Quality Assurance Agreement
for Suppliers

As at: 3 November 2015

between

Pöppelmann GmbH & Co. KG
Kunststoffwerk-Werkzeugbau
Pöppelmannstrasse 5
D-49393 Lohne

- hereinafter referred to as PÖPPELMANN FAMAC -

and

- hereinafter referred to as Supplier -

Preamble

PÖPPELMANN FAMAC is part of the globally operating group of companies Pöppelmann and is one of the leading manufacturers of plastic packaging and functional parts for the food, pharmaceutical, cosmetics and medical product industries. High-quality products form the basis of our commercial success and the quality of supplier products has a significant influence on this. Ensuring and consistently improving quality is a task taken on by all PÖPPELMANN employees and suppliers.

The management system of PÖPPELMANN FAMAC is in line with the requirements from DIN EN ISO 9001, DIN EN ISO 13485 and DIN EN ISO 14001 as well as the regulatory requirements (EU, USA) for pharmaceutical and medical technology products. Quality, hygiene and environmental protection are therefore of great importance across all of the business areas at PÖPPELMANN FAMAC and we expect corresponding behavior from our suppliers.

This Quality Assurance Agreement (hereinafter referred to as "QAA") designates and regulates all of the planned quality assurance measures between PÖPPELMANN FAMAC and the Supplier for deliveries to the company PÖPPELMANN, with the objective of ensuring product quality.

We regard our suppliers as partners. This QAA should help to avoid quality issues and ensure that processes run smoothly between the Supplier and PÖPPELMANN FAMAC while minimizing quality-related costs.

1. Introduction

1.1 Scope of Application

This QAA is valid for all products delivered by the Supplier on the basis of orders received and accepted from PÖPPELMANN FAMAC over the period of this agreement.
It is also valid for all products that the Supplier delivers to third parties on the basis of PÖPPELMANN FAMAC orders or PÖPPELMANN FAMAC specifications.
If the Supplier carries out or is involved in product development for PÖPPELMANN FAMAC, this agreement is also valid for all activities and results arising from these operations.

1.2 Specification

The products must fulfill the agreed specification (e.g. drawings, data sheets) and/or agreed samples. The Supplier will always check promptly whether the provided documents are clearly incorrect, unclear, incomplete or clearly deviate from the sample. If the Supplier sees that this is the case, he will inform PÖPPELMANN FAMAC immediately in writing.

2. Production / Provision of Services

2.1 Responsibility for Production

The Supplier is responsible for appropriate delivery of the products in line with specifications and quality standards, and, where appropriate, the use of any production equipment or products provided by PÖPPELMANN FAMAC and control of the production process.

2.2 Long-Term Availability of Source Materials/Raw Materials

The Supplier is responsible for ensuring the long-term availability of source materials and raw materials. Any changes must be reported in advance and in good time. Furthermore, the regulations from section 3.4 apply (Change Control).

2.3 Labeling and Traceability

The Supplier must adhere to the agreed drawing or specification in terms of product labeling and packaging. The labeling on the packaged products must also be visible during transportation and storage. Deviations from the labeling responsibilities require a written agreement.

The Supplier will use product/packaging labeling (or if labeling is not possible or unsuitable, other appropriate measures) to ensure that in the event of a product error, it is possible to immediately determine which other products/product batches may be affected.
The Supplier shall create complete, clear documentation which records the development of each manufactured product batch as well as all other facts that are relevant for product quality (batch documentation). This documentation must ensure traceability back to the source materials/raw materials used.
In the event of a quality issue, it must be possible to access batch and production data within one working day.

2.4 Production Conditions

The manufacture and packaging of the products must take place under clean, hygienic conditions. If required, special requirements such as particle loads or defined room classes shall be agreed in writing on a product-specific basis, e.g. in order specifications.

2.5 Premises and Equipment

The premises and equipment used by the Supplier, including utilities, must be appropriate and suitable for the manufacture of the products. For the manufacture, including quality control of the products, the Supplier shall guarantee that only qualified equipment is used and an appropriate maintenance and calibration program shall be implemented. Furthermore, the Supplier shall guarantee that products are not contaminated following maintenance and repair work.

2.6 Mix-Ups / Contamination

To avoid mixing up products with different geometries or identical geometries but different materials, appropriate measures must be put in place in terms of technical, organizational and premises requirements. This applies to product manufacture, inspections and the packaging process.
Production lines and workstations must be cleaned of previous materials before processing a new production order.

3. Quality Assurance

3.1 Quality Management System

The Supplier shall maintain a quality management system which meets the requirements of DIN EN ISO 9001 as a minimum and shall develop, manufacture and check the products according to the rules of this system.

The Supplier's quality management system may require other product-specific requirements (e.g. in accordance with DIN EN ISO 13485, GMP, food safety) which shall be agreed in writing (e.g. in an order specification).
The arrangement and function of the introduced quality management system must be proven with valid certificates issued by an accredited institution.
If the relevant certification is missing, the measures required to qualify the Supplier are agreed between the contractual partners in writing.
The Supplier will inform PÖPPELMANN FAMAC immediately if any significant changes are made to the quality management system and inform him of his certification status.

3.2 Main Contact Person concerning Quality

The contractual partners shall each name a Quality Assurance Officer in writing (Appendix 1) who must coordinate the execution of this agreement and make or lead any related decisions.
Other contacts for quality assurance at both the Supplier and at PÖPPELMANN FAMAC are named, both to manage critical quality processes and to guarantee that those responsible can be contacted to enable prompt troubleshooting.
Any changes to these contacts must be stated in writing.

3.3 Subsuppliers / Awarding Work to Third Parties (Subcontractors)

If the Supplier receives production or test equipment, software, services, materials or preliminary deliveries from subsuppliers for the manufacture or quality assurance of the products, these must be contractually included in the quality management system or he must assume personal responsibility for the quality of the deliveries.

If the Supplier intends to employ third parties to carry out contractually agreed work, whether in part or in full, this requires prior written agreement from PÖPPELMANN FAMAC.
If subcontractors are involved in relation to PÖPPELMANN FAMAC, the Supplier still bears sole responsibility for the fulfillment of all contractual duties. The Supplier is responsible for issues where the subcontractor is at fault in the same way as if it was his own fault.

3.4 Change Control

The Supplier shall inform PÖPPELMANN FAMAC in writing about any intended quality related changes to his quality management system or changes to his decisive production factors and gain written approval from PÖPPELMANN FAMAC prior to its implementation.
They should inform PÖPPELMANN FAMAC of intended or necessary changes in good time to enable checks to be made for any possible adverse effects.

Some of the changes requiring permission:

- Use of alternative materials or constructions
- Use of new or modified tools or replacement tools
- Changes to manufacturing methods or production processes
- Transfer of production, in terms of a site no longer being linked
- Use of new production equipment (e.g. machines, tools) even if production equipment is duplicated without changing the manufacturing procedure
- Changing subsuppliers (according to section 3.3), especially source material suppliers
- Changes to processes or equipment for checking products or other quality assurance measures

3.5 Deviations

The Supplier shall maintain a system to control deviations and enable the effective introduction and monitoring of corrective and preventative action (CAPA). This system must guarantee the collection and evaluation of internal and external quality information, the determination of error causes and the implementation of sustainable measures to eliminate error causes and avoid them reoccurring.

In the event of deviation from the agreed product or service specification (drawing, technical delivery conditions, specifications, raw materials, material properties etc.) or released processes, the Supplier can apply to PÖPPELMANN FAMAC for a written waiver to reduce damages before product delivery. In the interest of finding a quick solution, the Supplier is obliged to disclose all of the relevant data and facts.
The Supplier will then only continue production and deliver the affected products to PÖPPELMANN FAMAC after PÖPPELMANN FAMAC has issued such a written waiver. Products with a waiver must be specially labeled.
A one-off waiver only applies to the defined scope and has no effect on future deliveries that have not yet been recorded.
However, this does not release the Supplier from his responsibility for the quality of the products he produces. All of PÖPPELMANN FAMAC's rights concerning the delivery of defective goods remain untouched.

If products that are defective or suspected to be defective have already been delivered, PÖPPELMANN FAMAC must be immediately informed in writing. PÖPPELMANN FAMAC will assess the deviation and inform the Supplier in writing of the steps to be taken.

If either the Supplier or PÖPPELMANN FAMAC concludes that an event or a situation has occurred which requires the introduction of a recall campaign or warehouse clearance or the removal of the product from the market in order to ensure product safety, quality and production, then the Supplier and PÖPPELMANN FAMAC will contact each other immediately to determine which corrective measure should be introduced.
The final decision as to which measure shall be introduced lies with PÖPPELMANN FAMAC. PÖPPELMANN FAMAC will consider the interests of the Supplier appropriately when making his decision and the Supplier will support PÖPPELMANN FAMAC appropriately and as much as he can during the introduced measures.

3.6 Documentation

The Supplier shall maintain a system for steering documents and data which clearly and continuously documents the manufacturing procedure and specific product properties. It is particularly important to maintain transparency concerning changes to the products and their manufacturing processes.

3.7 Inspections / Audits

The Supplier will enable PÖPPELMANN FAMAC to monitor the implementation of the agreements contained in this QAA at appropriate time intervals and with a reasonable period of notice.
The Supplier shall allow employees of PÖPPELMANN FAMAC and/or representatives or customers of PÖPPELMANN FAMAC who are not competitors of the Supplier and are obliged to maintain confidentiality to carry out audits to inspect the production process, the quality assurance measures and the adherence to the specifications in this QAA. However, this does not release the Supplier from his responsibility for the quality of the products he produces. All of PÖPPELMANN FAMAC's rights concerning the delivery of defective goods remain untouched.
During this type of visit, the Supplier shall provide a professionally qualified employee as support.

On the basis of an audit report accepted by both parties, the Supplier promises to take corrective action if required. The Supplier shall grant PÖPPELMANN FAMAC the right to view audit reports from subsuppliers for the relevant contractual products.

The Supplier shall also declare his willingness to grant external auditors who are obliged to maintain confidentiality for professional reasons (e.g. authorities, test and certification bodies) the right to inspect the manufacturing premises and documentation and to inform PÖPPELMANN FAMAC of the inspection results and if necessary, of any corrective measures. The Supplier shall also guarantee the same for his subsuppliers.

4. Quality Checks

4.1 Inspection Equipment

The Supplier shall ensure that all of the inspection equipment required for the products produced for PÖPPELMANN FAMAC is always available and undergoes constant monitoring, calibration and maintenance.
If agreed in writing, the inspection equipment and methods must be jointly agreed between the Supplier and PÖPPELMANN FAMAC and a measurement comparison must be carried out if necessary.

4.2 Incoming Inspections at the Supplier

As part of their obligation to carry out an inspection upon goods receipt, the Supplier shall also check each batch of raw materials for properties affecting quality in order to guarantee that the identity of raw materials is correct. These inspections can be replaced by tests already carried out by the manufacturer/subsupplier for the same purpose, but a certificate must be presented as proof.

4.3 Initial Sample Inspections

Before the start of series delivery for the first time or after changes in accordance with section 3.4 (Change Control), the Supplier is obliged to send PÖPPELMANN FAMAC the affected products as an initial sample and provide a complete initial sample inspection report.
The number of initial samples, the initial sample procedure and the initial sample scope are agreed by the Supplier and PÖPPELMANN FAMAC in writing.
The products used for initial sampling must be manufactured under series production conditions.
Once the initial sample has been checked by PÖPPELMANN FAMAC and a positive release decision has been sent, the start of series production is considered approved on the part of PÖPPELMANN FAMAC.

4.4 In-Process Control (IPC)

To ensure that the product batches are qualitatively uniform, the production must be monitored using controls for process parameters and significant quality characteristics.
An inspection schedule must be created for each product/product family, containing information on inspection criteria, tolerances, inspection equipment, inspection methods, inspection frequency and release criteria.
Upon request, the Supplier shall allow PÖPPELMANN FAMAC to view the inspection schedules. If it is specifically stated in writing, the inspection schedules must be submitted as part of the initial sample inspection and approved by PÖPPELMANN FAMAC in writing.

The in-process controls are also proof of process capability. If necessary, the required process capability characteristics and parameters are defined in writing in the agreed product drawing or in additional agreements (e.g. order specification).

The results of the in-process control must be documented in a suitable form (CAQ system, error collection chart, control chart) and evaluated.

4.5 Final Tests/Goods Issue Inspections

Before dispatching the products, the Supplier shall ensure that the product meets the agreed requirements and specifications. The records from the in-process controls can be used for evaluation.
If necessary, other product-specific final tests are defined in writing.

4.6 Test Certificate / Acceptance Test Certificate

If agreed in writing, an acceptance test certificate as per DIN EN 10204/3.1 must be shown for each delivered production batch, showing that the quality of the delivered products meets the agreed specifications.
The information on the certificate must clearly reference the delivery and the delivered production batches.

4.7 Incoming Inspections at PÖPPELMANN FAMAC

Immediately after products have been received, PÖPPELMANN FAMAC will check whether they correspond with the amount and type ordered and whether there is any noticeable damage from transportation or noticeable exterior faults.

If PÖPPELMANN FAMAC notices any damage or faults during the inspections mentioned, he will report these to the Supplier immediately. If PÖPPELMANN FAMAC notices any damage or faults at a later point in time, they will report these to the Supplier immediately.

Other than the inspections and reports mentioned, PÖPPELMANN FAMAC has no further obligations to the Supplier.

4.8 Documentation of Inspection and Production Data

The Supplier shall maintain a documentation system which documents all recorded inspection and production data during each manufacturing stage.
These data must be retained for at least 15 years from the date of creation. Longer periods can be agreed in writing on a product-specific basis.

4.9 Retention Samples

For each batch, retention samples of source materials, intermediate products and products are retained in suitable quantities for a period of least 5 years.
If necessary, longer periods can be agreed in writing on a product-specific basis.

5. Packaging, Transportation and Delivery Scope

5.1 Packaging and Transportation

The delivery of the products takes place in containers suitable for transportation and storage which guarantee sufficient protection against any dirt or reduction in quality.
If agreed with PÖPPELMANN FAMAC in writing, specific packaging, labeling and transportation requirements must be adhered to.

5.2 Delivery Quantity

Delivery quantities can be requested via blanket orders or individual requests. The delivery quantity agreed on for a specific date must be delivered as a continuous delivery batch. Any deviations from this require prior written permission from PÖPPELMANN FAMAC.

5.3 Documentation

Each delivery must include a delivery note which clearly references the order and the delivered goods.
If agreed, a test certificate for each batch delivered is also part of the delivery scope (section 4.6).

6. Product Claims / Complaints

6.1 Acceptance Conditions

PÖPPELMANN FAMAC reserves the right to reject deliveries, either whole or in part, and to demand fault-free replacement deliveries immediately, especially if:

- It is noticed at the incoming inspection that an acceptance criterion as per the incoming goods inspection plan has been exceeded
- It is proved that provisions of this agreement and additional product-specific specifications have not been taken into account

Acceptance of the delivery by PÖPPELMANN FAMAC does not relinquish the Supplier from the responsibility to deliver replacements for faulty units (within legal regulations) if discovered at a later date.

6.2 Complaint Measures

Complaints must be processed by the Supplier in the form of an 8D report and submitted to PÖPPELMANN FAMAC as a written statement within 10 working days. Immediate measures must be communicated via fax or e-mail within one working day and agreed upon with PÖPPELMANN FAMAC.
If it is not possible to issue the concluding statement within 10 working days, an immediate, informal message must be sent to PÖPPELMANN FAMAC with information on the status of the complaint process.
The Supplier receives information from PÖPPELMANN FAMAC which details whether the faulty goods can be conditionally processed, sorted or reworked, or if they must be scrapped. If the Supplier allows third parties to carry out work, this does not exempt him from the briefing, material planning and required replacement delivery.

7. Warranty

In the event of a defective delivery, PÖPPELMANN FAMAC is entitled to all statutory warranty rights. The warranty period is 60 months, starting from delivery.

8. Confidentiality

Each contractual partner shall use the documentation and knowledge received from the other partner within this agreement only for the purposes of this co-operation, and shall keep them confidential from third parties with the same care as they would apply to their own documentation and knowledge.
This obligation does not apply to documentation and knowledge which is common knowledge or was already known to the contractual partner at the time of receipt without being subject to confidentiality, or which was subsequently transferred by a third party authorized to pass it on, or was developed by the receiving contractual partner without the use of confidential documents or knowledge from the other contractual partner.

9. Product Liability Insurance

Proof of product liability insurance covering an adequate amount and including cover for the cost of recall campaigns is an important prerequisite for being employed as a supplier of PÖPPELMANN FAMAC. The supplier must immediately provide PÖPPELMANN FAMAC with appropriate proof in the form of a valid insurance coverage confirmation.

10. Duration of the Agreement

This QAA comes into force upon its signature by both contractual partners. It is valid indefinitely. However, it can be terminated in writing by both of the contractual partners within a period of three months before the end of a calendar year and replaced with a new version acknowledged by the Supplier. The termination of this agreement does not exempt the Supplier from their duties to uphold the QAA for existing delivery contracts until they have been processed fully.

11. Changes and Additions to the Agreement

Changes and additions to this agreement must be in writing and signed by both contractual parties. This also applies to the requirement for the written form as mentioned above.

12. Severability Clause

If individual provisions in this contract are or become ineffective or invalid, this shall not affect the validity of the remaining provisions of this contract.
PÖPPELMANN FAMAC and the Supplier are obliged to replace ineffective or invalid provisions with new provisions which fulfill the economic regulatory content contained in the ineffective or invalid provisions in a legally permissible manner. In the event of a loophole in the contract, the same applies. To close the loophole, the contractual partners are obliged to establish appropriate regulations which come as close as possible to what the contractual parties would have intended in terms of the agreement's meaning and purpose, had they considered this point.

13. Applicable Law and Place of Jurisdiction

This agreement is subject to the law of the Federal Republic of Germany. The application of the United Nations Convention on Contracts for the International Sale of Goods (CISG) is excluded. The place of jurisdiction is the headquarters of PÖPPELMANN FAMAC.

Place Date

Supplier

Lohne,

Pöppelmann

Appendix 1

Main Contact Person Concerning Quality

Person responsible at the Supplier

Role	Name	Telephone	E-mail
Quality Management (QM Officer)			
Quality Management Representative			
Quality Assurance, Quality Control			
Quality Assurance Representative			

Person responsible at Pöppelmann

Role	Name	Telephone	E-mail
Quality Management (QM Officer)			
Quality Management Representative			
Quality Assurance, Quality Control			
Quality Assurance Representative			