

Standard Answers to FAQs from Customer Questionnaires

1. Organisation

1.1 Details about the company

| | |
|-------------------|--|
| Company name | Hänseler AG |
| Street | Industriestrasse 35 |
| Postcode, town | 9100 Herisau |
| Country | Switzerland |
| Homepage | www.haenseler.ch |
| Company structure | Stock corporation |
| Founding | 1975 |

1.2 Staff (FTE; Full-time-equivalent)

| | |
|--|---------------|
| Total | 137.60 |
| including those in quality management | 19.90 |
| including those in purchasing / marketing / business development | 24.90 |
| including those in production, warehousing and logistics | 74.90 |
| therefrom administration | 11.10 |
| therefrom financial department & administration | 6.80 |

1.3 Quality management system

Certificates:

| QM system: | Certificate issued on: | Audit interval | Last audit |
|------------|--|----------------|----------------|
| GMP | February 06 th 2026 (valid indefinitely) | 2 years | September 2025 |
| GDP | February 06 th 2026 (valid indefinitely) | 2 years | September 2025 |

Licences:

| Type of licence | Date of issue | Issuing authority |
|--|---|--|
| Licence to manufacture medicinal products*) | October 25, 2024 (valid indefinitely) | Swissmedic |
| Licence to trade in controlled substances, to manufacture and process controlled substances, to trade in precursor chemicals | January 1, 2026 (valid until December 31 2030) | Swissmedic |
| Registration to produce and market feedstuffs | February 4, 2008 (valid until further notice) | Swiss Federal Department of Economic Affairs (EVD) |
| Authorization for the processing of animal products in accordance with Art. 21 LGV | June 22, 2023 (valid until further notice) | Intercantonal laboratory |

*) Authorized activities:

- 1 Manufacture of medicinal products (without labile blood products)**
 - 1.2 Non-sterile products
 - 1.4 Other products or manufacturing activity
 - 1.5 Packing
 - 1.6 Quality control testing
 - S.1.8 Blinding of medicinal products for clinical trials
 - S.1.9 Contract manufacturing in accordance with Art. 9 para. 2bis HMG of medicinal products not subject to authorization
 - S1.11 Filling and labeling of starting materials with container-by-container guarantee of their identity in accordance with Chapter 20.1.6.4. Ph.Helv. for the manufacture of medicinal products not subject to authorization in accordance with Art. 9 para. 2 Bst. a-cbis HMG
- S.2 Import of medicinal products (without labile blood products)**
 - S.2.1 Import of medicinal products not ready for use
 - S.2.2 Import of ready-to-use medicinal products, including market release
 - S.2.6 Placing manufacturing orders for medicinal products as the client
- 3 Manufacture of active substances**
 - 3.1 manufacture of active substance by chemical synthesis
 - 3.2 Extraction of active substance from natural sources
 - 3.5 General finishing steps
 - 3.6 Quality control testing
- S.4 Wholesale of medicinal products (without labile blood products)**
 - S.4.1 Wholesale of medicinal products not ready for use
 - S.4.2 Wholesale of ready-to-use medicinal products, including market release
- S.5 Export of medicinal products (without labile blood products)**
 - S.5.1 Export of medicinal products not ready for use
 - S.5.2 Export of ready-to-use medicinal products
- S.6 Trade abroad in medicinal products (without labile blood products)**
 - S.6.1 Trade in medicinal products not ready for use abroad, without warehousing in Switzerland
 - S.6.2 Trade in ready-to-use medicinal products abroad, without warehousing in Switzerland

1.4 Contact partners

| Contact person | Title/name | Position | Telephone no. | Email |
|---|---------------------|---|---------------|--|
| Chief Executive Officer | Dr. Dominik Hauser | Chief Executive Officer CEO | 071 353 58 88 | Dominik.Hauser@haenseler.ch |
| Chief Operations Officer | Benedikt Flammer | Chief Operations Officer COO | 071 353 55 67 | Benedikt.Flammer@haenseler.ch |
| Chief Quality Officer, Qualified Person | Dr. Christoph Titze | Chief Quality Officer, CQO Qualified Person QP | 071 353 58 01 | Christoph.Titze@haenseler.ch |
| Quality control | Stephan Wallimann | Head of quality control | 071 353 58 05 | Stephan.Wallimann@haenseler.ch |
| Manufacturing | Roman Schläpfer | Head of manufacturing | 071 353 58 71 | Roman.Schlaepfer@haenseler.ch |
| Quality assurance | Sandro Dilettoso | Head of quality assurance | 071 353 58 07 | Sandro.Dilettoso@haenseler.ch |
| Complaints / objections | Stephan Wallimann | Head of quality control | 071 353 58 05 | Stephan.Wallimann@haenseler.ch |
| Procurement | Raphaela Trivelli | Head of Procurement | 071 353 58 40 | Raphaela.Trivelli@haenseler.ch |
| Business Unit Industrie | Nicole Trott | Business Head Unit Industrie | 071 353 58 12 | Nicole.Trott@haenseler.ch |
| Business Unit Pharmazie | Dr. Marco Würsch | Business Head Unit Pharmazie | 071 353 58 16 | Marco.Wuersch@haenseler.ch |
| Sales Order Management | Michele Floreancig | Head of sales Order Management | 071 353 58 18 | Michele.Floreancig@haenseler.ch |

1.5 Company activities

Activities:

- Manufacturing medicinal products
- Manufacturing of API natural origin and chemical synthesis
- Contract manufacturing of liquid, paste-like and solid drug forms
- Trading with pharmaceutical, cosmetic and chemical raw materials

Detailed:

| Products | Activities | | | | | | |
|-----------------------|---------------|-----------|---------|---------|-----------------|----------|-------|
| | Manufacturing | Packaging | Filling | Storage | Quality control | Approval | Sales |
| Medicinal products | X | X | X | X | X | X | X |
| Active ingredients | X | X | X | X | X | X | X |
| Excipients | X | X | X | X | X | X | X |
| Controlled substances | X | X | X | X | X | X | X |
| Food | X | X | X | X | X | X | X |

Item groups

Medicinal products, active pharmaceutical ingredients (API), excipients, controlled substances, raw materials for chemical, pharmaceutical, foodstuffs and cosmetics industry, food supplements, chemicals and vitamins.

2. Quality management

2.1 General

| Area / activity | Yes | No | Comment |
|---|-------------------------------------|--------------------------|------------------------|
| Is the technical specialist responsible authorised to give instructions across divisions on quality issues? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | In the job description |
| Is quality control/quality assurance independent of production? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Are the responsibilities of the head of quality control clearly established? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | In the job description |
| Does quality control have the appropriate equipment and facilities in order to carry out its functions? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Are there occupational safety guidelines? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |

2.2 Staff

| Area / activity | Yes | No | Comment |
|---|-------------------------------------|--------------------------|--|
| Are job descriptions available for the staff? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Are the responsibilities and powers of the staff laid down? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | In the corresponding job descriptions and in the organisation and competency guidelines. |
| Does quality control have enough qualified staff? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Is there a procedural instruction on the further education and training of staff? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |

2.3 Approval

| Area / activity | Yes | No | Comment |
|---|-------------------------------------|--------------------------|---------|
| Is it established in writing which person or entity is authorised to approve a product? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Are there any regulations regarding the approval of a product and does product evaluation include all necessary specifications? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Is it ensured that products are only delivered if a specialist certifies that the batch was produced and tested according to the relevant regulations and meets the requirements? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Is there a set procedure in case of "out of specification" results? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |

2.4 Quality control

| Area / activity | Yes | No | Comment |
|---|-------------------------------------|-------------------------------------|--|
| Is there a procedural instruction for the sampling? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Are samples of incoming materials adequately tested? (Criteria: type of sample, number of specimens, testing method) | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Are reference samples retained of all shipments? | <input type="checkbox"/> | <input checked="" type="checkbox"/> | Only of those shipments that are analytically tested, i.e. not of transitory business. |
| Is it ensured that adequate quantities of reference samples are kept of the raw materials, intermediate products, and products, so as to allow follow-up studies at any time? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Are quality specifications available for all materials? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Is there a procedural instruction for each testing method? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Are the existing analytical processes adequate to ensure that each batch complies with the specifications in terms of quality, purity, and identity? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Are the current specifications always available for the staff concerned? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Is it ensured that old versions of specifications are no longer used? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Is there proper documentation of investigations/tests that are carried out, as well as test results? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Are analysis results reviewed by a responsible person? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Do the analysis certificates indicate target values, limit values and actual values? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Do the analysis certificates clearly refer to the labelled goods? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Do you have analyses carried out externally? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | Heavy metals, pesticides, microbiology, aflatoxins |
| Does QC review the production records as part of the approval criteria? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Are precise reasons indicated and documented if material is rejected during the production process? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| 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"/> | |
| Is each deviation fully recorded and investigated? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |

| Area / activity | Yes | No | Comment |
|--|-------------------------------------|-------------------------------------|---|
| Is there a procedural instruction regarding the maintenance, qualification, and requalification of test equipment? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Is there a system to ensure that measuring instruments and test equipment are calibrated regularly? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Are written records made of calibrations which have been performed? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| If you perform the calibration yourselves, are these calibration procedures defined according to appropriate standards and are they traceable? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| If the calibrations were performed externally, was the competence of these external bodies verified? | <input type="checkbox"/> | <input checked="" type="checkbox"/> | We do not check this specifically but assume that the equipment manufacturers/suppliers are qualified for this. |
| Are the precision, sensitivity, reproducibility, and selectivity of non-monographed testing/analysis methods validated? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | Partly |
| Are test/analysis methods revalidated at regular intervals? | <input type="checkbox"/> | <input checked="" type="checkbox"/> | There is no provision for revalidation at regular intervals. |
| Is there a program defined in writing for microbiological monitoring of sterile and non-sterile products? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Are there microbiological limit values that are set down in writing? Are measures defined which must be implemented in the event of exceeding limit values? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Are all necessary standards and reagents available for tests? Are the storage stability and retest date defined for each? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Are the content, batch number and best-before date of laboratory reagents and other chemicals identified? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Are investigations available in respect of the shelf-life data of the manufactured products? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | According to shelf-life concept |

2.5 Quality assurance

| Area / activity | Yes | No | Comment |
|---|-------------------------------------|-------------------------------------|--------------------------------------|
| Is there a written description of quality policy by corporate management? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Is there a full organisational chart of the corporate structure with job descriptions, staffing schedules and definition of responsibilities? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Is there a quality assurance system describing the organisational structure, responsibilities, and procedures? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Is there a quality assurance manual which describes the quality assurance system? | <input type="checkbox"/> | <input checked="" type="checkbox"/> | is described in the Site Master File |
| Is there a site master file which describes the quality assurance system? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Is there an internal quality review program? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | Self-inspection |
| Is there a continuous update service for QA requirements which ensures that obsolete versions are no longer used? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Are there written requirements regarding documentation (making corrections, ban on entries in pencil, etc.)? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Are records duly signed and dated? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Is there a system to ensure that validations are furnished for required production processes, equipment, and analysis methods? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Is there a system for following up CAPA measures? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Are there appropriate procedures for ensuring that machinery, tools, measurement instruments and test equipment are clean? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Is there a consistently applied batch numbering system? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Is the storage system designed so that the status (quarantine, approved, rejected) of raw materials / intermediate products / primary packaging materials and products is clearly identifiable? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Is there a procedural instruction about carrying out self-inspections (internal audits) and are these logged? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | Interval: annually |
| Do you allow the client to carry out an audit in your company? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Have audits already been carried out by other manufacturers of medicinal products? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | Regularly |
| Is there a procedural instruction on document control (change control, deviation)? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |

| Area / activity | Yes | No | Comment |
|--|-------------------------------------|--------------------------|--|
| Is there a procedural instruction on product recall? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Is there a system which allows each product batch to be recalled from delivery or sales? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Is there an adequate training program for all employees in the appropriate areas? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Is there a program for regular retraining? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Are certificates of conformity available? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | TSE, residual solvents, GMO, allergens |

2.6 Complaints

| Area / activity | Yes | No | Comment |
|---|-------------------------------------|--------------------------|---------------------|
| Are complaints/returns checked? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Are causes of quality defects investigated? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Is batch traceability ensured in the event of complaints? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | Batch documentation |
| Are suitable measures and precautions taken in respect of defective products in order to prevent any recurrence of the fault? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | CAPA system |
| Does the head of QC ensure that all necessary tests are carried out? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |

2.7 Computerised systems

| Area / activity | Yes | No | Comment |
|---|-------------------------------------|--------------------------|-----------------|
| Is the computer system validated? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Is the area of responsibility documented with regard to computerised systems? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Is system security ensured in terms of access rights? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Can the system check and log the identity of the users (audit trail)? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| 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"/> | |
| Is there a specified program for backing up software and data? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| How is the re-readability of data guaranteed in case of long-term storage? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | Backup on tapes |
| Are there precautions for an emergency power supply for critical systems? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | IT |

3. Procurement

| Area / activity | Yes | No | Comment |
|---|-------------------------------------|--------------------------|--|
| Is there a description in procurement documents of all raw materials/intermediate products/primary packaging materials that are used (drawings, specifications, data sheets)? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Is it ensured that the raw materials/intermediate products/primary packaging materials comply with set requirements? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Is there an evaluation system for suppliers? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | Supplier qualification and annual evaluation |
| Does the company have a list of approved suppliers? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Are suppliers audited regularly? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | Interval depends on the corresponding risk assessment. |
| Do agreements exist with subcontractors, analysis laboratories on a subcontracted basis and GMP-relevant providers? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |

4. Production

4.1 Premises and equipment

| Area / activity | Yes | No | Comment |
|--|-------------------------------------|-------------------------------------|---------|
| Are production conditions suitable for manufacturing products (criteria include ventilation, temperature, humidity)? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Is there suitable ventilation and lighting in the production area? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Are the ambient conditions monitored and recorded? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Can the windows to the production rooms be opened? | <input type="checkbox"/> | <input checked="" type="checkbox"/> | |
| Are there separate equipment, materials, and personnel flows? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Is room cleaning documented? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Are there procedural instructions regarding the cleaning, qualification and requalification of production plant and rooms? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Are ceilings, walls, and floors in perfect condition (no cracks or gaps) in order to exclude any contamination of the product through particles? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Are valves and connecting tubes in the production areas free of leaks? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Are content and direction of the tubes marked? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | Partly |

| Area / activity | Yes | No | Comment |
|--|-------------------------------------|--------------------------|-----------------------|
| Are air locks and outlets installed where necessary in order to prevent cross-contamination? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Is the required water quality defined in writing? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Does the water quality correspond to chemical and microbiological standards? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | Aqua purificata PhEur |
| Are the water treatment installations qualified and monitored (including reverse osmosis, deionization, ultrafiltration procedures)? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |

4.2 Staff

| Area / activity | Yes | No | Comment |
|---|-------------------------------------|--------------------------|---|
| Are the flow and organization of the manufacturing process set down in writing? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Are the staffs sufficiently qualified and are they trained regularly? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| In how many shifts do they work? | | | 1 shift (sometimes in 2 shifts) |
| Is it ensured that access to the production areas is only permitted to authorised persons? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | Access to the building is only possible by key, for staff and authorised persons. |
| Can it be assumed that the employees in the manufacturing areas have the necessary knowledge and commitment to quality? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |

4.3 Technical equipment

| Area / activity | Yes | No | Comment |
|--|-------------------------------------|-------------------------------------|---------|
| Are all quality-relevant installations qualified according to DQ, IQ and OQ principles? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Is equipment in the production areas appropriately designed (type and size), constructed (surface in contact with the product) and maintained so that there are no negative effects on product quality? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Are equipment/systems constructed and operated so as to exclude any negative effect on product quality as a result of foreign materials (such as lubricants, coolants, other operating materials or metal abrasion)? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Are equipment/systems installed in such a way as to allow extensive cleaning and maintenance work to be carried out on the systems? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Are equipment/systems only dedicated to one process/product? | <input type="checkbox"/> | <input checked="" type="checkbox"/> | |

| Area / activity | Yes | No | Comment |
|---|-------------------------------------|-------------------------------------|---|
| Are there validated cleaning regulations for the equipment/systems in order to ensure full removal of any residue from previous product/material? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Is the maintenance status of production systems evident? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Are there written requirements (SOPs) for environmental monitoring, cleaning, and maintenance of the equipment in production? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Do these SOPs include the definition of responsibilities, deadlines, method descriptions and acceptance criteria/tolerances, etc.? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Are cleaning, maintenance and calibration records archived? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | At least 15 years |
| Before each processing operation, is it ensured that the equipment is clean and free of foreign materials? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Is a logbook kept for very important or critical equipment (with details of maintenance, cleaning, repair work, calibration and validations carried out)? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | All systems have a logbook, not just the critical ones. |
| Do the products go through a metal detector? | <input type="checkbox"/> | <input checked="" type="checkbox"/> | |

4.4 Hygiene

| Area / activity | Yes | No | Comment |
|---|-------------------------------------|--------------------------|---------------------|
| Are there plans regarding room cleaning and is this cleaning documented? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Is there a hygiene program which includes personal and operational hygiene? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Are rooms clean and easy to clean, and disinfect if necessary? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Are the rooms cleaned, and if necessary disinfected, according to written instructions? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Are ceiling fixtures, tubes, lamps and other areas free of dirt? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Are requirements for special work clothing complied with (e.g. face mask, work clothing)? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Is attention paid to staff hygiene? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Are there enough sanitary installations? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Is eating, drinking, and smoking banned where necessary (above all in the production and warehousing areas)? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | Special drinks rule |
| When working with dry materials/products, are special precautions taken to prevent the build-up and spread of dust. | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |

| Area / activity | Yes | No | Comment |
|--|-------------------------------------|--------------------------|---------------------------------------|
| Are there appropriate exhaust systems in production rooms that are dusty or particularly at risk of contamination? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | Denios boxes, Glove box |
| Are the staffs trained regularly in hygiene? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Are there cleaning regulations? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Does the respective cleaning regulation take account of the fact that equipment which is used to manufacture different products must be cleaned differently depending on the previous process? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Are raw materials / intermediate products / primary packaging materials and products protected against microbial contamination? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Is there any documentation of the (regulation-compliant) cleaning? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Is hygiene monitored periodically? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Is pest control carried out? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| 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"/> | Minimum archiving period of 15 years. |
| Are only approved pesticides used for this purpose? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Is there regular monitoring of the efficacy of pest control measures and adherence to regulations? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Is staff health monitored? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Do you have a waste disposal system? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Is waste stored in appropriately marked containers? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |

4.5 Raw materials

| Area / activity | Yes | No | Comment |
|---|-------------------------------------|-------------------------------------|---------|
| Are the incoming goods checked in respect of required purity/specification? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Is a written approval issued before further use? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Is it exclusively materials/raw materials that are approved by quality control which are used? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Are there officially defined procedures for treating raw material which is to be reworked? | <input type="checkbox"/> | <input checked="" type="checkbox"/> | |
| Is it only materials which are pharmaceutically safe that are used in production as auxiliary materials and resources, which come into direct contact with the product? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |

4.6 Manufacturing processes

| Area / activity | Yes | No | Comment |
|--|-------------------------------------|--------------------------|----------|
| Are all processes carried out under the supervision of responsible specialists? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Before each manufacturing or packaging stage, is there a check to ensure that the working area is free of unnecessary materials/products/documents, and that the equipment is clean and ready for use? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Are there written cleaning instructions available and is the cleaning documented? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Are all stages run as batch processes and are they traceable throughout? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Are measures taken to avoid mix-ups and impurities? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Are all manufacturing stages defined by written instructions (manufacturing specifications)? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Are procedural stages clearly formulated to ensure that employees understand their tasks and cannot misinterpret instructions? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Are the written procedural instructions followed? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Is there a change control process? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Are process-relevant measurement and control systems (such as for temperature, pressure, conductance, etc.) calibrated regularly? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Is a written record drawn up of each production batch? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Is the respective processing stage clearly marked on the system/container? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Can the manufactured products be identified throughout the entire production process? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Are formal in-process controls carried out during production, packaging, and labelling stages? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Are manufacturing processes documented and monitored? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Are manufacturing records properly stored over a reasonable period? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | 15 years |
| Are there officially defined procedures in the event of deviation from standard manufacturing practice? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| When rejected batches are reworked or if earlier batches are introduced either entirely or in part, is it ensured that the necessary quality is maintained? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Is the introduction of a (part) batch to another batch of the same product approved by a competent person? Is reutilization recorded? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |

| Area / activity | Yes | No | Comment |
|--|-------------------------------------|--------------------------|----------------------------------|
| Is QC informed about such an introduction and does it decide on further tests? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Are the client's specifications and orders properly checked before starting to process the article? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Is it ensured that the customer is notified in good time of any changes in specification or manufacturing processes | <input checked="" type="checkbox"/> | <input type="checkbox"/> | Only if laid down contractually. |
| Are the theoretical yields defined in writing with reasonable limits? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | Exception: Extracts |
| Are investigations carried out if the current yield and consumed quantities lie outside the limits? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Is the manufacturing documentation subject to a final review? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Are the required product characteristics defined in writing? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Are there full requirements in writing, approved by Production, for each stage of manufacturing, filling and sterilization where applicable? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Are the current requirements always available for the staff concerned? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Is there an appropriate approval procedure for the manufactured products? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |

4.7 Labelling and packaging

| Area / activity | Yes | No | Comment |
|---|-------------------------------------|--------------------------|---|
| Are all outgoing goods identifiable by name, code and batch? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Are packaging lines marked with the name and batch number of the product currently being processed? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Does the batch number reflect a homogenous production process? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | Batch numbers are allocated by the ERP. |
| Is each container clearly marked? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Are the quantity, identity and uniformity of all products and packaging materials checked before packaging? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Are all containers individually marked with name, product code, batch, date of manufacture and expiry date? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| If you are re-labelling or re-packaging: Is it ensured that the right label is used, with the supplier's information regarding retesting and usability data transferred? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Are reference samples retained from all refilled batches? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | Retention period: 6 years |

5. Logistics

| Area / activity | Yes | No | Comment |
|--|-------------------------------------|--------------------------|--|
| Do you work together with contractually bound transport companies? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Are there written records regarding the acceptance of a shipment? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Are incoming goods checked according to set requirements? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Are there exact requirements as to when incoming raw materials/intermediate products/primary packaging materials are accepted or rejected? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Does the incoming goods check record the reasons for rejecting the goods? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Is a batch considered individually in terms of sampling, testing and approval if an incoming shipment consists of various batches? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Is there a room/procedure for sampling? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Can materials be clearly identified in order to avoid errors (e.g. when sampling, during storage and retrieval processes)? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Is there a precise marking (with product name and where applicable code and batch number) showing the test status of the goods? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Is use and delivery of rejected materials or finished products prevented by an appropriate IT system? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Are incoming shipments checked to make sure that the containers and, where applicable, seals are intact? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Are incoming and outgoing goods protected from weathering? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | Loading and unloading ramps are under cover. |
| Are the storage facilities suitable for storing the products in the required quality? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Are the storage facilities clean and tidy and are they maintained regularly? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Are the storage conditions (temperature, relative humidity, etc.) monitored and logged? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Are the storage facilities only accessible to authorised staff? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Is there suitable ventilation and lighting in the storage area? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |

| | | | |
|--|-------------------------------------|-------------------------------------|---|
| Are incoming materials handled and stored in such a way as to avoid damage (e.g. as a result of humidity, temperature, ventilation)? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Does the "First in – first out" principle apply in the storage system? | <input type="checkbox"/> | <input checked="" type="checkbox"/> | The FeFo principle is used (First Expired, First out) |
| Is the warehouse clean and well organised and are the stored materials easy to locate and identify? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Is there a separate warehouse or a specific place marked for rejected materials? | <input type="checkbox"/> | <input checked="" type="checkbox"/> | The process for rejected materials is regulated by QC/QA. |
| Are storage conditions calculated in such a way as to ensure that there are no negative influences on the stored materials (spoilage, physical, chemical, or microbial contamination, etc.)? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Is a specific batch number assigned with every receipt of goods, in order to ensure traceability? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Are incoming materials appropriately stored so that no mixups can occur? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Are there specifications in respect of the materials stored (with details of storage conditions, where applicable maximum period of storage until a follow-up inspection, best-before date, etc.)? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Are specifications available in order to monitor shipping requirements? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Are the shipping containers clearly marked to allow contents to be identified? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Is proper transport from the works site guaranteed? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Are reusable transport containers used (BKW, TKW, containers, etc.)? | <input type="checkbox"/> | <input checked="" type="checkbox"/> | |

6. *Basic principles of social responsibility at Hänseler AG*


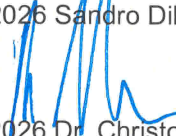
| Field / activity | Yes | No | Remarks |
|---|-------------------------------------|--------------------------|---------|
| Employment contracts: Hänseler AG employees have binding contracts of employment. | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Fair pay: Staff remuneration at Hänseler AG fulfils statutory, customary, local, and national standards in the industry. | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Working hours: Hänseler AG operates a flexible working hours model in compliance with statutory regulations. | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |

| Field / activity | Yes | No | Remarks |
|---|-------------------------------------|--------------------------|---------|
| No discrimination: Hänseler AG is against any form of discrimination in regard to gender, age, ethnic origin, nationality, skin colour, sexual orientation, political opinion, religious affiliation or social origin. | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Healthy working environment: Hänseler AG has introduced clear regulations and measures regarding occupational health and safety. | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Prohibition of forced labour: Forced labour of any kind and prison labour which violates basic human rights are prohibited in Switzerland by law. | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Prohibition of child labour: Child labour of whatever kind is prohibited in Switzerland by law. | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |

Hänseler AG shall not work with any suppliers known to have infringed against these basic principles of social responsibility.

7. Other Documents

| | |
|------------------------------|-------------|
| GMP certificate | See website |
| Operating licence | See website |
| Organisational chart | On request |
| Contents of site master file | On request |
| Current product list | See website |
| Code of Conduct Hänseler AG | See website |

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|----------------------------|--|
| Approved: | |
| Head of Quality Assurance: |  09.06.2026 Sandro Dilettoso |
| Qualified Person, COQ: |  09.06.2026 Dr. Christoph Titze |