



Caelo-Info 411

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	220
CEO	2
Quality control	28
Quality assurance	4
Production	112
Sales / Marketing	20
Purchasing	9
Warehouse / Distribution	29
Administration	13

1.3. Quality management

Certificates:

QM-System	Issued on	Audit interval	Last audit	Issuing authority
GMP-certificate Hilden Site	15.06.2020	3 years	26-28.03.2019	Bezirksregierung Düsseldorf
GMP-certificate Bonn Site	24.11.2020	3 years	26.-27.2020	Bezirksregierung Köln

Caelo currently possesses manufacturing authorisation 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 authorisation 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?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
2. Is quality control / quality assurance independent of production?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
3. Are there occupational safety guidelines?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
4. Do you allow the client to carry out an audit in your company?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
5. Do agreements exist with subcontractors, analysis laboratories on a subcontractors basis, maintenance companies and GMP-relevant providers?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
6. Do exist an internal batch key?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	CI 109

2.2. Quality management

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

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?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
2. Are the responsibilities of the head of quality control clearly established?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
3. Does quality control have enough qualified staff?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	

4. Are there suitable analytical instruments and facilities available for the purpose?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
5. Are all devices being maintained and calibrated at regular intervals?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	With the sub-support of external companies
6. Do log books exist for the lab equipment?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
7. Are there specifications for materials, base materials and products?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
8. Will the customer be informed, if changes occur in the specifications?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Visible on the CoA
9. Will the customer be informed of analysis results if these are outside of specifications?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
10. Are there test methods that are set out in writing? Have these test methods been validated?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
11. Is the proper documentation of investigations/tests that are carried out, as well as test results?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
12. Do you have analyses carried out externally?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	External analytic laboratories (e.g. microbiological testing, Pesticide-residues)
13. Are there all standards and reagents available needed for the tests?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
14. Are standards and reagents, respectively, marked with regard to their contents, batch codes and dates of shelf life?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
15. Have the storage conditions for standards and reagents been defined and are these being controlled?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
16. Are test results taken over from third parties and marked as such?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
17. Are retain samples being collected in sufficient quantity and kept from each batch?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
18. Does the head of quality control carry out a final inspection of the entire quality documentation?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
19. Does QC review the production records as part of the approval criteria?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Only finished medicinal products and APIs
20. Is it ensured that no goods will be dispatched before release?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
21. Are there any instructions of how to proceed in the case of out-of-spec results?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
22. Are precise reasons indicated and documented if material is rejected during the production process?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
23. Are corrective measures defined in the event of a batch being rejected, in order to avoid the same error occurring again?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	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?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
2. Is there a sufficient air-conditioning and ventilation system?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
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)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
4. Are there air locks between the operating spaces of different purity classes and are the rooms marked accordingly?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
5. Have precautionary measures been implemented against cross-contamination and mix-ups (mistakes)?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
6. Are there cleaning instructions and protocols for the production spaces?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
7. Does a hygiene monitoring programme exist for the production spaces?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
8. Does a system for line clearance exist?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
9. Is there a system that ensures that only explicitly released materials are used?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
10. Has all equipment in the production areas been properly designed, constructed and maintained?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
11. Has a preventive maintenance programme been established for the equipment?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
12. Have cleaning instructions been established in writing for the equipment installed?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
13. Have the cleaning procedures been validated?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Partly still in process
14. Are there production instructions available in writing?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
15. Are all stages run as batch processes and are they traceable throughout?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
16. Are measures taken to avoid mixups and impurities?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
17. Are manufacturing processes documented and monitored?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
18. Is the suitability (reproducibility) of the process being supported by a proof of evidence?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
19. Are in-process-controls being performed?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
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?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
21. Is the required water quality defined in writing?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
22. Does the water quality correspond to chemical and microbiological standards?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Aqua Purificata Ph. Eur.
23. Are the water treatment installations qualified and monitored (including reverse osmosis, deionisation, ultrafiltration procedures)?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
24. Are equipment/systems only dedicated to one process/product?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
25. Does the company have a program to combat rodents, birds, insects and other pests, and are the records archived?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Pest Control
26. Has the company a waste disposal system?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
27. Is waste stored in appropriately marked containers?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
28. Are the outgoing goods identifiable by name, code and batch?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
29. Is each container clearly marked?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	

30. Are the quantity, identity and uniformity of all products and packaging materials checked before packaging?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
31. Are all containers individually marked with name, product, code, batch, date of manufacture and expiry date?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	

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?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
2. Are there detailed job specifications and have responsibilities been set for the entire staff?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
3. Has a training programme been elaborated for the staff working in production and quality control?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
4. Are training courses being offered for topical reasons?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
5. Is access to the operating areas restricted to authorised staff only?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	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?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
7. Have hygiene rules and instructions been laid down for production and quality control areas?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
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?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	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 for the sampling?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
2. Is there a separate sampling zone?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
3. Does a specific sampling instruction exist?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
4. Does appropriate sampling equipment exist?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
5. Is the cleaning status of the sampling equipment recognisable?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
6. Are there written data available from this inspection, including the decision; ' goods accepted / rejected'?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
7. Does the company work with contractually bound transport companies?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	

8. Are there written records regarding the acceptance of a shipment?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	QA-Agreements with transport companies
9. Is use and delivery of rejected materials or finished products prevented by an appropriate IT system?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
10. Are incoming and outgoing goods protected from weathering?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
11. Are the storage facilities suitable for storing the products in the required quality?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
12. Have appropriate conditions for climate and ventilation been defined and, if so, are these being monitored?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
13. Are the storage facilities suited in terms of size and condition, status and cleanliness?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
14. Have all measuring systems, used for climate monitoring, been calibrated?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
15. Have precautions been taken against attack by rodents and insects?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Pest Control
16. Are there cleaning instructions and protocols for all storage facilities?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
17. Is there a separate storage space available for non-released goods? (quarantined or blocked)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Only blocked goods are separately stored (locked)
18. Are the goods marked with product type, batch no. and release status?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
19. Does the 'first-in-first out' principle apply in the warehouse?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	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?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
2. Is it ensured that only goods from approved suppliers are purchased?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
3. Are the shipping containers (from the supplier) clearly marked so that the contents can be identified according to type and quantity?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
4. Are all outgoing goods identifiable by name, code and batch?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
5. Is proper transport from the works site guaranteed?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
6. Are the transport containers used (BKW, TKW, containers, etc.)?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
7. Does the Transport follow according to GDP-directive?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	

2.8. Computerised systems

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

2.9. Complaints / Recalls

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

3. Dokuments (Attachements)

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

Hilden, 19.01.2021

signed Dr. Ulrich Beckmann
Quality assurance manager