

Johnson Matthey Supplier Management System Clean Air

Part 2: Global Supplier Manual
Appendix C – Product Approval Process

Valid from: April 2021

The latest version of all documents associated with the Global Supplier Manual can be found at the following address:

<https://matthey.com/en/enhancing-life/sustainability-governance/clean-air-global-supplier-manual>

The English version of this document is the master version. Although translations are provided by Johnson Matthey, should there be any ambiguity in the translation, then the English language text will prevail.

Table of Contents

Section	Description	Page
1	Introduction	3
2	Validation of a New or Changed Raw Material	3
3	Validation of a New or Changed Substrate Designated by an OEM	4
4	Validation of a New or Changed Substrate Designated by Johnson Matthey	4
5	Ten-Batch Review of the Johnson Matthey Specification	5

1 Introduction

This appendix details the requirements for the approval of new and changed raw materials and substrates delivered to Johnson Matthey (JM).

After a raw material has gained technical approval from a JM Technology Site and a JM specification has been issued and approved, a purchase order can be raised for the validation batch.

After a substrate has gained technical approval from either an OEM or the JM manufacturing location that will first use this substrate (where the substrate is designated by JM), and a specification has been issued and approved, a purchase order can be raised for the validation batch.

Where a draft specification has been agreed, this may be revised based on actual production data.

2 Validation of a New or Changed Raw Material

The supplier shall produce and submit a validation batch for all new raw materials for use in JM production, or for any change to an existing raw material, which requires notification to JM (see Appendix D).

Production of the supplier's validation batch shall take place using regular raw materials on the production equipment to be used for subsequent production batches. Production shall use the processes and controls detailed in the process flow diagram (PFD) and process control plan (PCP).

Sampling frequency and reporting for all product and process parameters identified in the PCP shall be a minimum of double that for a normal production batch, or in line with the requirements agreed in writing with the appropriate JM Technology Site.

Unless otherwise agreed the supplier shall submit all required information to support a validation batch to the appropriate JM Technology Site in line with the details in Table 1.

Table 1: Summary of JM Production Approval Process Submission Requirements for Raw Materials

ID	DESCRIPTION
1	JM Specifications ¹
2	Product risk assessment documents (Design FMEA) ¹
3	Process Flow Diagrams ¹
4	Process risk assessment documents (Process FMEA) ¹
5	Material Key Characteristics definition ¹
6	Process Control Plan (PCP) ¹
7	Measurement System Analysis Studies ¹
8	Raw Material Approval Test Summary (SMS-034)
9	Material performance test results (COA)
10	Initial Process Capability Studies
11	Material Approval Sample (validation sample) ²
12	Retention of a representative sample of the validation batch/lot ³
13	Material Health and Safety Data Sheet (SDS)
14	Raw Material Submission Warrant (SMS-043) In case of analytical changes it shall be used Analytical Change Approval form (SMS-017)

1. Documentation may be retained by the supplier, but must be available for review upon request.
2. A minimum of 1 kg or a quantity as agreed in writing by the appropriate JMTS (JM Technology Site).
3. Supplier shall retain a representative sample of the validation batch/lot

The validation batch shall be approved in writing by the JM Technology Site (JMTS) to confirm requirements are met. This will be completed by the JMTS signing and returning the Raw Material Submission Warrant before subsequent deliveries can be made to a JM manufacturing location.

If the JMTS gives only interim approval of a Raw Material Submission Warrant, the supplier shall address the reasons for full approval not being given, and produce a new validation batch and a further Raw Material Submission Warrant in order to gain full approval. This shall take place before subsequent deliveries can be made to a JM manufacturing location, unless otherwise instructed in writing by the JMTS.

Unless otherwise agreed, suppliers shall always send the PSW and all requested documents for raw material approval both to the JMTS and to the following e-mail address:

RawMatSubs@matthey.com

Each received email should always have the same format for the subject as follows:

E-MAIL SUBJECT	[JM material code]_[JM spec. No.]_[Supplier Name]_[YYYYMMDD]_ZZ
E-MAIL ENCLOSURES	<ul style="list-style-type: none"> • PSW (both in PDF and WORD version) • COA • MSDS • ...(any other document requested by JM)
Remarks	<ol style="list-style-type: none"> 1) ALWAYS USE CAPITAL LETTERS ONLY when typing subject. 2) YYYYMMDD is the Submission date. It shall always be written in the following way and sequence: 4 digits for year; 2 digits for month; 2 digits for day. 3) ZZ is the nr. of times the PSW has been submitted to JM.
Example	Supplier "XYZTW" on 25 th December 2021 submits to JM for the 2 nd time the approval pack for raw material "Abc123" with spec No. SINT96-WWW Abc123_SINT96-WWW_XYZTW_20211225_02

The first batch of modified raw materials that have been approved by JM shall be properly identified.

3 Validation of a New or Changed Substrate Designated by an OEM

The supplier shall submit a copy of the relevant Part Submission Warrant (PSW) signed by the OEM for all new substrates delivered to JM for use in JM production, or for any change to an existing substrate. In case of concerns these shall be raised by JM to the substrate manufacturer and the OEM.

4 Validation of a New or Changed Substrate Designated by Johnson Matthey

The supplier shall produce and submit a validation batch for all new substrates delivered to JM for use in JM production, or for any change to an existing substrate, which requires notification to JM (see Appendix D).

Production of the supplier's validation batch shall take place using regular materials on the production equipment to be used for subsequent production batches. The validation batch shall consist of at least 300 pieces. Production shall use the processes and controls detailed in the PFD and PCP.

Sampling frequency and reporting for all product and process parameters identified in the PCP shall be a minimum of double that for a normal production batch, or in line with the requirements agreed in writing with the appropriate JM manufacturing location.

The supplier shall submit all required information to support a validation batch to the appropriate JM manufacturing location in line with the details in Table 2.

Table 2: Summary of JM Production Approval Process Submission Requirements for Substrates Designated by JM

ID	DESCRIPTION
1	JM Specifications ¹
2	Product risk assessment documents (Design FMEA) ¹
3	Process Flow Diagrams ¹
4	Process risk assessment documents (Process FMEA) ¹
5	Material Key Characteristics definition
6	Process Control Plan (PCP)
7	Measurement System Analysis Studies

8	Material Approval Plan
9	Material performance test results (COA)
10	Initial Process Capability Studies
11	Material Approval Samples (validation samples) ²
13	Material Health and Safety Data Sheet (SDS)
14	PSW - Substrate Submission Warrant (SMS-014)

1. Documentation may be retained by the supplier, but must be available for review upon request.
2. Quantity as agreed in writing by the appropriate JM manufacturing location.

The validation batch shall be approved in writing by the JM manufacturing location to confirm requirements are met. This will be completed by the JM manufacturing location signing and returning the Raw Material Submission Warrant before subsequent deliveries can be made.

If the JM manufacturing location gives only interim approval of a Raw Material Submission Warrant, the supplier shall address the reasons for full approval not being given, and produce a new validation batch and a further Raw Material Submission Warrant in order to gain full approval. This shall take place before subsequent deliveries can be made, unless otherwise instructed in writing by the JM manufacturing location.

5 Ten-Batch Review of the Johnson Matthey Specification

Upon request and after the supply of the first ten batches of any raw materials and JM-designated substrates, the supplier shall provide the validating JM Technology Site / JM manufacturing location with the trend data for all key characteristics and COA items. This may result in a revision of the specification. If the specification is revised, a further ten-batch review shall be completed if requested by a JM Technology Site or JM manufacturing location, but a new validation batch will not be required.