SUPPLIER QUESTIONNAIRE

Honeywell Sparta Systems

GENERAL INFORMATION					
Company Name		Address			
Phone Number					
Contact Name		Title			
Contact Email		No. Employees			
Is your facility registered with the FDA?	☐ Yes ☐ No	If yes, Registration Number		Product Code(s)	
Is your facility certified to ISO?	☐ Yes ☐ No	If yes, please provide a copy of the certificate inclusive of the scope of registration.			
Date of the last FDA inspection	☐N/A Date: _____	Was a 483 or Warning Letter issued?	☐ Yes ☐ No ☐ N/A		
Product(s) supplied	Bulk raw materials Bulk raw materials for pharmaceuticals Active pharmaceutical ingredients Technical products Packaging material Labeling material Chemicals Other _____		☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No		
Who is required to sign the Certificate of Analysis or the Certificate of Conformance Report?					
Would you allow an on-site, hybrid, or remote quality system audit of your facility? ☐ Yes ☐ No					

SURVEY QUESTIONS

Instructions for completing Sections 1 through 6:
Using the following rating system, answer each question by circling the number that best describes your response.

Rating System
N/A = Not applicable.
1 = Procedure or system does not exist currently**.**
2 = Procedure or system exists but is currently being reviewed/updated and not followed.
3 = Procedure or system is thoroughly documented and tracked.

1.0	CONTRACT REVIEW and DOCUMENT CONTROL	RATING
1.1	Is there a Quality Manual available that describes quality-related procedures and policies? (Attach a copy)	Make Selection
1.2	Are you familiar with the quality system requirements related to (applicable regulation)?	☐Yes ☐No
	If not, are you willing to be trained on regulations?	☐Yes ☐No
1.3	Is the quality department independent of the production department?	☐Yes ☐No
1.4	Is there an up-to-date organization chart? (Attach a copy)	Make Selection
1.5	Is there a procedure for controlling process/product/document changes?	Make Selection
1.6	Is there a regular management review meeting?	Make Selection
1.7	Are customers notified of specifications or product changes?	Make Selection
1.8	Does your company perform documented internal audits in all areas relating to servicing activities?	Make Selection
2.0	**PURCHASE CONTROLS**	**RATING**
2.1	Is there an approved suppliers list (ASL)?	Make Selection
2.2	Is there a supplier evaluation program in place?	Make Selection

SUPPLIER QUESTIONNAIRE

2.3	Are incoming goods inspected to ensure requirements are met?	Make Selection
2.4	Is a sampling plan or Statistical Process Control tool utilized to monitor product realization?	Make Selection
2.5	Are areas adequately marked to allow segregation of products to avoid mix-ups?	Make Selection
2.6	Is there a system in place to document incoming testing/inspections?	Make Selection
2.7	Are first article inspections performed on new parts/materials/goods or when materials, processes, or suppliers are changed?	Make Selection
3.0	**TRAINING**	**RATING**
3.1	Is there a procedure that defines the responsibilities and training requirements for each position?	Make Selection
3.2	Have training and development plans been implemented for all employees who have an impact on quality?	Make Selection
3.3	Are training records maintained on each employee?	Make Selection
3.4	Does the training include GMP, hygiene, product integrity?	Make Selection
3.5	Are employees provided documented servicing work instructions and trained to perform the required servicing tasks with relevant training records maintained on file (if applicable)?	Make Selection
3.6	Are employees made aware of customer concerns?	Make Selection
3.7	Are employees trained when changes are made that would affect their function area?	Make Selection
3.8	Are periodic assessments completed on established employees?	Make Selection
4.0	**CONTINUOUS IMPROVEMENT**	**RATING**
4.1	Is there a continuous improvement method used?	Make Selection
4.2	Is there a procedure for implementing corrective and preventive actions?	Make Selection
4.3	Is there a follow-up system to identify, evaluate effectiveness, and close corrective actions?	Make Selection
4.4	Is there a system used for trending corrective actions?	Make Selection
4.5	Is there a procedure for the receipt and evaluation of customer and service complaints?	Make Selection
5.0	**PROCESS AND PRODUCTION CONTROLS**	**RATING**
5.1	Are there written procedures for manufacturing processes and procedures?	Make Selection
5.2	Do all required products comply with Unique Device Identification?	Make Selection
5.3	Are records of production activities maintained?	Make Selection
5.4	Are line clearances performed between different labeling and packaging operations?	Make Selection
5.5	Is the product acceptance status discernible throughout Production?	Make Selection
5.6	Is final inspection/final release performed on a lot-by-lot basis?	Make Selection
5.7	Is there a formal procedure for deviating from standard practices?	Make Selection
5.8	Is there a preventive maintenance program for equipment and tooling is suitable to ensure continuing process capability?	Make Selection
5.9	Are software changes validated before approval, and are there adequate controls to ensure that only the most current version can be used?	Make Selection
5.10	Are lubricants and non-production materials controlled to prevent contamination of products?	Make Selection
5.11	Are there sanitation and pest control procedures in place to prevent contamination of products?	Make Selection
5.12	Are all measurement equipment clearly labeled with the last date of calibration and when due for recalibration?	Make Selection
5.13	Are there written procedures that describe calibration intervals and maintenance requirements for all measurement equipment, and what to do if it is out-of-range?	Make Selection
5.14	Is the measurement equipment that is not required to be calibrated labeled?	Make Selection
5.15	Are all calibrations performed using equipment traceable to the National Institute for Standards and Technology (NIST) or other suitable standards?	Make Selection
6.0	**PACKAGING, STORAGE, AND SHIPPING**	**RATING**
6.1	Is there a procedure that describes proper handling, packaging, storage, preservation, and shipping methods?	Make Selection
6.2	Are there Procedure(s) for documenting raw material information (lots, quantity, etc.)?	Make Selection
6.3	Are materials/parts stored and used on a first-in, first-out basis?	Make Selection

SUPPLIER QUESTIONNAIRE

6.4	Are the labels verified to ensure compliance with customer and regulation standards?	Make Selection
6.5	Is there sufficient traceability to recall any defective product/item if necessary?	Make Selection
6.6	Are finished goods effectively segregated and labeled?	Make Selection
6.7	If environmental control is required, is the process documented?	Make Selection
6.8	Do you have manufacturing alternatives/fallbacks?	☐ Yes (3) ☐ No (1)
6.9	**If yes, how many weeks of inventory for products?**	
7.0	**SUPPLIER QUALITY SURVEY COMPLETION**	
7.1	Are you able to comply with the stated specific requirements and provide appropriate documentation of such?	☐ Yes ☐ No
7.2	Are you willing to enter into a supplier agreement outlining the responsibilities related to the services provided by your company?	☐ Yes ☐ No
7.3	Do you agree to notify us of any changes to the supplied services before implementing any changes?	☐ Yes ☐ No

Please include a copy of the following documentation with your response, if applicable:

- Proof of ISO Certification
- FDA Registration Number
- Quality Manual
- Organizational Chart
- Other _____

Survey completed by (Print Name and Title)			
Signature and Date			
Email		Phone Number	

FOR COMPANY USE ONLY	
Survey Review By (Print Name and Title)	
Signature and Date	
On-site Audit Required	☐ Yes ☐ No
Supplier Overall Audit Rating	

Instructions for Use

1. For each section, add the total score
2. Calculate the maximum possible score by multiplying the number of relevant questions by three (3)
3. Record the sum
4. Total the sum column
5. Total the maximum possible score
6. Divide the total sum by the total maximum score
7. Audit rating