

APPROVED

By Jean Gildner at 10:34 am, Jul 19, 2016

From: [Alimchandani, Meghna](#)
To: [Gildner, Jean](#)
Cc: [Thomas, John](#); [Tull, Lori](#); [Riggins, Patrick](#)
Subject: IR for MACI (BLA 125603)
Date: Wednesday, May 25, 2016 3:09:42 PM

Jean: I would like to send the IR below to Vericel to clarify certain details of the pharmacovigilance plan – please will you facilitate? Please let me know if you have any questions. Thanks, Meghna

Information Request for BLA 125603\0 (original application) MACI™:

One of Vericel's proposed risk management measures in the pharmacovigilance plan (module 1.16) for MACI is described as a "controlled distribution system." Please elaborate on the following:

- i. At **what** stage of distribution of MACI will Vericel determine if healthcare provider (HCP) training was completed?
- ii. **How** will Vericel ensure that the HCP received/completed surgical training specific to cartilage biopsy and MACI implantation procedures?