

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
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