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	**118.32**
including those in quality management	17.4
including those in purchasing / marketing / business development	22.5
including those in production, warehousing and logistics	59.82
therefrom administration	16.0
therefrom financial department & administration	2.5

1.3 Quality management system

Certificates:

QM system:	Certificate issued on:	Audit interval	Last audit
GMP	October 20th 2021 (valid indefinitely)	2 years	June 2021
GDP	October 20th 2021 (valid indefinitely)	2 years	June 2021

Licences:

Type of licence	Date of issue	Issuing authority
Licence to manufacture medicinal products*)	October 20 2021 (valid indefinitely)	Swissmedic
Licence to trade in controlled substances, to manufacture and process controlled substances, to trade in precursor chemicals	September 1 2021 (valid until December 31 2025)	Swissmedic
Registration to produce and market feedstuffs	February 4 2008 (valid until further notice)	Swiss Federal Department of Economic Affairs (EVD)

*) Product groups:

- Active pharmaceutical ingredients, intermediate products and ready-to-use medicinal products (without labile blood products) in liquid, semi-solid and solid drug forms.
  Aseptically prepared products are excluded
  Terminally sterilised products are excluded
  Processing of biological products is excluded
  Processing of highly active or allergising active ingredients is excluded
- Medicinal products for clinical trials
- Medicinal products based on a magistral formula, officinal formula or an individual formula according to Art. 9 (2) Sections a, b and c of the Swiss Law on Therapeutic Products to be issued by the client
- Filling and labelling of raw materials which are used to manufacture medicinal products according to a magistral formula, officinal formula or an individual formula according to Art. 9 (2) Sections a, b and c of the Swiss Law on Therapeutic Products, **including containerwise guarantee of identity** of these raw materials according to Chapter 20.1.6.4 of the Pharmacopoea Helvetica 10.

1.4 Contact partners

Contact person	Title/name	Position	Telephone no.	Email
Chief Executive Officer	Dr. Dominik Hauser	Chief Operation Officer	071 353 58 88	Dominik.Hauser@haenseler.ch
Chief Operations Officer	Daniel Hirsbrunner	Head of production division	071 353 58 70	Daniel.Hirsbrunner@haenseler.ch
Quality management, QP	Dr. Christoph Titze	Head of quality management division	071 353 58 01	Christoph.Titze@haenseler.ch
Head of quality control	Stephan Wallimann	Head of quality control	071 353 58 05	Stephan.Wallimann@haenseler.ch
Head of manufacturing	Dominique Schreiber	Head of manufacturing department	071 353 58 09	Dominique.Schreiber@haenseler.ch
Head of quality assurance & regulatory affairs	Sandro Dilettoso	Head of quality assurance & Regulatory Affairs	071 353 58 07	Sandro.Dilettoso@haenseler.ch

Complaints / objections	Stephan Wallimann	Head of quality control	071 353 58 05	Stephan.Wallimann@haenseler.ch
Purchasing	Raphaela Trivelli	Head of purchasing	071 353 58 40	Raphaela.Trivelli@haenseler.ch
Marketing	Michael Born	Head of marketing	071 353 58 50	Michael.Born@haenseler.ch
Industry sales	Nicole Trott	Head of industry sales	071 353 58 12	Nicole.Trott@haenseler.ch
Pharmacy sales	Reto Meier	Head of pharmacy	071 353 58 16	Reto.Meier@haenseler.ch
Industry steering	Michele Floreancig	Head of industry steering	071 353 58 18	Michele.Floreancig@haenseler.ch

1.5 Company activities

Activities:

- Manufacturing medicinal products
- 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.

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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?	☒	☐	In the job description
Is quality control/quality assurance independent of production?	☒	☐	
Are the responsibilities of the head of quality control clearly established?	☒	☐	In the job description
Does quality control have the appropriate equipment and facilities in order to carry out its functions?	☒	☐	
Are there occupational safety guidelines?	☒	☐	

2.2 Staff

Area / activity	Yes	No	Comment
Are job descriptions available for the staff?	☒	☐	
Are the responsibilities and powers of the staff laid down?	☒	☐	In the corresponding job descriptions and in the organisation and competency guidelines.
Does quality control have enough qualified staff?	☒	☐	
Is there a procedural instruction on the further education and training of staff?	☒	☐	

2.3 Approval

Area / activity	Yes	No	Comment
Is it established in writing which person or entity is authorised to approve a product?	☒	☐	
Are there any regulations regarding the approval of a product and does product evaluation include all necessary specifications?	☒	☐	
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?	☒	☐	
Is there a set procedure in case of "out of specification" results?	☒	☐	

2.4 Quality control

Area / activity	Yes	No	Comment
Is there a procedural instruction for the sampling?	☒	☐	
Are samples of incoming materials adequately tested? (Criteria: type of sample, number of specimens, testing method)	☒	☐	
Are reference samples retained of all shipments?	☐	☒	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?	☒	☐	
Are quality specifications available for all materials?	☒	☐	
Is there a procedural instruction for each testing method?	☒	☐	
Are the existing analytical processes adequate to ensure that each batch complies with the specifications in terms of quality, purity, and identity?	☒	☐	
Are the current specifications always available for the staff concerned?	☒	☐	
Is it ensured that old versions of specifications are no longer used?	☒	☐	
Is there proper documentation of investigations/tests that are carried out, as well as test results?	☒	☐	
Are analysis results reviewed by a responsible person?	☒	☐	
Do the analysis certificates indicate target values, limit values and actual values?	☒	☐	
Do the analysis certificates clearly refer to the labelled goods?	☒	☐	
Do you have analyses carried out externally?	☒	☐	Heavy metals, pesticides, microbiology, aflatoxins
Does QC review the production records as part of the approval criteria?	☒	☐	
Are precise reasons indicated and documented if material is rejected during the production process?	☒	☐	
Are corrective measures defined in the event of a batch being rejected, in order to avoid the same error occurring again?	☒	☐	
Is each deviation fully recorded and investigated?	☒	☐	
Is there a procedural instruction regarding the maintenance, qualification, and requalification of test	☒	☐	

Area / activity	Yes	No	Comment
equipment?			
Is there a system to ensure that measuring instruments and test equipment are calibrated regularly?	☒	☐	
Are written records made of calibrations which have been performed?	☒	☐	
If you perform the calibration yourselves, are these calibration procedures defined according to appropriate standards and are they traceable?	☒	☐	
If the calibrations were performed externally, was the competence of these external bodies verified?	☐	☒	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?	☒	☐	Partly
Are test/analysis methods revalidated at regular intervals?	☐	☒	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?	☒	☐	
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?	☒	☐	
Are all necessary standards and reagents available for tests? Are the storage stability and retest date defined for each?	☒	☐	
Are the content, batch number and best-before date of laboratory reagents and other chemicals identified?	☒	☐	
Are investigations available in respect of the shelf-life data of the manufactured products?	☒	☐	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?	☒	☐	
Is there a full organisational chart of the corporate structure with job descriptions, staffing schedules and definition of responsibilities?	☒	☐	
Is there a quality assurance system describing the organisational structure, responsibilities, and procedures?	☒	☐	
Is there a quality assurance manual which describes the quality assurance system?	☐	☒	
Is there a site master file which describes the quality assurance system?	☒	☐	
Is there an internal quality review program?	☒	☐	Self-inspection
Is there a continuous update service for QA requirements which ensures that obsolete versions are no longer used?	☒	☐	
Are there written requirements regarding documentation (making corrections, ban on entries in pencil, etc.)?	☒	☐	
Are records duly signed and dated?	☒	☐	
Is there a system to ensure that validations are furnished for required production processes, equipment, and analysis methods?	☒	☐	
Is there a system for following up CAPA measures?	☒	☐	
Are there appropriate procedures for ensuring that machinery, tools, measurement instruments and test equipment are clean?	☒	☐	
Is there a consistently applied batch numbering system?	☒	☐	
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?	☒	☐	
Is there a procedural instruction about carrying out self-inspections (internal audits) and are these logged?	☒	☐	Interval: annually
Do you allow the client to carry out an audit in your company?	☒	☐	
Have audits already been carried out by other manufacturers of medicinal products?	☒	☐	Regularly
Is there a procedural instruction on document control (change control, deviation)?	☒	☐	

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

2.6 Complaints

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

2.7 Computerised systems

Area / activity	Yes	No	Comment
Is the computer system validated?	☒	☐	
Is the area of responsibility documented with regard to computerised systems?	☒	☐	
Is system security ensured in terms of access rights?	☒	☐	
Can the system check and log the identity of the users (audit trail)?	☒	☐	
Is there an up-to-date list of all persons who are able to input and change data?	☒	☐	
Is there a specified program for backing up software and data?	☒	☐	
How is the re-readability of data guaranteed in case of long-term storage?	☒	☐	Backup on tapes
Are there precautions for an emergency power supply for critical systems?	☒	☐	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)?	☒	☐	
Is it ensured that the raw materials/intermediate products/primary packaging materials comply with set requirements?	☒	☐	
Is there an evaluation system for suppliers?	☒	☐	Supplier qualification and annual evaluation
Does the company have a list of approved suppliers?	☒	☐	
Are suppliers audited regularly?	☒	☐	Interval depends on the corresponding risk assessment.
Do agreements exist with subcontractors, analysis laboratories on a subcontracted basis and GMP-relevant providers?	☒	☐	

4. Production

4.1 Premises and equipment

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

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

4.2 Staff

Area / activity	Yes	No	Comment
Are the flow and organization of the manufacturing process set down in writing?	☒	☐	
Are the staffs sufficiently qualified and are they trained regularly?	☒	☐	
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?	☒	☐	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?	☒	☐	

4.3 Technical equipment

Area / activity	Yes	No	Comment
Are all quality-relevant installations qualified according to DQ, IQ and OQ principles?	☒	☐	
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?	☒	☐	
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)?	☒	☐	
Are equipment/systems installed in such a way as to allow extensive cleaning and maintenance work to be carried out on the systems?	☒	☐	
Are equipment/systems only dedicated to one process/product?	☐	☒	

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?	☒	☐	
Is the maintenance status of production systems evident?	☒	☐	
Are there written requirements (SOPs) for environmental monitoring, cleaning, and maintenance of the equipment in production?	☒	☐	
Do these SOPs include the definition of responsibilities, deadlines, method descriptions and acceptance criteria/tolerances, etc.?	☒	☐	
Are cleaning, maintenance and calibration records archived?	☒	☐	At least 13 years
Before each processing operation, is it ensured that the equipment is clean and free of foreign materials?	☒	☐	
Is a logbook kept for very important or critical equipment (with details of maintenance, cleaning, repair work, calibration and validations carried out)?	☒	☐	All systems have a logbook, not just the critical ones.
Do the products go through a metal detector?	☐	☒	

4.4 Hygiene

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

Area / activity	Yes	No	Comment
Are there appropriate exhaust systems in production rooms that are dusty or particularly at risk of contamination?	☒	☐	Denios boxes, Glove box
Are the staffs trained regularly in hygiene?	☒	☐	
Are there cleaning regulations?	☒	☐	
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?	☒	☐	
Are raw materials / intermediate products / primary packaging materials and products protected against microbial contamination?	☒	☐	
Is there any documentation of the (regulation-compliant) cleaning?	☒	☐	
Is hygiene monitored periodically?	☒	☐	
Is pest control carried out?	☒	☐	
Does the company have a program to combat rodents, birds, insects and other pests, and are the records archived?	☒	☐	Minimum archiving period of 13 years.
Are only approved pesticides used for this purpose?	☒	☐	
Is there regular monitoring of the efficacy of pest control measures and adherence to regulations?	☒	☐	
Is staff health monitored?	☒	☐	
Do you have a waste disposal system?	☒	☐	
Is waste stored in appropriately marked containers?	☒	☐	

4.5 Raw materials

Area / activity	Yes	No	Comment
Are the incoming goods checked in respect of required purity/specification?	☒	☐	
Is a written approval issued before further use?	☒	☐	
Is it exclusively materials/raw materials that are approved by quality control which are used?	☒	☐	
Are there officially defined procedures for treating raw material which is to be reworked?	☐	☒	
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?	☒	☐	

4.6 Manufacturing processes

Area / activity	Yes	No	Comment
Are all processes carried out under the supervision of responsible specialists?	☒	☐	
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?	☒	☐	
Are there written cleaning instructions available and is the cleaning documented?	☒	☐	
Are all stages run as batch processes and are they traceable throughout?	☒	☐	
Are measures taken to avoid mix-ups and impurities?	☒	☐	
Are all manufacturing stages defined by written instructions (manufacturing specifications)?	☒	☐	
Are procedural stages clearly formulated to ensure that employees understand their tasks and cannot misinterpret instructions?	☒	☐	
Are the written procedural instructions followed?	☒	☐	
Is there a change control process?	☒	☐	
Are process-relevant measurement and control systems (such as for temperature, pressure, conductance, etc.) calibrated regularly?	☒	☐	
Is a written record drawn up of each production batch?	☒	☐	
Is the respective processing stage clearly marked on the system/container?	☒	☐	
Can the manufactured products be identified throughout the entire production process?	☒	☐	
Are formal in-process controls carried out during production, packaging, and labelling stages?	☒	☐	
Are manufacturing processes documented and monitored?	☒	☐	
Are manufacturing records properly stored over a reasonable period?	☒	☐	13 years
Are there officially defined procedures in the event of deviation from standard manufacturing practice?	☒	☐	
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?	☒	☐	
Is the introduction of a (part) batch to another batch of the same product approved by a competent person? Is reutilization recorded?	☒	☐	

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

4.7 Labelling and packaging

Area / activity	Yes	No	Comment
Are all outgoing goods identifiable by name, code and batch?	☒	☐	
Are packaging lines marked with the name and batch number of the product currently being processed?	☒	☐	
Does the batch number reflect a homogenous production process?	☒	☐	Batch numbers are allocated by the ERP.
Is each container clearly marked?	☒	☐	
Are the quantity, identity and uniformity of all products and packaging materials checked before packaging?	☒	☐	
Are all containers individually marked with name, product code, batch, date of manufacture and expiry date?	☒	☐	
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?	☒	☐	
Are reference samples retained from all refilled batches?	☒	☐	Retention period: 6 years

5. *Logistics*

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

Are incoming materials handled and stored in such a way as to avoid damage (e.g. as a result of humidity, temperature, ventilation)?	☒	☐	
Does the "First in – first out" principle apply in the storage system?	☒	☐	
Is the warehouse clean and well organised and are the stored materials easy to locate and identify?	☒	☐	
Is there a separate warehouse or a specific place marked for rejected materials?	☐	☒	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 (spoiling, physical, chemical, or microbial contamination, etc.)?	☒	☐	
Is a specific batch number assigned with every receipt of goods, in order to ensure traceability?	☒	☐	
Are incoming materials appropriately stored so that no mixups can occur?	☒	☐	
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.)?	☒	☐	
Are specifications available in order to monitor shipping requirements?	☒	☐	
Are the shipping containers clearly marked to allow contents to be identified?	☒	☐	
Is proper transport from the works site guaranteed?	☒	☐	
Are reusable transport containers used (BKW, TKW, containers, etc.)?	☐	☒	

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

Field / activity	Yes	No	Remarks
Employment contracts: Hänseler AG employees have binding contracts of employment.	☒	☐	
Fair pay: Staff remuneration at Hänseler AG fulfils statutory, customary, local, and national standards in the industry.	☒	☐	
Working hours: Hänseler AG operates a flexible working hours model in compliance with statutory regulations.	☒	☐	
No discrimination: Hänseler AG is against any form of discrimination in regard to gender, age, ethnic origin, nationality, skin colour, sexual orientation, political	☒	☐	

Field / activity	Yes	No	Remarks
opinion, religious affiliation or social origin.			
Healthy working environment: Hänseler AG has introduced clear regulations and measures regarding occupational health and safety.	☒	☐	
Prohibition of forced labour: Forced labour of any kind and prison labour which violates basic human rights are prohibited in Switzerland by law.	☒	☐	
Prohibition of child labour: Child labour of whatever kind is prohibited in Switzerland by law.	☒	☐	

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

Approved:

Head of Quality Assurance & Regulatory Affairs: 01.07.2023 Sandro Dilettoso

Qualified Person, COQ: 01.07.2023 Dr. Christoph Titze