API Compliance Institute
A Division of CONCEPT HEIDELBERG

SUPPLIER SELF-ASSESSMENT QUESTIONNAIRE

API Compliance Institute Business Unit of Concept Heidelberg GmbH

Section 1 – Company Details			
Name	API Compliance Institute Business Unit of Concept Heidelberg GmbH		
Address	P.O. Box 10 17 64 69007 Heidelberg Germany		
Telephone	+49 6221 84 44 0		
Website	https://www.api-compliance.org/home.html		
Contact Name	Ms Anne Günster	Contact E-mail	Guenster@api-compliance.org
Main Corporation	Concept Heidelberg GmbH		
Date Established	1 January 2003		

Section 2 – Service/Products/Equipment being Provided	
Are you providing a Service, Product or Equipment (if more than 1 provided detail in Appendix 1):	☐ Product ☐ Equipment ☒ Service
What kind of Service is being provided:	Third Party GMP Audits based on the "APIC Audit Programme". The "APIC Audit Programme" is a third party audit programme for auditing API manufacturers, distributors and API contract manufacturers and/or contract laboratories. The APIC/CEFIC has defined this audit standard which considers the strong regulatory requirements. Independent auditors perform audits according to a standardized approach. Only pharmaceutical manufacturers are able to initiate an audit.
Audit scenarios:	• Third Party Audit: A single customer applies for an audit of a manufacturing site of his API supplier. • Shared Audit: Several customers apply for an audit of a manufacturing site of their API supplier. • Mock Inspection/Audit: An API manufacturer wants to know, if its own company meets the ICH Q7 requirements.

Section 3 – Quality Standard	
Quality Standards:	There are three basic principles of the "APIC Audit Programme" for standardizing audits: • experienced and trained auditors that are registered as APIC certified auditors • standardised process for preparing audits and reports • release of audit report by experienced API specialists The audits are only conducted by APIC certified auditors.

Section 4 – Handling of Service/Products/Equipment			
☒ This section is Not Applicable			
Do you have a procedures for incoming 'products', including inspection and verification of the 'products' received	☐ YES	☐ NO	☐ N/A
Are 'products' received, handled and stored to prevent damage and deterioration	☐ YES	☐ NO	☐ N/A
Do you have product segregation procedures	☐ YES	☐ NO	☐ N/A
Are quarantined materials controlled to ensure they are not used	☐ YES	☐ NO	☐ N/A
Do you deal with Unlicensed Products (Specials)	☐ YES	☐ NO	☐ N/A
Do you deal with Hazardous Materials	☐ YES	☐ NO	☐ N/A

Section 5 – Facilities and Equipment			
☒ This section is Not Applicable			
Have risk assessments been performed with respect to Forced Entry, Fire, Flood, Power Outage and Pests	☐ YES	☐ NO	☐ N/A
Are procedures in place to describe responsibilities with respect to Forced Entry, Fire, Flood, Power Outage and Pests	☐ YES	☐ NO	☐ N/A
Is there a 24 hour response to the above risks	☐ YES	☐ NO	☐ N/A
Do you have procedures for validation, calibration and preventative maintenance for equipment and facilities	☐ YES	☐ NO	☐ N/A
Are calibration standards traceable to acceptable national and/or international standards	☐ YES	☐ NO	☐ N/A
Are all storage areas temperature mapped or monitored	☐ Mapped		☐ Monitored

Section 6 – Transportation			
☒ This section is Not Applicable			
Do you use validated packaging systems	☐ YES	☐ NO	☐ N/A
Do you use validated temperature controlled transportation	☐ YES	☐ NO	☐ N/A
Which company do you use to transport cold chain products			
Which company do you use to transport ambient products			
Is confirmation of all validated systems available on request	☐ YES	☐ NO	☐ N/A

Section 7 – Complaints and Recalls			
☒ This section is Not Applicable			
Do you have a complaint handling procedure	☐ YES	☐ NO	☐ N/A
Do you allow products to be returned as a result of a complaint or an incorrect order	☐ YES	☐ NO	☐ N/A
Do you have a recall procedure	☐ YES	☐ NO	☐ N/A

Section 8 – Subcontractors			
☒ This section is Not Applicable			
Has subcontractor been audited	☐ YES	☐ NO	☒ N/A
Date of last audit			
Would you provide copies of audit reports	☐ YES	☐ NO	☒ N/A
Are you notified by all subcontractors of critical or major changes to their Quality Systems	☐ YES	☐ NO	☒ N/A

Section 9 – Additional Information
APIC Audits are performed in accordance to "APIC Audit programme ". Pease see the website of API Compliance Institute for further information: APIC Audit Programme - API Compliance Institute (api-compliance.org)

Section 10 – Filled by			
Name	Anne Günster	Position	Director Operations
Signature		Date	01.10.2021