Supplier evaluation - CAELO Self-assessment for industrial customers

1. Organisation

1.1. Details about the company

Company name	**Caesar & Loretz GmbH**
Street	Herderstrasse 31
Post code, town	40721 Hilden
Country	Deutschland
Homepage	www.caelo.de
Telephone	0049 (2103) 4994 0
Company structure	Company with limited liability
Founding	1886
Management of the company	Ulrich von der Linde, Pharmacist (Chairman) Juliane Reinges (CEO)

1.2. Staff

Total number of employees	**223**
CEO	2
Quality control	30
Quality assurance	4
Production	109
Sales / Marketing	23
Purchasing	9
Warehouse / Distribution	31
Administration	14

1.3. Quality management

Certificates:

QM-System	**Issued on**	**Audit interval**	**Last audit**	**Issuing authority**
GMP-certificate Hilden Site	15.06.2020	3 years	28.03.2019	Bezirksregierung Düsseldorf
GMP-certificate Bonn Site	16.03.2017	3 years	26-27.02.2020	Bezirksregierung Köln

Caelo currently possesses manufacturing authorization according to §13 AMG (for human medicinal products, veterinary medicinal products and active agents) by the above mentioned responsible inspectorates:

Caelo observes the relevant legal regulations such as:

- German Pharmaceuticals Act (Arzneimittelgesetz (AMG))
- Regulation for the Manufacturing of Medicinal Products and Active Pharmaceutical Ingredients (Arzneimittel-und Wirkstoffherstellungsverordnung (AMWHV))
- EU GMP directives
- Pharmacopoeias (national such as DAB, Ph. Eur (official German edition) and HAB; and international, such as BP, USP, OEAB, Ph. Helv. etc. as well as other national pharmaceutical regulations e.g. DAC)

Due to the manufacturing authorization according to §13 AMG as well as the in-house Quality Control, Caelo is entitled to create valid test certificates according to §6 section 3 of the Regulation on the Operation of Pharmacies (ApBetrO).

1.4. Affiliation with Associations

Caelo is a full member of the
- Federal Association of Drug Manufacturers (Bundesverband der Arzneimittelhersteller (BAH)), Bonn
- Drug and Chemicals Association (Drogen- und Chemikalienverein (VDC)), Hamburg
- Society for Dermopharmacy (Gesellschaft für Dermopharmazie (GD))
- Association for Pharmaceutical Process Engineering (Arbeitsgemeinschaft für pharmazeutische Verfahrenstechnik e.V.)
- Galenos Group (European association of providers of pharmaceutical raw materials)

1.5. The necessary personally responsible pharmaceutical staffs according to the AMG (and others)

Position	**Title / Name**
Head of Production	Rolf Hinsch, Food chemist
Head of Quality assurance	Dr. Ulrich Beckmann, Pharmacist
Head of Quality control	Marc Bartschat, Pharmacist
	Dr. Eija Haßel, Chemist
	Dr. Miriam Schlenk, Pharmacist
Qualified Person	Marc Bartschat, Pharmacist
	Dr. Miriam Schlenk, Pharmacist
	Dr. Ulrich Beckmann, Pharmacist
Qualified Person, API	Dr. Eija Haßel, Chemist
Drug Safety manager	Frank Zimmermann (M.D.R.A./Dipl.Biol., QPPV), Kohne Pharma GmbH
Information Officer	Dr. Ulrich Beckmann, Pharmacist
Product management	Christin Hamann, Pharmacist Katja Hennig, Pharmaceutical technical assistant (PTA)
Hazardous Materials Officer	Birgit Jansen, GGSB.eu

1.6. Company activities

Hilden Site:
- Production of drug and tea mixtures
- Packaging of drugs (medicinal herbs) and basic pharmaceutical substances / pharmaceutical active ingredients (API) as well as excipients
- Finished medicinal products (FMP): powders, Liquid preparations, teas
- Finished products: Cosmetics / food supplements / Foods

Bonn Site:
- Production of ointments / ointment bases, oils and gels
- Packaging of basic pharmaceutical substances / pharmaceutical active ingredients (API) / Narcotic drugs and psychotropic substances
- Finished medicinal products (FMP): ointments, pastes, oils
- Finished products: Medicinal products / Cosmetics

Products	Activities					
	Production	Packaging	Storage	Quality control	Approval	Sales
FMP	x	x	x	x	x	x
APIs		x	x	x	x	x
Excipients		x	x	x	x	x
Herbs		x	x	x	x	x

Pastes	x	x	x	x	x	x

2. Company Overview / detailed self-assessment

2.1. General

Area / Activity	Yes	No	Comment
1. Is the Qualified Person responsible authorised to give instructions across divisions on quality issues?	▬	▭	
2. Is quality control / quality assurance independent of production?	▬	▭	
3. Are there occupational safety guidelines?	▬	▭	
4. Do you allow the client to carry out an audit in your company?	▬	▭	
5. Do agreements exist with subcontractors, analysis laboratories on a subcontractor's basis, maintance companies and GMP-relevant providers?	▬	▭	
6. Does an internal batch key exist?	▬	▭	CI 109

2.2. Quality management

Area / Activity	Yes	No	Comment
1. Is there a clearly described quality management system or quality assurance system?	▬	▭	
2. Has the quality management system been certified?	▬	▭	GMP /GDP
3. Does a Site Master File exist?	▬	▭	
4. Is there an organisational chart of the company's structure?	▬	▭	
5. Is there a quality assurance manual that describes the quality assurance system?	▬	▭	
6. Is batch traceability feasible in all areas involved?	▬	▭	
7. Does a self-inspection programme exist?	▬	▭	every 2 years
8. Does a change-control-programme exist?	▬	▭	
9. Does the change-control-programme encompass also the handling of changes requested by the client and the transfer of information to the client, respectively?	▬	▭	
10. Is there is system for the handling and documentation of deviations?	▬	▭	
11. Does a CAPA-management programme exist?	▬	▭	
12. Is product traceability ensured (documentation and labelling)?	▬	▭	
13. Are there written guidelines for GMP-compliant documentation?	▬	▭	
14. Is there a procedural instruction on document control (change control, deviation)?	▬	▭	
15. Are certificates of conformity available?	▬	▭	On request
16. Are the current safety data sheets attached to each delivery?	▬	▭	

2.3. Quality control

Area / Activity	Yes	No	Comment
1. Is it ensured that quality control is performed independently of any activities undertaken by other departments?	▬	▭	
2. Are the responsibilities of the head of quality control clearly established?	▬	▭	
3. Does quality control have enough qualified staff?	▬	▭	
4. Are there suitable analytical instruments and facilities available for the purpose?	▬	▭	

5. Are all devices being maintained and calibrated at regular intervals?	☐	☐	With the sub-support of external companies
6. Do log books exist for the lab equipment?	☐	☐	
7. Are there specifications for materials, base materials and products?	☐	☐	
8. Will the customer be informed, if changes occur in the specifications?	☐	☐	Visible on the CoA
9. Will the customer be informed of analysis results if these are outside of specifications?	☐	☐	
10. Are there test methods that are set out in writing? Have these test methods been validated?	☐	☐	
11. Is the proper documentation of investigations/tests that are carried out, as well as test results?	☐	☐	
12. Do you have analyses carried out externally?	☐	☐	External analytic laboratories (e.g. microbiolo-gical testing, Pesticide-residues)
13. Are there all standards and reagents available needed for the tests?	☐	☐	
14. Are standards and reagents, respectively, marked with regard to their contents, batch codes and dates of shelf life?	☐	☐	
15. Have the storage conditions for standards and reagents been defined and are these being controlled?	☐	☐	
16. Are test results taken over from third parties and marked as such?	☐	☐	
17. Are retain samples being collected in sufficient quantity and kept from each batch?	☐	☐	
18. Does the head of quality control carry out a final inspection of the entire quality documentation?	☐	☐	
19. Does QC review the production records as part of the approval criteria?	☐	☐	Only finished medicinal products and APIs
20. Is it ensured that no goods will be dispatched before release?	☐	☐	
21. Are there any instructions of how to proceed in the case of out-of-spec results?	☐	☐	
22. Are precise reasons indicated and documented if material is rejected during the production process?	☐	☐	
23. Are corrective measures defined in the event of a batch being rejected, in order to avoid the same error occurring again?	☐	☐	CAPA-System

2.4. Production

Area / Activity	Yes	No	Comment
1. Are the production premises suitable for the purpose in terms of size, structural condition, current status, and cleanliness? And are they easy to clean?	■	□	
2. Is there a sufficient air-conditioning and ventilation system?	■	□	
3. Have production characteristics (temperature, air humidity, particle number, air exchange rate) been defined for the process, and are these suited for the purpose? Are they routinely logged and monitored? (room classification)	■	□	
4. Are there air locks between the operating spaces of different purity classes and are the rooms marked accordingly?	■	□	
5. Have precautionary measures been implemented against cross-contamination and mix-ups (mistakes)?	■	□	
6. Are there cleaning instructions and protocols for the production spaces?	■	□	
7. Does a hygiene monitoring programme exist for the production spaces?	■	□	
8. Does a system for line clearance exist?	■	□	
9. Is there a system that ensures that only explicitly released materials are used?	■	□	
10. Has all equipment in the production areas been properly designed, constructed and maintained?	■	□	
11. Has a preventive maintenance programme been established for the equipment?	■	□	
12. Have cleaning instructions been established in writing for the equipment installed?	■	□	
13. Have the cleaning procedures been validated?	■	□	Partly still in process
14. Are there production instructions available in writing?	■	□	
15. Are all stages run as batch processes and are they traceable throughout?	■	□	
16. Are measures taken to avoid mix-ups and impurities?	■	□	
17. Are manufacturing processes documented and monitored?	■	□	
18. Is the suitability (reproducibility) of the process being supported by a proof of evidence?	■	□	
19. Are in-process-controls being performed?	■	□	
20. Is a final inspection of the manufacturing documentation carried out by the head of production (respectively by an authorised Person of head of production) or QA / QC?	■	□	
21. Is the required water quality defined in writing?	■	□	
22. Does the water quality correspond to chemical and microbiological standards?	■	□	Aqua Purificata Ph. Eur.
23. Are the water treatment installations qualified and monitored (including reverse osmosis, deionisation, ultrafiltration procedures)?	■	□	
24. Are equipment/systems only dedicated to one process/product?	□	■	
25. Does the company have a program to combat rodents, birds, insects and other pests, and are the records archived?	■	□	Pest Control
26. Hast he company a waste disposal system?	■	□	
27. Is waste stored in appropriately marked containers?	■	□	
28. Are the outgoing goods identifiable by name, code and batch?	■	□	
29. Is each container clearly marked?	■	□	

Area / Activity	Yes	No	Comment
30. Are the quantity, identity and uniformity of all products and packaging materials checked before packaging?	☐	☐	
31. Are all containers individually marked with name, product, code, batch, date of manufacture and expiry date?	☐	☐	

2.5. Staff

Area / Activity	Yes	No	Comment
1. Are there job descriptions available for the entire staff, working e.g. in production and quality control?	☐	☐	
2. Are there detailed job specifications and have responsibilities been set for the entire staff?	☐	☐	
3. Has a training programme been elaborated for the staff working in production and quality control?	☐	☐	
4. Are training courses being offered for topical reasons?	☐	☐	
5. Is access to the operating areas restricted to authorised staff only?	☐	☐	Access to the building is only possible with a chip and only for staff and authorized persons
6. Is the question of staff clothing in production and quality control areas regulated internally?	☐	☐	
7. Have hygiene rules and instructions been laid down for production and quality control areas?	☐	☐	
8. Is the health status of the staff working in production and quality control being monitored and are there specific rules relating to employee behaviour in the case of infectious diseases?	☐	☐	Monitoring of the health status only for the production staff

2.6. Receipt of goods / sampling / Storage facilities

Area / Activity	Yes	No	Comment
1. Is there a procedural instruction fort he sampling?	☐	☐	
2. Is there a separate sampling zone?	☐	☐	
3. Does a specific sampling instruction exist?	☐	☐	
4. Does appropriate sampling equipment exist?	☐	☐	
5. Is the cleaning status of the sampling equipment recognisable?	☐	☐	
6. Are there written data available from this inspection, including the decision; ‘goods accepted / rejected’?	☐	☐	
7. Does the company work with contractually bound transport companies?	☐	☐	
8. Are there written records regarding the acceptance of a shipment?	☐	☐	QA-Agreements with transport companies are available
9. Is use and delivery of rejected materials or finished products	☐	☐	

Area / Activity	Yes	No	Comment
prevented by an appropriate IT system?			
10. Are incoming and outgoing goods protected from weathering?	■	□	
11. Are the storage facilities suitable for storing the products in the required quality?	■	□	
12. Have appropriate conditions for climate and ventilation been defined and, if so, are these being monitored?	■	□	
13. Are the storage facilities suited in terms of size and condition, status and cleanliness?	■	□	
14. Have all measuring systems, used for climate monitoring, been calibrated?	■	□	
15. Have precautions been taken against attack by rodents and insects?	■	□	Pest Control
16. Are there cleaning instructions and protocols for all storage facilities?	■	□	
17. Is there a separate storage space available for non-released goods? (quarantined or blocked)	■	□	Only blocked goods are separately stored (locked)
18. Are the goods marked with product type, batch no. and release status?	■	□	
19. Does the 'first-in-first out' principle apply in the warehouse?	□	■	FEFO „First Expiry, First Out"-principle

2.7. Purchasing / Sales

Area / Activity	Yes	No	Comment
1. Is there a system available to assess potential suppliers?	■	□	
2. Is it ensured that only goods from approved suppliers are purchased?	■	□	
3. Are the shipping containers (from the supplier) clearly marked so that the contents can be identified according to type and quantity?	■	□	
4. Are all outgoing goods identifiable by name, code and batch?	■	□	
5. Is proper transport from the works site guaranteed?	■	□	
6. Are the transport containers used (BKW, TKW, containers, etc.)?	□	■	
7. Does the Transport follow according to GDP-directive?	■	□	

2.8. Computerised systems

Area / Activity	Yes	No	Comment
1. Is the computer system validated?	■	□	
2. Is the area of responsibility documented with regard to computerised systems?	■	□	
3. Is system security ensured in terms of access rights?	■	□	
4. Is there an up-to-date list of all persons who are able to input and change data?	■	□	

2.9. Complaints / Recalls

Area / Activity	Yes	No	Comment
1. Is there a fixed procedure of how to handle and settle customer complaints?	▬	▭	
2. Are the complaints recorded and analysed in product-specific manner?	▬	▭	
3. Does the company have an established process for the correct and uniform initiation and conduct of recalls?	▬	▭	
4. Are suitable measures and precautions taken in respect to defective products in order to prevent any recurrence of the fault?	▬	▭	
5. Is the client informed of measures and actions carried out?	▬	▭	

3. Dokuments (Attachements)

GMP-certificate	on request
Manufacturing authorisation	on request
Organisational chart	on request
Site Master File	on request
Contents of QA-Manual	on request
Current SOP-List	on request

Hilden, July 2020

signed Dr. Ulrich Beckmann
Quality assurance manager