1) General Information	
Name and Address of Company:	
Name and Address of Head Office (if different):	
Phone:	
Fax:	
Email:	

2) Contact person for Quality related issues and their position	
Name:	
Position:	
Direct dial telephone:	
Direct email:	

3) Business Activities	
Describe the main activities of your business:	
For how long has your company been supplying products or services to the pharmaceutical/healthcare industry?	
Approximately what percentage of your customers are pharmaceutical/healthcare customers?	
Summarise the products or services your company will be providing to Link:	
List all products or services which will be provided to Link or attach separate list:	
Please list all applicable Licences / Certificates relevant to the products / services you are providing to Link (e.g. Wholesale, Manufacturer Licence, GDP, GMP) together with the licence/certificate number below. Please also provide copies together with your response.	☐ Attached
Warehouse Licence,	
Do you have a business continuity plan?	☐ Yes ☐ No
Do you manufacture the products you supply?	☐ Yes ☐ No

If you do not manufacture the products you supply, how do you establish the compliance level of the manufacturer?	
Do you subcontract any other part of the process (including storage, transport, testing) in the product/service provided to Link?	☐ Yes ☐ No
If yes, please state the parts that are subcontracted and how you ensure the required compliance level of your subcontractor.	
Has your manufacturing/distribution/company site been inspected by a relevant regulatory Authority or independent quality certification organisation?	☐ Yes ☐ No
If yes, please provide details on date(s) of inspection and name of relevant regulatory authority in the last 5 years:	

4) Storage and Delivery			
Are storage facilities controlled and monitored for temperature?			☐ Yes ☐ No
Are storage facilities controlled and monitored for humidity?			☐ Yes ☐ No
Are storage facilities open to the environment?			☐ Yes ☐ No
If yes, what types of materials are stored in open areas?			
Do you have a pest control programme?			☐ Yes ☐ No
If yes, please describe briefly			
Are the storage facilities subject to a documented cleaning schedule?			☐ Yes ☐ No
Do you have segregated areas for:			
(a) products in quarantine awaiting disposition?			☐ Yes ☐ No
(b) rejected products?			☐ Yes ☐ No
(c) controlled drugs?			☐ Yes ☐ No
Storage conditions available:			
☐ +15°C to +25°C	☐ +2°C to +8°C	☐ -20°C	☐ -70°C
☐ Others: Please specify _____			

5) Quality Assurance	
Do you have a Quality Management System?	☐ Yes ☐ No
Do you have a Quality Manual? (**If yes, please supply a copy** or a copy of the SOP index)	☐ Yes ☐ No
Do you have a Quality Policy? (**If yes, please supply a copy**)	☐ Yes ☐ No
Do you have a Site Master file?	☐ Yes ☐ No
Is the Quality Unit organised as a separate?	
(a) Quality Control Department	☐ Yes ☐ No
(b) Quality Assurance Department	☐ Yes ☐ No
Is the Quality Unit independent of the Production Unit/Operations?	☐ Yes ☐ No
Do you have a current Organisation chart? (**If yes, please supply a copy**)	☐ Yes ☐ No
Is your company registered with one of the current Quality Standard Organisations?	
(a) ISO 9000 series	☐ Yes ☐ No
(b) FDA Pharmaceutical cGMP	☐ Yes ☐ No
(c) EU Pharmaceutical cGMP	☐ Yes ☐ No
(d) EU GDP	☐ Yes ☐ No
(e) Others (If yes, please specify below)	☐ Yes ☐ No
Do you have a change control policy?	☐ Yes ☐ No
Do you have an internal audit programme?	☐ Yes ☐ No
Are internal audit findings acted on?	☐ Yes ☐ No
Do you have a procedure for investigating non-conformances or CAPA situations?	☐ Yes ☐ No
Are remedial actions initiated due to non-conformance/CAPA investigations?	☐ Yes ☐ No
Are actions taken to prevent re-occurrence of non-conformances/CAPA?	☐ Yes ☐ No
Are products supplied to the pharmaceutical industry subject to approval/release by the Quality unit?	☐ Yes ☐ No
Do you have an active calibration/maintenance programme?	☐ Yes ☐ No
Do you have a validation/qualification system?	☐ Yes ☐ No

If any software or computer systems are used in the production or control of materials/products or services supplied to Link, how do you control the software version used?	
What tools are used to validate software?	
Do you have the capability to confirm compliance with the technical requirements of 21 CFR Part 11 and Annex 11 of the EC Guide to GMP (Eudralex vol. 4)?	☐ Yes ☐ No
6) Personnel	
Total number of employees in the company	**40**
Does the company operate on a shift system?	☐ Yes ☐ No
Do you have a training program for all employees?	☐ Yes ☐ No
Are all training records of personnel maintained and kept?	☐ Yes ☐ No
Is there an effective program in place to address health, safety and hygiene matters?	☐ Yes ☐ No
7) Environmental	
Do you have an environmental policy for disposal of rejects and waste material?	☐ Yes ☐ No
Do you monitor the environmental impact of your operation?	☐ Yes ☐ No
8) Review	
Are you willing to allow Link to carry out an onsite Quality audit of your company/manufacturing/distribution facility?	☐ Yes ☐ No
If no, please give justification	
9) Signatures	
Questionnaire completed by:	
Name:	
Position:	
Signature:	
Date:	.2019

FOR OFFICE USE ONLY (To be completed by Link, IMMC)	
Evaluation: ☐ Approved ☐ Not approved	
Reviewed By:	
Position:	
X3 Supplier Code:	
Date:	