

**TEMPLATE**

**QUALITY ASSURANCE AGREEMENT**  
**Production of packaging and/or**  
**services for the pharmaceutical industry**

between

**[company name]**

[street & number]

[zip code - town or city], [country]

- hereinafter referred to as: the CUSTOMER -

and

**August Faller GmbH & Co. KG**

Freiburger Strasse 25

79183 Waldkirch, Germany

- hereinafter referred to as: FALLER -

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### Section 1 Subject of the contract

1. The subject of this agreement is the quality assurance and control of the manufacture, testing and documentation of packaging and/or packaging services for the pharmaceutical industry, in accordance with the rules of this agreement.
2. For each order, FALLER will receive a written purchase document with the quality requirements of the CUSTOMER, in particular with precise product and material specifications and where applicable with the functional, application and safety requirements. Any changes to the purchase document must always be made in writing. Each order always requires explicit acceptance by means of an order confirmation from FALLER. Unless otherwise specified by the CUSTOMER and agreed with FALLER, FALLER standard specifications apply (additionally). FALLER will provide their currently valid standard specifications to the CUSTOMER for information.
3. Unless otherwise explicitly agreed in writing, the General Terms and Conditions of Business, in particular any purchasing conditions of the CUSTOMER, do not apply. This is the case even if the CUSTOMER refers to them in business correspondence and FALLER does not expressly object to their inclusion.

### Section 2 Input materials

1. The input materials will be specified by the CUSTOMER and/or individually approved. For the manufacture of the subject of the contract, FALLER will only use and process input materials that comply with the CUSTOMER's quality requirements. Alternative materials may only be used when these have been specifically approved by the CUSTOMER.
2. The CUSTOMER is entitled to change the quality requirements that it expects of the input materials before issuing a production order, by notifying FALLER in writing. Equally, the approval of individual input materials can be revoked. In these cases, FALLER is entitled in particular to refuse to accept the contract until the parties have reached a binding agreement regarding the quality requirements for the input materials.

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### Section 3 Production, tests and storage

1. FALLER shall manufacture the subject of the contract in its own production facilities, see Appendix 1. Any change in production site requires prior written approval from the CUSTOMER.
2. The involvement of subcontractors and/or production at production sites other than FALLER's own requires the CUSTOMER's written agreement. In this case, FALLER is liable for ensuring compliance with the agreed quality standards by the subcontractor. The CUSTOMER will only refuse consent for cause.
3. FALLER produces the subject of the contract according to the rules of its quality management systems and with the required (in-process) controls, in compliance with the agreed quality requirements of the CUSTOMER.
4. FALLER ensures that the production, quality control and assessment of the subject of contract is done in compliance with the applicable regulatory and legal requirements for packaging of pharmaceutical products in Germany (incl. DIN standards, EU directives, EU standards, EU-GMP guidelines). If the CUSTOMER wants special regulations or guidelines to be taken into account for individual products or services, it must indicate this to FALLER in writing FALLER will then review the requirements. In the event of a positive decision, the parties will agree the conditions in writing.
5. The CUSTOMER's production or control manager, or a person nominated by them is entitled to inspect the production facilities of FALLER with regard to quality assurance aspects during normal office hours after advance and timely notification. All information acquired by the CUSTOMER during this process are subject to the obligation of non-disclosure pursuant to Section 6 of this agreement.
6. Before the start of each production run, FALLER checks initially whether the quality requirements named in the respective order document as defined in Section 1 para. 3 of this agreement can be met for the production of the subject of the contract. If this is not the case or it is doubtful, FALLER will immediately inform the CUSTOMER about this in writing. The final clarification is then the CUSTOMER's responsibility. FALLER may not commence production until after binding approval from the CUSTOMER. The CUSTOMER is responsible for the correctness and completeness of the quality requirements and for the other instructions regarding the production of the subject of the contract (e.g. technical data). FALLER has no obligation to check or provide information in this regard.

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7. If FALLER recognizes in the course of the order preparation or production, if it is not obligated to check, that the quality requirements and other specifications of the CUSTOMER to produce the subject of contract are incomplete or erroneous, in particular are contradictory, require further clarification or need to be changed or supplemented for quality or production technology aspects, it will point this out to the CUSTOMER immediately. Before further production, the parties will once again jointly agree the technical data, at least for the time being. FALLER is authorized to suspend further production of the contract until such a solution is agreed. The products manufactured by FALLER prior to this will be accepted by the CUSTOMER and paid for as defined in the order. Whenever possible for FALLER in individual cases, they will put forward proposals on their own initiative for an agreed change in the quality requirements and other specifications. The approval is solely the CUSTOMER's responsibility.

8. In the interests of change control, FALLER will inform the CUSTOMER in a timely manner about planned changes that affect them in materials and production procedures, if it is discernible that the change will influence the quality or the ability to process the packaging supplied.

9. FALLER carries out an outgoing goods inspection for each production run. The outgoing goods inspection includes checking the batch documentation for proper execution of production and a quality check based on random samples. If the CUSTOMER has specified that a sample is to be provided with each batch, this is done on the same basis. The sample and test product are packed, sealed and marked accordingly and added to the last pallet of a batch.

The following applies in addition for packaging materials: the outgoing goods check is done on the basis of the error checklists for secondary packaging, in the current version, from the Editio Cantor Verlag, Aulendorf (<http://www.ecv.de/>). The samples are taken directly before packaging during the last production step. The sampling is done in such a way as to be representative of the entire batch. The starting point for the quantity of samples (derived from ISO 2859-1, test level S-4, scheme 2-A) to be taken is the target quantity (order quantity). The assessment and analysis of the samples and the approval and creation of the test product are done during the final test by quality testing employees.

10. Based on the quality management system at FALLER agreed between the parties, the CUSTOMER can restrict the inbound inspection required by Section 377 of the German Commercial Code (HGB) to a check of the products delivered (subjects of the contract) for visible faults and based on a sample per batch individually for their identity and freedom from defects to the extent that obvious defects (e.g. transport damage, contamination) are easily detectable. The following deadlines for giving notice of defects apply:

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- i) Missing quantities and transport damage must be notified immediately on delivery and be noted on the transport documents in the presence of a representative of the forwarding agent. The CUSTOMER will provide FALLER with a copy at the latest within one day after delivery without being asked to do so.
  - ii) Other obvious defects (except those under clause i) are to be notified in writing immediately, but at the latest 8 days after delivery; hidden defects at the latest 3 days after they are discovered.
  - iii) If these deadlines are exceeded, the delivery is deemed to have been approved in relation to defects, and the CUSTOMERs rights for liability for defects expire.
11. FALLER undertakes to examine complaints from the CUSTOMER without delay. FALLER shall send the CUSTOMER a well-founded statement on the cause and on the corrective measures taken within 7 working days at the latest. The CUSTOMER shall provide FALLER with clear evidence of the defect.
12. FALLER undertakes to store the products provided by the CUSTOMER such that these are not damaged during the agreed storage duration. For the packaging supplied by FALLER, unless otherwise stipulated in Appendix 3, the following storage and processing conditions apply for proper handling, starting from the date of manufacture:
- i) Processing: Folding boxes and labels ideally at 15-25°C and a relative air humidity of 45-65%. Package inserts ideally at 20-25°C and a relative air humidity of 50-55%.
  - ii) Duration of storage/processing: ideally within 6 months, maximum 12 months.
  - iii) Storage conditions: ideally at 15-20°C, but not below 10°C or above 35°C, and a relative air humidity of 45-65%. The packaging should be stored in its sealed original containers. Direct sunlight must be avoided.

## Section 4 Documentation and retention samples

1. FALLER will attach a test certificate to each batch of a delivery as proof that the delivery has been manufactured and checked according to the rules of its quality management system and that the results of these checks correspond to the CUSTOMER's quality requirements.
2. As proof of the implementation of its quality assurance measures, and of compliance with the CUSTOMER's quality requirements, FALLER will prepare order-related records and retention samples, the type and quantity of which are defined in the requirements of their quality management

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- system. The CUSTOMER can inspect all these documents at any time during normal business hours. FALLER will keep the documents for ten years and the retention samples for two years from the date of production.
3. The records for the documentation are to be signed by the responsible employees at FALLER. The final approval is given by the person who is responsible under the rules of the quality management system.
  4. For the implementation of this agreement and the necessary coordination and other agreements, each contractual partner will name without delay a quality officer and his/her deputy to the other contractual partner. These are to be given necessary authority to implement this agreement. The contractual partners will notify each other immediately in writing of any change in the aforesaid persons.
  5. To ensure the integrity of GMP relevant data (both on paper and in electronic form) generated during manufacturing process of packaging materials, FALLER applies the principles of the ALCOA (Attributable, Readable, Contemporaneous, Original and Accurate) are to be applied like achieving and reviewing of relevant audit trails (e.g. for inspection systems, ERP system).

## Section 5 Liability

Unless otherwise agreed, for example in a master contract, the following applies:

1. for all products or services purchased by the CUSTOMER and supplied for the production of the subject of the contract, the CUSTOMER is responsible for their proper quality.
2. The CUSTOMER is solely responsible for the regulatory market approval for putting the product on the market.
3. FALLER is liable for whatever legal reason, in the event of intent or gross negligence, according to the statutory provisions.
4. In the case of simple negligence, unless otherwise provided for below in section 5 no. 5 herein, FALLER is only liable for the infringement of an essential contractual duty, the fulfilment of which is necessary for the proper execution of the contract at all, and on compliance with which the CUSTOMER as a rule relies, and may rely on, limited for compensation for foreseeable damage. For the rest, the liability of FALLER is expressly excluded, subject to Section 5 no. 5.

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5. FALLER's liability arising from injury to life, limb or health, under German Product Liability Law and resulting from assuming an independent guarantee, shall remain unaffected.



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### Section 6 Non-disclosure

1. The parties hereby mutually undertake not to disclose those facts which become known to them, or to persons commissioned by them, who the relevant parties to the contract must require to agree to non-disclosure, in the course of carrying out this agreement, and which relate to the operation, products, production methods, expertise, technical and commercial knowledge, systems, equipment, tools, CUSTOMER relations, etc. of the respective other contractual party. If a contractual partner wishes to make use of expertise belonging to the other contractual partner, a separate license contract is required for this purpose. However, there is no obligation to conclude such a license contract.
2. The obligation to non-disclosure pursuant to the previous paragraph does not exist if the respective facts
  - i) are communicated to a court or an authority based on a statutory or legal obligation or
  - ii) are the state of the art and of knowledge which are accessible to the general public and are forwarded without any action by the partner receiving this information or
  - iii) were already known to the receiving partner in this specific form, or were notified by a third party entitled to provide it without an obligation of non-disclosure or
  - iv) were developed independently by the receiving partner without the help of the other partner and without the processing of use of the information or knowledge acquired through this business contact.
3. These non-disclosure obligations continue to apply for a period of 5 years after the termination of this agreement.
4. Breaches of this non-disclosure obligation by a party to the contract entitle the other party to demand compensation for the damage it has incurred, at the least a flat-rate contractual penalty of EUR 25,000.00 per individual breach. The right to file further compensation claims remains unaffected.



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## Section 7 Final provisions

1. All disputes arising from or in conjunction with this agreement are governed by German law. The application of the UN Convention on the Contracts for the International Sale of Goods (CISG) is excluded. The sole place of jurisdiction is the registered office of FALLER. FALLER, however, is also entitled to file in court in pursuit of their rights at the registered office of the CUSTOMER.
2. Unless otherwise agreed, the place of performance is the registered office of FALLER.
3. This agreement becomes valid when it is signed by both parties and applies for an indefinite period of time. It can be terminated by either party giving notice of 3 months to the end of the month. Notice of termination must be given in writing. The right to terminate the contract for cause remains unaffected.
4. Should individual provisions of this contract be or become invalid in their entirety or in part, the validity of the remaining provisions shall not be affected. The invalid or unenforceable provisions will be replaced by a legally permissible provision that comes closest to the commercial outcome of the invalid or unenforceable provision.

**[Customer]**

**August Faller GmbH & Co. KG**

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Place, date

Waldkirch, .....

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Company director

Dr. Daniel Keesman .....

.....  
Head of Quality Management

ppa. Bernd Bosch .....