



ComDel Innovation Inc.

Total Quality Management Program

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Total Quality Management Program

This document outlines and explains the requirements and elements CDI requires that are critical to successful relationships with our suppliers. CDI's suppliers shall comply with the quality program requirements set forth in this document.

Supplier Questionnaire

The image shows a 'Supplier Questionnaire' form from CDI. It includes instructions for completion, a header with the CDI logo, and several sections: 'A. Manufacturing Facility Management', 'B. Manufacturing Quality Management System/Operational Control System', and 'C. Suppliers'. Section C contains a table with columns for 'Supplier Name', 'Part No.', 'Part Desc', 'Part Qty', 'Part Unit', 'Part Cost', 'Part Price', and 'Part Status'. The form is labeled 'Page 1 of 1'.

All suppliers supplying material or services affecting product quality are selected on the basis of their ability to meet CDI 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's M1 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.

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 9001:2000 and if applicable, ISO 13485 and AS9100. The Supplier shall notify CDI 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 of any changes they have made in their system.

The supplier is responsible to flow down to sub-tier suppliers the ComDel's requirements, including key characteristics.

CDI Audits

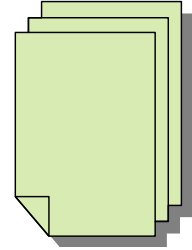
On a periodic basis, CDI may conduct audits/visits at the supplier's manufacturing locations. The supplier shall, at CDI's request, permit access to manufacturing operations involved in the production and/or inspection of Imation's products, including access to sub-contractor facilities. Periodic audits 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 CDI's visits.



Document / Record Control

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.



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

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 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 quality technician 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.

Supplier Visits

ComDel Innovation Inc. will meet with suppliers on a yearly basis or as needed to discuss current business issues or future opportunity.



Certificate of Analysis Requirement

The supplier is responsible for sending the Certificate of Analysis (C of A) data on all shipments. The C of A's can be mailed, faxed or sent with the material. Electronic access to supplier product test data is an acceptable alternative to the Certificate of Analysis.

The quality 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 requires inspection status.

A Nonconforming Report may be issued. If the Cpk level is below 1.33 an inspection requirement will be determined.

CERTIFICATE OF ANALYSIS			
Product:	Concentrated Omega (F)3 Esters		
Batch No:	Typical analysis		
Packaging:			
Component	Level	Analysis	Method of Analysis
Total Omega	35-50%	>40%	Internal GC. Area under trace Verified by InLab & SOANAS2 (1985)
DHA (Docosahexaenoic C22:6n-3)	20-35%	>25%	-
EPA (Eicosapentaenoic C20:5n-3)	8-15%	8%	-
MICROBIOLOGICAL INFORMATION			
% Water activity (AW)	0.01 - 0.70	Undetected	Microbial Ecology of Food, 1 (1981)
% Total Plate Count	<10 - <100/gm	-	A.P.H.A. Comp. 16 th Ed.
SAPROL PCH SURVEY FEBRUARY 2005			
% Total PCB	< 50 ppb N/A		GC & EMS, Albany, et al., Chromosphere 2K, 1049 - 1067
% Total PEQ	< 10 ppb incl. LOD	N/A	
PESTICIDES			
ppm DDT	< 60 ng/g	N/A	GC & EMS, International Standards
ppm DDE	< 20 ng/g	N/A	GC & EMS, International Standards
ppm DDEP	< 60 ng/g	N/A	GC & EMS, International Standards
ppm DDEP	< 200 ng/g	N/A	GC & EMS, International Standards
Alpha Tocopherol as supplied by client added at 0.15%. The head space of all containers flushed with CO ₂ . No other additive applied.			
Authorized by:	Position: Company Manager	Date: 20 Feb 2005	

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.

Supplier product that does not meet requirements shall be communicated prior to product shipment. Supplier product discovered after shipment by the supplier to be nonconforming to any requirement shall be immediately disclosed to ComDel 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.

Any nonconformance report 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
- Wrong item shipped



The quality technician 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 and the supplier.

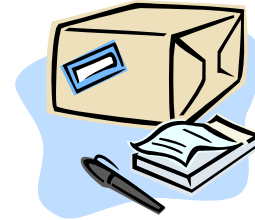
Supplier is responsible for completing each section by requested due date and submitting to the quality technician.

Document Requirements

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:

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

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



Invoicing/Billing

All invoicing and billing sent to CDI 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 part number
- Purchase order number and/or release number, including line item number printed adjacent to the CDI 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

It is the responsibility of the supplier to ensure the required items listed above are true and accurate. Any discrepancy will significantly delay payment.

Supplier Challenge

This form is intended for the use of all CDI suppliers to document their ideas or suggestions for unit cost reduction, inventory reduction, waste reduction, critical cycle time reduction or energy reduction.

The following submissions will not be accepted:

- Supplier is not capable of doing the proposed challenge
- Savings calculation has not been calculated

Supplier Challenge

DOC854-FR.6 (07/09/08)



This form is intended for the use of all CDI suppliers to document their ideas or suggestions for cost reduction.

Supplier Name		Supplier Address		Submitted By / Phone		Date	
CDI ID Number				Material Description			
Present: <i>(description of the product under consideration & the current method of buying the product. Include price & other pertinent information)</i>							
Proposed: <i>(describe the changes being recommended along with the effect on unit cost or inventory. Include any implementation costs)</i>							
Type of Proposed Savings <i>(Examples)</i>							
<input checked="" type="checkbox"/> Unit Cost Reductions <i>(Price Reduction)</i>		<input type="checkbox"/> Waste		<input type="checkbox"/> Critical Cycle Time		<input type="checkbox"/> Energy	
<input type="checkbox"/> Inventory Reduction <i>(examples: Consignment, SMI)</i>		<input type="checkbox"/> Product Substitution		<input type="checkbox"/> Freight Savings		<input type="checkbox"/> Cost Avoidance <i>(example: Surcharges or price increases announcement not applied)</i>	
Savings Calculation: <i>(project the net savings to CDI in dollars)</i>							
Savings Measurement		(Inventory)		(Days)		(Units)	
	Avg. \$	Avg. Days	Lead Time	Make Cycle	Min. Order Qty		
Current:	_____	_____	_____	_____	_____		
Target:	_____	_____	_____	_____	_____		
Implemented: No <input type="checkbox"/> Yes <input type="checkbox"/>				Action Taken			
Date Implemented: _____							
Reviewed By:				Date:			

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 I - Supplier Assessment

Phase II - Supplier Qualification

Phase III - Continuous Improvement

Phase IV - Recognition

Supplier Performance is rated quarterly on suppliers who are considered a key supplier for CDI. A key supplier is one who affects the product quality and CDI purchases over a certain dollar amount per year. A review summary will be mailed to each supplier, 30 days following the end of the quarter. All items purchases from a supplier will be on one performance report.

Rating Criteria

Quality - evaluated on the basis of conformance to specifications and commitment to continuous quality improvement. Condition of received materials, corrective action requests, COA data and discrepancy reports.

Cost - evaluated on the basis of cost reduction efforts and competitiveness.

Service - evaluated on the basis of on-time delivery, documentation, and timely response to corrective action requests.

Recognition

Supplier Certification—supplier must meet the following minimum requirements to receive Certified status.

- Maintain 95 points or greater, each quarterly review for four consecutive reviews.

De-Certification

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

- Total points fall below the minimum required points (95) for four (4) 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 meet the Rating Criteria for two quarterly reviews..



Supplier Performance Quarterly Report



DOC751-FR8 (07/31/08)

To determine supplier's performance, points are determined in each category and totaled for a final score.

Supplier Name

Supplier Status:	Qualified
Rating Period	x rd Quarter 200x
Total # of shipments	
Total Score	

Supplier Quality shall be evaluated on the basis of conformance to specifications and commitment to continuous quality improvement. Condition of received materials, corrective action requests, COA data, and discrepancy reports will be considered.

Quality	Item Measured	Comments	Maximum Points	Scoring
	Shipments with no issues. % Accepted / 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	Nonconformance Reports issued for each discrepant shipment.	10	10
	Failure Costs Penalties (examples: Product rework due to defects & Line shut down)	Penalty given if a production line shuts down due to lack of acceptable parts or production reworks finished product due to quality of parts.	10*	10
	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	Certificate of Analysis must contain data. Data sent might be used to release shipment.	10	10
	Each shipment key parameters met 1.5 Cpk (supplier data), any below have a process improvement plan in place. Cpk => 1.5 / 10 points Cpk below 1.5 with improvement plans / 10 points Cpk levels with no improvement plan 1.33 - 1.49 / 8 points 1.0 - 1.32 / 6 points below 1.0 / 4 points No data / 0 points CDI will contact each supplier to participate and to develop a implementation plan. Any supplier not asked to participate will automatically receive these points.	CDI will contact each supplier to participate and to develop a implementation plan. Any supplier not asked to participate will automatically receive these points. Agreed upon parameters must meet 1.5 Cpk or have a process improvement plan in place. CDI will report the parameter with the lowest Cpk for items with multiple parameters. Refer to purchasing, if investment is needed to reach Cpk capability. Improvement plan must be implemented within 6 months.	10	10

Total points for Quality 40

Supplier service shall be evaluated on the basis of on-time delivery, documentation, and timely response to corrective action requests.

Service	Item Measured	Comments	Maximum Points	Scoring
	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	Percent of shipments with acceptable ship dates and quantity.	10	10
	Failure Costs Penalties for Service (example: Line shut down due to no material).	Penalty given if a production line shuts down due to lack of material.	10*	10
	Delivery Lead Time: = or < than 30 days OR Consignment plan in place.	Any changes in lead-time must be communicated to Buyer.	3*	3
	Corrective Action Requests issued for Service/Customer Service.	SCAR issued for service related issues or customer service problems. Example: Incorrect quantity shipped continuously	5*	5
	Percent of shipments with correct documentation (packing slips, labels, invoices, etc.) % Acceptance / Points 100 / 2 99-95 / 1 <or= 94 / 0	Examples: Incorrect PO # listed, incorrect quantity listed. or box label does not match packing slip. Invoice Hold issues.	2	2
	On-time responses for Corrective Action Requests / Nonconformance Reports.	CDI will review past quarter requested timely responses.	10*	10

Total points for Service 40

* No partial points awarded. Awarded points are either 0 or maximum points.



Supplier cost shall be evaluated on the basis of cost reduction efforts and competitiveness.

Cost	Item Measured	Comments	Maximum Points	Scoring
	Supplier has been proactive in reducing costs by suggesting options and alternatives by submitting Supplier Challenge Forms to CDI.	Supplier Challenges are due 1 st and 3 rd quarter. Points for 2 nd and 4 th quarter will be awarded if challenges were received in the prior quarter. Suggestions have no limit. Forms to be submitted to Kathy Lenk.	7*	7
	Supplier has competitive prices (Best Value)	Is supplier market competitive?	7*	7
	Freight Costs to CDI: * Best rate * Correct carrier * Correct routing	All non-agreed upon rates, carriers, and routing will be noted.	6*	6

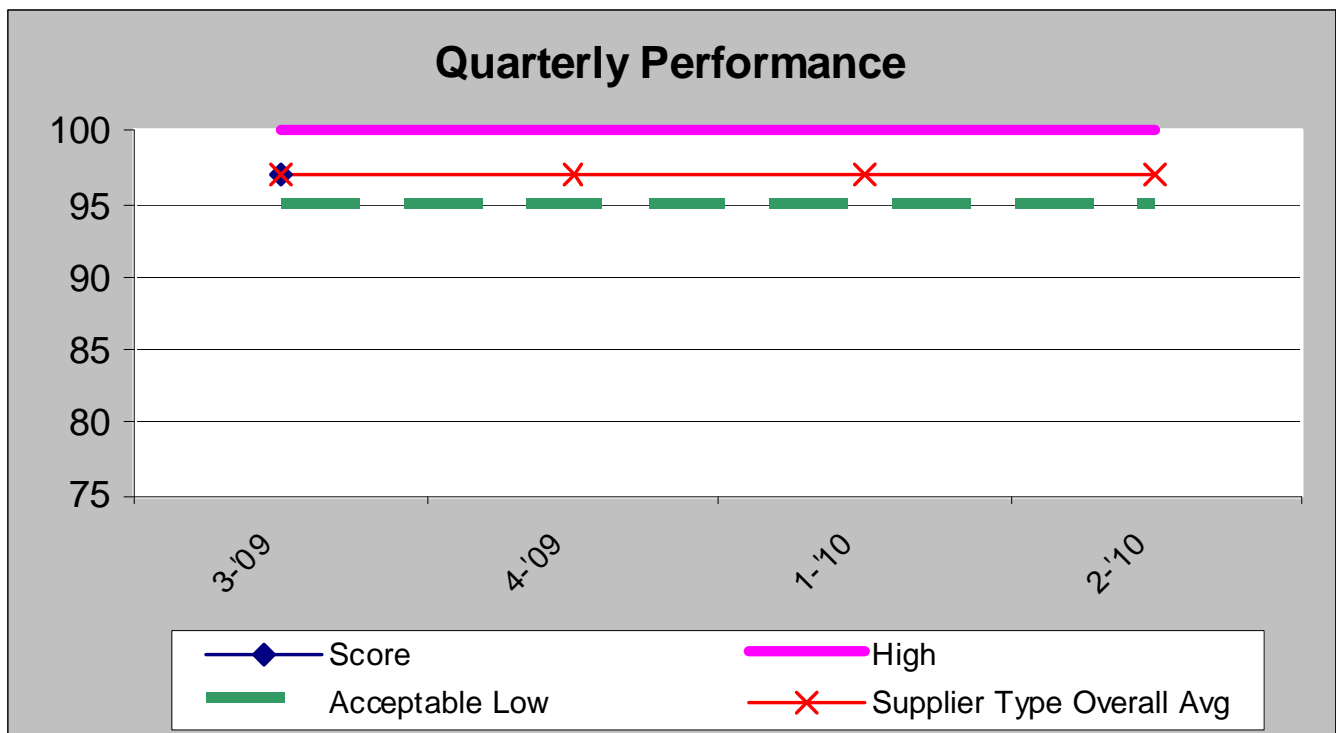
Total points for Cost 20

* No partial points awarded. Awarded points are either 0 or maximum points.

Supplier Scoring Summary

Supplier Status / Definition	Date Completed
Qualified - The first 3 lots of material have been inspection by Imation and are acceptable per Imation's specifications.	
Certification - Supplier has achieved 95 points or greater for four (4) consecutive quarter reviews.	
De-Certification - Occurs after supplier is placed on temporary suspension and has not reached the necessary points (95) for 4 consecutive reviews.	

Current Quarter Score		Past 4 Quarterly Review Scores		For question please contact: Kathy Lenk Phone: 701.671.6149 Fax: 701.642.8206 kathy.lenk@comdelinc.com
Total Quality	40	3 rd Quarter 2009		
Total Service	40	4 th Quarter 2009		
Total Cost	20	1 st Quarter 2010		
Total Score	100	2 nd Quarter 2010		



Glossary

Approved: Supplier status given when supplier in Imation's database as a supplier, no other criteria is needed for the "approved" status level.

Certification: Award/status given by CDI to suppliers when they achieve a score of 95% or better on the CDI Supplier Performance Report for four (4) consecutive quarters.

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 under 95 for four (4) consecutive quarters 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 Imation when the supplier shuts down a production line at CDI due to a delivery failure.

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

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

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