GENERAL ANSWERS QUESTIONNAIRE	J. Adriaans QA Manager 4MedChem	Date of preparation: 3 Sept. 2024

A: General information		
1.	Company name	4MedChem BV
2.	Address	Steenovenweg 5 5708 HN Helmond The Netherlands
3.	E-mail address	sjonni@4MedChem
4.	Website	https://4medchem.com

B: Contact information		
1.	Primary contact person for Quality	Joris Adriaans
2.	Job title	QA manager
3.	Department	QA
4.	Address (if different to above)	N/A
5.	E-mail address	joris@4medchem.com

C: Organization		
1.	Do you have an organization chart, showing all (key)positions?	☒ Yes, please enclose a copy: QM410 – Quality manual, paragraph: 1.2 Organizational chart ☐ No ☐ N/A
2.	Number of employees	15
3.	Number of sites	3
4.	Year of establishment	2017
5.	Are all operations performed at the site mentioned above? If not, please specify?	The specified scope as mentioned in the QA agreement is done at the site: purchase, storage and delivery of specified raw materials. Production of the goods is done off-site at selected and qualified suppliers.

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D: Product and/or service information		
1.	Product or services of the company	Purchase, storage and delivery of specified raw materials.
2.	Possibility of service and/or maintenance contracts or qualify agreements	Sourcing for specified raw materials.
3.	Does the company use subcontractors and how is this arranged?	Yes. Subcontractors are selected based on their compliance with the required specifications. Subcontractors are qualified according to the QMS of 4MedChem and for critical suppliers change control or quality agreements are maintained.
4.	Does the company have customers in the field of medical devices and/or pharmaceuticals?	Yes. 4MedChem has several customers in the field of medical devices or pharmaceuticals.

E: Quality Management		
1.	Is the company compliant to GxP regulations, please explain which. Please enclose a copy.	No.
2.	Is the company certified for other (inter)national quality standards or programs, such as ISO, CE etc..? Please enclose (a) cop(y)ies.	ISO13485. Certificate identity number: 10601255 Issuing body: LRQA.
3.	Would you allow to audit your facility? If not, please explain.	Yes.
4.	Has the company received any previous (regulatory) audits and/or inspections? (please specify)	Yes, our internal audits are done by ConformISO (yearly) and the certified body LRQA (yearly).

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E: Quality Management			
5.	Does the company have a: - Quality policy - Quality manual	☒ Yes ☐ No ☒ Yes ☐ No	
6.	Does the company have an internal Quality Control program? (please describe)	Yes, we have an internal audit program to monitor our QMS system and a yearly management review to assess the defined KPI's of our QMS system.	
7.	Does your company have a Quality Assurance manager? Please state name.	Joris Adriaans	
8.	Does your company have a designated person(s) responsible for product release? Please state names/functions.	No, not designated. The manufacturing site does have designated persons.	
9.	Are products/services supplied with a certificate of analysis? Who is signing the certificate of analysis, if applicable?	☒ Yes, please describe below which function/department ☐ No, please explain the process below Sjonni van Oosterwijk Sjonni@4MedChem.com	
10	What kind of Document Control system does the company have in place?	We have a written document control system identified under: SOP420-01.02 - Document control.	
11	Are there written procedures in place for:	Change control Document control Employee training Complaint handling Process validation Product batch testing Deviation handling Out of specification handling Supplier qualification Purchase Internal auditing	☒ Yes ☐ No ☒ Yes ☐ No ☒ Yes ☐ No ☒ Yes ☐ No ☒ Yes ☐ No ☒ Yes ☐ No ☒ Yes ☐ No ☒ Yes ☐ No ☒ Yes ☐ No ☒ Yes ☐ No ☒ Yes ☐ No

F: Archiving documents

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1.	Does the company have archiving and/or fire-proof storage facilities? Please describe purpose.	No, not internally only at external locations for flammable materials.
2.	How long are batch documents archived?	10 years.
3.	Are storage conditions monitored? (temperature, humidity control)	Only in conditioned storage locations such as the freezer.

G: Training		
1.	Is (internal) training of employees registered? If yes, how? (example)	Yes, required training documentation per function is logged in: LOG610-01.01 - Training overview.
2.	Does every employee have an individual training plan?	Yes, please see the above answer.
3.	Is there an employee training registration overview?	Yes: LOG610-01.01 - Training overview

H: Process descriptions and operation methodology		
1.	Does the manufacturing process contain in-process-control and/or QC testing? (please describe)	Yes, the product is checked on each synthesis step and during release of the product. Procedures can be requested at our manufacturing site.
2.	Is raw material subjected to incoming control inspection upon delivery?	Yes, upon on arrival of the goods all COA's and labels are checked on their specification during the incoming inspection.
3.	How is maintenance and calibration of equipment arranged e.g. frequency and responsibilities?	The general process is described in: SOP760-01.01 - Control of monitoring and measuring.
4.	Is there physical access control for the facility?	Yes.

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5.	What kind of environmental procedures are there in place?	For our current site we have a written procedure: SOP630-01.01 - Infrastructure, work environment and contamination control
6.	Do you supply any products of animal origin? If yes, do you comply with the TSE/BSE regulations?	☐ Yes, describe below product names ☒ No ☐ Yes ☐ No ☒ N/A