KEY SUPPLIER QUALIFICATION SUMMARY	
Initiation date: (x/xx/xxxx)	**Review Date: (mm/dd/yyyy)**
☐ **Questionnaire**	☐ **On-site**
Initial Qualification ☐ **Yes** ☐ **No**	**If subsequent qualification, was periodic testing conducted on components where Supplier's Certificate of Analysis is accepted in lieu of full testing upon receipt?** ☐ **Yes** ☐ **No (if no, testing to be initiated prior to audit close out)** ☐ **N/A**
Component Type Approval ☐ **Product** ☐ **Product Contact Component** ☐ **Labeling** ☐ **Subcontractor** ☐ **Secondary Component** ☐ **GMP Service** ☐ **Other** ***(please specify):*** _____	
Supplier Approve ☐ **Yes** ☐ **No**	**If not approved provide rationale:**
Completed By:	**Date:**
Reviewed By (Purchasing if necessary for ISO Sites):	**Date:**

Section 1 – SUPPLIER IDENTIFICATION	
Company Name:	Company Address:
Internet Address: (Web site)	Contact Name:
E-mail Address:	Title:
Phone Number:	Fax Number:

Section 2 – MANUFACTURING FACILITY IDENTIFICATION	
If information identical to Section 1 please check box ☐	
Facility Name:	Facility Address:
Contact Name:	Phone Number:
Title:	Fax Number:
Internet Address: (Web site)	E-Mail Address:

Section 3 - PRODUCT(S) IDENTIFICATION			
Name(s):		Product Code number(s):	
Check all categories of materials supplied or to be supplied	☐ Product ☐ Product Contact Component ☐ GMP Service ☐ Labeling ☐ Secondary Component ☐ Subcontractor ☐Other *(please specify):*_____		
Section 4 – SUPPLIER INFORMATION			
Corporate Name:		Legal Status: ☐ Public ☐ Private	
Foundation Date:	Total Number of Staff:	This Site:	Worldwide:
Are your operations GMP compliant? *If yes, inidicate which section*		☐ Yes _____ ☐ No	
Is your Quality System certified to ISO? *If yes, please specify ISO standard* ***Please provide a copy of most recent certification***		☐ Yes _____ ☐ No	
Has your company been inspected by government agencies? *If yes, please specify agency*		☐ Yes _____ ☐ No	
Are there any outstanding major issues from regulatory authority inspections? *If yes, please eleborate*		☐ Yes _____ ☐ No	
Percentage of business in the pharmaceutical industry:			
Do you require license(s) for pharmaceutical product(s) or services? If yes, please provide a copy of current license(s)		☐ Yes ☐ No	
Size of manufacturing operations:	Number of shifts	Hours of operation	Percentage of temporary employees
Total staff in Quality Assurance:			
Describe the role, function and structure of the company's QA group.			
Does QA operate as a separate entity within the organization? *Please attach copies of yoru site organizational charts*		☐ Yes	☐ No
Total staff in Quality Control:			
How many materials are produced at this site?			
Section 4 – SUPPLIER INFORMATION (continued)			

What are the 5 main products? ☐ Yes ☐ No	1.	
	2.	
	3.	
	4.	
	5.	
Describe company history and growth.		
	Yes	**No**
Do you have a union?	☐	☐
If yes, name of union		
Indicate date of last signed agreement		
Do you have a specific shutdown period?	☐	☐
If yes, please indicate dates		
Do you have the following activities at the site?		
Research	☐	☐
Development	☐	☐
Purchasing	☐	☐
Raw material testing	☐	☐
Finished product testing	☐	☐
Storage / Expedition	☐	☐
Technical Assistance	☐	☐
Customer Services	☐	☐
Do you subcontract any activities?	☐	☐
If yes, please specify activities		
Have there been any significant changes related to the material we buy within the past 12 months with respect to the following?		
Facilities	☐	☐
Equipment	☐	☐
Personnel / organization	☐	☐
Manufacturing process	☐	☐
Regulatory / registrations	☐	☐
Financial	☐	☐
Please provide details of significant changes identified from above question.		
Has your firm addressed requirements of 21 CFR Part 11? Electronic Records and Electronic Signatures	☐	☐
Would you accept to receive us for a quality audit?	☐	☐
Section 4 – SUPPLIER INFORMATION (continued)		
Is a confidentiality agreement required for our company to audit your facility?	☐	☐

If yes, please **attach a copy of the agreement**		

Section 5 – QUALITY SYSTEM RANKING

Instructions: Please check the ranking in the right hand column that best describes the existence of the listed policies and procedures in use at your company as per the following ranking scheme. If N/A, please justify in Comments section.

Please attach an index / table of contents of your current SOPs.

Procedure Status	Rank
No Procedure	1
Procedure exists but is not followed	2
Procedure is infrequently followed	3
Procedure is generally followed	4
Procedure is always followed	5
Not applicable to business	N/A

		1	2	3	4	5	N/A
Quality Assurance							
1	Quality Manual	☐	☐	☐	☐	☐	☐
2	Responsibilities for Quality	☐	☐	☐	☐	☐	☐
3	Management Quality Reviews	☐	☐	☐	☐	☐	☐
4	Internal Audit Program	☐	☐	☐	☐	☐	☐
5	Supplier Evaluation and Qualification Program	☐	☐	☐	☐	☐	☐
6	Contract Review Procedure	☐	☐	☐	☐	☐	☐
7	Corrective and Preventive Action	☐	☐	☐	☐	☐	☐
8	Complaint Handling	☐	☐	☐	☐	☐	☐
9	Recall Program	☐	☐	☐	☐	☐	☐
10	Continuous Improvement Program	☐	☐	☐	☐	☐	☐
Premises							
11	Warehouse Management	☐	☐	☐	☐	☐	☐

Section 5 – QUALITY SYSTEM RANKING (continued)

		1	2	3	4	5	N/A
Premises (continued)							
12	Installation, Operations and Performance Qualification Program (Utilities)	☐	☐	☐	☐	☐	☐

Equipment							
13	Installation, Operations and Performance Qualification Program (Equipment)	☐	☐	☐	☐	☐	☐
14	Equipment Use / Maintenance / Cleaning Log Procedure	☐	☐	☐	☐	☐	☐
15	Calibration	☐	☐	☐	☐	☐	☐
16	Preventive Maintenance	☐	☐	☐	☐	☐	☐
17	Equipment Cleaning Procedure	☐	☐	☐	☐	☐	☐
Personnel							
18	GMP Training Program	☐	☐	☐	☐	☐	☐
19	Training Program for New Employees	☐	☐	☐	☐	☐	☐
20	Retraining Program	☐	☐	☐	☐	☐	☐
21	Consultants / Contractor Qualification Program	☐	☐	☐	☐	☐	☐
Sanitation							
22	Sanitation Program	☐	☐	☐	☐	☐	☐
23	Cleaning Validation	☐	☐	☐	☐	☐	☐
24	Hygiene Program	☐	☐	☐	☐	☐	☐
25	Pest Control Program	☐	☐	☐	☐	☐	☐
26	Environmental Monitoring Program	☐	☐	☐	☐	☐	☐
Raw Materials Testing							
27	Raw Material Specifications	☐	☐	☐	☐	☐	☐
28	Vendor Certification Program	☐	☐	☐	☐	☐	☐
Manufacturing Control							
29	Quarantine Procedure	☐	☐	☐	☐	☐	☐
30	Master Production Records	☐	☐	☐	☐	☐	☐
31	Installation, Operations and Performance Qualification Program (Process)	☐	☐	☐	☐	☐	☐
Section 5 – QUALITY SYSTEM RANKING (continued)							
		1	**2**	**3**	**4**	**5**	**N/A**
Manufacturing Control (continued)							
32	Process Procedures	☐	☐	☐	☐	☐	☐
33	Process Deviation Procedures	☐	☐	☐	☐	☐	☐
34	Expiration Dating	☐	☐	☐	☐	☐	☐

35	Reject Procedure	☐	☐	☐	☐	☐	☐
Quality Control							
36	Method Validation	☐	☐	☐	☐	☐	☐
37	QC Reagent / Solution / Standard Control	☐	☐	☐	☐	☐	☐
38	Out of Specification Procedure	☐	☐	☐	☐	☐	☐
39	Rework and Reprocess Procedure	☐	☐	☐	☐	☐	☐
40	Change Control Program	☐	☐	☐	☐	☐	☐
Packaging Testing							
41	Label Control	☐	☐	☐	☐	☐	☐
Finished Product Testing							
42	Product Specifications	☐	☐	☐	☐	☐	☐
43	In-Process / Final Product Testing Program	☐	☐	☐	☐	☐	☐
44	Handling / Storage / Distribution Procedures	☐	☐	☐	☐	☐	☐
45	Transportation Procedure	☐	☐	☐	☐	☐	☐
Records							
46	Good Documentation Practices	☐	☐	☐	☐	☐	☐
47	SOP Management	☐	☐	☐	☐	☐	☐
48	Documentation Control	☐	☐	☐	☐	☐	☐
49	Quality Records Retention	☐	☐	☐	☐	☐	☐
Samples							
50	Sampling Procedure	☐	☐	☐	☐	☐	☐
Stability							
51	Stability Program	☐	☐	☐	☐	☐	☐
Section 5 – QUALITY SYSTEM RANKING (continued)							
		1	**2**	**3**	**4**	**5**	**N/A**
Other							
52	Purchasing Controls	☐	☐	☐	☐	☐	☐
53	Receipt of Goods	☐	☐	☐	☐	☐	☐
54	Requalification Program	☐	☐	☐	☐	☐	☐
55	Software Validation	☐	☐	☐	☐	☐	☐
56	Restricted Software Access	☐	☐	☐	☐	☐	☐

57	Customer Notification of Change	☐	☐	☐	☐	☐	☐
58	Disaster Plan	☐	☐	☐	☐	☐	☐

Comments:

Section 6 – PRODUCT INFORMATION			
	Yes	No	N/A
Do you automatically send the customer the latest edition of safety data sheet, specifications and analytical methods?	☐	☐	☐
Does a registered file of the product exist?	☐	☐	☐
Section 6 – PRODUCT INFORMATION (continued)			
	Yes	No	N/A
If yes specify type of file? (CEP, DMF-US, EDMF …) in which countries? date of submission? is it periodically updated			
	☐	☐	☐
Do you have a Site Master File that you could provide us?	☐	☐	☐
Could you send us the flow chart of the process? Or give us a summary of the process? **please attach a copy**	☐	☐	☐
Have the key parameters of the process been identified?	☐	☐	☐
Have the limits of the key parameters been stated?	☐	☐	☐

Are there validation reports of the critical stages of the synthesis?	☐	☐	☐
Are the manufacturing operations running continuously?	☐	☐	☐
Which other products, if not a dedicated area, are manufactured in the same area?			
Is the process equipment dedicated?	☐	☐	☐
If not, which are the other products manufactured with the same equipment?			
Have cleaning procedures and schedules been established regarding equipment?	☐	☐	☐
Have they been validated?	☐	☐	☐
Are there equipment cleaning logs?	☐	☐	☐
Are there logbooks for repair and maintenance?	☐	☐	☐
Do you have a list of instruments which have to be calibrated?	☐	☐	☐
Do you have the calibration records?	☐	☐	☐
What is the typical size of a batch?			
What is the lot number system?			
Is there a final quality review of both the batch record and test results before releasing the product?	☐	☐	☐
By whom?			
Are subcontractors used for any part or all of the manufacturing process?	☐	☐	☐
Water system: please describe the source of water used for manufacturing and cleaning			
Are all raw materials controlled at reception?	☐	☐	☐
Section 6 – PRODUCT INFORMATION (continued)			
	Yes	No	N/A
Which raw materials are not controlled?			
Does an approved sampling plan exist indicating the sampling procedure and the number of containers to be sampled?	☐	☐	☐
Is the sampling made in a separate area?	☐	☐	☐
Are materials awaiting testing properly segregated from tested materials?	☐	☐	☐
Are written specifications available for all materials?	☐	☐	☐
Do you evaluate your suppliers?	☐	☐	☐
Do you evaluate your transportation companies?	☐	☐	☐
Do you keep a representative sample of each delivery you	☐	☐	☐

make? How long?			
Do you have different qualities of this product, for different customers?	☐	☐	☐
Do you have our specifications of the delivered product?	☐	☐	☐
Are raw data checked by a second person?	☐	☐	☐
How long are the raw data kept?			
Are all control methods validated?			
How many (on average) rejected batches per year, versus produced batches do you have?			
How many (on average) Out Of Specification batches per year, versus produced batches do you have?			
Is there a schedule for maintenance of equipment?	☐	☐	☐
Is there a procedure to assure that testing instrument is calibrated?	☐	☐	☐
Do you record each equipment / instrument used during the manufacturing of the batches?	☐	☐	☐
Do you have a program in place to assess the on-going stability?	☐	☐	☐
Are stability studies performed according to ICH guidelines	☐	☐	☐
What are the storage conditions of the product in your warehouse for raw material, intermediates and finished Product? Are these parameters recorded?	☐	☐	☐
Is there a FIFO system for stock rotation?	☐	☐	☐
Section 6 – PRODUCT INFORMATION (continued)			
	Yes	No	N/A
Does each container have a label which clarifies its status?	☐	☐	☐
Do you have segregated areas for quarantine, rejected and released material / products?	☐	☐	☐
Is there a computerized system for inventory management?	☐	☐	☐
Are all containers upon expedition legibly and completely labeled with the name of the product, the code number, the batch number, and safety requirements?	☐	☐	☐
Is a Certificate of Analysis sent with each lot? **Please attach an example copy.**	☐	☐	☐
Is a Certificate of Compliance sent with each lot? **Please attach an example copy.**	☐	☐	☐
Do you manage, retain and archive your documentation in paper version?	☐	☐	☐

Do you manage, retain and archive your documentation in electronic version?	☐	☐	☐
How long do you retain batch records documentation?			
How long do you retain analytical records documentation?			
How long do you retain validation protocols & records documentation?			
How long do you retain complaints and recalls documentation?			

Comments:

THE QUESTIONNAIRE HAS BEEN COMPLETED BY:		
Name and Title	**Signature**	**Date**