

APPROVED

By Jean Gildner at 4:25 pm, Dec 02, 2016

From: [Amin, Pankaj \(Pete\)](#)
To: [Gildner, Jean](#)
Cc: [Thomas, John](#)
Subject: Vericel - quick IR request
Date: Tuesday, November 01, 2016 11:33:09 AM

Hi Jean,

I have following information request for Vericel:

IR question:

Regarding supplier qualification describe in the BLA (section 3.2.S.2, 3.1 “supplier qualification”), Please provides the most recent vendor audit (supplier qualification) that was performed for the Matricel facility and brief summary of Matricel supplier qualification. If Vendor audit was not performed, Please provide your rational for not conducting vendor audit and propose timeline.

(Please ask Vericel to response by this Friday).

Thanks
Pete Amin
CBER/OCBQ/DMPQ