Version xxxxxx	**SUPPLIER QUESTIONNAIRE**		
	Company Name:	Ref.No:	

Please complete this questionnaire, by hand and within 30 days return to (Name of contact person).

Name and title of person returning the questionnaire				
Date				
Are you:	Producer	Distributor	Contract manufacturer	Contract Lab
	☐	☐	☐	☐
Name of substance/s supplied				

Annexes: Questonnaire APIs/Excipients/Packaging/QC-Labs/Toll Manufacturer etc.

1 General Information

1.1 Primary contacts

1.1.1 Name of company	
1.1.2 Adress of company	
1.1.3 Telephone Number	
1.1.4 Fax Number	
1.1.5 E-Mail	
1.1.6 Web site	
1.1.7 Name of Chief Executive	
1.1.8 Name of Sales Respresative	
1.1.9 Name of QP/Members of the Quality Unit	
1.1.10 Name of person responsible for Quality Management	
1.1.11 Name of person responsible for Regulatory Affairs	
1.1.12 Name of person responsible for Customer Service	

1.1.13 Company organigram	
1.1.14 Number of employees in total	
1.1.15 Number of employees in QC/QA/QM	
1.1.16 Number of employees in production	
1.1.17 Number of employees in Administration	

1.2 Company Profile

1.2.1 If the company is part of a larger group, give the name and address of head office				
1.2.2 Legal Status of the Company				
1.2.3 Annual Turnover	1 – 10 M€ ☐	10 – 100 M€ ☐	100 – 1000 M€ ☐	>1000 M€ ☐
1.2.4 Founding year				
1.2.5 Business activities				
1.2.6 Subsiduaries				
1.2.7 Area of production sites				
1.2.8 Location of production sites				

1.3 General commercial and Customer Service

1.3.1 Would you allow us or a third party to inspect your facilities?	☐ YES	☐ NO
1.3.2 Has any other company or third party audited you? If yes, how many?	☐ YES	☐ NO
1.3.3 Would you provide us a copy of a third party audit report?	☐ YES	☐ NO
1.3.4 Please note down any major customers particularly pharmaceutical customers, with whom you work (optionel)		

1.3.5 If any other companies are subcontracted in any of the activities related to this product please give their name and address.	
Activity	**Name and Address**

1.4 Site Information

1.4.1 Would you supply a site master file?	☐ YES ☐ NO

2 Quality System

2.1 Quality Policy

2.1.1 Is your company registred at the responsible GMP authority	**Please attach copie of the registration letter**
2.1.2 Is your company under surveillance by the responsible GMP authority	**Please state name and adresss of the authority**
2.1.3 Does the company have current ISO / HACCP / IFS / GMP or any other relevant certification?	**Please attach copie**
2.1.4 Does the certification apply to the whole operation?	☐ YES ☐ NO

2.1.5 If NO, please explain the scope of the certification	
2.1.6 If the company is not certified, do you have plans to get certified?	☐ YES ☐ NO
2.1.7 If YES, when is your first inspection expected?	
2.1.8 Does your company have a Quality Manual? If so, attach table of contens	☐ YES ☐ NO
2.1.9 Has any Authority or Regulatory body inspected your facilities? Please state Name and Country:	☐ YES ☐ NO

2.2 Quality Improvement

2.2.1 Do you carry out self-inspections of your facilities and systems?	☐ YES ☐ NO
2.2.2 How often?	
2.2.3 How do you monitor effectiveness and closure of corrective actions?	
2.2.4 How is the senior management kept aware of the quality improvement program?	

2.3 Purchasing

2.3.1 How are you suppliers approved, and by whom?	
2.3.2 Do you maintain a list of certified, and acceptable suppliers, categorised accordingly?	☐ YES ☐ NO
2.3.3 Do your systems allow you to use products of unapproved suppliers?	☐ YES ☐ NO
2.3.4 Do you purchase against agreed specifications only?	

2.4 Materials Management – Warehousing & Dispatching

2.4.1 What type of pest control system do you use?	
2.4.2 How often do you inspect for pests?	
2.4.3 Are storage conditions monitored/controlled in warehouse?	☐ YES ☐ NO **If Yes please state the ranges**
2.4.4 How do you dispatch finished goods?	☐ own transport ☐ contract transport

2.4.5 Do you consider the rules of Good Distribution and Transportation Practice?	☐ YES ☐ NO **If YES please SPECIFY**

2.5 Materials Management – Labelling

2.5.1 What checks are carried out on incoming materials?	
2.5.2 Do you apply in – house identily labels on incoming goods?	☐ YES ☐ NO
2.5.3 If not how do you identify materials?	
2.5.4 Do you operate "First in – First out" ?	☐ YES - **manua**l ☐ Yes - **comuterised** ☐ No
2.5.5 Do you operate a material location system?	☐ YES - **manua**l ☐ Yes - **comuterised** ☐ No
2.5.6 If the system is computerised, is it validated?	☐ YES ☐ NO
2.5.7 Do you store more than one product per location?	☐ YES ☐ NO

2.5.8 Do you operate a quarantine system for incoming raw materials?	☐ YES ☐ NO
2.5.9 How do you prevent quarantine material from being used?	
2.5.10 Do you have a status labelling system?	☐ YES ☐ NO
2.5.11 How is your batch numbering system build up?	
2.5.12 What system do you use to maintain he traceability of materials?	
2.5.13 How are rejected materials separated?	

2.6 Document Control

2.6.1 Is there a formal system for reviewing and updating SOP's, specifications, manufacturing instructions?	☐ YES ☐ NO

2.6.2 How do you ensure that obsolete/ superseded documents according to **2.7.1** are not used?	
2.6.3 How long, how and where are batch documents archived?	

2.7 Change Control

2.7.1 Is a change control system in place?	☐ YES ☐ NO
2.7.2 What scopes are subjected to Change Control?	
2.7.3 By whom are risks of changes assessed, classified and authorized?	
2.7.4 When and how do you inform your customers about changes?	
2.7.5 Are you willing to sign a change control agreement	☐ YES ☐ NO

2.8 Deviation Management

2.8.1 Is a deviation management system in place?	☐ YES ☐ NO
2.8.2 What scopes are subjected to Deviation Management?	
2.8.3 By whom are risks of deviations assessed? Who determines correctives and preventive actions?	
2.8.4 When and how do you inform your customers about deviations?	

2.9 Training

2.9.1 Is a GMP compliant training system in place?	☐ YES ☐ NO
2.9.2 Is training documented and verified by testing?	☐ YES ☐ NO
2.9.3 At what interval do you retrain staff?	
2.9.4 Which training other than GMP is carried out?	

2.10 Complaints and Recall

2.10.1 Is there a formal complaint procedure?	☐ YES ☐ NO
2.10.2 Do you report findings to customers?	☐ YES ☐ NO
2.10.3 Who is responsible for this procedure?	
2.10.4 In what time period would you normally reply to a formal complaint?	
2.10.5 Is there a recall policy?	☐ YES ☐ NO
2.10.6 Who is responsible for recalls?	
2.10.6 How do you ensure traceability of all products an case of a recall?	

2.11 Computer Systems

	Are IT Systems used?		Is the computer system validated?		Does data storage comply with US requirements (21 CFR part 11)	
2.11.1 For documentation	Yes ☐	No ☐	Yes ☐	No ☐	Yes ☐	No ☐
2.11.2 Warehousing	Yes ☐	No ☐	Yes ☐	No ☐	Yes ☐	No ☐
2.11.3 Laboratory (LIMS)	Yes ☐	No ☐	Yes ☐	No ☐	Yes ☐	No ☐
2.11.4 Manufacturing process control	Yes ☐	No ☐	Yes ☐	No ☐	Yes ☐	No ☐
2.11.5 ERP (Enterprise Resource planning)	Yes ☐	No ☐	Yes ☐	No ☐	Yes ☐	No ☐

3 Quality – Testing and Release of Materials and Products

3.1 Quality Control – laboratory facilities and systems

3.1.1 Do you have on-site laboratory or QC facilities?	☐ YES ☐ NO
3.1.2 If yes, what kind of testing do you apply?	
3.1.3 Is your QC department independent from production? (please provide organigram)	☐ YES ☐ NO
3.1.4 Do use contract laboratories?	☐ YES ☐ NO
3.1.5 If Yes, which labs and which tests?	
3.1.6 Are the labs accredited/ certified? According to which standard?	
3.1.7 Are the labs qualified and audited by your company or a third party?	
3.1.8 Are written quality contracts in place?	

3.1.9 Are all laboratory instruments and measuring devices & calibrated?	☐ YES ☐ NO **Comment:**
3.1.10 Do you maintain a calibration schedule?	☐ YES ☐ NO
3.1.11 Are there written instructions for the laboratory equipment?	Operation ☐ YES ☐ NO Mainteneance ☐ YES ☐ NO Calibration ☐ YES ☐ NO Cleaning ☐ YES ☐ NO
3.1.12 Do you have a sampling plan for the material delivered to us? Please give a short description.	
3.1.13 Who conducts sampling and where?	

3.2 Quality Control – laboratory testing

3.2.1 Do you have specifications for the raw materials, intermediates and finished products?	☐ YES ☐ NO
3.2.2 Do you use reference standards?	☐ YES ☐ NO **If Yes, which ones:** ☐ **EP** ☐ **USP** ☐ **OTHER**
3.2.3 Is a written procedure for handling of reference standards, chemicals and reagents in place?	
3.2.4 What testing is carried out on the final product?	
3.2.5 Are there written instructions for the tests?	☐ YES ☐ NO
3.2.6 Are the tests validated or do you use verified compendial methods?	
3.2.7 How do you deal with out of spec test results?	
3.2.8 Do you retain samples from raw materials and finished products?	☐ YES ☐ NO
3.2.9 If YES, please indicate amount, storage time and conditions	

3.2.10 Do you provide certification of each batch/ lot of product?	☐ **Certificate of Analysis** ☐ **certificate of conformance** ☐ **other**
3.2.11 Can provide certification to include a specific customer requirement?	☐ YES ☐ NO
3.2.12 Do you execute storage stability testing acc. to ICH and can you provide corresponding stability?	☐ YES ☐ NO
3.2.13 If YES, please indicate the shelf live/ retest date and corresponding storage conditions.	

3.3 Batch Release

3.3.1 Are there written procedures for the dispositioning (approval or rejection) of incoming materials?	☐ YES ☐ NO
3.3.2 Are there written procedures for the dispositioning (approval or rejection) of finished products?	☐ YES ☐ NO
3.3.3 Does a qualified person/ quality unit review the batch records before the batch is released and certified?	☐ YES ☐ NO

3.4 Hygiene system

3.4.1 Are you operating a functional hygiene system? If YES please specify?	☐ YES ☐ NO
3.4.2 What areas are included by this system?	
3.4.3 Please describe the fey elements and scopes of your hygiene plan.	
3.4.4 Do you operate a hygiene monitoring system? If YES please specify.	☐ YES ☐ NO
3.4.5 How do you evaluate your hygiene monitoring system? Please specify.	

3.5 Final evaluation by submittor:

	No significant deficiencies	Minor deficiencies	Mayor deficiencies	Deficiencies not acceptable	N.A
2.1 Quality Policy					
2.2 Quality Improvement					
2.3 Purchasing					
2.4 Materials Management – Warehousing & Dispatching					
2.5 Materials Management - Labelling					
2.6 Document Control					
2.7 Change Control					
2.8 Deviation Management					
2.9 Training					
2.10 Complaints and Recall					
2.11 Computer Systems					
3.1 Quality Control – laboratory facilities and systems					
3.2 Quality Control – laboratory testing					
3.3 Batch Release					
3.4 Hygiene system					

Name and title of person evaluating the questionnaire	
Date	