



## ISO 13485:2016 Supplier Flow Down Requirements

*Version 2020-06-12 Approved by Xiomara Perdomo, Director of Quality*

THE SUPPLIER REQUIREMENTS BELOW APPLY TO ALL SUPPLIERS AND SUB-TIER SUPPLIERS TO PRECISION ADM INC. (PADM) PROVIDING MATERIALS AND SERVICES WITH RESPECT TO PADM'S ISO 13485 COMPLIANT MANUFACTURING. ACCEPTANCE OF A PURCHASE ORDER FROM PADM BINDS THE SUPPLIER TO THE REQUIREMENTS LISTED IN THIS DOCUMENT. THE SUPPLIER IS NOT AUTHORIZED TO OUTSOURCE ANY PORTION OF THE PURCHASE ORDER REQUIREMENTS UNLESS SPECIFICALLY AUTHORIZED BY PADM AND SHALL FLOW DOWN THESE REQUIREMENTS TO ANY SUB-TIER SUPPLIERS. NOTE THAT THESE REQUIREMENTS CORRESPOND WITH THE REQUIREMENTS OF PADM'S CUSTOMERS AND WITH THE REQUIREMENTS OF ISO 13485, CLAUSE 7.4.2.

**A.** PADM's Purchase Order provides information on the processes, products, and services to be provided including the identification of relevant technical data (e.g., specifications, drawings, process requirements, work instructions).

**B.** Each supplied order shall be accompanied by one legible copy of a certificate of analysis (C of A) or certificate of Compliance (C of C). Material certifications shall show quantitative analysis of each element and physical testing as required by specifications referenced. Traceability for Raw Material is required and shall be retained and provided to PADM with product. Final acceptance of product shall be at PADM after receiving inspection.

**C.** The Supplier shall ensure that employees and people working on its behalf are competent and trained in accordance with the requirements of ISO 13485 or ISO 9001, where applicable.

**D.** In addition to the other requirements recorded within this document, Suppliers shall hold all information received from PADM in confidence and no third-party request for information shall be authorized unless approved, in writing, by PADM. The Supplier shall not implement any changes to drawings, specifications, materials, and/or processes without written approval from PADM.

**E.** PADM shall review Suppliers based on Quality, Delivery, and/or Service. Suppliers shall be issued corrective actions as required. Supplier late shipments and corrective actions shall be reviewed at Management Review meetings for increased action at

Management's discretion. Suppliers that fail to perform in these areas may receive further Corrective Actions and may be considered for probation or removal from PADM's supplier list.

**F.** PADM and its customers reserve the right to perform verification and/or validation activities at the Supplier's premises.

**G.** The Supplier is responsible for the validation, and periodic revalidation, of the ability to achieve planned results of the processes for production and service provision, where the resulting output cannot be verified by subsequent monitoring or measurement

**H.** All gauges and instruments used to verify product shall be calibrated using standards whose accuracies are NIST traceable. All provided calibration certifications shall specifically state this traceability. The Supplier shall maintain a quality / inspection system that shall ensure all goods and services conform to contract requirements whether manufactured or processed by the Supplier or procured from Sub-Tier Suppliers.

**I.** The Supplier shall use a sampling plan for product acceptance, consistent with typical industry standards, unless otherwise specified or agreed upon in writing by PADM.

**J.** When specifically requested by PADM in writing, the Supplier shall maintain a quality management system in compliance to ISO 13485 or ISO 9001 that is certified by an accredited third-party certification body to the latest revision.

**K.** When required by PADM or its customers, Suppliers shall use customer-specified sources. The Supplier shall notify PADM of nonconforming processes, products, or services and obtain approval for their disposition. To prevent the purchase of counterfeit or suspect / unapproved products and to ensure product identification and traceability, the Supplier shall institute controls that include staff training on the effect and identification of counterfeit / suspect parts, the requirement of Material Certificates, Certificates of Conformity, and/or other supporting documentation as appropriate. Material and part substitutions are not allowed. The Supplier shall notify PADM of any change in ownership, management, location, product, or process that affect PADM's product or services. When requested by PADM or its customers, the Supplier shall provide test specimens for inspection / verification, investigation and/or auditing purposes. Unless otherwise specified on the Purchase Order, the latest specification revision in effect at the time the lot of raw material/parts was originally manufactured or processed shall apply. In the event a document has been superseded, the latest revision of the superseding document shall apply. All certifications, test reports, and inspection reports, as well as receiving inspection, in-process inspection, final inspection, and calibration records shall be retained for a minimum of five years, unless otherwise specified by PADM, and shall be made available to PADM, its customers, or regulatory agency upon request.

**L.** Suppliers shall flow-down to Sub-Tier Suppliers the applicable requirements as required by the purchase order either specifically or by reference.

**M.** PADM and its customers reserve the right to perform an on-site inspection of the Supplier's facility or visit the facility. PADM

shall give reasonable notification to the Supplier prior to the on-site inspection. The on-site inspection may include surveillance of the Supplier's facilities, procedures, production methods, processes, and the Supplier's Quality Management System. The Supplier shall furnish, at no cost, the necessary data as required by applicable Purchase Orders, specifications, and inspection instructions to facilitate the on-site inspection.

**N.** The Supplier shall be committed to the highest standards of ethics and business conduct, and shall comply with the law, honor commitments, act in good faith, and be accountable. The Supplier shall not offer, promise, authorize, or provide, directly or indirectly, anything of value (including business gifts or courtesies) with the intent or effect of inducing anyone to engage in unfair business practices and shall avoid involvement in activities that may be perceived as a conflict-of-interest. The Supplier shall respect the legitimate proprietary rights and intellectual property rights of customers and Suppliers and take proper care to protect sensitive information, including confidential, proprietary and personal information. The Supplier shall support product safety by ensuring robust management of special requirements, critical items, and key characteristics. If there are concerns with respect to product safety, the Supplier shall communicate them to PADM. The Supplier shall ensure that employees and people working on its behalf are aware of their contribution to product or service conformity, their contribution to product safety, and the importance of ethical behaviour.

**O.** Unless otherwise specified, the Supplier shall use best commercial practices for preservation and packaging for all items supplied