

APPROVED

By Jean Gildner at 2:27 pm, Dec 12, 2016

From: [Lorien Armour](#)
To: [Gildner, Jean](#)
Cc: [Margarita Aguilera](#)
Subject: BLA125603 Information Request Response -- Follow up to Late Cycle Review Meeting Actions
Date: Thursday, October 27, 2016 4:54:26 PM
Attachments: [1-11-1 Follow up to September 15 Information Request APV approach 26 Oct....pdf](#)

Dear Jean,

In follow up to our September 15th Information Request response and a discussion that occurred during the Late Cycle Review Meeting (LCM), we are providing a risk assessment of our aseptic process validation (media fill) approach as it relates to MACI. Should the reviewers have additional questions after reading the assessment, I suggest a brief teleconference be considered as an efficient way to address remaining concerns.

SOP MP1-005 Purchasing Controls was also requested during the LCM to be submitted by October 31st. We received a related information request today and in order to provide a complete response, this SOP will be provided by the suspense date of November 1st for the new request.

Please confirm receipt of this information.

Kind Regards,

Lorien Armour, RAC

CMC Regulatory Consultant

Vericel Corporation

Cell: 919-949-2063 (Use this through November 10th)

Office: 919-450-0802

Fax: 734-239-7401