Supplier Quality Agreement

The Supplier Quality Agreement defines the expectations of Mevion Medical Systems related to supplier performance to ensure that Supplier products and/or services satisfy the Quality and Regulatory requirements identified in this agreement and related Purchasing Information. Both parties agree to cooperate in the success of this agreement. Supplier agrees to meet or exceed all requirements and guidelines defined in this document.

Quality Management System

If Supplier is a manufacturer or distributor of medical devices, then Supplier must maintain a Quality Management System that conforms to the requirements of the FDA's Quality System Regulations, ISO 13485, and ISO 14971. European Suppliers must also comply with CE Marking requirements of the Medical Device Directive (MDD) / Medical Device Regulations (MDR), as appropriate. Confirmation of certification and updates shall be provided to Mevion.

If the Supplier is not a manufacturer or distributor of medical devices, then Supplier shall establish and maintain a Quality Management System consisting of quality best practice processes, as relevant to Supplier's industry. Upon request, Supplier shall provide evidence of QMS controls and records of compliance upon Mevion's request.

Product Specifications and Requirements

If Supplier is intended to deliver custom, made-to-order, or configured products or services, then the following apply:

- Mevion shall define the requirements and/or specifications for the product to be provided by the Supplier. These defined requirements and/or specifications could take many forms, including drawings, formal requirements or specifications documents, reference to commercial specification or catalog numbers, etc. These requirements and/or specifications may be provided in hardcopy, electronic, or other appropriate medium or format.
- Changes to requirements or specifications are made by mutual agreement between Mevion and Supplier. In addition to the agreement to make the change, the parties will agree upon the effective date of the change.

Process Controls

Mevion expects Supplier to maintain the following QMS controls:

Equipment / Test Equipment

Supplier shall ensure that all equipment used in the manufacturing process for product is appropriately designed, constructed, installed, calibrated, and operated. Supplier shall develop, maintain, and comply with schedules for adjustment, cleaning, calibration, and all other required maintenance. Supplier shall maintain records of these activities and make them available to Mevion upon request.

Automated Processes / Software

If Supplier uses computers, software, or other automated methods as part of its production process, then the Supplier shall validate the computers, software, or other automated methods to ensure ability to fulfill intended use and meet quality requirements and specifications. Changes or upgrades shall be validated prior to implementation. Supplier shall maintain records of these activities and make them available to Mevion upon request.

Employee Training

Supplier shall ensure that employees are competent to perform work responsibilities per defined Mevion requirements and specifications.

Declaration of Conformity

If required by Mevion per product requirements or specifications, Supplier shall execute a Declaration of Conformity (DOC) with each product or batch of product delivered to Mevion. The Declaration of Conformity shall be a formally executed conclusion of satisfaction of requirements or specifications based upon defined performance requirements and/or measured or tested performance.

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Required Notifications

Regulatory Activities
The Supplier shall promptly notify Mevion of the performance and results of any inspections, audits, formal visits, etc. of any regulator, notified body, or other certification body acting in a formal capacity. The Supplier shall promptly notify Mevion of any inspection or audit findings that impact the safety, effectiveness, conformity, availability, or quality of any product that the Supplier provides to Mevion.

Change Requests
Supplier and Mevion shall mutually evaluate and conclude the appropriateness of change Requests. Mevion remains ultimately responsible for product design requirements and specifications. Acceptable changes shall be documented as formal specifications and/or requirements revisions and communicated to Supplier. For acceptable changes, Supplier and Mevion will work together to develop a plan to implement the change.

Deviations
If the supplier needs to deviate from a requirement or specification, the Supplier shall document the deviation request, including the specific deviation, the reason for the deviation, and period of applicability of the deviation. In response, Mevion will consider the acceptability of the deviation and, if acceptable, shall document such deviation in pertinent Purchasing Information. If Mevion concludes the deviation is unacceptable, the parties will work together to redress the cause of the deviation.

Adverse Event Reports / Corrections and Removals
If the Supplier files FDA or other foreign Adverse Event Report, Correction and Removal / Field Safety Corrective Action Report, or initiates any form of field corrective activity, Supplier shall provide Mevion with copies of the reports and any Corrective Action documentation. Supplier and Mevion shall work together to manage any Corrective Action associated with nonconforming or otherwise afflicted product.

Disposition of Nonconforming Material
Supplier shall segregate, investigate, and disposition all nonconforming material. The Supplier must seek Mevion concession or repair disposition to remediate nonconforming materials. If Supplier requests authorization for a repair or concession disposition, Supplier shall formally document and request the disposition in writing. Mevion shall consider disposition within its Nonconforming Materials process and return the documented disposition conclusion to Supplier.

Corrective Action
When requested by Mevion, based upon reported or discovered nonconformity to requirements or specifications, Supplier shall initiate Corrective Action to mitigate and remediate the cause of the nonconformity. Corrective Action shall include determination of root cause, the need for action to prevent recurrence, the action to be taken to prevent recurrence, implementation of the correction, and review of the effectiveness of the corrective action. Supplier shall communicate Corrective Action plans and updates of progress to Mevion every two weeks until completion.

Supplier Audits
For the purposes of Supplier Qualification or for cause to identify root cause or corrective action necessary to address performance nonconformities, Supplier shall permit Mevion to conduct Supplier Audits of its operations, personnel, and documentation. Mevion shall submit notification and audit strategy information to Supplier in advance of the audit and shall take all necessary steps not to unduly interfere with the performance of Supplier's business operations. Mevion shall provide an audit report within two weeks of completing a Supplier Audit and issues any formal requests for Corrective Action, based upon evidence-based findings. Supplier shall respond within two weeks with a Corrective Action plan to address the nonconformities and timeline for completion.

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