SUPPLIER PERFORMANCE EXPECTATIONS FOR AFFILIATES OF ORGANON & CO., JERSEY CITY, N.J. USA

I. This section applies to all Suppliers of Direct and Indirect products / services:

SYSTEM EXPECTATIONS

Suppliers of our company shall comply with all applicable quality system requirements (e.g., cGMP, EUDRALEX, ISO 9001, and internal supplier quality management systems) and maintain registrations as required. Applicable certificates shall be available for review.

Any written or electronic documentation or data relevant to activities performed, including without limitation any GMP documentation, must be original, accurate, legible, controlled, retrievable, and safe from intentional or unintentional manipulation or loss. These items are required throughout the retention period of such data / documentation

PERFORMANCE EXPECTATIONS

- Supplier shall have capability to respond to all our internal company generated customer issues related to the items and services provided by Supplier to our company. Initial response should be received within 1 business day and final response within 14 calendar days. Substantiated problems may warrant Supplier being placed on a supplier performance improvement plan until the problem is contained and irreversible corrective action has been implemented and verified as effective.
- Supplier shall monitor its performance and demonstrate efforts to improve measures such as defects, customer issues, audit performance (as our company deems applicable), delivery, responsiveness, innovation, and cost. The goal is zero customer issues and zero defects shipped.
- Supplier shall have financial responsibility for non-conforming items and services, and their effects, which may include cost recoveries for additional company resources involved with remediation of non-conforming items and services, re-work, scrap, premium transportation, etc.
- Supplier shall ensure 100% on time and in full delivery per our company's schedule requirements.

LABELING, PACKAGING AND SHIPPING EXPECTATIONS

- All items shall be properly identified with appropriate label information.
- Supplier's labeling system shall ensure no mis-identification will occur and allow for complete lot traceability.
- Item shall arrive at point of use unopened and undamaged.

II. This section applies to Suppliers of specific products / services, as indicated by the "X":

SUPPLIER PERFORMANCE EXPECTATIONS	DIRECT CUSTOM	DIRECT NON-CUSTOM	RESEARCH GM
For any Supplier item provided to our company, Supplier shall provide us with advance notification to allow us review and approval time prior to Supplier implementing any changes as defined in the Quality or Change Control Agreement.	X	X	X
Supplier shall notify our company of any customer issues or potential recalls of Supplier material that result from their quality analysis system.	X	X	X
Critical Process Parameters (CPP's) and Critical Quality Attributes (CQA's), defined by our company, shall be monitored and trended by Supplier and provided to our company for review.	X	X	
Measurement System Analysis (for example, Gage Repeatability & Reproducibility).	X	X	
Retention of product samples.	X	X	
Supplier shall submit all documents in language provided by our company.	X	X	
Supplier shall have a supplier quality management process that includes a supplier audit process in place with sub-suppliers.	X	X	
Supplier shall permit our company or its delegate a periodic quality audit of Supplier's manufacturing, testing and packaging processes, and/or a quality audit on a For Cause basis, should quality performance issues be identified.	X	X	
FMEA for Design Responsible Suppliers.	X		
Established Process Control Limits (PCL's) for in-process and final release testing.	X		
Approved Process Flow Diagrams (PFD's).	X		
Periodic Re-Qualification and Validation of item supplied.	X		
Supplier to have all testing performed by an accredited lab.	X		