATION / VERIFICATION / VALIDATION		
2.2.1	Is laboratory equipment qualified (with supporting documentation)?	Yes ☐ No ☐
	If the answer is no, is the equipment proven suitable for intended use?	Yes ☐ No ☐
2.2.2	Is manufacturing equipment qualified (with supporting documentation)?	Yes ☐ No ☐
	If the answer is no, is the equipment proven suitable for intended use?	Yes ☐ No ☐
2.2.3	Are analytical methods validated (with supporting documentation)?	Yes ☐ No ☐
	If the answer is no, are the analytical methods verified for suitability of intended use?	Yes ☐ No ☐
2.2.4	Are production processes validated (with supporting documentation)?	Yes ☐ No ☐
	If the answer is no, are processes proven to be suitable and consistent?	Yes ☐ No ☐
COMMENTS:		
2.3 REJECTION		
2.3.1	Are raw materials, intermediates and products failing to meet established specifications rejected?	Yes ☐ No ☐
2.3.2	Is a procedure for handling of rejected products in place?	Yes ☐ No ☐
2.3.3	Are rejected materials identified as such and blocked for use?	Yes ☐ No ☐

Supplier Quality Questionnaire

Questionnaire for Manufacturers of Critical Raw Materials – version 1

Page 4 of 15

2.3.4	Is a procedure for reprocessing or reworking of rejected materials in place?	Yes ☐ No ☐
2.3.5	Is the disposition of rejected material recorded?	Yes ☐ No ☐
COMMENTS:		
2.4 RETURNS		
2.4.1	Is a procedure for handling of returned goods in place?	Yes ☐ No ☐
2.4.2	Are returned products identified as such and labelled accordingly?	Yes ☐ No ☐
2.4.3	Are returned products stored physically separated?	Yes ☐ No ☐
2.4.4	Are records of returned goods maintained?	Yes ☐ No ☐
COMMENTS:		
2.5 PRODUCT QUALITY REVIEW (PQR), ANNUAL QUALITY SYSTEM REVIEW (MANAGEMENT REVIEW)		
2.5.1	Are regular Product Quality Reviews / Management Reviews conducted? If yes, please indicate the frequency:	Yes ☐ No ☐
2.5.2	Do you evaluate / assess Product Quality Reviews whether corrective actions/preventive actions need to be taken?	Yes ☐ No ☐ N/A ☐
COMMENTS:		

3. Personnel

3.1 PERSONNEL - HYGIENE

3.1.1	Is a written gowning procedure in place to make sure personnel is wearing appropriate and clean clothing for different activities to protect the personnel as well as the product from contamination?	Yes ☐ No ☐
3.1.2	Do you perform personal hygiene training for employees who handle open products as a precaution to prevent contamination of the products and the employees?	Yes ☐ No ☐
COMMENTS:		

4. Buildings and Facilities		
4.1 DESIGN AND CONSTRUCTION		
4.1.1	Are written procedures established, followed and documented for cleaning of manufacturing areas, packaging areas, sampling areas and buildings?	Yes ☐ No ☐
4.1.2	Are manufacturing areas and buildings part of the preventive maintenance program?	Yes ☐ No ☐
	Are there defined areas for the following activities:	
4.1.3	• Receipt of raw materials?	Yes ☐ No ☐
4.1.4	• Sampling of materials?	Yes ☐ No ☐
4.1.5	• Quarantine storage before release for raw materials, intermediates and products?	Yes ☐ No ☐
4.1.6	• Storage of released raw materials, intermediates and products?	Yes ☐ No ☐
4.1.7	• Storage of rejected raw materials, intermediates and products before further disposition (re-processing, return, destruction, ...)?	Yes ☐ No ☐
4.1.8	• Manufacturing and processing operations?	Yes ☐ No ☐
4.1.9	• Packaging and labelling operations?	Yes ☐ No ☐
4.1.10	• Control and laboratory operations?	Yes ☐ No ☐
4.1.11	Does the design and construction of the buildings prevent the flow of material and personnel from contamination / mix-up?	Yes ☐ No ☐
COMMENTS:		
4.2 UTILITIES		
4.2.1	Are all utilities which can impact on product quality (steam, gases, compressed air, ventilation, ...) qualified and monitored?	Yes ☐ No ☐
4.2.2	Are there adequate ventilation, air filtration and exhaust systems in place to minimize the risk of cross-contamination?	Yes ☐ No ☐
COMMENTS:		
4.3 WATER SYSTEM / WATER QUALITY		
4.3.1	Do you have a written specification for process water?	Yes ☐ No ☐ N/A ☐
4.3.2	Does the water quality meet at least the specification on drinking water?	Yes ☐ No ☐ N/A ☐
4.3.3	Is feed water coming into the plant periodically monitored for chemical quality?	Yes ☐ No ☐ N/A ☐
4.3.4	Is feed water coming into the plant periodically monitored for microbial quality?	Yes ☐ No ☐ N/A ☐

Supplier Quality Questionnaire

Questionnaire for Manufacturers of Critical Raw Materials – version 1

Page 6 of 15

4.3.5	Is feed water monitoring performed on a regular basis on points of use?	Yes ☐ No ☐ N/A ☐
4.3.6	Is a procedure in place in case the chemical or microbial action limits for process water are exceeded?	Yes ☐ No ☐ N/A ☐
4.3.7	Is the treatment to achieve a defined water quality validated and monitored on all points of use?	Yes ☐ No ☐ N/A ☐

COMMENTS:

4.4 CONTAINMENT

4.4.1	Are the necessary measures taken to prevent cross-contamination from personnel and materials from one dedicated area to another?	Yes ☐ No ☐
-------	--	--

COMMENTS:

4.5 PEST CONTROL

4.5.1	Is a pest control program on the manufacturing site in place?	Yes ☐ No ☐
4.5.2	Is pest control performed by an external partner?	Yes ☐ No ☐
4.5.3	Are reports about the pest control program available?	Yes ☐ No ☐
	Are measures taken inside the warehouse(s) (e.g. traps, UV lamps) against:	
4.5.4	• Rodents?	Yes ☐ No ☐
4.5.5	• Flying insects?	Yes ☐ No ☐
4.5.6	• Crawling insects?	Yes ☐ No ☐

COMMENTS:

5. Process Equipment

5.1 DESIGN AND CONSTRUCTION

5.1.1	Is production equipment only used within its qualified operating range?	Yes ☐ No ☐
5.1.2	Is ensured that heating fluids, coolants, ... can't get in contact with the product?	Yes ☐ No ☐
5.1.3	Are lubricants used which can get in contact with the product?	Yes ☐ No ☐
5.1.4	If the answer on question 5.1.3 is yes: is it ensured by a statement that they are food grade?	Yes ☐ No ☐ N/A ☐
5.1.5	Do you have measures in place to avoid particles caused by equipment failures and/or other abnormal occurrences?	Yes ☐ No ☐

COMMENTS:

5.2 EQUIPMENT MAINTENANCE		
5.2.1	Do you have a preventive maintenance program in place?	Yes ☐ No ☐
5.2.2	Are written procedures established and followed for preventive maintenance of equipment?	Yes ☐ No ☐
5.2.3	Are records kept of preventive maintenance, repairs and use?	Yes ☐ No ☐
COMMENTS:		
5.3 CALIBRATION		
5.3.1	Are there written procedures for the calibration of quality-critical equipment in place?	Yes ☐ No ☐
5.3.2	Are there a schedule and frequency for re-calibration defined?	Yes ☐ No ☐
5.3.3	Are limits for accuracy and precision of the equipment defined?	Yes ☐ No ☐
5.3.4	Are the calibration records maintained?	Yes ☐ No ☐
5.3.5	Is the calibration status (e.g. date of last and next calibration) indicated on the instruments (e.g. calibration labels)?	Yes ☐ No ☐
5.3.6	Is there a system / procedure specifying that equipment and instruments cannot be used if they are beyond the calibration date?	Yes ☐ No ☐
5.3.7	Are calibration deviations which might have an impact on the product quality investigated?	Yes ☐ No ☐
5.3.8	Is the equipment used calibrated / verified at specific intervals against traceable national or international measurement standards?	Yes ☐ No ☐
5.3.9	Will you provide us with the calibration certificates of the equipment used for the services you deliver to CUSTOMER?	Yes ☐ No ☐
COMMENTS:		
5.4 COMPUTERIZED SYSTEMS		
5.4.1	Has computer system validation been performed (e.g. according to GAMP 5) for systems which have an impact on product quality (e.g. system for status management)?	Yes ☐ No ☐
5.4.2	Are documents for computer system validation available?	Yes ☐ No ☐
5.4.3	Are there sufficient controls in place to prevent unauthorized access, changes to data and omissions in data?	Yes ☐ No ☐
5.4.4	Do you record who made a change, when a change was made as well as the previous entry?	Yes ☐ No ☐
5.4.5	Is the entry of critical data additionally checked on accuracy of the entry (by a second operator, the system itself, ...)?	Yes ☐ No ☐

5.4.6	Are incidents with computerized systems investigated towards a written procedure?	Yes ☐	No ☐
5.4.7	Are changes to the computerized system made towards a written procedure?	Yes ☐	No ☐
5.4.8	Do you have a back-up system in place in case of system breakdowns, failures, ...?	Yes ☐	No ☐
COMMENTS:			

6. Materials Management

6.1 MATERIAL RECEIPT & SAMPLING/TESTING

6.1.1	Are materials purchased against agreed specifications?	Yes ☐	No ☐
6.1.2	Do you have a system ensuring that materials are purchased from approved suppliers only?	Yes ☐	No ☐
6.1.3	Are shipping documents compared to the purchasing order?	Yes ☐	No ☐
6.1.4	Do you perform a visual check on the delivery of materials (labelling, damages, broken seals, ...)?	Yes ☐	No ☐
6.1.5	Do you ask for a certificate of analysis for each delivery of material?	Yes ☐	No ☐
6.1.6	Do you identify each raw material batch with an internal and unique number?	Yes ☐	No ☐
6.1.7	Are written procedures for sampling and testing of materials in place?	Yes ☐	No ☐
6.1.8	Is sampling conducted in a defined area to prevent contamination and cross-contamination of the material sampled and contamination of other materials?	Yes ☐	No ☐
6.1.9	Are incoming materials released before they are mixed with existing stocks?	Yes ☐	No ☐

COMMENTS:

6.2 WAREHOUSE: STORAGE & DISTRIBUTION

6.2.1	Do you use an ERP for warehouse and materials management (e.g. SAP)?	Yes ☐	No ☐
6.2.2	Are raw materials held under quarantine until they have been tested and released by the Quality Unit?	Yes ☐	No ☐
6.2.3	Are rejected materials identified and controlled under an appropriate system to prevent unauthorised use in manufacturing?	Yes ☐	No ☐
6.2.4	Are raw materials and products handled and stored in a manner to prevent degradation, contamination and cross-contamination?	Yes ☐	No ☐
6.2.5	Do you have scientific evidence (e.g. stability data) to indicate the acceptable storage conditions for your products (e.g. humidity, temperature, protected from light)?	Yes ☐	No ☐
6.2.6	Are temperature and humidity controlled appropriately for the materials stored in the warehouse?	Yes ☐	No ☐

Supplier Quality Questionnaire

Questionnaire for Manufacturers of Critical Raw Materials – version 1

Page 9 of 15

6.2.7	Do you monitor the temperature in the storage areas?	Yes ☐	No ☐
6.2.8	Has a temperature mapping been performed to determine the hottest and coldest spot of the storage area(s)?	Yes ☐	No ☐
6.2.9	Are materials requiring special storage conditions stored accordingly?	Yes ☐	No ☐
COMMENTS:			
6.3 VENDOR QUALIFICATION (SUPPLIER / SUBCONTRACTOR – including Contract Laboratories)			
6.3.1	Is a written procedure for vendor qualification in place?	Yes ☐	No ☐
6.3.2	Does the procedure on vendor qualification consider a re-qualification?	Yes ☐	No ☐ N/A ☐
6.3.3	Is vendor qualification documented?	Yes ☐	No ☐
6.3.4	Does the vendor qualification consider the primary source (manufacturer) of the product?	Yes ☐	No ☐
6.3.5	Are quality relevant processes outsourced to subcontractors (e.g. contract manufacturer, contract laboratories and technical service provider)?	Yes ☐	No ☐
6.3.6	Is a documented system in place to qualify subcontractors (e.g. contract manufacturer, contract laboratories and technical service provider)?	Yes ☐	No ☐
6.3.7	Is a system in place to assure that your suppliers and subcontractors notify you about significant changes in their processes?	Yes ☐	No ☐
COMMENTS:			

7. Manufacturing			
7.1 MANUFACTURING DOCUMENTATION			
7.1.1	Are written manufacturing instructions in place for each product?	Yes ☐	No ☐
7.1.2	Is a system in place to assure that only current versions of approved manufacturing instructions are used?	Yes ☐	No ☐
7.1.3	Is the information about which major equipment, instruments, production lines, ... have been used during manufacturing included in the batch production records?	Yes ☐	No ☐
7.1.4	Is each product identified with a unique batch or identification number?	Yes ☐	No ☐
7.1.5	Are critical manufacturing steps witnessed by a second operator?	Yes ☐	No ☐
7.1.6	Are changes and deviations that occur during the manufacturing process documented in the manufacturing records?	Yes ☐	No ☐
7.1.7	Are critical and major deviations investigated?	Yes ☐	No ☐

Supplier Quality Questionnaire

Questionnaire for Manufacturers of Critical Raw Materials – version 1

Page 10 of 15

7.1.8	Do you have records in place for all your equipment describing its use (or as an alternative is the usage fully traceable)	Yes ☐ No ☐
COMMENTS:		
7.2 DESIGN & CONSTRUCTION – CONTAMINATION CONTROL		
7.2.1	Are the rooms where final manufacturing steps are performed classified (e.g. ISO 7 or ISO 8)?	Yes ☐ No ☐
7.2.2	Is a zone concept with pressure differences for the rooms where final manufacturing steps are performed in place?	Yes ☐ No ☐
7.2.3	Are areas where products are handled or exposed to the production environment, provided with adequate air filtration, dust collection and exhaust systems to control airborne contaminants and prevent cross contamination?	Yes ☐ No ☐
7.2.4	Is the manufacturing equipment designed to minimize the possibility of contamination from the operator (e.g. closed systems)?	Yes ☐ No ☐
7.2.5	Is a written procedure for handling of open products in place to prevent contamination and cross-contamination?	Yes ☐ No ☐
COMMENTS:		
7.3 MANUFACTURING EQUIPMENT		
7.3.1	Is a system in place to identify major equipment, instruments and production lines (e.g. equipment numbers and labels)?	Yes ☐ No ☐
7.3.2	Are logbooks kept for all major equipment to show which activities have been performed on the equipment (e.g. type of product manufactured)?	Yes ☐ No ☐
COMMENTS:		
7.4 MANUFACTURING OPERATIONS		
7.4.1	Are raw materials handled (including weighing, measuring, loading, ...) appropriately to maintain their identity, quality and purity?	Yes ☐ No ☐
7.4.2	Do you perform reprocessing (repeating process steps that are already part of the regular process)?	Yes ☐ No ☐
7.4.3	Do you perform rework (performing process steps that are not part of the regular process)?	Yes ☐ No ☐
7.4.4	If reprocessing or reworking is performed, is there sufficient investigation, evaluation and documentation to assure that the final product is at least equivalent to other acceptable product, meeting all established standards, specifications and characteristics?	Yes ☐ No ☐ N/A ☐
7.4.5	If reworking is performed, is the impact on stability, impurities etc. considered and are appropriate controls applied for these issues?	Yes ☐ No ☐ N/A ☐

Supplier Quality Questionnaire

Questionnaire for Manufacturers of Critical Raw Materials – version 1

Page 11 of 15

7.4.6	Do you use recovered solvents for the products covered by this questionnaire?	Yes ☐ No ☐ N/A ☐
	If so, please describe how you do such recoveries:	
7.4.7	Is a procedure for blending and mixing of batches in place?	Yes ☐ No ☐
7.4.8	Are parameters for blending and mixing defined?	Yes ☐ No ☐
7.4.9	Are individual non-conforming batches blended with others?	Yes ☐ No ☐
7.4.10	Is the blending and mixing process reproducible to ensure homogeneity of the blended batches?	Yes ☐ No ☐ N/A ☐
7.4.11	Does the batch number assigned to the final batch allow traceability back to the individual batches that make up the blend?	Yes ☐ No ☐
COMMENTS:		
7.5 EQUIPMENT CLEANING		
7.5.1	Is the equipment cleaned at defined intervals (in case of dedicated as well as multi-purpose equipment)?	Yes ☐ No ☐
7.5.2	Are written procedures established where cleaning of equipment is described?	Yes ☐ No ☐
7.5.3	Is a system in place to assure that only current versions of approved cleaning instructions are used?	Yes ☐ No ☐
7.5.4	Is a system in place for documenting cleaning and the use of equipment (e.g. cleaning records/logbooks and use logbooks)?	Yes ☐ No ☐
7.5.5	Is a system in place to indicate the cleaning status of the equipment (e.g. cleaning label on the equipment)?	Yes ☐ No ☐
7.5.6	Is a system in place to indicate the cleaning status of controlled areas?	Yes ☐ No ☐
7.5.7	Are acceptance criteria for residues determined to show that cleaning procedures for multi - purpose equipment are adequate to remove the previous materials?	Yes ☐ No ☐ N/A ☐
7.5.8	Are cleaning methods validated?	Yes ☐ No ☐ N/A ☐
7.5.9	Is the validation of cleaning methods documented?	Yes ☐ No ☐ N/A ☐
7.5.10	Do you visually verify the cleaning success after a product change over?	Yes ☐ No ☐
7.5.11	Did you define hardest to clean spots at your manufacturing equipment?	Yes ☐ No ☐
7.5.12	Do you record the cleaning success of hardest to clean spots?	Yes ☐ No ☐
COMMENTS:		

8. Packaging and Labelling		
8.1	Are written procedures for labelling and packaging operations in place?	Yes ☐ No ☐
8.2	Is there a written procedure for clearing the packaging area after each packaging operation before the next operation, especially if the area is used for packaging of different materials à Line clearance?	Yes ☐ No ☐
8.3	Are labels and packaging materials representatively sampled, examined or tested and released before use?	Yes ☐ No ☐
8.4	Are product containers that are shipped outside of the manufacturer's control sealed?	Yes ☐ No ☐
8.5	Are tamper-proof seals used for shipping of finished products?	Yes ☐ No ☐
	Do the shipping labels for finished products contain the following information:	
8.6	• name and address of the original manufacturer?	Yes ☐ No ☐
8.7	• manufacturing and expiration (retest) date?	Yes ☐ No ☐
8.8	• special storage conditions?	Yes ☐ No ☐
COMMENTS:		

9. Quality Control / Laboratory		
9.1 ORGANISATION		
9.1.1	Is the Quality Control laboratory internal (at the address specified above)?	Yes ☐ No ☐
	If not, please explain below if it is done at another site / affiliate / 3 rd party.	
COMMENTS:		
9.2 SPECIFICATIONS & RECORDS		
9.2.1	Are written specifications and test methods for raw materials, intermediates, packaging materials and finished products in place?	Yes ☐ No ☐
9.2.2	Are all specifications approved by the Quality Unit?	Yes ☐ No ☐
9.2.3	Is there a system in place to ensure that customer specifications are fulfilled?	Yes ☐ No ☐
9.2.4	Is a system in place to assure that only current versions of approved specifications are used?	Yes ☐ No ☐
9.2.5	Is a system in place to assure that only current versions of approved testing methods are used?	Yes ☐ No ☐
9.2.6	Are records of all analytical tests available?	Yes ☐ No ☐

COMMENTS:		
9.3 BATCH TESTING & CERTIFICATION		
9.3.1	Is a procedure in place for the handling of results that are out of specification (OOS procedure)?	Yes ☐ No ☐
9.3.2	Are out-of-specification results investigated and documented?	Yes ☐ No ☐
9.3.3	Is re-sampling performed according to a written procedure?	Yes ☐ No ☐
9.3.4	Are authentic certificates of analysis (CoA) issued for each single batch?	Yes ☐ No ☐
9.3.5	Are name and address of your manufacturing site stated on the CoA?	Yes ☐ No ☐
COMMENTS:		
9.4 RETAIN SAMPLES		
9.4.1	Are identified reserve samples of each batch of product retained?	Yes ☐ No ☐
9.4.2	Are reserve samples retained for at least one year after the retest date?	Yes ☐ No ☐
9.4.3	Are reserve samples retained for at least three years after distribution?	Yes ☐ No ☐
9.4.4	Is the retain sample size at least twice the amount required to perform all specification testing?	Yes ☐ No ☐
COMMENTS:		
9.5 STABILITY		
9.5.1	Is a written stability program in place?	Yes ☐ No ☐
9.5.2	Is the expiration, re-test date and storage conditions assigned to the material based on stability testing?	Yes ☐ No ☐
9.5.3	Are the stability chambers (re) qualified?	Yes ☐ No ☐
9.5.4	Is the qualification of the stability chambers documented?	Yes ☐ No ☐
9.5.5	Do you perform monitoring of the conditions for the stability chambers?	Yes ☐ No ☐
COMMENTS:		

10. Comments / References

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]

11. Statements

Required statements / documents to be attached to this Questionnaire:

- ☐ Current Route of Synthesis
- ☐ BSE / TSE
- ☐ GMO
- ☐ Metal Impurities
- ☐ Elemental Impurities Statement for excipients
- ☐ Residual Solvents
- ☐ Melamine
- ☐ Pesticide
- ☐ Phthalate
- ☐ Toxic compound
- ☐ Latex
- ☐ Gluten

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: