

PURCHASE ORDER TERMS AND CONDITIONS

Acceptance - Agreement. Seller's commencement of work on the goods and/or services subject to this purchase order or shipment of such goods, whichever occurs first, shall be deemed an effective mode of acceptance of this purchase order. Any terms proposed in Seller's acceptance of Purchaser's offer which add to, vary from, or conflict with the terms herein are hereby objected to and rejected, but such proposals shall not operate as a rejection of this offer, unless such variances are in the terms of the description, quantity, price or delivery schedule of the goods and/or services, but shall be deemed a material alteration thereof, and this offer shall be deemed accepted by Seller without said additional or different terms. If this purchase order has been issued by Purchaser in response to an offer and if any of the terms herein are additional to or different from any terms of such offer, then the issuance of this purchase order by Purchaser shall constitute an acceptance of such offer subject to the express condition that Seller assents to such additional and different terms herein and acknowledges that this purchase order constitutes the entire agreement between Purchaser and Seller with respect to the subject matter hereof and the subject matter of such offer, and Seller shall be deemed to have assented and acknowledged unless Seller notified Purchaser to the contrary in writing within ten (10) days of receipt of this purchase order and Purchaser, in writing, acknowledges its acceptance of the variance of terms. In the event purchase orders are sent via facsimile, Purchaser shall have no liability for orders erroneously placed upon Seller due to the malfunction of the facsimile data processing equipment. Purchaser will pay for goods provided hereunder pursuant to Purchaser's standard payment terms.

Delivery of Goods and Risk of Loss. Unless otherwise stated on the face of this purchase order, Seller shall arrange for the delivery of goods and bear all risk of loss until the goods are delivered to Purchaser's plant or facility. Shipment shall be made by Seller to Purchaser in accordance with a delivery date provided by Purchaser's ordering location. Seller shall notify Purchaser within 3 hours of receipt of any order if it cannot comply with the schedule supplied by Purchaser. For all goods delivered, Seller must provide the name and address of the manufacturer (if Seller is not the actual manufacturer), the part number, and the manufacturing batch/lot number of the goods being purchased.

Termination. Purchaser reserves the immediate right to terminate this order or any part hereof for its sole convenience. In the event of such termination, Seller shall immediately stop all work hereunder, and shall immediately cause any of its suppliers or subcontractors to cease such work. Seller shall be paid a reasonable termination charge consisting of a percentage of the order price reflecting the percentage of the work satisfactorily performed prior to the notice of termination. Seller shall not be paid for any work done after receipt of the notice of termination nor for any costs incurred by Seller's suppliers or subcontractors which Seller could reasonably have avoided. Purchaser may also terminate this order or any part hereof for cause in the event of any default by the Seller, or if the Seller fails to comply with any of the terms and conditions of this order. Late deliveries, deliveries of products which are defective or do not meet specifications or do not conform to this order, oversupplies and undersupplies of more than 5%, and/or failure to provide Purchaser, upon request, of reasonable assurances of future performance, shall all be causes allowing Purchaser to terminate this order for cause. In the event of termination for cause, Purchaser shall be liable to Seller for goods and/or services that comply with the terms and conditions of this purchase order and any corresponding specifications and Seller shall be liable to Purchaser for any and all damages, including but not limited to damages and expenses incurred, including consequential damages, by reason of the default which gave rise to the termination.

Proprietary Information - Confidentiality-Advertising. Seller shall consider all information furnished by Purchaser to be confidential and/or proprietary and shall not disclose any such information to any other person, or use such information itself for any purpose other than performing this contract, unless Seller obtains written permission from Purchaser to do so. This paragraph shall apply to drawings, specifications, or other documents prepared by Seller for Purchaser in connection with this order. Seller shall not advertise or publish the fact that Purchaser has contracted to purchase goods and/or services from Seller, nor shall any information relating to the order be disclosed without Purchaser's written permission. Seller expressly disclaims to Purchaser any and all interest in any intellectual property and/or know-how ("IPR") created under this purchase order which contain or are based upon Purchaser's confidential and/or proprietary information. All such IPR shall belong (and is hereby assigned to) Purchaser.

Warranty. Seller expressly warrants that all goods and/or services furnished under this Agreement shall conform to all specifications and appropriate standards and will be free from defects in material or workmanship. Seller warrants that all such goods and/or services will conform to any statements made on the containers or labels or advertisements for such goods and/or services and that any goods will be adequately contained, packaged, marked and labeled. Seller warrants that all goods and/or services furnished hereunder will be merchantable, and will be safe and appropriate for the purpose for which goods and/or services of that kind are normally used. If Seller knows or has reason to know the particular purpose for which Purchaser intends to use the goods and/or services Seller warrants that such goods and/or services will be fit for such particular purpose. Seller warrants that goods and/or services furnished will conform in all respects to samples. As to manufactured goods, Seller warrants that it shall, as applicable, manufacture and perform all of its obligations hereunder with the current good manufacturing practices as defined by applicable laws, standards, rules, regulations and

requirements, including, without limitation, Good Manufacturing Practices and General Biologics Products Standards as promulgated under the United States Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq., and all applicable national implementing laws, regulations and guidelines, and all applicable standards, including, but not limited to, ISO 9000 and ISO 13485 standards, and EN 724 standards. These warranties shall survive inspection, test, acceptance and use. Seller agrees to replace or correct defects in any goods and/or services not conforming to the foregoing warranty promptly, without expense to Purchaser, when notified of such nonconformity by Purchaser. In the event of failure of Seller to correct defects in or replace nonconforming goods and/or services promptly, Purchaser, after reasonable notice to Seller, may make such corrections or replace such goods and services and charge Seller for the cost incurred by Purchaser in doing so. Seller (i) represents, as of the date hereof, that (a) Seller has provided to Purchaser for inclusion in Purchaser's electronic system, a completed copy of Purchaser's Supplier Diversity Classification Form, (SDCF) in respect of such Seller, and (b) the size or socioeconomic representations and certifications made in such Classification Form are current, accurate, complete, and applicable to the Work under this Agreement (including business size standards applicable to the NAICS code) as of the date hereof or within the last twelve months, and (ii) covenants that Seller shall provide to Purchaser an updated Supplier Classification Form from time to time within thirty (30) days of Purchaser's request, each of which updated SDCFs shall be current, accurate and complete as of the date of submission by Seller to Purchaser.

Price Warranty. Seller warrants that the prices for the articles sold to Purchaser hereunder are not less favorable than those currently extended to any other customer for the same or similar articles in similar quantities. In the event Seller reduces its price for such article during the term of this order, Seller agrees to reduce the price hereof correspondingly. Seller warrants that prices shown on this purchase order shall be complete, and no additional charges of any type shall be added without Purchaser's express written consent. Such additional charges include, but are not limited to shipping, packaging, labeling, custom duties, taxes, storage, insurance, boxing, and crating.

Force Majeure. It shall not be deemed default hereunder and neither Purchaser nor Seller shall be liable for a failure to perform hereunder arising from causes or events beyond the reasonable control and without the fault or negligence of Purchaser or Seller including, without limitation, riot, terrorism, war or hostilities between nations, governmental action (other than action taken in response to violation or failure to act of a party or any of its affiliates with respect to any law or governmental regulation, in which case the party at fault shall not be permitted to claim the benefit of this paragraph), acts of God (including, for example, floods, windstorms, earthquakes and other natural disasters), fire, accidents, and strikes and other labor disputes of any kind. Each party will notify the other in writing of the cause of such delay within five (5) days after the beginning thereof. To the extent that, and so long as the obligations of either party are affected by any such cause or event, such obligations shall be suspended provided, however, that time is of the essence of this order and should Seller fail to comply with Purchaser's delivery schedule or otherwise fail to comply with its obligations hereunder, Purchaser may terminate this order without liability.

Insurance. In the event that Seller's obligations hereunder require or contemplate performance of services by Seller's employees, or persons under contract to Seller, to be done on Purchaser's property, or property of Purchaser's customer, the Seller agrees that all such work shall be done as an independent contractor and that the persons doing such work shall not be considered employees of the Purchaser. Seller shall maintain all necessary insurance coverages, with coverage limits of no less than \$2 million, and with Insurance carriers as deemed appropriate by Purchaser, including, but not limited to, public liability (including contractual and product coverage), auto liability, Workers' Compensation Insurance, and professional liability (errors and omissions). Seller shall furnish a Certificate of Insurance to Purchaser as evidence of appropriate coverages prior to providing goods and/or services to the Purchaser, if requested.

Indemnification. Seller shall defend, indemnify and hold harmless Purchaser and its affiliates, and their respective directors, officers, shareholders, employees, and agents (collectively, "Indemnified Parties") against all damages of any kind, claims, liabilities and/or expenses (including attorney's fees) arising out of or resulting in any way to or from any defect in the goods and/or services purchased hereunder, or from any act or omission of Seller, its agents, employees or subcontractors. This indemnification shall be in addition to the warranty obligations of Seller, whether or not stated herein. In addition, Seller shall defend, indemnify and hold harmless the Indemnified Parties against all damages of any kind, claims, liabilities and/or expenses (including attorney's fees) arising out of or resulting in any way from any allegation that the goods and/or services purchased hereunder infringe or violate any patent, copyright, trade secret, trademark, or other third-party proprietary rights, provided that Seller is notified in writing of such claim and given the authority, information and assistance necessary for the defense of said allegation. If, as a result of any such claim, an injunction or exclusion order prevents Purchaser's use, sale, lease, license, or other distribution of any of the goods and/or services purchased hereunder, Seller shall, at its expense and upon Purchaser's request, use commercially reasonable efforts to (i) obtain for Purchaser and its customers the right to continue using such goods and/or services; (ii) replace or modify the infringing goods and/or services so that they become non-infringing while providing substantially the same functionality; or (iii) if the remedies in (i) and (ii) are not reasonably available, refund to Seller all of the fees paid by Seller for such infringing goods and/or services.

Inspection/Testing. Payment for the goods and/or services delivered hereunder shall not constitute acceptance thereof. Purchaser shall have the right to inspect such goods and/or services and to reject any or all of

said goods and/or services which are in Purchaser's judgment defective or nonconforming. Goods and/or services rejected and goods and/or services supplied in excess of 105% of quantities called for herein may be rejected and returned to Seller at its expense and in addition to Purchaser's other rights. Purchaser may charge Seller all expenses of correcting, unpacking, examining, repacking and reshipping such goods and/or services. In the event Purchaser receives goods and/or services whose defects or nonconformity are not apparent on examination, Purchaser reserves the right to require compliance with the terms of this purchase order and/or replacement, as well as payment of damages, including but not limited to consequential damages. Nothing contained in this purchase order shall relieve in any way the Seller from the obligations of testing, inspection and quality control.

Compliance.

- a. Seller warrants that all goods and/or services supplied hereunder will have been produced in compliance with and Seller agrees to be bound by all applicable federal, state, and local laws of the United States and each jurisdiction in which it conducts business, along with relevant governmental orders, rules and regulations. Seller will comply with product-related regulatory obligations that impact product packaging (as supplied by Seller), chemical substance use, material safety data sheet development, and similar product-related environmental legislation. Seller agrees that it shall, as applicable, manufacture and perform all of its obligations hereunder with the current good manufacturing practices as defined by applicable laws, standards, rules, regulations and requirements, including, without limitation, Good Manufacturing Practices and General Biologics Products Standards as promulgated under the United States Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq, and all applicable national implementing laws, regulations and guidelines, and all applicable standards, including, but not limited to, ISO 140001, ISO 9000 and ISO 13485 standards, and EN 724 standards.
- b. In addition to and without limiting the above obligation, Seller expressly warrants that no article sold pursuant to this order is: (1) adulterated or misbranded within the meaning of the Federal Food Drug and Cosmetic Act; (2) an article which may not under the provisions of said Act be introduced into interstate commerce; or (3) misbranded or a banned hazardous substance, if it is a hazardous substance within the meaning of the Federal Hazardous Substances Act, as amended.
- c. Seller further warrants that goods and/or services produced in accordance with the Agreement shall comply with all of the provisions of Executive Order No 11246 of September 24, 1965, as amended; The Vietnam Era Veterans' Readjustment Assistance Act of 1974 (38 U.S.C. 2012); and The Rehabilitation Act of 1973. as amended; and all of the rules and regulations promulgated by the Secretary of Labor (41 CFR, Chapter 60), as from time to time amended.
- d. Non-Discrimination and Affirmative Action: Purchaser is an Equal Opportunity and Affirmative Action Employer. Unless exempt, the E.O. Clause set forth at 41 CFR § 60-1.4(a) (for women and minorities) and the provisions of 41 CFR § 61-300.10 (veterans' employment reports) and 29 CFR Part 471, Appendix A to Subpart A (posting notice of employee rights) are incorporated as terms and conditions of this agreement and are binding on Seller. **Seller shall also abide by the requirements of 41 CFR 60-300.5(a) (for veterans) and 41 CFR § 60-741.5(a) (for individuals with disabilities). These regulations prohibit discrimination against qualified protected veterans and individuals on the basis of disability, and require affirmative action by covered prime contractors and subcontractors to employ and advance in employment qualified protected veterans and individuals with disabilities.**
- e. Seller shall complete all service work in accordance with all federal, state, and local regulations regarding safety and environmental protection. This includes, but is not limited to, the requirements of the United States Occupational Safety and Health Administration (OSHA) and the Environmental Protection Agency (EPA).
- f. It is agreed that when the items purchased are to be utilized by Purchaser in its performance under a Government contract and when applicable by their terms, the following provisions are incorporated in this purchase order by reference with the force and effect as though set forth in full text herein: FAR 52.219-8 (Utilization of Small Business Concerns); FAR 52.222-26 (Equal Opportunity); FAR 52.222-35 (Affirmative Action for Disabled Veterans and Veterans of the Vietnam Era); FAR 52.222-36 (Affirmative Action for Workers with Disabilities); FAR 52.222-39 (Notification of Employee Rights Concerning Payment of Union Dues or Fees); FAR 52.222-41 (Service Contract Act of 1965); FAR 52.247-64 (Preference for Privately-Owned U.S. Flag Commercial Vessels). The full text of a FAR clause may be accessed electronically at <http://www.acquisition.gov>.
- g. Seller represents and warrants that it is not excluded from participation in Medicare, Medicaid, or any other federal health care program, as defined under 42 U.S.C. § 1320a-7b(f). Seller further represents and warrants that, in the event it becomes excluded from any federal health care program, it shall immediately notify Purchaser of such exclusion.
- h. With respect to goods sold by Seller to Purchaser under this Purchase Order, and in future supply transactions, Seller agrees to provide Purchaser with such information, including an appropriate certificate of origin, under NAFTA, CBI, GSP, CAFTA or other relevant, existing or future, trade

agreements or tariff preference programs, as will enable Purchaser to determine the country of origin under such trade agreements or tariff preference programs.

- i. In the event of an investigation resulting from a reportable product incident or recall, the Seller will grant recognized regulatory agencies (i.e. FDA, Competent Authorities) and Notified Bodies with access to the Seller's premises and quality system records as requested.
- j. Seller agrees to indemnify Purchaser from any liability (including attorney's fees) caused by Seller's failure to comply with any applicable laws.

Security Interest. Seller hereby grants Purchaser a security interest in any goods that are the subject of this purchase order, any work in process related thereto and all materials that are to be incorporated into such goods (collectively, the "Collateral") for which Seller has received whole or partial payment. Seller hereby appoints Purchaser or its agents as Seller's limited attorney-in-fact to execute and record all documents (including, without limitation, UCC financing statements) reasonably necessary to perfect or maintain the perfection of Purchaser's security interest in the Collateral. Seller agrees to pay the bills of its suppliers promptly and to comply with a reasonable request for evidence of payment. Seller agrees to protect the interest of Purchaser as defined in this section by not permitting any attachments to the Collateral of liens, encumbrances or claims for labor or material and to protect and hold Purchaser harmless from all such claims, liens and encumbrances growing out of the design, manufacture, assembly, transit and installation of the Collateral.

Entire Agreement. This purchase order, and any documents referred to on the face hereof, constitute the entire agreement between the parties. Purchaser may, in its sole discretion, change these terms and conditions at any time. Seller is bound by all such modifications, and it is Seller's responsibility to review these terms and conditions on a regular basis.

Assignment and Subcontracting. This order cannot be assigned nor can any part of it be subcontracted without Purchaser's consent.

Setoff. All claims for money due or to become due from Purchaser shall be subject to deduction or setoff by the Purchaser by reason of any counterclaim arising out of this or any other transaction with Seller.

Waiver. Purchaser's failure to insist on performance of any of the terms or conditions herein or to exercise any right or privilege of Purchaser's waiver of a breach hereunder shall not thereafter waive any other terms, conditions or privileges, whether of the same or similar type.

Limitation on Purchaser's Liability-Statute of Limitations. In no event shall Purchaser be liable for anticipated profits or for incidental or consequential damages. Purchaser's liability on any claim of any kind for any loss or damage arising out of or in connection with or resulting from this agreement or from the performance or breach thereof shall in no case exceed the price allocable to the goods and/or services or unit thereof which gives rise to the claim. Purchaser shall not be liable for penalties of any description. Any action resulting from any breach on the part of Purchaser as to the goods and/or services delivered hereunder must be commenced within one year after the cause of action has accrued.

Litigation. Should litigation result from any transactions contemplated hereunder, the losing party shall indemnify the other party for all costs of such litigation including attorney's fees.

Data Privacy.

1. Definitions.

- a. "Personal Data" shall mean any information that can be used to (directly or indirectly) identify, locate or contact an individual, including, but not limited to: (a) first name or initial and last name; (b) home or other physical address; (c) telephone number; (d) email address or online identifier associated with the individual; (e) social security number or other similar identifier; (f) employment, financial or health information; or (g) any other information relating to an individual, either directly or indirectly, that is combined with any of the above.
- b. "Applicable Personal Data" shall mean Personal Data Processed by Seller as a result of entering into this Agreement or performing the Services.
- c. "Process" or "Processing" shall mean any operation or set of operations which is performed upon Personal Data, whether or not by automatic means (such as collection, recording, utilization, storage, disclosure, transmission, dissemination or otherwise making available, erasure, or destruction).
- d. "Data Security Breach" shall mean (a) the loss, misappropriation or misuse (by any means) of Applicable Personal Data; (b) the inadvertent, unauthorized and/or unlawful Processing, access, disclosure, alteration, corruption, transfer, sale or rental, destruction or use of Applicable Personal Data; (c) any other act or omission that could or does compromise the security, confidentiality, and/or integrity of Applicable Personal Data.

2. Obligations.

- a. Purchaser warrants that its sharing of Applicable Personal Data with Seller complies with applicable data protection laws.
- b. Seller may Process Applicable Personal Data on behalf of Purchaser (as an agent/processor). Seller shall not Process Applicable Personal Data other than as in accordance with the instructions of Purchaser and as necessary to perform the Services under the Agreement.
- c. Seller agrees to comply with and protect Applicable Personal Data in accordance with all applicable international data protection laws, including, but not limited to EU, Swiss, and local jurisdiction data protection standards and U.S. federal and state laws and regulations governing the confidentiality, privacy and/or security of Applicable Personal Data.
- d. Seller shall implement adequate and reasonable safeguards to prevent the use or disclosure of Applicable Personal Data, and to protect the confidentiality, integrity, and availability of such information.
- e. With respect to Applicable Personal Data originating from the European Union or Switzerland that Seller receives from Purchaser, Seller agrees to abide by the relevant Safe Harbor principles as an agent of Purchaser when Processing such Applicable Personal Data. The Safe Harbor principles are available here: <http://export.gov/safeharbor/>. Purchaser shall promptly respond to any request made by Seller concerning the origin of any Applicable Personal Data, including whether it originates in the European Union.
- f. Where Seller receives assistance from Seller affiliates, subcontractors, or other third-parties in performing the Services and processing Applicable Personal Data, Seller will ensure that all of these parties enter substantially similar confidentiality, privacy and security agreements with Seller that cover the subject matter described in these terms and conditions. Such agreements shall serve to facilitate Seller's compliance with this Agreement. If Purchaser determines that it is necessary in connection with an audit or governmental inquiry, Seller shall supply copies of such agreements within seven (7) business days of receipt of Purchaser's written request.
- g. Seller shall also ensure that its own employees, as well as any Seller affiliates, permitted subcontractors, temporary employees and other third-parties who assist Seller in performing the Services, and who have access to any Applicable Personal Data, receive appropriate privacy and security training. Such training shall be updated periodically in accordance with applicable laws, regulations, and industry standards, or as otherwise requested by Purchaser.
- h. Seller, its affiliates and subcontractors shall not Process Applicable Personal Data in a manner that involves the transfer of/or access to such Applicable Personal Data from any other country outside of the United States, Switzerland, or the EEA/EU countries, without the prior written consent of Purchaser.
- i. At any time during the Processing of Applicable Personal Data, Seller shall notify Purchaser immediately (and no later than (3) days from the date Seller has knowledge) of any Data Security Breach involving Applicable Personal Data. Seller agrees to assist and cooperate with Purchaser concerning any disclosures to affected parties, government or regulatory agencies and with any other remedial measures requested by Purchaser or required under any law.
- j. Seller shall take reasonable steps to ensure that each individual whose Applicable Personal Data was, or is, in its possession, is able to assert his or her rights of access to view and correct his or her Applicable Personal Data. Seller shall notify Purchaser promptly, but no later than five (5) business days from its receipt of any communication received from an individual whose Applicable Personal Data was, or is, in its possession relating to said individual's rights of access or to correct his or her Personal Data and shall comply with all instructions of Purchaser in responding to such communications.
- k. Without limitation of any provision of the Agreement, (a) Seller shall ensure that it has appropriate processes in place for the destruction/purging of any documents, materials, or media that may contain Applicable Personal Data; and (b) upon termination or expiration of this order, or if and when requested by Purchaser, Seller will, upon request only, return promptly all such information to Purchaser and/or complete and have an officer of its organization sign a Certificate of Destruction in a form provided by Purchaser.
- l. Without limitation of any of Purchaser's rights under the order, Purchaser reserves the right to modify any Services upon thirty (30) days written notice to Seller should there be a change in the applicable privacy or security laws, regulations, guidelines, interpretations, or industry standards, or a new court case or claim, that, in Purchaser's opinion, alters the risk of continuing such Services.

Seller agrees that Purchaser may inspect, upon reasonable notice of not less than three (3) business days, its Processing of Applicable Personal Data, and that Seller will furnish Purchaser with all materials reasonably necessary for Purchaser to confirm that Seller, its affiliates and subcontractors have complied with their data protection obligations contained in these terms and conditions.

Seller acknowledges that Purchaser will be storing basic contact information in its internal transaction systems and any related processes where information is required to place orders, receive goods and services, and make payments. Seller consents to the storage and processing of this data for Purchaser's purposes of organizing, managing, and otherwise gaining understanding or building strategies around its supplier spend.

Responsible Procurement. Purchaser, a Novartis company, promotes the societal and environmental values of the United Nations Global Compact to its Third Party Suppliers. Purchaser expects suppliers with whom we work to comply with the law and to adhere to the Novartis Supplier Code (the "Code") found at <https://www.novartis.com/about-us/corporate-responsibility/resources-news/codes-policies-guidelines>. Seller shall: (i) familiarize itself with and comply with the requirements of the Code; (ii) provide information on request to Purchaser concerning compliance with the Code; (iii) allow Purchaser (or its nominated third party experts) adequate access for the purposes of auditing compliance with the Code; and (iv) use its best efforts to rectify identified non-compliances with the Code and report remediation progress to Purchaser on request. At Purchaser's discretion, failure to adhere to the Code shall entitle Purchaser to terminate this order without compensation.

Goods or Services Used in Manufacture of Purchaser's Finished Product. If Seller is or will be supplying Purchaser with a good (i.e., an ingredient, component, or process aid) or a service (for the purpose of this section, the "Product") to be used in the manufacture of Purchaser's product(s) ("Purchaser Finished Product"), Seller shall comply with the following terms:

- a. Purchaser has the right to perform periodic audits at the Seller's facility.
- b. In the event that Seller receives an announced or unannounced health authority inspection, Seller will notify Purchaser immediately. Upon Purchaser's request, Seller shall provide to Purchaser a copy of any report and other written communications received from such government or regulatory agency in connection with such visit or inspection. Each of the parties agrees to cooperate to the extent reasonably requested by the other in connection with any communications with the FDA, other health authority, or Purchaser's Notified Body.
- c. Prior to making any changes in the design, processes, methods, specifications, equipment, production systems, manufacturing site, relevant regulatory compliance status, ownership, or procedures relative to the manufacturing, packaging and/or labeling of the Product supplied to Purchaser, Seller shall provide Purchaser with reasonable prior written notice of such change to allow Purchaser to assess the impact and obtain regulatory approvals if necessary; Seller will obtain Purchaser's prior written consent before implementing such change.
- d. If Seller experiences a process shift or process excursion during the Seller manufacturing process such that there might be a potential impact to the quality of the Product supplied to Purchaser, Seller will notify Purchaser. Seller will work with Purchaser to build the appropriate corrective and preventative actions and to determine disposition of the affected Product.

Purchaser will handle, process and respond to all customer complaints related to the Purchaser Finished Product, including complaints related to the Product supplied by Seller to Purchaser, for all markets. Purchaser and Seller shall maintain complaint files regarding the Product supplied to Purchaser, including, without limitation, any Product quality complaints, for such period as may be required by applicable law. All complaints received by Seller relating to a Product provided to Purchaser, or relating to a product that is not specifically the Product provided to Purchaser but which is identical or materially similar in some particular way to the Product furnished to Purchaser, will be promptly forwarded, in no event later than fifteen (15) days after receipt thereof, to Purchaser for appropriate and timely reporting and response in accordance with applicable law, including, without limitation, adverse event reporting pursuant to 21 CFR Part 314, medical device reporting pursuant to 21 CFR Part 803, compliance with all guidelines adopted by the European Commission from time to time and published in Volumes 4 and 9 of the Rules Governing Medicinal Products in the EU (including Chapter 8 (Complaints and Product Recall)), and MEDDEV 2.12-1; provided, however, Seller shall notify Purchaser of any serious adverse reaction, patient injuries, or device malfunctions, as defined in FDA or other applicable regulations, pertaining to the Product, within twenty-four (24) hours after receipt thereof. Seller agrees to cooperate with Purchaser to investigate and resolve all complaints and to take remedial action to avoid similar complaints in the future. This Section shall survive the expiration or termination for whatever reason of this Agreement.

Supplier Diversity. As a part of Purchaser's commitment to supplier diversity, Seller is requested to demonstrate a good faith effort to locate and utilize diverse businesses as noted in FAR 52.219-8 guidelines when making purchases of goods or services on behalf of, or in support of, the goods or services to be provided by Seller pursuant to this Purchase Order. If Seller's operation includes the ability to track and report on supplier diversity spend and activity, Seller agrees to provide quarterly reporting to Purchaser on any second tier diversity spend referencing the following applicable categories of businesses: Women-owned, Minority-owned, Veteran-owned (small), Service Disabled Veteran-owned (small), LGBT-owned, Disabled-owned, Small-owned, Small Women-owned, Small Disadvantaged-owned, and HubZone businesses. If Seller does not have the ability to track and report supplier diversity spend as requested, Seller agrees to provide requested reports at such time Seller's operation implements mechanisms to track and report on such spend