

Guidance 056 Material of Construction (MOC) Documentation

obtained and confirmed during the Commissioning phase. The focus should be on components where the MOC could present a risk to product quality. Thus, the documentation criticality is higher where there is more risk that inappropriate alloys or materials may be present (such as custom-fabricated equipment where alloy, welding details or surface finish specifications are pertinent to protecting the product.)

The following are examples of inspection documentation for metallic and non-metallic materials that can be supplied to the purchaser directly from the manufacturer of the products, or through an intermediary or agent.

Example 1 -Vendor / Intermediary supplied Certificate of Conformance

Document in which the manufacturer (or an *intermediary*) declares that the items supplied are in compliance with the requirements of the purchase specification, without inclusion of specific inspection test results. This declaration of conformance is based on manufacturer-issued documentation.

Example 2 -Vendor / Intermediary supplied Materials Test Certification

Documents, issued by the manufacturer and based on *specific inspection*, in which it is declared that the items supplied are in compliance with the requirements of the order and in which test results are supplied.

The tests to be carried out and their limits are defined by the individual items' specifications, official regulation(s) and/or the purchase order. The documentation issued by the manufacturer is confirmed by the manufacturer's authorised inspection representative, independent of the manufacturing department.

The manufacturer is allowed to transfer onto this inspection certificate relevant test results obtained by specific inspection, provided that the manufacturer operates traceability procedures and can provide the corresponding inspection documents required.

Additional documentation to support confirmation of materials of construction, per example 2 above, may be required for new systems and components, if it is decided that there is an insufficient level of confidence in the vendor or their intermediary, based on the following considerations:

- É Lack of experience dealing with a particular vendor.
- É Vendor has a lack of experience in the pharmaceutical industry.
- Level of uncertainty regarding the vendor's quality systems and traceability of materials through production of the equipment or component. A Vendor Audit could be conducted in order to obtain confidence of the vendor's quality systems, if this is decided necessary. The audit report could incorporate a review of the vendor's quality systems with respect to vendor-issued materials' conformity documentation or certification.
- There is a unique requirement for the product as specified in the purchase specifications; for example a specific surface roughness and finish (Ra values).
- New/exotic materials, for example Hastelloy, are being purchased, with which the purchaser has no previous experience.

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to confirm suitability for intended use. The following documentation can be examined to provide evidence of the material of construction of a system or component:

- É Purchase ledgers/orders ó Procurement records often include model, serial number and material of construction information. This information can be cross-referenced to a system or component by way of the Engineering Project number of the original installation indicated on the Purchase Order system.
- Vendor-supplied Functional or Design Specifications ó Existing Vendor-supplied FS or DS documentation can provide a source of information to support MOC verification.
- Vendor/Contractor P&IDs, pipe-work Isometrics ó Engineering records created during the project, such as drawings approved for construction may contain information regarding the MOCs.
- Maintenance records -Reviewing historical maintenance records can provide supporting evidence, particularly by way of replaced parts or repaired equipment or pipe-work.
- Equipment or Component User Manuals -Reviewing available equipment and user manuals can sometimes provide information to support MOC verification.
- Existing Commissioning and/or Qualification Documentation ó A review of existing commissioning and / or qualification documentation, if available, can also be used to support MOC verification. From a review of the above documentation and any supporting information that may be obtained directly from suppliers or vendors, the MOC for legacy direct-impact systems and related critical components may be able to be determined.

Field Verification methods for Determining Material of Construction

If obtaining the MOC of a legacy system or component is not possible by reviewing existing documentation, and it has been determined that further investigation is justified based on product risk from MOC, then the following method may be used to verify the MOC.

Identification Overview - Many methods can be used to identify an unknown metallic or non-metallic material. Destructive testing is not recommended or needed as a method of identification of material of construction used in legacy direct impact systems and related critical components. For enclosed piping and equipment systems, there is no expectation to disassemble or remove the covering materials of piping and equipment in order to visually inspect materials.

There are usually sufficient exposed materials in order to be able to adequately determine material of construction following the visual inspection methodology detailed below.

Visual Inspection of Surface Appearance (Metallic materials) - Sometimes it is possible to identify metals by a visual inspection of their surface appearance. Identification can often be easily conducted by inspecting the pipe-work or component for specific information such as:

- É Stamped markings on pipe-work or equipment, indicating material type or recognized manufacturing code and / or standard.

Glossary

Vendor - The Vendor, as referred to within this document, can be the direct manufacturer of the products being purchased, or an intermediary, as indicated below.

Intermediary - An Organisation which is supplied with products by the manufacturer and which then in turn supplies them to another company without further processing and without changing the properties specified in the purchase order and referenced product specification.

Non-specific inspection

Inspection carried out by the manufacturer in accordance with their own procedures to assess whether or not products defined by the same product specification and made by the same manufacturing process are in compliance with the requirements of the order.

Specific inspection

Inspection carried out before delivery according to product specification. Inspection of the products to be supplied, or of test units of the products, to verify that they comply with the purchase order.