

1 The External Supplier's responsibility for quality assurance

1.1 General considerations

The quality of supplied products and/or rendered services is the sole responsibility of the External Supplier. To fulfil this requirement, it is essential for every External Supplier to set up and maintain a fully-functional quality management system that matches the structure and size of the supplier's company.

1.2 Tests

1.2.1 Manufacturing control

Every External Supplier is obligated to comply with the specifications and drawings stipulated by SABEU GmbH & Co. KG (hereinafter referred to as "SABEU"). Before shipping out the merchandise and/or after rendering the service, the External Supplier agrees to verify the compliance with the specifications and drawings and to ensure that the merchandise is shipped in a suitable fashion. The results of the verification must be documented adequately and archived at the External Supplier's company and made available to SABEU for review upon request.

1.2.2 Inspection certificates

Unless specified otherwise, every merchandise shipment must generally be accompanied by inspection certificates 3.1 in accordance with the DIN EN 10204 standard. The supplier automatically receives a lower grade if the inspection certificate is missing. If SABEU requests proof of other tests, e.g. a 100% inspection rate, these may be sufficient and no inspection certificate may be required. This should be double-checked on a case-by-case basis.

1.2.3 Test schedules

If special precautions with respect to certain product characteristics are required for a product (safety-relevant components, etc.), SABEU reserves the right to arrange for special test schedules. These are created by the corresponding department of SABEU and made available to the External Supplier.

1.3 Duty of information and vigilance

Should the External Supplier gain knowledge of any circumstances indicating a correlation between the deliverables or similar products of the External Supplier and harmful effects on a human being, he will promptly inform SABEU in accordance with the provisions set forth in ANNEX B. The External Supplier will respond to any incidence reports from SABEU and handle them appropriately. The External Supplier is responsible for the technical or pharmaceutical examination as well as the in-house inspection with regard to the deliverables.

If SABEU obtains information about such an incident, SABEU will notify the External Supplier promptly after confirming the incident. Upon receipt of the incident notification, the External Supplier and SABEU will arrange the necessary examinations without delay and inform each other about the findings, in order to facilitate the prompt compilation of a vigilance report. Based on this examination, the External Supplier will assist SABEU in determining the necessary remedial procedures.

2 Error prevention

2.1 Requirements

The purpose is to detect and prevent potential sources of error as early as possible. Consequently, error prevention procedures must already be implemented and maintained before the start of the production. During the production, errors that may have occurred earlier must also be identified quickly and procedures initiated to remedy them. Moreover, the occurrence of repeat errors must be prevented with suitable measures.

2.2 Review of the technical feasibility

Before accepting the order, the External Supplier is obligated to review whether he is able to manufacture the requested product in accordance with the surrendered specifications and/or drawings or to render the service.

The External Supplier must inform SABEU of the result of this review. If any doubts arise with respect to the fulfilment of the technical feasibility in the context of the facilities available at the External Supplier's company, an audit will be conducted in consultation with SABEU's corresponding operational divisions. The results of the audit will then be used to make a decision.

3 QM system of the External Supplier

3.1 Certification

Since SABEU has been certified, it seeks the cooperation with External Suppliers that are likewise operating a certified QM system. Any External Suppliers with a certified QM system must mail a copy of their latest certificate to SABEU. After the certificate has expired, an updated copy must automatically be submitted. If no certification has been carried out, SABEU reserves the right to conduct its own audits.

3.2 Auditing by SABEU

SABEU, competent authorities as well as notified bodies are entitled to carry out audits with their own employees after prior announcement and approval of the External Supplier. The results of such audit will be shared with the External Supplier in the form of an audit report. If any deviations are identified, the audit report will include an action plan with corresponding deadlines. After the timely handling, this action plan must automatically be sent back to SABEU.

3.3 Sub-suppliers

The External Supplier is responsible for the qualification of his sub-suppliers with regard to the satisfactory quality of the purchased materials, products or services. This can be verified with certified QM systems of the External Suppliers, comprehensive information provided by the External Suppliers or with an audit of the sub-supplier conducted by the External Supplier. It must be possible to present documented proof of this.

3.4 Process control

The External Supplier guarantees that the deliverables are manufactured in compliance with all relevant provisions as well as the recognized state of the art technology. The External Supplier monitors the manufacturing and test processes to ensure that the accuracy and constancy of the equipment used to manufacture and measure the products, including settings and adjustments, are safeguarded, that the skills, abilities and know-how of the operating personnel meet the requirements and that factors affecting the process control, such as e.g. time, temperature and special ambient conditions, are fulfilled and documented.

3.5 Traceability

For the purpose of lot traceability, the External Supplier labels the products with a distinct LOT number (manufacturing lot). This LOT number must make it possible to track back the lot all the way to the raw material. The External Supplier is responsible for compiling and safekeeping the complete lot documentation as part of the manufacturing documents. Any additional traceability shall be regulated in the supply contract.

3.6 Reference samples

The External Supplier ensures that lot-related reference samples will be retained for the manufactured products.

3.7 Test equipment

The External Supplier ensures that all test equipment required for testing the products to be manufactured for SABEU is operational at all times and subject to permanent monitoring, calibration and maintenance.

4 Initial procurement and initial sampling

4.1 Submission of initial samples

Prior to the serial delivery, SABEU has the right to request the submission of initial samples. This applies in particular in connection with:

- 🔄 new suppliers
- 🔄 change of supplier
- 🔄 introduction of a new part
- 🔄 significant change in the production process.

The submission of initial samples is compulsory for machined products as well as products manufactured with the use of tools, dies, etc.

4.2 Compilation of the initial sample inspection report

The submitted initial samples must be accompanied by an initial sample inspection report according to the VDA [German Association of the Automotive Industry], which contains at least all tolerated dimensions of the detail drawing. If any other dimensions or tests are required, the External Supplier will be notified about this in advance.

For raw materials, additives, color batches, etc., the initial sample inspection report must be replaced with a certificate of analysis documenting the verification of the data specifications for the merchandise.

4.3 Adherence to the submission date

The promised sample submission date is tantamount to a stated delivery date for a serial delivery. If the parts contain any deviations at the time of the sample submission, the submission date shall be deemed not adhered to. If the deadline cannot be met, the business division "Central Services" must be notified promptly about this delay. If there are any deviations, a request for approval of the deviations must additionally be submitted.

4.4 Evaluation of the initial samples

SABEU reviews the compliance with the specified dimensions, functions and optical appearance of the submitted initial samples. If the result of this evaluation is positive, the release for the serial production is sent to the External Supplier on the cover page of the submitted initial sample inspection report according to the VDA and/or on the certificate of analysis.

However, if any deviations are determined, which may be due both to dimensions specified in the initial sample inspection report as well as the organization in the External Supplier's QM system, the business unit "Central Services" must be provided with a new sample submission date. Still, it should not be deduced from this approach that SABEU is obligated to accept the submission of other samples in all cases.

5 Serial deliveries

5.1 Requirements

Prior to the serial delivery, the External Supplier must be provided with the written delivery authorization and possible requirements stipulated in connection with the initial sampling must be fulfilled. Moreover, there may be no deviations in the External Supplier's QM system and/or the procedures specified in the audit reports etc. must have been implemented.

5.2 Change of manufacturing conditions at the External Supplier's end

The External Supplier shall inform SABEU in writing in regards to any changes related to

- 🔄 production/manufacturing procedures
- 🔄 relocations
- 🔄 starting materials
- 🔄 recipes
- 🔄 change of sub-suppliers

no later than three months before the planned changes are scheduled to take effect. The External Supplier must grant SABEU the opportunity to place a final order that covers the average supply for one year. The calculation is based on the average annual order quantity of the past three years. Depending on the quantity, the final order can be placed in the form of a blanket order with regular stand-by deliveries. The decision about whether a new sample submission is required will be made on a case-by-case basis.

Agreements deviating from this are to be regulated in the supply contract.

5.3 Delivery and labeling

As a general rule, the following applies to products intended for the medical technology, biotechnology and laboratory technology industries:

- 🔄 delivered in clean, stable packing drums;
- 🔄 parts are wrapped in double lined PE bags, with the inner bag heat sealed and the outer bag folded over.

The following applies to all products:

- 🔄 delivered in clean, stable packages;
- 🔄 every packing drum is labeled with the manufacturing lot;
- 🔄 delivered with inspection certificates 3.1 in accordance with the DIN EN 10204 standard, unless specified otherwise.

Other agreements regarding the delivery and labeling may be defined in a specification.

5.4 Notification of delayed delivery

The External Supplier agrees to inform SABEU within 24 hours if it is determined that the agreed delivery date cannot be met.

6 Supplier evaluation

6.1 Initial External Supplier grading

Together with the first order, new External Suppliers will receive form FO/116 "Supplier survey - self-evaluation" with the request to complete and return it. Then, they will be graded by the head of the QS business unit based on the following system:

- 🔄 A: if certified according to the DIN ISO 9000 et sqq. standard or all requirements are met based on the self-evaluation
- 🔄 B: if not certified, but the majority of requirements are met based on the self-evaluation
- 🔄 C: if no self-evaluation was provided or if the self-evaluation is poor.

The head of the QS business unit enters the grading results into the master file.

6.2 Evaluation of shipping companies

The evaluation is based on the following criteria:

- 🔄 1: everything as promised
- 🔄 2: delayed pickup/delivery from/to the customer on the same day with advance notification
- 🔄 3: delayed pickup/delivery from/to the customer on the next day with advance notification or on the same day without advance notification, repackaging due to transport-related damage, etc.
- 🔄 4: delayed pickup/delivery from/to the customer of more than one day, irrespective of whether advance notification was provided, merchandise damaged during transport, etc.

6.3 Evaluation of shipments

The evaluation is based on the following criteria:

6.3.1 Evaluation of the quality of the delivered merchandise and documents

- 🔄 1: everything as promised
- 🔄 2: minor deficiencies (delay in delivery of up to three days, incorrect or missing documentation, packaging deficiencies, etc.)
- 🔄 3: moderate deficiencies (product defects released under authorized concession)
- 🔄 4: serious deficiencies (product defects resulting in rejection)

If the grade is >1, the reason for the deficiency additionally allocated:

- 🔄 quality
- 🔄 adherence to deadlines
- 🔄 documentation
- 🔄 quantity variance
- 🔄 cooperation.

The reasons for the deficiencies are weighted, with quality being most relevant.

Quality assurance agreement for External Suppliers



6.3.2 Over/underdelivery

- 🔄 up to $\pm 10\%$ => grade 1 (if the quality, etc. is adequate)
- 🔄 up to $\pm 20\%$ => grade 2 (if the quality, etc. is adequate)
- 🔄 higher => grade 3 (if the quality, etc. is adequate)

If the quality, etc. is inadequate, the grade will be reduced commensurately by 1-2 levels.

6.3.3 Unannounced postponements

The business unit "Central Services" must be notified promptly of any delivery postponements (see item 5.5). If this is not done and deliveries are postponed, this delivery will automatically be assigned a grade of 2, subject to the condition that no other deficiencies are detected.

6.4 Analysis and grading

6.4.1 Calculation

Using the reasons for the deficiencies mentioned in item 6.4.1, the overall grade is calculated by totaling the weighted partial grades.

6.4.2 Grading and approval of External Suppliers

Based on the calculation formula above, all External Suppliers are re-graded in accordance with the following grading system:

- 🔄 from ≥ 1.0 to < 1.5 : A
- 🔄 from ≥ 1.5 to < 2.5 : B
- 🔄 from ≥ 2.5 to < 3.5 : C
- 🔄 greater than ≥ 3.5 : not approved
(a special arrangement can be made if the number of deliveries is < 3).

The evaluation will be conducted monthly and serves as basis for the placement of orders in the following month.

7 Binding force of the supplier quality guidelines

The supplier quality guidelines (Quality Assurance Agreement for External Suppliers) of SABEU GmbH & Co. KG are binding and to be complied with.

Northeim, 6/12/2018

Signed: Dennis Benkmann, CEO