
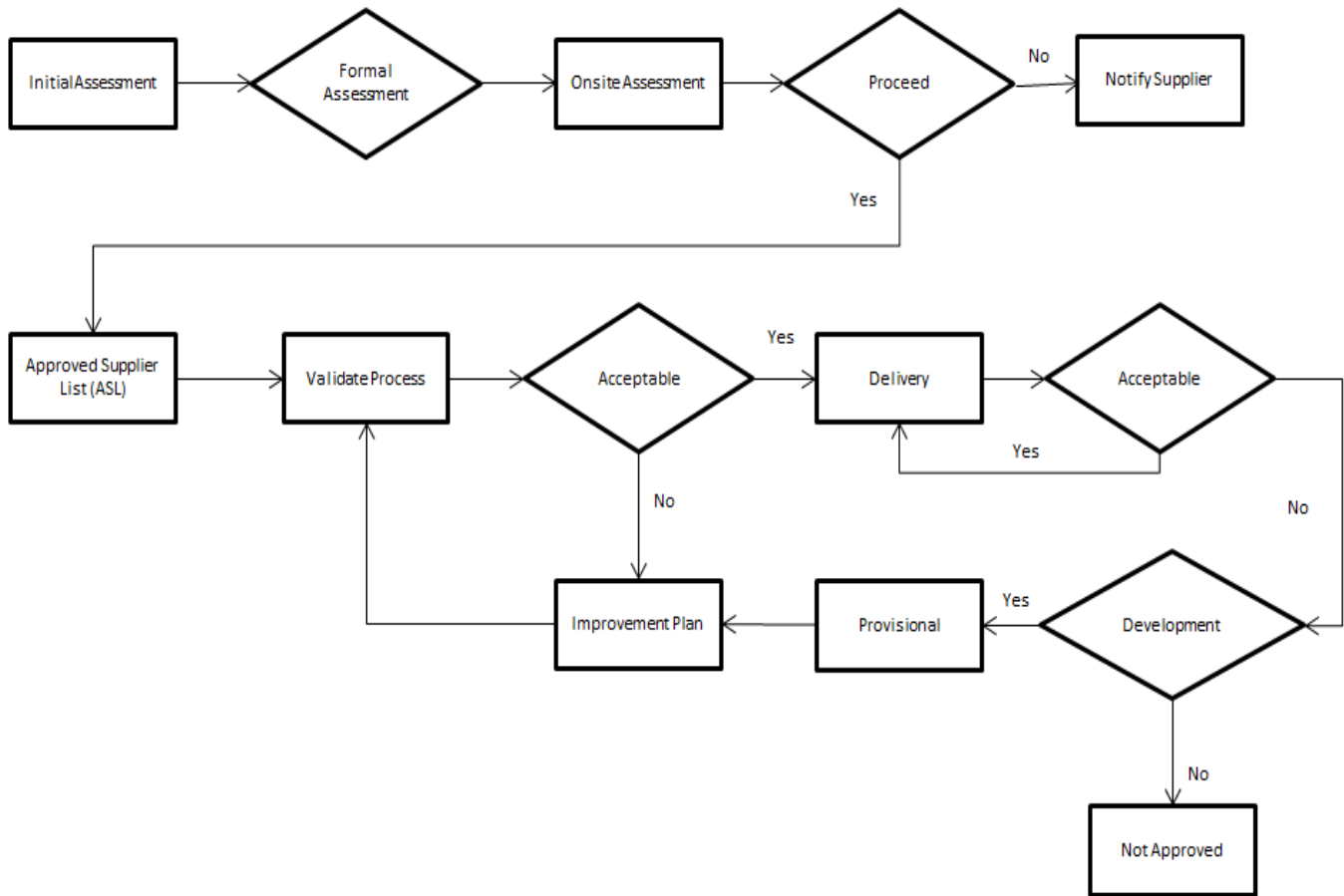
	Document Title: Supplier Handbook		Document #: QMS-3-PUR-004	Rev C
	Document Owner: Purchasing	Date: 10/3/17	Approved for Release By: Management Rep	Date: 11/18/20

1. Purpose
 - 1.1. The purpose of the handbook is to provide a guide to suppliers for performing business with C&H Enterprises.
2. Scope
 - 2.1. The Supplier Handbook applies to all suppliers of C&H Enterprises.
3. Procedure
 - 3.1. Introduction
 - 3.1.1. C&H is committed to delivering quality product to our customers. A critical element of our business is Supplier quality management. We encourage partnerships with Key Suppliers in order to maintain and improve our world-class quality levels and Customer satisfaction. We have established this procedure for selecting Suppliers and for the periodic assessment of their quality management system. It is important that C&H maintains Suppliers who consistently deliver high quality products and services. The purpose of this manual is to inform our Suppliers of our core expectations and to ensure all requirements herein are met for the purpose of doing business with C&H Enterprises.
 - 3.2. Application
 - 3.2.1. C&H purchase orders shall define product or services requested. The supplier manual will flow down requirements using the following quality clauses to define requirements when purchasing services or goods from Suppliers.
 - 3.3. Quality system requirements
 - 3.3.1. We encourage our Suppliers to implement an ISO 9001 quality system or equivalent and have their systems certified by an accredited registrar. If your company has achieved such certification, please provide a current copy to your C&H buyer. We ask that you notify your buyer if loss of certification has occurred.
 - 3.4. Supplier Approval Process
 - 3.4.1. C&H requires all Suppliers to be approved prior to the issuance of contracts, regardless of approvals by customers or other entities. In some cases, Supplier may be awarded contract upon urgency and nature of criticality during approval process.
 - 3.4.2. Flow Chart

Any reproduction of the “**CONTROLLED**” document is considered “**UNCONTROLLED**”.

The information contained in this document is proprietary and shall not be reproduced without the written authorization of C&H Enterprises.

	Document Title: <p style="text-align: center;">Supplier Handbook</p>	Document #: <p style="text-align: center;">QMS-3-PUR-004</p>	Rev #: <p style="text-align: center;">C</p>
--	---	---	--



3.4.2.1. Supplier Initial Assessment

3.4.2.1.1. Supplier provides a copy of:

- 3.4.2.1.1.1. Quality management system certification or C&H Supplier Survey.
- 3.4.2.1.1.2. W9
- 3.4.2.1.1.3. Non-Disclosure Agreement


3.4.2.2. Onsite Assessment

3.4.2.2.1. C&H may request an onsite assessment or audit for the following:

- 3.4.2.2.1.1. Quality Management System to determine whether the Supplier’s quality management system meets the applicable standards and is functioning effectively.
- 3.4.2.2.1.2. Process of Record Audit to determine all processes are defined and are not changed without prior approval from C&H.
- 3.4.2.2.1.3. Business and Manufacturing Operations to determine whether the Supplier has the financial resources, production capacity and other business resources needed to fulfill production needs and continuity of supply.
- 3.4.2.2.1.4. Continual Improvement Initiative to determine if the Suppliers culture, methods and skills are present to actively pursue continual improvement.
- 3.4.2.2.1.5. Technology Assessment to determine whether the Supplier has the needed technical resources, including production and inspection equipment, facilities, engineering resources, etc.

Any reproduction of the “**CONTROLLED**” document is considered “**UNCONTROLLED**”.

The information contained in this document is proprietary and shall not be reproduced without the written authorization of C&H Enterprises.

 <p>C&H ENTERPRISES MANUFACTURING • MEDICAL • DISTRIBUTION</p>	Document Title: <p style="text-align: center;">Supplier Handbook</p>	Document #: <p style="text-align: center;">QMS-3-PUR-004</p>	Rev #: <p style="text-align: center;">C</p>
---	--	--	---

3.4.2.3. Process Validation

3.4.2.3.1. The Supplier is responsible to submit a copy of the First Article Inspection report to C&H with the completed order and tag the inspected part for validation. When defined in purchase order, the FAI shall be submitted to C&H's quality department prior to the continuation of a production run. Supplier shall notify C&H 24 hours prior to completion of FAI, as applicable. C&H will validate FAI and/or processes are compliant.

3.4.2.3.2. C&H reserves the right to source inspect at the Supplier's facility. C&H will notify the Supplier in advance.

3.4.2.4. Product Delivery

3.4.2.4.1. C&H will monitor delivery is met and will routinely evaluate for compliance.

3.5. General Requirements

3.5.1. Compliance to contractual requirements

3.5.1.1. Upon accepting a C&H purchase order, or contract, the Supplier is responsible for compliance to all requirements (e.g., drawing, specification, material, etc.). All documents, drawings and specifications, regardless of origin, are applicable to the Supplier when specified in the purchase order and are required to be used at all levels of the supply chain. The document revision on the date of issue applies to the contract. Neither audit, surveillance, inspection nor tests made by C&H, representatives of C&H or its customer(s), at Supplier's facilities, at any sub-tier facilities, or upon receipt at C&H, relieves the Supplier of the responsibility to furnish acceptable products or services that conform to all contract requirements, nor does it preclude subsequent rejection by C&H or its customers.

3.5.2. C&H Designated Sources

3.5.2.1. Where specified by contract, the Supplier shall purchase products, materials or services from C&H designated sources. However, the Supplier is responsible to ensure that items procured from such sources meet all applicable technical and quality requirements.

3.5.3. Control of Sub-Tier Suppliers

3.5.3.1. The Supplier, as the recipient of the contract, is responsible for meeting all requirements, including work performed by the Supplier's sub-tier Suppliers. When the Supplier uses sub-tier sources to perform work on products scheduled for delivery to C&H, the Supplier shall include flow-down on contracts to its sub-tier Suppliers, including quality system requirements, regulatory requirements, C&H designated sources, key characteristics or processes, test reports, or inspection reports as required. C&H and its customers reserve the right of entry to sub-tier facilities.

3.5.4. Risk Management

3.5.4.1. The Supplier shall establish a risk management program to effectively assess those elements from all aspects of the business that could affect the quality of the products and/or services scheduled for delivery to C&H. A copy of the analysis may be requested by C&H.

3.6. Product Safety and Ethical Behavior

3.6.1. Flow Down of Requirements 8.4.3 m

3.6.1.1. Supplier must be committed to the highest standards of ethics and business conduct.


3.6.1.2. Supplier must comply with the law, honor commitments, act in good faith, and be accountable.

3.6.1.3. Supplier must strive to maintain full compliance with all laws and regulations applicable to the operation of the business and customer relationships.

3.6.1.4. Supplier must not offer, promise, authorize, or provide, directly or indirectly, anything of value (including business gifts or courtesies) with the intent or effect of inducing anyone to engage in unfair business practices.

3.6.1.5. Supplier will avoid involvement in activities that may be perceived as a conflict-of-interest.


3.6.1.6. Supplier will respect the legitimate proprietary rights and intellectual property rights of customers and Suppliers and take proper care to protect sensitive information, including confidential, proprietary and personal information.

 <p>C&H ENTERPRISES MANUFACTURING • MEDICAL • AEROSPACE</p>	Document Title: <p style="text-align: center;">Supplier Handbook</p>	Document #: <p style="text-align: center;">QMS-3-PUR-004</p>	Rev #: <p style="text-align: center;">C</p>
--	--	--	---


- 3.6.1.7. Supplier will support product safety by ensuring robust management of special requirements, critical items and key characteristics. If there are concerns with respect to product safety,
- 3.6.1.8. Supplier will communicate them to C&H Enterprises. If there is a concern at the Supplier's premises with respect to safety during the manufacture of the product,
- 3.6.1.9. Supplier will notify its own employees of the concern and whenever possible, mitigate the concern.
- 3.6.1.10. Supplier will ensure that employees and people working on its behalf are aware of:
- 3.6.1.10.1. Their contribution to product or service conformity
 - 3.6.1.10.2. Their contribution to product safety
 - 3.6.1.10.3. The importance of ethical behavior
- 3.7. Control and Release of C&H Furnished Documents
- 3.7.1. Documents furnished by C&H to the Supplier are provided solely for the purpose of doing business with C&H. Proprietary documents may be furnished to the Supplier in hard copy or electronic. The Supplier is responsible for controlling and maintaining such documents to preclude improper use, loss, damage, alteration and/or deterioration. Unless authorized by C&H in writing, the Supplier may not transmit or furnish any C&H documents to anyone outside the Supplier's business organization except to a sub-tier source used by the Supplier for performance of work on the C&H contract. The Supplier shall flow down this requirement to all sub-tier sources.
- 3.8. Non-Conforming Product
- 3.8.1. A Supplier shall not knowingly ship product that deviates from the drawing or specifications without prior **written authorization from C&H. The Supplier is required to notify C&H prior to shipment of any nonconforming product that will impact the contract of the purchase order. Such materials shall be held from shipment until authorized by C&H with a discrepant material report, which includes a clear description of the nonconformity, quantity of parts affected and part number(s). The Supplier is responsible to complete the C&H DMR.** If the problem is recurring or is deemed necessary, a corrective action request will be issued. Any reworked nonconforming material shall be resubmitted as such so C&H can verify rework is acceptable.
- 3.9. Counterfeit Parts
- 3.9.1. Approved suppliers shall assure prevention of entry of counterfeit parts into C&H's supply chain.
- 3.9.2. Supplier or subcontractor shall maintain a documented counterfeit part control plan compliant to the AS 9100 D requirements.
- 3.9.3. Refer to QMS-3-QA-036 for C&H's counterfeit work instruction for more details.
- 3.10. Control of Sub-tier Providers
- 3.10.1. All First-tier suppliers that are required to apply appropriate controls to their direct and their sub-tier providers in order to control externally provided processes/products/services.
- 3.10.2. Responsibility for the acceptance of the final deliverable product to C&H cannot be delegated to any sub-tier supplier unless supplier establishes delegation requirements and maintains the delegation list.
- 3.10.3. Additional acceptance inspection may be required by C&H through source inspection and/ or government source inspection as directed by the purchase order.
- 3.10.4. Both ISO 9001 and AS9100 require suppliers to have purchasing information that describes the product to be purchased. In addition, C&H QMS mandates that the applicable quality elements be contractually imposed throughout the supply chain. As such, the first tier supplier shall review all requirements that shall be incorporated in their purchasing information.
- 3.10.5. Below is a list of items to be incorporated in the sub-tier's purchase order.
- 3.10.5.1. Quality Management System, such as ISO 9001, AS9100
 - 3.10.5.2. Special process approval requirements
 - 3.10.5.3. Customer approval for use and control of digital data
 - 3.10.5.4. First Article Inspection requirements
 - 3.10.5.5. Variation Management of Key Characteristics
 - 3.10.5.6. Statistically valid sampling plan
 - 3.10.5.7. Source inspection vs. receiving inspection
 - 3.10.5.8. Engineering drawing for dimensions, finish, materials & process requirement
 - 3.10.5.9. Drawing revision, as required by customer purchase order

Any reproduction of the "**CONTROLLED**" document is considered "**UNCONTROLLED**".

The information contained in this document is proprietary and shall not be reproduced without the written authorization of C&H Enterprises.

	Document Title: Supplier Handbook	Document #: QMS-3-PUR-004	Rev #: C
--	--	----------------------------------	-----------------

- 3.10.5.10. Right of access by C&H, their customer, and authorities to all facilities involved in the purchase order and to all applicable records
- 3.10.6. Suppliers to C&H are encouraged to utilize sub-tiers that are certified to ISO 9001:2015 or AS9100 Rev. D. As a minimum, sub-tiers throughout the supply chain shall be compliant to the above quality management systems.
- 3.10.6.1. As a minimum, suppliers should perform:
- 3.10.6.2. Onsite evaluation in lieu of “mail-in” survey.
- 3.10.6.3. Periodic on-site surveillance to ensure continued compliance to industry standards, engineering specifications, special process requirements, and appropriate record keeping.
- 3.10.6.4. If a sub-tier has been delegated for product inspection on behalf of the supplier, additional oversight should be incorporated into the process.
- 3.10.6.5. In addition to initial and periodic process verification reviews, first-tier providers shall have a sub-tier performance reporting process that includes, at a minimum:
- 3.10.6.5.1. Quality and delivery with defined thresholds
- 3.10.6.5.2. The ability to monitor customer satisfaction as a performance metric
- 3.10.6.5.3. Heightened inspections with poor performing sub-tiers
- 3.10.6.5.4. Recovery or “Exit” plans from poor performing sub-tiers where applicable.
- 3.10.6.5.5. An Approved Supplier List (ASL) should be maintained. The first-tier supplier should have a formal process to restrict future procurement with disapproved sub-tier providers to ensure only approved sub-tier suppliers receive purchase orders.
- 3.10.7. Special processes for production and service provision, where the resulting output cannot be verified by subsequent monitoring or measurement, must be evaluated and qualified prior to manufacturing. C&H and its customers have identified processes that require increased focus through validation and control.
- 3.10.8. Changes to product or process
- 3.10.8.1. The Supplier must receive written authorization for any changes made to an existing process. All requests will be evaluated, tested as needed and approved, as applicable, prior to Supplier change. Any testing or documentation will be forwarded to C&H for evaluation and saved at Supplier site, as applicable.
- 3.10.9. Performance Monitoring
- 3.10.9.1. C&H monitors quality, price and on-time delivery constantly and reports at a minimum of once a year. The Supplier is expected to deliver quality parts 100% of the time. All parts are expected to be delivered by due date on purchase order. Cost improvements and payments terms will be rated. The Supplier will be notified if their overall score drops below 85%. A corrective action request may be submitted to any Supplier for any quality or on-time delivery issues.
- 3.10.9.1.1. Quality System Performance score 60%.
- 3.10.9.1.2. On Time Delivery score 30%
- 3.10.9.1.3. Pricing score 10%
- 3.10.10. Corrective Action
- 3.10.10.1. A corrective action request may be initiated by C&H for quality or on-time delivery issues. The Supplier shall take action to determine and eliminate the cause of non-conformance in order to prevent reoccurrence and to improve process. The Supplier shall respond in a timely manner with containment, root cause, and corrective action. Suppliers who repeatedly fail to deliver satisfactory products and/or do not deliver on time are downgraded to either provisional or not approved status.
- 3.10.11. Packaging
- 3.10.11.1. The Supplier must adequately plan for packaging designed to prevent product deterioration or loss and shipping damage. Suppliers should provide expendable packaging or returnable containers must meet local and national standards for safe disposal and/or recycling.
- 3.10.12. Delivery
- 3.10.12.1. The Supplier should systematically inform C&H of any delay in delivering product and provide a new dispatch date. The Supplier is responsible for additional transport costs due to delays, as applicable.
- 3.10.13. Certificate of Conformance

 <p>C&H ENTERPRISES MANUFACTURING MEDICAL EQUIPMENT</p>	Document Title: <p style="text-align: center;">Supplier Handbook</p>	Document #: <p style="text-align: center;">QMS-3-PUR-004</p>	Rev #: <p style="text-align: center;">C</p>
---	---	---	--

3.10.13.1. Each shipment shall be accompanied by a dated certification, as applicable, signed by a competent authority confirming that the product or services provided under the purchase order have been manufactured, processed, inspected, and tested in accordance with the provisions therein. Certifications from sub-tier Suppliers must also be furnished with each shipment. Serialization must be included when applicable.

3.10.14. Record Retention

3.10.14.1. All C&H approved Suppliers shall establish and maintain records. Records shall be retained for seven (7) years unless otherwise specified in purchase order. Records shall be made available to C&H, its customers and regulatory agencies upon request.

3.10.15. Counterfeit Materials


3.10.15.1. The Supplier shall ensure that only new and authentic materials are used in products delivered to C&H and verified to be non-counterfeit.

3.10.16. Right of Access

3.10.16.1. All C&H approved Suppliers agree to the right of entry and access for C&H, its customers and regulatory agencies into all facilities, processes and access to applicable records.

3.10.17. Confidentiality

3.10.17.1. All C&H approved Suppliers shall hold information received in confidence. A third party request for information is not authorized unless approved in writing by C&H.

 C&H ENTERPRISES MANUFACTURING MEDICAL EQUIPMENT	Document Title: Supplier Handbook	Document #: QMS-3-PUR-004	Rev #: C
--	--	----------------------------------	-----------------

Acknowledgement Receipt

Please sign and return this page as an acknowledgement of receipt and acceptance of terms outlined in C&H Enterprises Supplier Handbook. Acknowledgement should be returned within 2 weeks of receipt. If acknowledgement is not received within this time period, C&H Enterprises will consider as acceptance of this handbook.

Company

Company Name

Printed Name

Printed Name

Signature

Signature

Title


Title

Date

Date

Any reproduction of the "CONTROLLED" document is considered "UNCONTROLLED".

The information contained in this document is proprietary and shall not be reproduced without the written authorization of C&H Enterprises.

 <p>C&HENTERPRISES <small>MAKING THE WORLD A BETTER PLACE</small></p>	Document Title: <p style="text-align: center;">Supplier Handbook</p>	Document #: <p style="text-align: center;">QMS-3-PUR-004</p>	Rev #: <p style="text-align: center;">C</p>
---	---	---	--

REVISIONS HISTORY

Rev	Description	Requestor	Date	Approver	Date
A	Initial Release	Mansi Mavani	10/11/16	Jami Massey	10/11/16
B	Include Sub-tier, counterfeit, and edit monitoring	Baqar Hasan	10/5/17	Jami Massey	10/5/17
B	Added Purpose & Scope Upload updated on 10/15/18 at C&H Website	Mansi Mavani	10/15/18	Jami Massey	10/15/18
C	Added Product Safety and Ethical Behavior - - Flow Down of Requirements 8.4.3 m Section 3.6. Added Acknowledge Receipt Page 7 Upload updated on 11/18/20 at C&H Website	Mansi Mavani	11/9/2020	Jami Massey	11/18/20

Any reproduction of the **“CONTROLLED”** document is considered **“UNCONTROLLED”**.

The information contained in this document is proprietary and shall not be reproduced without the written authorization of C&H Enterprises.