

1 General Information – Supplier:

Company		
Address	Street	
	Postal code and City	
	Country	
	Phone	
	Fax	
Contact Person	Name	
	Function	
	Department	
	E-Mail	
Quality Management		
Quality Manager	Name	
	Phone	
	Fax	
	E-Mail	

The information relates to the product / product range as listed below.

Product / product range:	
Production site / dispatch location:	

1 General Information

1.1 Did your company respond to a questionnaire of the K+S group related to the products named above before?	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No
If yes: Please send enclosed a copy of that questionnaire.				
1.2 Has your company been audited by a member of the K+S group for the products listed above?	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No
If yes: Please send enclosed a copy of the audit report.				

1.3	Has the quality system regarding the listed products been certified by an accredited body?	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No
	If yes: Please send enclosed a copy of the corresponding certificate.				
1.4	Is your company part of another company or group?	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No
	If yes: Please refer the name of the company / group:				
1.5	How many employees are working at your company?				
1.6	How many employees are working at the production site of the named products?				
	In production:	<input type="text"/>			
	In quality assurance/quality control:	<input type="text"/>			
1.7	Is the production site working in shifts?	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No
1.8	Are you a supplier for other customers in the				
	<input type="checkbox"/> Pharmaceutical industry?				
	<input type="checkbox"/> Food industry?				
	<input type="checkbox"/> Feed industry?				
	<input type="checkbox"/> Cosmetics industry?				
1.9	If yes: Please list references.				

2	Purchasing						
2.1	Are the requirements for purchased materials (e.g. raw materials, preliminary products, intermediate products, packaging) documented?	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>	n.a.
2.2	Does your company have an incoming goods inspection program for purchased materials?	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>	n.a.
2.3	Does your company formally qualify its suppliers before initial consignment?	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>	n.a.
2.4	Does your company judge the efficiency of suppliers? (Knock out criterion for Pharmaceutical, Food, Feed and Cosmetic industries)	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>	n.a.

3	Production						
3.1	Where do your raw materials come from?						
	<input type="checkbox"/> Own production						
	<input type="checkbox"/> Third-party-production						

3.2	Do materials have to be released by the quality control unit before use? (Knock out criterion for Pharmaceutical, Food, Feed and Cosmetic industries)	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>	n.a.
3.3	Are there written procedures for the process and organization of all manufacturing processes?	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>	n.a.
3.4	Are there documented product specifications? (Knock out criterion for Pharmaceutical, Food, Feed and Cosmetic industries)	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>	n.a.
3.5	Are there written procedures for the control of nonconforming products?	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>	n.a.
3.6	Are there written procedures for the release of manufactured goods?	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>	n.a.
3.7	Is there a system for identifying the status of goods (including product name, code, batch number)?	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>	n.a.
3.8	Is the usage of stopped materials or goods excluded on the basis of separate storage and/or using an appropriate electronic data processing?	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>	n.a.
3.9	Does your company have a calibration program for control and measuring devices (e.g. temperature, pressure, weight)?	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>	n.a.
3.10	Are there written procedures for the cleaning of manufacturing equipment?	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>	n.a.
3.11	Is there an access control system in place to prevent access of unauthorized persons to production and storage facilities?	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>	n.a.
3.12	Are there written hygiene instructions? (Knock out criterion for Pharmaceutical, Food, Feed and Cosmetic industries)	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>	n.a.
3.13	Is there a pest control program at production and storage facilities?	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>	n.a.

4	Quality Control						
4.1	Is the quality control (QC) department independent from other departments, particularly from the production department? (Knock out criterion for Pharmaceutical industries)	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>	n.a.
4.2	Are there written procedures for quality control of incoming materials and the end products which specifies the methods of control and acceptance criteria?	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>	n.a.
4.3	Does your company supply certificates of analysis with the quality control results?	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>	n.a.
4.4	Are test deviations recorded and analyzed?	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>	n.a.
4.5	Do you start a corrective and preventive action after products have failed the quality control tests, in order to prevent the problem from re-occurring?	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>	n.a.
4.6	Is there a calibration program for calibrating measuring devices used in QC?	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>	n.a.
4.7	Are calibration results recorded in writing?	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>	n.a.

Die gültige Fassung dieses Dokumentes liegt als EDV-Version im **Dokumenten-Verwaltungs-System**
Ausgedruckte Exemplare unterliegen nicht dem Änderungsdienst!

4.8 Are the products traceable to manufacturing methods and materials used? (Knock out criterion for Pharmaceutical, Food, Feed and Cosmetic industries)	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>	n.a.
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5 QM - System						
5.1 Is your quality system based on ISO 9001?	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>	n.a.
5.2 Are company internal responsibilities documented in writing?	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>	n.a.
5.3 Is there a written Quality Policy?	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>	n.a.
5.4 Is there a Quality Management Manual with written operating procedures?	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>	n.a.
5.5 Are there written procedures for the control of documents?	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>	n.a.
5.6 Does your company regularly perform self-inspections (internal audits) to control the effectiveness of the QM-System?	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>	n.a.
5.7 Is there a regular, documented management review on the effectiveness of the QM system?	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>	n.a.
5.8 Is there a systematic follow up on actions resulting from audits and management reviews?	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>	n.a.
5.9 Is there a written definition of quality relevant data?	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>	n.a.
5.10 Does your company record quality relevant data?	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>	n.a.
5.11 Are there written procedures for the control of quality records?	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>	n.a.
5.12 Are there written procedures for the handling of records?	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>	n.a.
5.13 Has the organization determined the qualification and competence requirements for personnel to perform the tasks adequately ?	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>	n.a.
5.14 Do you regularly evaluate the need for training in order to fulfil these requirements, and then perform training accordingly?	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>	n.a.
5.15 Does your company maintain training records?	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>	n.a.
5.16 Will your company agree to a customer on site audit performed by K+S KALI GmbH? (Knock out criterion)	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>	n.a.

n.a. = not applicable

* Procedure: Description of the operations to be carried out, the precautions to be taken and measures to be applied directly or indirectly related to the manufacture of a product.

Please use back for notes and additions.

Thank you very much for answering our questions.

		Name	
Date		Signature	

Änderungen: Spalte n.a. eingefügt. K.O.-Kriterien gekennzeichnet.

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