ComDel Innovation / Heartland Precision

Total Quality Management Program (TQMP)

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SUPPLIER QUESTIONNAIRE

All suppliers supplying material or services affecting product quality are selected on the basis of their ability to meet CDI/HP requirements, including quality and supplier performance requirements.

Any purchased item that affects product quality must be purchased from an approved supplier qualified to provide that specific item - that is, a supplier who has been evaluated, with acceptable results, and is entered into CDI/HP's ERP system.

A Supplier Questionnaire Record is required to document the findings and outcome of each supplier evaluation. A supplier evaluation may result in a request for an action plan if findings are cited during the evaluation process.

Approved (Jan 17, 2024) DOC770-FR6 F-04803 Doc Rev: 2
Supplier Questionnaire

This survey provides support for qualifying your company as an approved supplier.

Please complete the questionnaire and return it to the address below. Direct all questions to this ComDel Innovation contact as well.

Please add any additional information as an attachment which you feel necessary for proper completion and understanding of this questionnaire. Reference any explanation to the specific lettered section.

Thank you!

Please Complete and return to:

Beth Shaffer
ComDel Innovation LLC
Supplier Coordinator
2100 15th Street North Wahpeton, ND 58075
Beth.Shaffer@comdelinc.com
Phone: 701.671.6193 Fax: 701.671.7566

A. Organization

Company Name			Telephone Number	Fax Number	Date
Address			City, State, Zip Code		
Parent Company Location			Other/Related Manufacturing Locations		
Contact Name			Phone	E-mail	
Total Employees	Office	Technical	Production	Q.C./Q.A.	☐ Union ☐ Non-Union
Years in business	Ownership ☐ Single ☐ Partnership ☐ Corporation		What is your current working schedule		
List in-house manufacturing processes/services					

B. Management *(attach organizational chart if available)*

Function/Job Title	Name	Title	Reports To

QUALITY PROGRAM

The Supplier is required to implement and maintain a quality program that shall assure design and manufacture of products is consistent with the requirements of ISO 9001 and if applicable, ISO13485. The Supplier shall notify CDI/HP of any changes in its quality program **prior to implementation**. The Supplier will have an organization that supports, implements and maintains the quality system at all levels. The supplier will notify CDI/HP of any changes they have made in their system. The following are examples of changes requiring notification to CDI/HP:

- Product and/or process
- Raw material and Sub-tier supplier change
- Manufacturing facility location change

The supplier is responsible to flow down to sub-tier suppliers the ComDel / Heartland's requirements, including key characteristics. The supplier shall determine and manage the risk when selecting and using sub-tier suppliers.

CDI/HP requires suppliers to ensure their employees are aware of:

1. their contribution to product or service conformity;
2. their contribution to product safety;
3. the importance of ethical behavior

Product Identification & Lot Traceability

The Supplier shall establish and maintain procedures and processes for the identification and lot traceability of critical items during all stages of production, delivery, and installation. This is to be traceable through the finished product serial number or equivalent method.

QUALIFICATION PLAN

Any purchased item affecting product quality must undergo product qualification consisting of sample material submissions by the supplier, indicative of product manufactured from a supplier's line.

Product that has been purchased from a supplier previously but, has been affected by a change to a drawing, specification, or supplier's manufacturing process must undergo product qualification as well. **Supplier is required to notify CDI of any changes they have made**.

Product qualification may include, but is not limited to:

- Certificate of Analysis
- Sample material/product run in CDI manufacturing environment
- CDI inspection/test of supplier material/product
- Supplier inspection/test of material product witnessed by CDI personnel
- Correlation of supplier inspection/test methods against CDI's methods

PROCESS CONTROL

The Supplier shall ensure that all manufacturing processes that affect the quality of a product are carried out in a controlled condition. CDI/HP defines controlled conditions as:

- Documented work instructions that provide clear and concise direction for the assembly, inspection, tests, and acceptance criteria of products.
- Identification of critical parameters, implementation of statistical process controls, and initiation of corrective actions when necessary. Additionally, triggers shall be defined and documented for the purpose of initiating a stop build and/or stop shipment action.
- Proofing out the manufacturing, inspection and test processes prior to mass production.
- Validation that manufacturing equipment (including fixtures) can produce a product meeting design intent and customer requirements. This should include formal gage repeatability and reproducibility (GR&R) studies where appropriate.
- Detailed workmanship criterion that stipulates the highest standard of quality.
- Preventive maintenance program for all equipment used in the manufacturing, inspection, and test of products.

CDI requests information regarding supplier's application of process behavior charts, statistical analysis of process capability (Cpk), and information regarding variability of measurement gauges and devices used to develop data on the critical performance characteristics.

CDI requests that the agreed upon process behavioral charts and Cpk level be submitted to the supplier management coordinator either with the C of A, the shipment or monthly. Data submitted electronically is preferred. Each key parameter must meet 1.5 Cpk (supplier data); any parameters below 1.5 Cpk require that a process improvement plan is in place.

DOCUMENTATION

The supplier shall assure that all documents such as software/firmware, engineering drawings, specifications, contracts, policies, procedures, and work instructions (including test procedures) are under revision control and available to all necessary personnel in the manufacturing environment. A system shall be established for the effective updating/removal of any obsolete documentation from all areas.

Packing Slips

One packing slip is required for each individual purchase order/release number. Supplier must show the following information on Packing List, Bill of Lading and Invoice:

- ✓ CDI/HP Part Number
- ✓ Part Description
- ✓ Quantity Shipped
- ✓ Number of pallets
- ✓ Gross weight per pallet
- ✓ Number of cartons
- ✓ PO#
- ✓ PO Line #
- ✓ PO Line - Shipment # if applicable (used when there are multiple shipments against the same line)
- ✓ PO Release #, if applicable


[Company Name]

PACKING SLIP

Note: on the Bill of Lading and Invoice - please include in the Buyer's Ship To address section the CDI/HP PO information, CDI/HP Item #, Supplier # and the Packing List #.

Record Control

All quality records shall be kept for at least three years unless otherwise specified by CDI/HP or as noted below. These records shall be stored in an environment that protects documents from deterioration and are readily accessible upon request by a ComDel / Heartland Precision representative and/or regulatory authority.

Container & Pallet Requirements

Palletizing:

- Maximum overhang on pallet shall be 1 ½" on width and 3" on length.
- Total height shall not exceed 48" including pallet height.
- A minimum of 2 ½ stretch wraps around load.

Placards for Identification of Pallet or Loads:

Each shipping load shall bear a load ticket which legibly displays (at least 24 pt. type) the information shown below:

- Part #
- Description
- Quantity
- Supplier Name
- Purchase Order #

Container marking:

- Mark each container with:
- Part Number
- Description
- Revision level
- PO #
- Quantity of pieces contained
- Suppliers name
- Lot Identification

Note: this includes internal bag labeling

CERTIFICATE OF ANALYSIS / CONFORMANCE

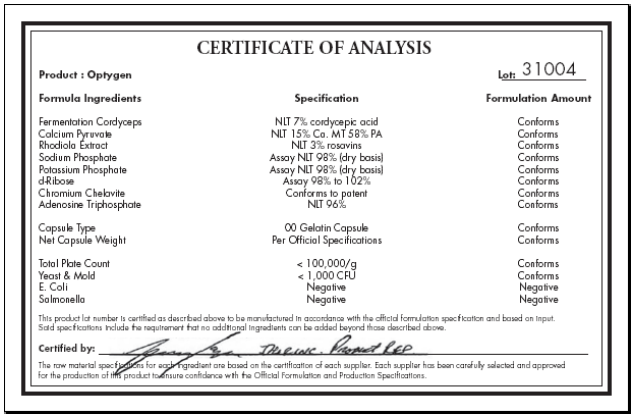
The supplier is responsible for sending the Certificate of Analysis (C of A) data ot Certificate of Conformance on all shipments. The certificate can be emailed, mailed, faxed or sent with the material. Electronic access to supplier product test data is an acceptable alternative to the Certificate of Analysis. ***The preferred method for submitting certificate is email (certs@comdelinc.com).***

Required information on the certificate:

- Supplier Name
- Part Description
- Part Number
- Revision
- Purchase Order #
- Quantity Shipped
- Lot # or Traceability information
- Inspection Results
- Raw material information or certs

The supplier management coordinator/incoming technician will verify that the C of A data meets the specifications. If the C of A data does not meet the specifications, the technician will place the material on hold for further review. A Nonconforming Report may be issued.

If the Cpk level is below 1.5 an inspection requirement will be determined.



CERTIFICATE OF ANALYSIS

Product : Optygen — Lot: 31004

Formula Ingredients	Specification	Formulation Amount
Fermentation Cordyceps	NLT 7% cordycepic acid	Conforms
Calcium Pyruvate	NLT 15% Ca. MT 58% PA	Conforms
Rhodiola Extract	NLT 3% rosavins	Conforms
Sodium Phosphate	Assay NLT 98% (dry basis)	Conforms
Potassium Phosphate	Assay NLT 98% (dry basis)	Conforms
d-Ribose	Assay 98% to 102%	Conforms
Chromium Chelavite	Conforms to patent	Conforms
Adenosine Triphosphate	NLT 96%	Conforms
Capsule Type	00 Gelatin Capsule	Conforms
Net Capsule Weight	Per Official Specifications	Conforms
Total Plate Count	< 100,000/g	Conforms
Yeast & Mold	< 1,000 CFU	Conforms
E. Coli	Negative	Negative
Salmonella	Negative	Negative

This product lot number is certified as described above to be manufactured in accordance with the official formulation specification and based on input. Said specifications include the requirement that no additional ingredients can be added beyond those described above.

Certified by: _____

The raw material specifications for each ingredient are based on the certification of each supplier. Each supplier has been carefully selected and approved for the production of this product to ensure confidence with the Official Formulation and Production Specifications.

CERTIFICATE NO.

CERTIFICATE OF COMPLIANCE

Customer Name:
Purchase order no.:
Product id:
Product description:
Specifications:

The company certifies that the above material are manufactured and inspected as per the standards, customer specific requirements and technical condition sheet.

Authority Signature.

Name & designation:
Date:
Document no. :

CONTROL OF NONCONFORMING PRODUCT

The Supplier's quality program shall have an effective system for controlling nonconforming product. The system shall provide for the identification, documentation, evaluation, segregation, timely disposition of nonconforming products and for notification (both internal and external). The supplier's system shall include controls for product returned from CDI/HP.

Supplier product that does not meet requirements shall be communicated and obtain approval disposition prior to product shipment. Supplier product discovered after shipment by the supplier to be nonconforming to any requirement shall be immediately disclosed to ComDel/Heartland upon discovery, including but not limited to quantity shipped, date shipped, and the extent of the nonconformance. Suppliers that receive notification of Nonconforming product shall take appropriate action to contain the nonconforming condition and prevent it from occurring again.

A Supplier Inspection Report / Corrective Action Request (IR/CAR) is used to communicate issues to suppliers and can be written for the following reasons:

- Material not in accordance with specification
- Material creating problems with production automation
- Packaging is incorrect or damaged
- Wrong item shipped

CDI/HP will send a copy of report and samples of the defect to the supplier. Supplier is responsible for acknowledging the receipt of the report within 48 hours. Requests for a Return Authorization number shall be satisfied within 48 hours. The response shall be submitted within 3 weeks of issue or a time frame agreed upon between ComDel/Heartland and the supplier. Supplier is responsible for completing each section by requested due date and submitting to CDI/HP Requestor as noted on report.

Approved

Supplier Inspection Report / Corrective Action Request

ComDel Innovation

Form	Owner: Kathy K. Lenk	
F-04565 DOC594-FR8	Doc Rev: 0	Effective: Oct 18, 2016

Supplier:		Issue Date:		Report No.:	
Contact:		Type of Request: ☐ Quality ☐ Analytical ☐ Service			
Address:		Return Authorization Required ☐ No ☐ Yes			
		Return Authorization Number			
Debit Memo Number (return only)		Material Location			

ComDel Innovation/Heartland Precision ID # / Description	PO #	Received Date	Lot #	Quantity

Specification Requirement	Inspection Results	Quantity Sampled	Quantity Discrepant

This Section To Be Completed by Supplier

1. Containment Action	Due Date 48 hours from Issue Respond Date	
2. Root Cause	Due Date 10 days from Issue Respond Date	
3. Corrective Action Plan	Due Date 20 days from Issue Respond Date Expected Implementation Date	
4. Permanent Corrective Action (s) Date Implemented and lot #/job # (if applicable):	Due Date 7 days after Implementation Date Respond Date	
5. Verification result	Supplier Signature / Date	

Responses should be submitted to:

Name	Address	Email address	Phone
Kathy Lenk	2100 15th Street North Wahpeton, ND 58075	Kathy.lenk@comdelinc.com	701-671-6149

This Section To Be Completed By ComDel Innovation/Heartland Precision

Verification Summary Action:	Result:
Comments	
Reviewer / Approver:	Date:

INVOICING / BILLING

All invoicing and billing sent to CDI/HP must contain the following:

- Accurate name and address of Supplier issuing the invoice, including remit-to address
- Correct Shipper address, Delivery address, Billing address clearly indicated
- Invoice Number and Date
- CDI/HP part number
- Purchase order number and/or release number, including line item number printed adjacent to the CDI/HP part numbers
- Item unit price (must match that of the PO)
- Quantity ordered and quantity delivered
- Currency of invoicing must be stated
- Freight Terms and Terms of Sale
- Payment Terms
- Unit of measure must be consistent with purchase order
- Invoice price must be consistent with purchase order
- One purchase order and release number per invoice
- Clearly stated invoice total (currency must match PO)
- For service purchase orders, the supplier may be required to submit an itemized statement documenting the work that was completed for the order, to the requestor, in addition to the invoice. Always review the purchase order closely to determine what additional information may be required.

All Invoices to be sent to via email: accounts.payable@comdelinc.com or accounts.payable@heartlandprecision.com

AUDITS / VISITS

CDI/HP may conduct audits/visits at the supplier's manufacturing locations. Periodic audits will include quality inspection data and other data related to the product being produced or process audits to verify compliance to the contractual requirements. Under normal circumstances, the supplier shall be given advance notice of visits.

The supplier shall, at CDI/HP's request, permit access to manufacturing operations involved in the production and/or inspection of purchased CDI/HP's products or services, including access to sub-contractor facilities. Supplier and their sub-tier shall grant right of access to CDI/HP, customer and regulatory bodies to all areas involved in the order and to all applicable records.

CDI/HP will meet with suppliers on a as needed to discuss current business issues or future opportunity.

SUPPLIER PERFORMANCE PROGRAM

Continuous improvement, commitment and active participation by you, our supplier, will result in improved processes/changes for your company, continued business for CDI, and satisfaction of our customers. A positive outcome resulting in systematic improvement of our organization and performance through process changes.

Phase 1 - Supplier Assessment - Reference “Supplier Questionnaire”.

Phase 2 - Supplier Qualification - Reference “Qualification Plan”.

Phase 3 - Continuous Improvement

Supplier Performance is rated monthly on suppliers who are considered a key supplier for CDI/HP. Key supplier applies to the min top 10% of ComDel’s previous year purchases, customer dictated, and/or high concern. A key supplier is one who affects the product quality and/or customer delivery requirements. A list of suppliers being rated is kept by the supplier management coordinator and is updated at the beginning of each year.

A review summary will be mailed to each supplier, 20 days following the end of the month. All items purchased from a supplier will be on one performance report.

Rating Criteria

Quality - evaluated on the basis of conformance to specifications. Condition of received materials, corrective action requests, and discrepancy reports.

Delivery - evaluated on the basis of on-time delivery, lead-time and proper freight.

Documentation - evaluated on the basis of COA data provided, proper documentation and timely response to corrective action requests.

Rolling Average

An rolling average below 85, requires supplier to visit CDI/HP. Supplier shall present an corrective action plan. CDI/HP will visit the supplier’s facility if the average falls below 75.

Phase 4 - Status Recognition

Supplier Certification—supplier must meet the minimum requirements to receive Certified status. Minimum requirements = Maintain 95 points or greater, each monthly review for twelve (12) consecutive reviews.

De-Certification

De-certification may take place when any of the following occurs:

- Total points fall below 85 points (red) for twelve (12) consecutive reviews.
- The supplier makes a change to its process that is outside the normal processing parameters and fail to notify CDI of these changes.
- A visit to the supplier's facility reveals a condition or circumstance, which in the judgment of CDI will jeopardize CDI's production or product performance.
- The supplier fails to comply with any of the requirements.

Resume Certified Status

A supplier must achieve 95 points or greater for twelve (12) reviews.

Supplier Performance Scorecard

Supplier Name	
Month:	Status:

Quality Score	*Delivery Score*	*Documentation Score*
50	***30***	***20***

Performance Score			*Rolling Avg.*		*Risk Rating*		
100			***100***		***Low***		
Green > 95	*Yellow >85*	*Red <= 85*	*>85*	*<85 - Supplier required to visit ComDel/HP*	*High*	*Medium*	*Low*

Month/Year	*# of Shipments*	*Shipment Quality*	Quality Penalty	On-time Shipments	Delivery Penalty	Lead-Time / Freight	Documentation	On-time Responses	Performance Score
1st Qtr. 2017		*40*	*10*	*10*	*10*	*10*	*15*	*5*	***100***
2nd Qtr. 2017		*40*	*10*	*10*	*10*	*10*	*15*	*5*	***100***
3rd Qtr. 2017		*40*	*10*	*10*	*10*	*10*	*15*	*5*	***100***
4th Qtr. 2017		*40*	*10*	*10*	*10*	*10*	*15*	*5*	***100***
1st Qtr. 2018		*40*	*10*	*10*	*10*	*10*	*15*	*5*	***100***
2nd Qtr. 2018		*40*	*10*	*10*	*10*	*10*	*15*	*5*	***100***
Jul-2018		*40*	*10*	*10*	*10*	*10*	*15*	*5*	***100***
Aug-2018		*40*	*10*	*10*	*10*	*10*	*15*	*5*	***100***
Sep-2018		*40*	*10*	*10*	*10*	*10*	*15*	*5*	***100***
Oct-2018		*40*	*10*	*10*	*10*	*10*	*15*	*5*	***100***
Nov-2018		*40*	*10*	*10*	*10*	*10*	*15*	*5*	***100***
Dec-2018		*40*	*10*	*10*	*10*	*10*	*15*	*5*	***100***

Quality: Supplier shall be evaluated on the basis of conformance to specifications. Condition of received materials, corrective action requests, and discrepancy reports will be considered.

Shipments with no issues. % Accepted / Points
100 / 40 99-98 / 36 97-96 / 32 95-94 / 28 93-92 / 24 91-90 / 20 89-88 / 16 87-86 / 12 85-84 / 8 83-82 / 4 < or = 81 / 0

Failure Costs Penalties (examples: Product rework due to defects & Line shut down)

Comments:

Delivery: Supplier shall be evaluated on the basis of on-time delivery, lead-time and proper freight.

Percent of On-Time shipments *(Delivered/Shipped - Early/Late).*% On-Time / Points
100 / 10 99-98 / 9 97 / 8 96 / 7 95-94 / 6 93 / 5 92 / 4 91-90 / 3 89-88 / 2 87-86 / 1 < or = 85 / 0

Failure Costs Penalties for Service (*example: Line shut down due to no material).*

Delivery Lead Time: = or < than 30 days OR Consignment plan in place.

Freight: is supplier using the best rate, correct carrier and correct routing.

Comments:

Documentation: Supplier shall be evaluated on the basis of COA data provided, proper documentation and timely response to corrective actions requests.

Certificate of Analysis data provided with each shipment. % Provided / Points
100 / 10 99 / 9 98 / 8 97 / 7 96 / 6 95-94 / 5 93-92 / 4 91-90 / 3 89-88 / 2 87-86 / 1 < or = 85 / 0

Percent of shipments with correct documentation (packing slips, labels, invoices, etc.) % Acceptance / Points
100 / 5 99-98 / 4 97-96 / 3 95-94 / 2 93-92 / 1 <or= 91 / 0

On-time responses for Inspection Reports / Corrective Action Requests.

Comments:

GLOSSARY

Approved Supplier: Status given when supplier has completed an acceptable questionnaire and is in CDI/HP's database as an active supplier.

Certification: Status given by CDI/HP to suppliers when they achieve a score of 95% or better on the CDI/HP Supplier Performance Scorecard for twelve (12) consecutive months.

COA: Certificate of Analysis

Cost of Quality - The costs associated with providing poor quality of products or services. There are 4 categories of costs:

- Internal failure costs are associated with defects found before the customer receives the product or service. Ex. inspection.
- External failure costs found after the customer receives the product or service. The most expensive cost & can lead to lost customers & sales.
- Appraisal costs are incurred to determine the degree of conformance to quality requirements. Ex. cost of testing & instruments.
- Prevention costs are incurred to keep failure & appraisal costs to a minimum.

De-certification: Status given to a previously certified supplier when they score below 85 for twelve (12) consecutive months and fails to improve.

Delivery lead-time: The time from the receipt of a customer order to the delivery of a product.

Delivery Failure Cost Penalty: Penalty given by ComDel Innovation / Heartland Precision when the supplier shuts down a production line at CDI/HP due to a delivery failure.

Qualified Supplier: Status given to the supplier by CDI/HP when they have provided three (3) lots of materials and the lots have passed inspection and met CDI/HP's specifications.

Quality Failure Cost Penalty: Penalty given by CDI/HP when the supplier shuts down a production line at CDI/HP due to a quality failure.

Shipment: Is defined as an CDI/HP purchase order line item.

The signature below indicates acceptance of this TQMP.

Supplier Signature _____ Date _____