Quality Agreement for Subcontractor

Commented [AES1]: This agreement must be used when a subcontractor performs certain processes instead of the manufacturer. It can be the whole production, some part of the production process (sterilization, packaging, plasticization), or some special part of the final product.

[illegible]

[illegible]

Between ("Subcontractor")

Name of the Subcontractor	
[illegible]	
[illegible]	

Commented [AES2]: Include your supplier's information.

and ("Manufacturer")

Name of the Manufacturer	
[illegible]	
[illegible]	

Commented [AES3]: Include your organization's information.

1. Administrative Elements

1.1. Scope

This agreement defines the Quality Agreement between the parties identified above. [illegible]

1.2. Processes Covered by this Agreement

This agreement applies to the processes listed in the table below.

Process	[illegible]

Commented [AES4]: As processes, you can include production of a medical device, production of a special part of the medical [illegible]

[illegible]

1.3. Terms of the Agreement

This agreement shall become effective and binding upon the date of the final signature. This agreement shall be effective for all orders present and in the future, that will be confirmed before the termination of this agreement. [illegible]

Commented [AES5]: Adapt to the organization's practice.

Changes or additions to this agreement require a written form in order to be effective.

2. Compliance for Subcontractors that are not Certified According to Harmonized ISO 13485

Commented [AES6]: Use this section if the subcontractor is not

2.1. Processes

Subcontractor agrees to perform the processes stated in point 1.2 of this agreement in accordance with harmonized ISO 13485 [and other relevant standards].

Commented [AES7]: You can delete this part, or include other

[illegible]

2.2. Changes in Processes

Subcontractor shall promptly notify Manufacturer of changes in the processes so the Manufacturer [illegible]

2.3. Activity by Regulators, Notified Bodies, or Certification Bodies

Subcontractor shall promptly notify the Manufacturer of any inspection or audit findings that impact the safety, effectiveness, or conformity of processes Subcontractor provides to Manufacturer.

[illegible]

2.4. Third-Party Quality Agreements

Subcontractor shall have a Quality Agreement with Third-Party Subcontractors used for production, packaging, testing, processing, or release. [illegible]

3. Compliance for Subcontractors that are Certified According to Harmonized ISO 13485

Commented [AES8]: Use this section if the Subcontractor is

3.1. Processes

Subcontractor agrees to perform the processes stated in point 1.2 of this agreement in accordance with harmonized ISO 13485 [and other relevant standards].

Commented [AES9]: You can delete this part or include other

The Subcontractor undertakes to effectively maintain its Quality Management System in accordance with ISO 13485, to regularly conduct audits with a recognized Certification Body, and to notify the Manufacturer of major and minor nonconformities raised during these audits.

[illegible]

Commented [AES10]: Delete if any of the regulations do not

The Subcontractor agrees to notify the Manufacturer immediately in the event of a suspension of the ISO 13485 certificate.

3.2. Changes in Processes

Subcontractor shall promptly notify Manufacturer of any changes in the processes stated in point 1.2 of this agreement, so the Manufacturer may determine whether the changes may affect the quality of a finished device.

3.3. Activity by Regulators, Notified Bodies, or Certification Bodies

Subcontractor shall promptly notify the Manufacturer of any inspection that impacts the safety, effectiveness, conformity, or availability of processes Subcontractor provides to Manufacturer.

Upon the Manufacturer's request, Subcontractor shall disclose the results of any inspections or audits and the associated cause and corrective action.

3.4. Third-Party Quality Agreements

Subcontractor shall have a Quality Agreement with Third-Party Subcontractors used for production, packaging, testing, processing, or release. Upon Manufacturer's request, the Subcontractor will provide a copy of the Quality Agreement.

4. Nonconformance, Corrective and Preventive Measures, and Complaints

4.1. Corrective Actions

4.1.1. Subcontractor-Initiated Corrective Action

Subcontractor shall initiate corrective action for all detected nonconformities regardless of disposition. Corrective action shall be processed according to Subcontractor's corrective action procedure.

Subcontractor shall keep records of corrective actions and detected nonconformities and make them available to the Manufacturer upon request.

4.1.2. Manufacturer-Initiated Corrective Action

If the Manufacturer identifies a nonconformity after receipt of the Subcontractor's product and service, the Manufacturer will initiate corrective action according to the Procedure for Corrective and Preventive Action and inform Subcontractor about it.

Subcontractor will be involved in investigating the cause and proposing the corrective action. Subcontractor shall report the results of the corrective action to the Manufacturer within [number of days] working days of initiation. When the corrective action is not completed within [number of days] working days, the Subcontractor shall provide a status report every [number of days] working days until the corrective action is completed, but not to exceed 6 months. Subcontractor shall keep records of these activities and make them available to the Manufacturer upon request.

Commented [AES11]: Choose the one that applies, or both if

Commented [AES12]: You can find a template for this

Commented [AES13]: Insert a number of days that is

Commented [AES14]: Insert a number of days that is

Commented [AES15]: Insert a number of days that is

4.2. Complaints

4.2.1. Subcontractor-Received Complaints

If the Subcontractor receives a complaint related to the process, or a product/service, Subcontractor shall promptly notify the Manufacturer.

[illegible]

4.2.2. Manufacturer-Received Complaints

If the Manufacturer receives a complaint related to the process of the Subcontractor, the Manufacturer will enter the complaint in Customer Feedback Report and review and evaluate the complaint to determine whether an investigation is necessary according to the Procedure for Customer Communication, Feedback and Complaints.

[illegible]

Commented [AES16]: You can find a template for this [illegible]

Commented [AES17]: You can find a template for this [illegible]

5. Audits

5.1. Manufacturer Audits of Subcontractor's Facilities

The Subcontractor shall allow the Manufacturer, or its authorized representative, to perform audits of the Subcontractor's facilities, systems, documentation, and other requirements related to this agreement. Audits shall be conducted at mutually agreed dates and times.

[illegible]

Commented [AES18]: Insert a number of days that is [illegible]

[illegible]

Commented [AES19]: Insert a number of days that is [illegible]

5.2. Auditing Subcontractor by Manufacturer's Notified Body

The Subcontractor shall allow the Manufacturer's Notified Body to perform audits of the Subcontractor's facilities, systems, documentation, and other requirements related to this agreement.

[illegible]

Date	Date
[redacted]	[redacted]
Signature	Signature

Commented [AES20]: Enter the name and the job title of the [redacted]

Commented [AES21]: Enter the name and the job title of the [redacted]