

**TheraSphere® Training Record – Alexandria Jo, MD**

Community Health Network

Indianapolis, IN

January 20, 2022	- Mock infusion training, 3 in-vitro administrations
October 21, 2021	- Completed NRC required Safe Handling Practices training

This is to confirm that Boston Scientific provided training on the recommended use of TheraSphere in accordance with TheraSphere Package Insert at Community Health Network. Dr. Jo has successfully completed the Authorized User training program. The full scope of training included the following.

1. Has completed three in-vitro administrations with manufacturer representative, Brody Ring, with focus on:
  - Safe handling practices
  - TheraSphere Administration Set and TheraSphere Administration Accessory Kit overview
  - Dose Calibrator verification using Calibration Data Sheet for Y-90
  - Preparation of TheraSphere dose vial
  - Assembly of the Administration Set
  - System priming
  - TheraSphere administration
  - Disassembly
2. Has training provided by a Y-90 microsphere manufacturer representative involving:
  - a. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys; and
  - b. Performing quality control procedures on instruments used to determine the activity of Y-90 microspheres and performing checks for proper operation of survey meters; and
  - c. Calculating and measuring the activity and safely preparing the Y-90 microspheres to be delivered to the patient or human research subject; and
  - d. Using procedures to control and to contain spilled byproduct material, including Y-90 microspheres, safely and using proper decontamination procedures. The procedures should address any special circumstances that may be encountered, such as the electrostatic charge of Y-90 microspheres and the proper survey instrument and survey technique for beta emitters; and
  - e. Preparing and administering patient dosage. The individual does not have to be the physician who places the micro-catheter or administers patient dosage, but it is necessary that the individual have training in the administration process, including selection of activity of Y-90 microspheres to be administered to each treatment site and catheter positioning to ensure administration of the Y-90 microspheres is in accordance with the written directive; and
  - f. Using administrative controls to prevent a medical event involving the use of byproduct materials; and
  - g. Evaluation of patient or research subject's treatments to determine whether the administered dosage was in accordance with the written directive or if a medical event has occurred.

*Cynthia Ann Hollenbeck*

Cynthia Ann Hollenbeck, PhD  
Medical Science Liaison

April 7, 2022

## Pavon, Martha

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**From:** Bell, Erin <EBell2@ecomunity.com>  
**Sent:** Tuesday, August 16, 2022 11:07 AM  
**To:** Parker, Bryan  
**Subject:** [External\_Sender] FW: External: RE: Dr. Jo TEC Letter  
**Attachments:** Therasphere AU Conditional Training Letter - Alexandria Jo.pdf

Hi Bryan,

Attached, please find the Theraspheres letter with manufacturer rep listed for mock infusions.

Let me know if you need anything else.

Thank you!

Erin

### Erin Bell, MHP, DABSNM

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## Pavon, Martha

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**From:** Parker, Bryan  
**Sent:** Tuesday, August 16, 2022 12:14 PM  
**To:** Pavon, Sandy; Pavon, Martha  
**Cc:** Tomczak, Tammy  
**Subject:** Please add more AI to CN631355  
**Attachments:** [External\_Sender] FW: External: RE: Dr. Jo TEC Letter; 631355 AI 665.pdf

Sandy/Martha,

Martha fulfilled my earlier request to add AI. This is another request to add some more AI to this same CN.

Please add the attached Additional Info for CN631355 to ADAMS. A 665 is also attached.

Please let me know if you have any questions.

Thanks.

*Bryan*