

APPROVED

By Jean Gildner at 4:15 pm, Dec 12, 2016

From: [Margarita Aguilera](#)
To: [Gildner, Jean](#)
Subject: BLA 125603 Information Request Response
Date: Friday, September 23, 2016 4:53:46 PM
Attachments: [QA1-045.pdf](#)
[QA1-054.pdf](#)
[QC1-055.pdf](#)
[MP1001.DFT.A.PDF](#)
[MR1-003.DFT.A.PDF](#)
[Matricel Quality Agreement 2015 \(signed\).pdf](#)

Dear Jean,

In response to the Request for Information received September 22, enclosed please find Vericel' s response and attached documentation:

1. Purchasing Controls SOP MP1-005

The current version of SOP MP1-005 is attached, but please note it is under revision. As Vericel continues to transition from Genzyme/Sanofi systems and procedures, SOPs are being revised accordingly.

2. All SOPs referenced in SOP MP1-005

Many of the SOPs referenced within the current version of MP1-005 are no longer relevant (Genzyme SOPs) and are being deleted/obsoleted during the revision. The table below lists the SOPs referenced in MP1-005 and the corresponding Vericel SOP, if applicable.

SOPs referenced in current MP1-005	Status / Corresponding Vericel SOPs
GCQO-SUP-S001 Quality Technical Agreements	Genzyme SOP which will be deleted from MP1-005. Vericel SOP QA1-071 Quality Technical Agreements is in the process of being written and circulated through the document management system
GCQOS001 Purchasing Controls	Genzyme SOP which will be deleted from MP1-005.
QA1-045 Quality Management Review	Current version attached; under revision.
MP-001-11 Using the Supplier Scorecard to Monitor Material Suppliers	Genzyme SOP which will be deleted from MP1-005. The following Vericel SOPs are followed: QA1-054 Supplier Change Notification (attached) QC1-055 Supplier Corrective Action Request Procedure (attached) QA1-045 Quarterly Management Review Meetings (attached)

MP-001-19 Creating a Business Agreement	<p>Genzyme SOP which will be deleted from MP1-005.</p> <p>Vericel SOP MP2-008 Creating a Business Agreement is in the process of being written and circulated through the document management system.</p>
MR-001-73 Receipt of Materials at (b) (4) [REDACTED], and (b) (4) [REDACTED]	<p>Genzyme SOP which will be deleted from MP1-005.</p> <p>The following Vericel SOP is followed: MP1-001* Procedure for the Receipt and Distribution of Quality Control and Non-Quality Control Inspected Material (attached)</p>
MP-001-21 Purchasing Inventory Materials or Finished Goods	<p>Genzyme SOP which will be deleted from MP1-005.</p> <p>The following Vericel SOP is followed: MR1-003* Purchase Requisition Submission Process (ReQlogic) (attached)</p>
MP-107-01 Notifying Supplier of Change to a Specification	<p>Genzyme SOP which will be deleted from MP1-005.</p> <p>The following Vericel SOP is followed: QA1-054 Supplier Change Notification (attached)</p>
MR-001-06 Creating a Purchase Order	<p>Genzyme SOP which will be deleted from MP1-005.</p> <p>The following Vericel SOP is followed: MR1-003* Purchase Requisition Submission Process (b) (4) (attached)</p>

*Note – Approved procedures that are awaiting finalization of the associated change control. Documents are stamped DRAFT until the change control is implemented and fully closed. No additional editing is permitted on the documents in this stage.

3. Matricel Quality Service Agreement

The Matricel Quality Technical Agreement is attached.

Thanks in advance for confirming receipt of this information.

Regards,
Margarita

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