



Please complete this questionnaire in its entirety and include all relevant information describing the company's EXCiPACT management system as well as all activities (company prospectus). Upon receipt of these documents, AJA Registrars Germany GmbH will provide you with a detailed offer for review, which includes all costs related to the audit and the time required.

EXCiPACT 2021 CERTIFICATION QUESTIONNAIRE

COMPANY NAME			
Company addresses to be certified. (Please add more lines if needed)	HEAD OFFICE		
	ADDRESS 2		
	ADDRESS 3		
	ADDRESS 4		
	TAX ID/ VAT ID.		

CONTACT NAME		POSITION	
TELEPHONE		FAX	
EMAIL		WEBSITE	
CONSULTANT NAME (IF APPLICABLE)			
IS THERE A VALID ISO 9001 CERTIFICATION? Please attach a copy of the valid certificate.			
ACCORDING TO WHICH STANDARD SHOULD CERTIFICATION BE CARRIED OUT? GDP AND/OR GMP AND/OR GWP?			

Type of application (please tick the options below)						
NEW	<input type="checkbox"/>	RE-ZERT	<input type="checkbox"/>	EXTENSION OF THE SCOPE OF APPLICATION	<input type="checkbox"/>	<input type="checkbox"/>
PLEASE ATTACH YOUR CURRENTLY VALID ISO 9001:2015 CERTIFICATE TO THE QUESTIONNAIRE						
COLLEAGUE	TOTAL NUMBER OF EMPLOYEES	OF WHICH IN PRODUCTION	SERVICE STAFF	OFF-SITE	TOTAL NUMBER OF EMPLOYEES AVAILABLE DURING THE AUDIT	
FULL TIME						
PART-TIME						
HELPS						
SUBCONTRACTORS/SUPPLIERS						
SHIFTWORK (Y/N)	<input type="checkbox"/>	NUMBER OF LAYERS	<input type="checkbox"/>	NUMBER OF EMPLOYEES PER SHIFT	<input type="checkbox"/>	



Please describe the products, processes and/or services you intend to include in the scope to be registered.		
Are pharmaceutical excipients only manufactured or distributed in a part of the plant?		
Are manufacturing equipment used for multiple purposes other than the production of pharmaceutical excipients?		
Please name all pharmaceutical excipients that are manufactured or distributed in the factory?		
Are operations and/or activities carried out at other locations?	Number of sites	

Please tick below which exclusions from the ISO 9001 standard your company has defined, defined and justified										
7.1.5.2	<input type="checkbox"/>	8.3	<input type="checkbox"/>	8.4	<input type="checkbox"/>	8.5.3	<input type="checkbox"/>	8.5.5	<input type="checkbox"/>	

Please tick the appropriate box below if your company is interested in further certifications, thank you.											
ISO 13485	<input type="checkbox"/>	ISO 14001	<input type="checkbox"/>	ISO 45001	<input type="checkbox"/>	ISO 22000	<input type="checkbox"/>	ISO 50001	<input type="checkbox"/>	OTHER	<input type="checkbox"/>

SUB-SIGNATURE		DATE	
By signing, I declare that the above information is correct and complete to the best of my knowledge.			
POSITION IN THE COMPANY			

For a certification quote, please send this questionnaire to:

**CERTIFICATION MANAGER
AJA REGISTRARS GERMANY GMBH, WORMSER STRASSE 18; 67346 SPEYER
FAX: 06232-76568; E-MAIL: info@ajaregistrars.de**

THIS SECTION IS COMPLETED BY THE AJA REGISTRARS AUDITOR WHO CONDUCTED THE STAGE 1 AUDIT		
I hereby confirm that the above information has been checked for accuracy. If further information was available, this was included in the Stage 1 report.	Name:	
	SIGNATURE:	