



## Standard Answers to FAQs from Customer Questionnaires

### 1. Organisation

#### 1.1 Details about the company

Company name	Hänseler AG
Street	Industriestrasse 35
Postcode, town	9101 Herisau
Country	Switzerland
Homepage	<a href="http://www.haenseler.ch">www.haenseler.ch</a>
Company structure	Stock corporation
Founding	1975
Sales	approx. CHF 40 million

#### 1.2 Staff

<b>Total number of employees</b>	<b>135</b>
including those in quality control	12
including those in quality assurance	3
including those in registration	2
including those in maintenance	8
including those in purchasing / marketing / business development	35
including those in production, warehousing and logistics	66

#### 1.3 Quality management system

##### Certificates:

QM system:	Certificate issued on:	Audit interval	Last audit
GMP	June 18, 2010	2 years	Juli 2011



**Licences:**

Type of licence	Date of issue	Issuing authority
Licence to manufacture medicinal products*)	24 June 2011 (valid until 10 July 2016)	Swissmedic
Licence to trade in controlled substances, to manufacture and process controlled substances, to trade in precursor chemicals	01 October 2010 (valid until 31 December 2015)	Swissmedic
Registration to produce and market feedstuffs	4 February 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
Management	Dr. Thomas Hediger	CEO	071 353 58 88	<a href="mailto:Thomas.Hediger@haenseler.ch">Thomas.Hediger@haenseler.ch</a>
Qualified person	Dr. Rolf Locher	Head of quality management division	071 353 58 01	<a href="mailto:Rolf.Locher@haenseler.ch">Rolf.Locher@haenseler.ch</a>
Head of quality control	Nino Pilotto	Quality control manager	071 353 58 05	<a href="mailto:Nino.Pilotto@haenseler.ch">Nino.Pilotto@haenseler.ch</a>
Head of production	Alex Klöti	Head of production division	071 353 58 70	<a href="mailto:Alex.Kloeti@haenseler.ch">Alex.Kloeti@haenseler.ch</a>
Head of manufacturing	Daniel Hirsbrunner	Head of manufacturing department	071 353 58 09	<a href="mailto:Daniel.Hirsbrunner@haenseler.ch">Daniel.Hirsbrunner@haenseler.ch</a>
Quality assurance	Dr. Rolf Locher	Head of quality management division	071 353 58 01	<a href="mailto:Rolf.Locher@haenseler.ch">Rolf.Locher@haenseler.ch</a>
Complaints / objections	Nino Pilotto	Head of quality control department	071 353 58 05	<a href="mailto:Nino.Pilotto@haenseler.ch">Nino.Pilotto@haenseler.ch</a>



Purchasing	Klaus Fink	Head of purchasing	071 353 58 40	<a href="mailto:Klaus.Fink@haenseler.ch">Klaus.Fink@haenseler.ch</a>
Marketing a.i.	Dr. Thomas Hediger	Head of marketing & sales division	071 353 58 88	<a href="mailto:Thomas.Hediger@haenseler.ch">Thomas.Hediger@haenseler.ch</a>
Sales	René Bühler	Head of sales Industry	071 353 58 12	<a href="mailto:Rene.Buehler@haenseler.ch">Rene.Buehler@haenseler.ch</a>
Sales	Ruedi Kuster	Head of sales pharmacies CH	071 353 58 50	<a href="mailto:Ruedi.Kuster@haenseler.ch">Ruedi.Kuster@haenseler.ch</a>
Sales	Sabine Kleinhans	Head of sales export	071 353 58 14	<a href="mailto:Sabine.Kleinhans@haenseler.ch">Sabine.Kleinhans@haenseler.ch</a>

## 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.

## 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"/>	



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"/>	

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 programme 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 type="checkbox"/>	<input checked="" type="checkbox"/>	There are currently still tests where not all references are available. Mainly GC fingerprints. We are in the process of bridging this gap.
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 there a site master file which describes the quality assurance system?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Is there an internal quality review programme?	<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 programme for all employees in the appropriate areas?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Is there a programme 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 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"/>	



Area / activity	Yes	No	Comment
Are content and direction of the tubes marked?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Partly
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, deionisation, ultrafiltration procedures)?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	

#### 4.2 Staff

Area / activity	Yes	No	Comment
Are the flow and organisation 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?			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"/>	

Area / activity	Yes	No	Comment
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"/>	
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 13 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 programme 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"/>	



Area / activity	Yes	No	Comment
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"/>	
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 and in what areas?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	In the herbs areas
Does the company have a programme to combat rodents, birds, insects and other pests, and are the records archived?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Minimum archiving period of 13 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 mixups 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"/>	



Area / activity	Yes	No	Comment
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"/>	13 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 reutilisation recorded?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
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 type="checkbox"/>	<input checked="" type="checkbox"/>	Apart from a few exceptions, no yield limits are defined. Manufacturing requirements are regularly supplemented with theoretical yields, however.
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 sterilisation 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"/>	



Area / activity	Yes	No	Comment
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 checked="" type="checkbox"/>	<input type="checkbox"/>	
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"/>	
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"/>	

Area / activity	Yes	No	Comment
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. Documents (appendices)

GMP certificate	<input checked="" type="checkbox"/>
Operating licence	<input checked="" type="checkbox"/>
Organisational chart	<input checked="" type="checkbox"/>
Contents of site master file	On request
Current product list	<input checked="" type="checkbox"/>