



DARE

TO GO FOR QUALITY

(QAA)
ONTEX SUPPLIER QUALITY AGREEMENT

WE DARE TOGETHER *Ontex*

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1.1 OUR SUPPLIERS

Ontex recognizes the very important role of our suppliers towards the quality we offer our consumers and customers.

We rely on our suppliers to provide products and/or services to meet all the requirements as stated in our agreed specifications.

In addition to these, please find the Ontex supplier quality requirements as outlined in this document.

1.2 PURPOSE

The purpose of this document is to inform Ontex suppliers of the core requirements we have regarding the supplier's Quality Management Systems (QMS).

1.3 SCOPE

This document applies to all suppliers providing Ontex with products and/or services purchased by and delivered to Ontex by the supplier or by any of its affiliates or sub-contractors.





Suppliers shall maintain a Quality Management System (QMS) suitable to the products and services provided to Ontex, that is certified by an accredited third-party certification body to the latest version of the following international standard:

ISO 9001 – Quality Management Systems Requirements

The supplier will notify Ontex of any changes to the third-party certification maintained by the supplier.

In absence of a third-party certification, depending on the product or service, its application, value and criticality, Ontex may authorize other evidence of compliance. This may include a second-party (Ontex) audit or a first-party (self) assessment to the applicable criteria above.

2.1 QUALITY MANUAL

Upon request the supplier shall present Ontex a copy of the supplier's Quality Management Systems Manual, which is to be current and approved by the supplier's management, including or referring to related documents.

The Quality Management System Manual shall include supplier's statements of a quality policy and objectives. Top management shall define quality objectives and measurements which should address customer expectations and be achievable within a defined period.

The supplier shall promptly notify Ontex of any relevant change to the supplier's quality management system or personnel.



2 QUALITY MANAGEMENT SYSTEM REQUIREMENTS



2.2 MANUFACTURING CHANGES (CHANGE CONTROL):

The supplier shall notify Ontex of their intention to make any change that may affect the safety, quality, security, shelf-life, ingredient statement or functionality of the products and/or services delivered to Ontex– such as changes in material formula, raw materials, production line, production facility or processes.

This applies to all changes except minor process optimization and minor maintenance changes that have no impact on the quality and/or functionality of the delivered products and/or services.

Ontex shall be notified in a timely manner (at least 3 months prior to implementation, preferably 6 months) of such changes in writing.
Ontex will assess whether a new approval is needed before implementation.

2.3 PRODUCT AND/OR SERVICE DISCONTINUATION:

The supplier shall notify Ontex in writing twelve (12) months prior to discontinuation of a product or a service.

2.4 SPECIAL CERTIFICATIONS:

If Ontex requirements include specific product certifications (such as Organic, FSC, ...) this certification shall be valid in the country the products or services will be delivered.

2.5 RECORD RETENTION

The supplier shall identify and maintain records to demonstrate effective implementation of the Quality Management System. Records must be legible and authentic. Procedures necessary for identification, storage, protection, retrieval, retention and disposal of these records shall exist.

The supplier shall retain quality records for at least 5 years after production.
Upon request the supplier shall be capable of retrieving and delivering required records to Ontex within one working day from time of request by Ontex.

2 QUALITY MANAGEMENT SYSTEM REQUIREMENTS

2.6 IDENTIFICATION AND TRACEABILITY

The supplier shall establish and maintain procedures that allow the traceability of products and the raw materials/components used in production. Relevant production batches shall be identified, permitting realistic recalls and product redrawals.

This procedure shall be documented and tested regularly. (at least annually)

2.7 RETENTION SAMPLE

The supplier shall take a representative sample of each delivered batch and store this in appropriate conditions for at least 12 months.

2.8 CONTROL OF SUB-CONTRACTORS

When the supplier uses sub-suppliers to produce products or deliver services to Ontex, the supplier shall include in the sub-suppliers' contracts, all the applicable technical and quality requirements contained in the Ontex contract, including quality system requirements, regulatory requirements and the requirements to document and control "key-processes" and to furnish certifications and test reports as required.

The sub suppliers' contract shall also include the right of entry to sub-contractor's facilities by Ontex and its customers.



2 QUALITY MANAGEMENT SYSTEM REQUIREMENTS



Ontex requires all suppliers to be approved prior to the issuance of contracts. All suppliers must be approved by Ontex, regardless of approvals by customers or other entities.

Approval is mandatory for each individual production plant. Production of specified materials is limited to the agreed production facilities and cannot be shifted to other production facilities or subcontractors without prior written approval by Ontex.

The supplier approval process may include the following:

- **Supplier Initial Assessment**

Ontex may request the supplier to provide a copy of its quality management system certificate and/or complete a self-assessment of its business and quality management system.

- **Documentation Audit**

In those cases where a supplier's quality management system has not been certified by an accredited certification body, Ontex may request a copy of the supplier's quality documentation and supporting procedures (including internal audit reports) to determine if the supplier's Quality Management System meets Ontex requirements.

- **On-site Assessment (audit)**

Ontex may elect to conduct an on-site assessment of a supplier product or process capabilities. In this case Ontex will inform the supplier giving reasonable prior written notice. The supplier shall allow Ontex and – if required – its customers, consultants, representatives access to the production site and production facilities, testing centres and warehouses. During this on-site assessment all quality relevant reports and all procedures that guarantee quality of the product or services delivered to Ontex shall be available for consultation.

Ontex will inform the supplier about the results of these audits.

Approval will only be given, providing the supplier can present a corrective action/preventive action (CAPA) plan within 28 calendar days.

Documented proof of implementation can be requested.

3 SUPPLIER APPROVAL PROCESS



4.1 GENERAL

All non-conformities communicated by Ontex require a Corrective and/or Preventive action plan. The supplier shall perform a root-cause analysis and have an effective CAPA program to ensure that non-conformities are addressed in a timely and appropriate manner.

An effective CAPA program shall include the following steps:

- Identification of CAPA opportunities.
- Determination of immediate action(s) to be taken (including responsibility and timing).
- Root cause analysis and quantification of the problem (prioritization).
- Identification of long-term (permanent) solutions (including responsibilities and timing). When required, resources (e.g., personnel, equipment) must also be identified.
- CAPA plan implementation.
- Further analysis of data to validate if the desired results were achieved (e.g. was the plan effective in resolving the root cause).
- Periodic review of CAPA by the management team.
- The CAPA program shall include procedures for analysis of effectiveness of corrective actions.

4.2 REWORK

Rework (corrections) on rejected products may only be executed by the supplier if agreed by Ontex. The release of the reworked material should be done by QA at the supplier.



4 CORRECTIVE AND PREVENTIVE ACTION (CAPA)



Ontex maintain an Incident (1) & Crisis (2) Management program in order to manage any quality failures that could impact negatively on our Customers or Consumers.

A vital principle of this Incident & Crisis Management program is the involvement and engagement of our Suppliers and Partners within our Value Chain, at the earliest opportunity and in a timely manner. The earlier we are notified of non-compliance to our quality specifications, the earlier we can trigger the appropriate response. Speed is vital if there are any possible safety or harmful outcomes related to a raw material or production defect.

We expect Suppliers and Partners to notify Ontex, at the appropriate level and speed, when there are variances to our quality agreements, that could possibly impact our manufacturing processes and that in turn could adversely affect our products when released to our Customers and Consumers.

To facilitate this notification, we would expect any supplier or Partner in the Value Chain to:

- 1.** Have a nominated, named individual(s), accountable for notifying Ontex of any potential incident or crisis, at the earliest opportunity. This cover should be 365 days a year, 24 hours a day. This would require a robust process that can cover individual absence from the business, such as holidays, sickness or working away.
- 2.** The nominated individual understands the Ontex Incident and Crisis Management process – See attached Annex A. Members of the Ontex Quality Management function are available to coach Partners and Suppliers on the Incident & Crisis Management process during our routine interactions throughout the year.
- 3.** Deploy your own internal systems to advise Ontex at the earliest opportunity and never longer than 24 hours (1), of an incident that could impact on the safety of any Ontex product.

5 INCIDENT AND CRISIS MANAGEMENT REQUIREMENTS

4. In some significant Crisis situations, Ontex may request the exchange of liaison people to co-locate with Ontex and/or at the Supplier/Partner location, in order to speed up decision making and ensure accuracy of data.
5. Implement a Communication Protocol during any Incident or Crisis notified to/from Ontex. This is to ensure accuracy of facts and to meet any legal requirements on behalf of the Ontex stakeholders. The Communications protocol requires: No-one releases any comments, information, or data related to the Incident or Crisis to the media or on social media, without the written permission of the Director of Communications at Ontex. This will include all your employees, given the nature and 'reach' of social media platforms and you may wish to consider internal reminders of this requirement, if a Crisis is ever declared.

Notes:

- An Incident is defined as a departure from the quality specification that could impact on the quality of an Ontex product released to Customers or Consumers.
- A Crisis is defined as the release of an Ontex product to a Customer or Consumer that is defective and could cause harm to a Customer's brand or to a Consumer.
- Incidents can escalate to a crisis level, even though they will never harm consumers, simply because the size and scale of the incident, that would damage Ontex or a Customer's brand.



5 INCIDENT AND CRISIS MANAGEMENT REQUIREMENTS

ANNEX A to the Incident & Crisis Management

Quality Agreement

Incident & Crisis Management Process

Incident Management Process



Crisis Management Process



Notes:

- The Incident management process Local Risk Assessment determines whether there are any safety factors that would require the decision making to be escalated in to the Crisis Management process.
- If an incident is escalated and requires a Crisis Response Strategy, the level of decision making is upgraded to the Crisis Management Team that is Chaired by the COO of Ontex.

- At this stage a variety of protocols are triggered and Ontex would expect a similar level of commitment and speed of response from Suppliers and Partners in the Value Chain.
- It is important to stress: A Crisis is an unusual event, but it will require our Suppliers and Partners to respond to requests and support urgently. Ontex will always set the expectation of speed of response, set by the scenario of the crisis.

5 INCIDENT AND CRISIS MANAGEMENT REQUIREMENTS

6 CHANGES AND AMENDMENTS

Changes and amendments to this document can only be accepted upon mutual written agreement between Ontex Quality Department and the supplier.

7 SUPPLIER ACKNOWLEDGEMENT

The supplier hereby confirms reception and acceptance of the Ontex Supplier Quality Agreement as described in this document.

8 DOCUMENT HISTORY

Version	Date	Reason for change
0	14/04/2017	Initial Release
1	05/02/2019	First review

Company: _____

Printed name: _____

Title: _____

Date: _____

Signature: _____