

From: Do, Yu
To: Joan.robertson@grifols.com
Subject: Information Request (Response Due by Friday, February 03, 2017): Original BLA, BL 125640/0, Fibrin Sealant (Human), Instituto Grifols, S.A.
Date: Tuesday, January 10, 2017 10:27:00 AM
Attachments: [image001.png](#)
Importance: High

Dear Ms. Robertson:

We are reviewing your original November 3, 2016, submission to BLA 125640 for Fibrin Sealant (Human). We determined that the following information is necessary to continue our review:

1. Please provide a comprehensive listing of all products, including those that are also manufactured or manipulated in the same manufacturing areas as fibrinogen and thrombin.
2. Please identify all process steps as either open or closed systems and indicate in a table format the room classification of the areas for which process steps occur.
3. Please provide the following information on all computer systems that control critical manufacturing processes:
 - a. List of manufacturing steps which are computer-controlled and computer systems used to control these steps
 - b. Validation summary of the computer systems that includes a description of the validation process with acceptance criteria, certification that IQ/OQ was completed, an explanation of the parameters monitored and tests performed along with summary of the data, an explanation of all excursions and/or failures, and deviation reports and results of investigations of all excursions or failures

The review of this submission is ongoing, and issues may be added, expanded upon, or modified as we continue to review this submission. Please submit your response as an amendment to this file by February 03, 2017, referencing the date of this request. If you anticipate you will not be able to respond by this date, please contact the Agency immediately so a new response date can be identified.

If we determine that your response to this information request constitutes a major amendment, we will notify you in writing.

The action due date for this file is November 3, 2017.

Please acknowledge receipt of this request and contact me at (240) 402-8343 or Yu.Do@fda.hhs.gov if you have any questions.

Sincerely,

Yu Do, M.S.

Regulatory Project Manager
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