



SUPPLIER QUALIFICATION

DCVMN Workshop – Hyderabad, India.

Victor G. Maqueda, Argentina – April 2017





Objectives

- To identify the role of Supplier Qualification in the quality management system

9.2 Internal audit



- 9.2.1 The organization shall conduct internal audits at planned intervals to provide information on whether the quality management system conforms to the organization's own requirements for its quality management system; is effectively implemented and maintained.
- 9.2.2 The organization shall:
 - a) plan, establish, implement and maintain an audit program including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the processes concerned, changes affecting the organization, and the results of previous audits;
 - b) define the audit criteria and scope for each audit;
 - c) select auditors and conduct audits to ensure objectivity and impartiality;
 - d) ensure that the results of the audits are reported to relevant management;
 - e) take appropriate correction and corrective actions without undue delay;
 - f) retain documented information as evidence of the implementation of the audit program and the audit results. NOTE See ISO 19011 for guidance.

8.4.1 General

(ISO 9001:2015)

8.4.1 The organization shall ensure that externally provided processes, products and services conform to requirements.

Determine the controls to be applied to externally provided processes, products and services when:

- a) products and services from external providers are intended for incorporation into the organization's own products and services;
- b) a process, or part of a process, is provided by an external provider.

- Determine and apply criteria for the evaluation, selection, monitoring of performance, and re-evaluation of external providers

- Retain documented information of these activities and any necessary actions arising from the evaluations.

8.4.2 Type and extent of control

(ISO 9001:2015)

Ensure that externally provided processes remain within the control of its quality management system;

- a) Define both the controls that it intends to apply to an external provider and those it intends to apply to the resulting output;
- b) take into consideration:
 - 1) the potential impact of the externally provided processes, products and services on the organization's ability to consistently meet customer and applicable statutory and regulatory requirements;
 - 2) the effectiveness of the controls applied by the external provider;
- c) determine the verification, or other activities, necessary to ensure that the externally provided processes, products and services meet requirements.

8.4.3 Information for external providers

(ISO 9001:2015)

The organization shall ensure the adequacy of requirements prior to their communication to the external provider.

The organization shall communicate to external providers its requirements for:

- a) the processes, products and services to be provided;
- b) the approval of:
 - 1) products and services;
 - 2) methods, processes and equipment;
 - 3) the release of products and services;
- c) competence, including any required qualification of persons;
- d) the external providers' interactions with the organization;
- e) control and monitoring of the external providers' performance to be applied by the organization;
- f) verification or validation activities that the organization, or its customer, intends to perform

SUPPLIER AUDIT AND APPROVAL

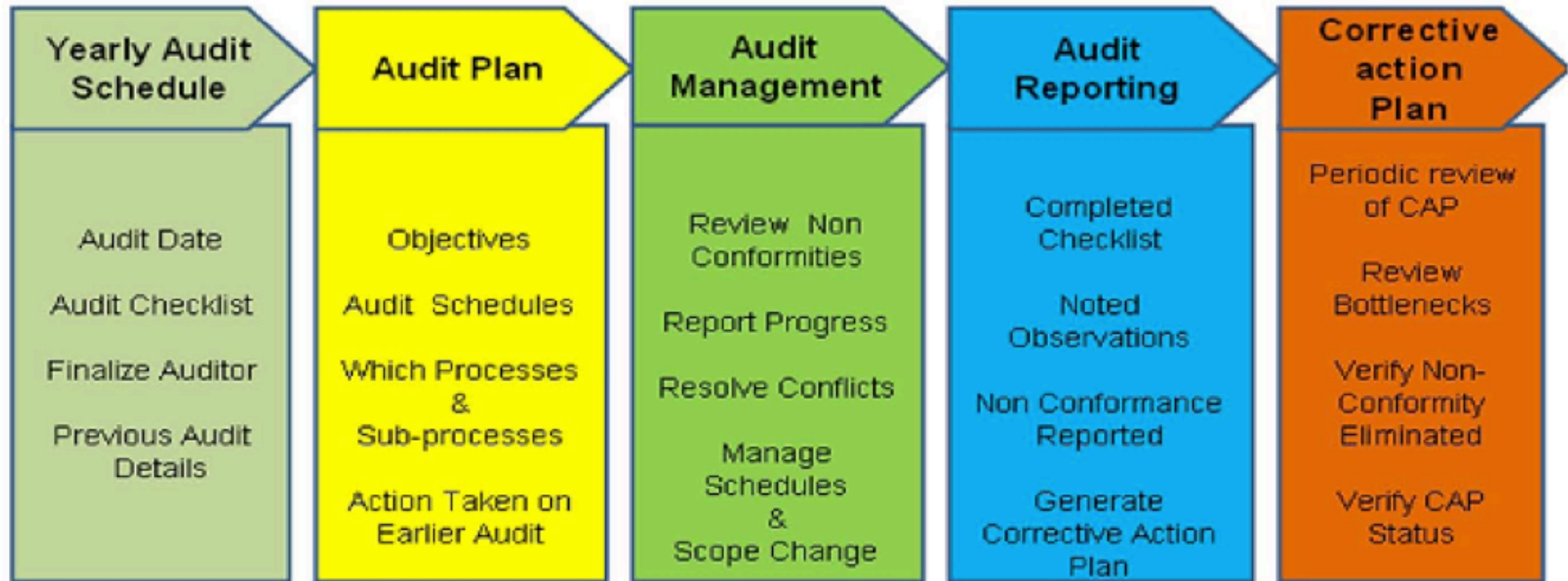


- Ensures suppliers can reliably supply materials that meet established specifications
- Suppliers should be evaluated and approved before they are included in approved supplier's lists
- Purchasing, QC, QA and Manufacturing involvement
- Due diligence - Audit
- Degree of qualification based on supplier's history and nature of materials to be supplied (RISK)
- Define criteria to select suppliers (mandatory-regulatory; desired): first on quality-regulatory matters, then logistics, capacity, cost.
- Qualification program should requalify periodically based on performance indicators (e.g., rejection rate,.....)

CONTINUOUS IMPROVEMENT PROCESS – VENDOR MANAGEMENT



VENDOR AUDIT PROGRAM



SUPPLIER QUALIFICATION PROGRAM FOR CONYINUOUS IMPROVEMENT BASED ON QUALITY METRICS & CAPA

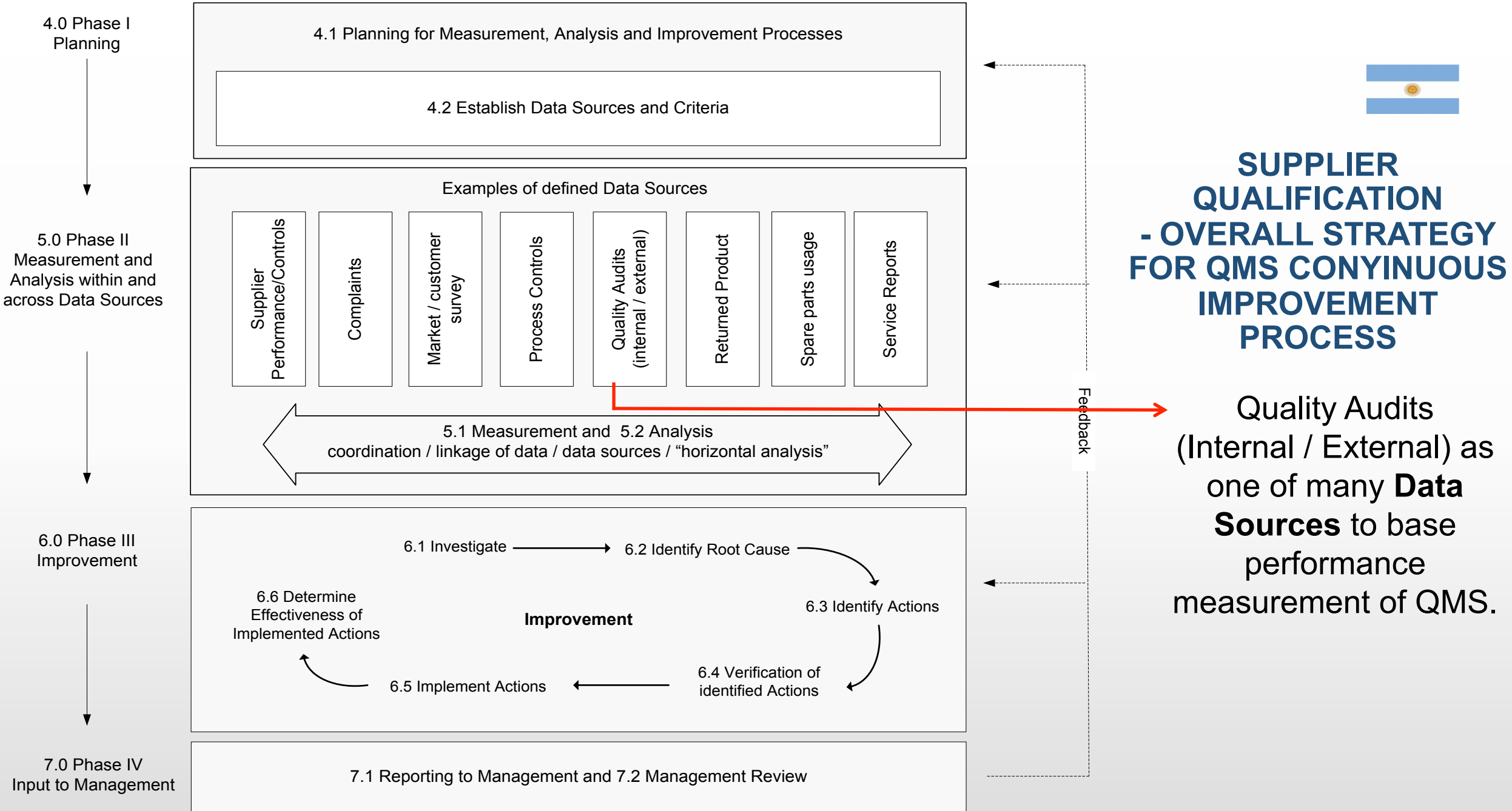


Global Harmonization Task Force



Title: Quality management system –Medical Devices – Guidance on corrective action and preventive action and related QMS processes

Date: 22nd September 2009



QUALITY SHOULD BE MEASURED – Pareto



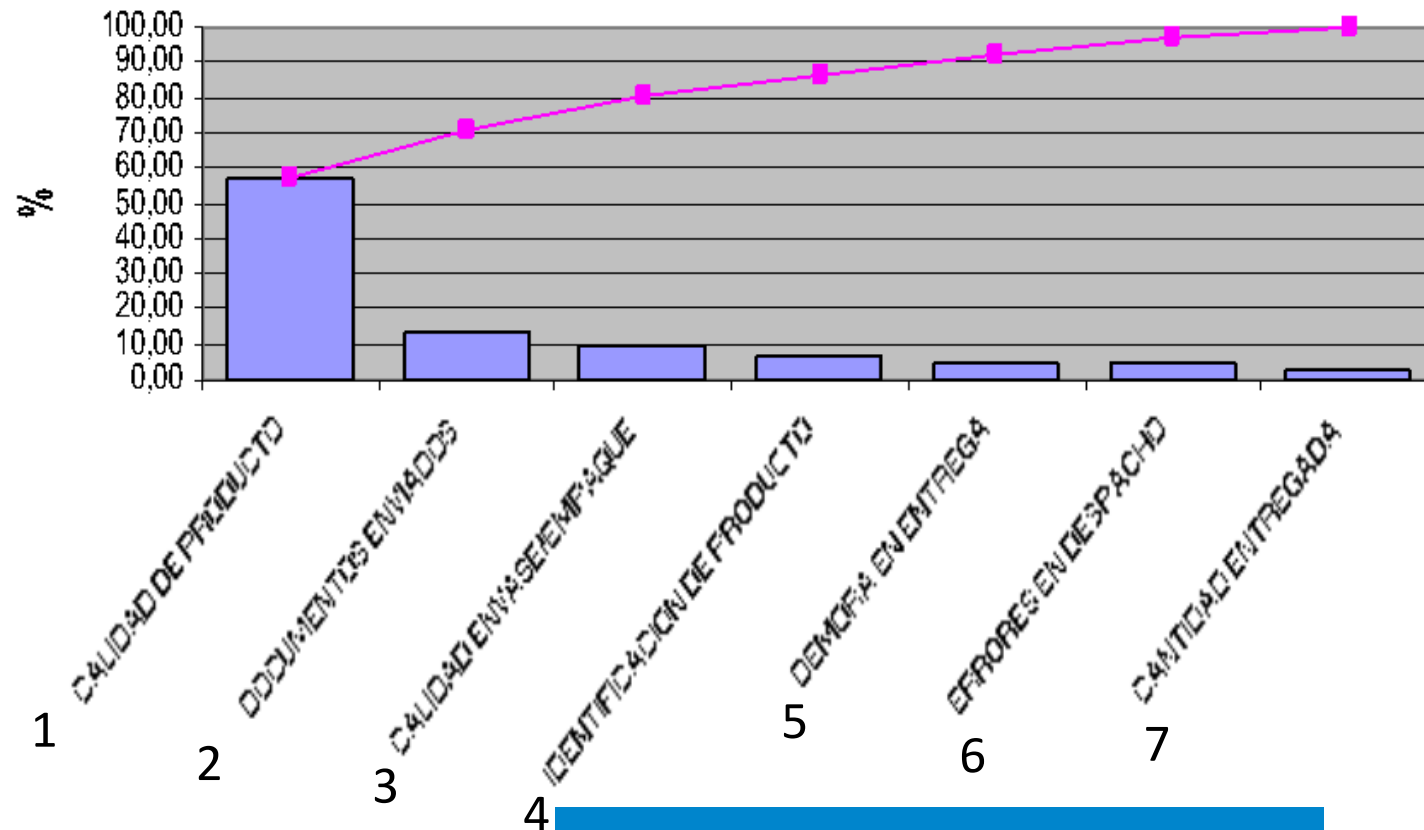
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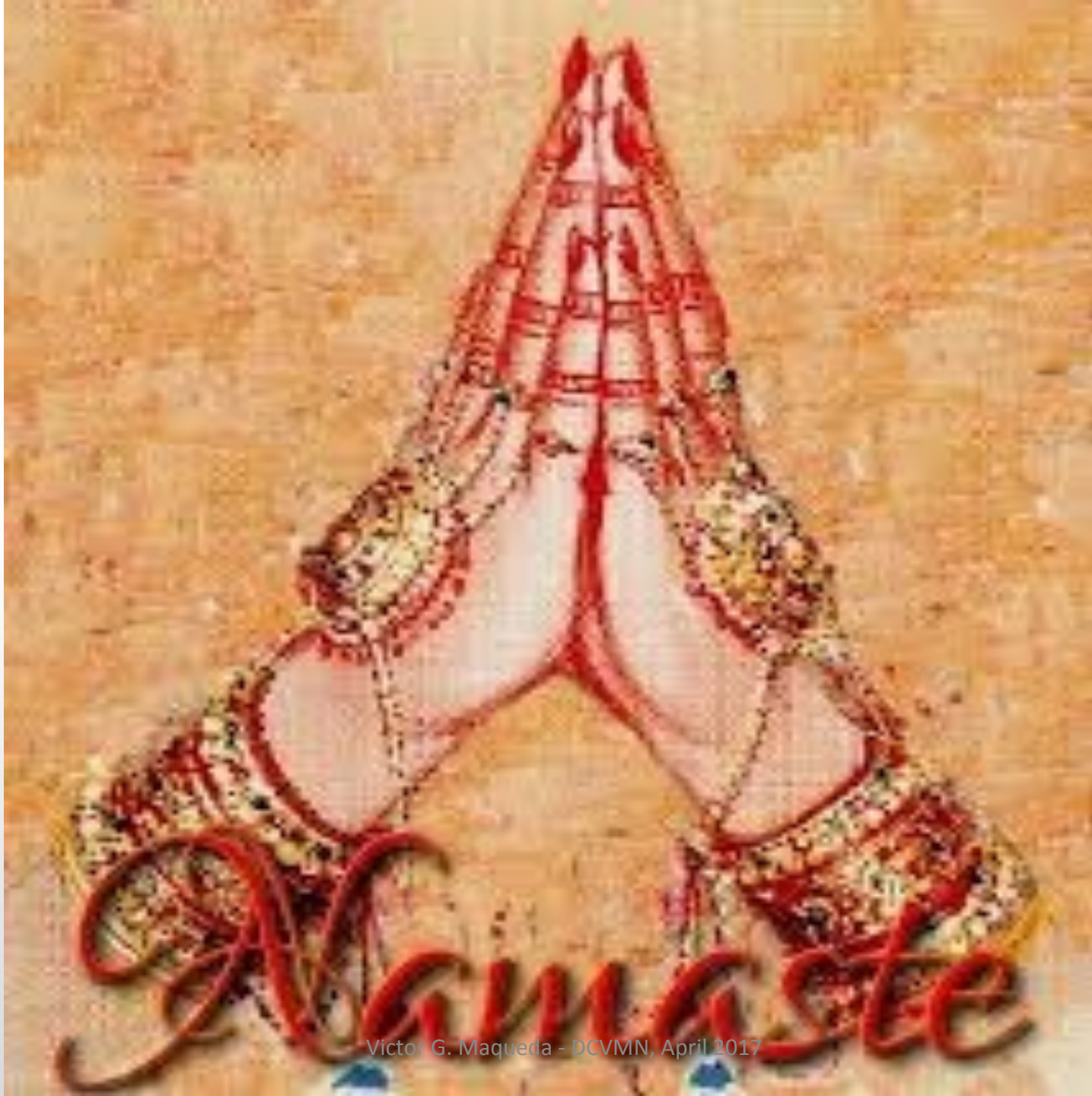


Customer complaints



Categories

1. Product performance
2. Sent documents
3. Packaging
4. Labeling
5. Delivery time
6. Shipping errors (product)
7. Shipping errors (quantity)



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