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|  | PROGRAM/SPEAKER INFORMATION FORMNote: this form is optional if the information is submitted elsewhere. |
| *Program Number:*  |
| *Program Title:* **FDA Perspectives on Point-of-Care Testing** |
| *Date:* June 14, 2018 *Contact Hours:* 1.0*Location:* Columbia, MD |
| *P.A.C.E.® Provider:* |
| *Format: (Lecture, slides, discussion group, live webinar, archived webinar, Computer-Driven Instruction, etc.)*PowerPoint presentation |
| *Speaker Name, Credentials, and Affiliation: List your name and credentials, as they should appear in the program.* Tamara Pinkney, MT(ASCP)Scientific Reviewer, Hematology BranchDivision of Immunology and Hematology DevicesCenter for Devices and Radiological Health Office of In Vitro Diagnostics and Radiological HealthU.S. Food and Drug AdministrationJacqueline Cleary MT(ASCP)Scientific Reviewer, Immunology BranchDivision of Immunology and Hematology DevicesCenter for Devices and Radiological Health Office of In Vitro Diagnostics and Radiological HealthU.S. Food and Drug Administration*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_* |
| *List your professional affiliation, as it should appear in the program:* |
| *The moderator or speaker will disclose to the audience any conflict of interest regarding the topic being presented.*  |
| *­Description of Session: Limit to 50 words. Type or print, being as specific as possible about learning to take place.***This presentation will focus on FDA clearance processes for POC tests, including requirements for clinical and analytical validation. Participants will be provided examples of waived and non-waived POC tests. The presentation will also highlight the review process used for the clearance of the first CLIA waived hematology analyzer.**  |
| *Level of Instruction:* ***BASIC INTERMEDIATE ADVANCED*** *(Circle one)****BASIC:*** *Entry level; no prior knowledge of subject necessary to attend this program;* ***INTERMEDIATE:*** *Refresher course; some basic knowledge required;* ***ADVANCED:*** *Highly technical; for those with at least five years of experience in a specialty area.**PROGRAM OBJECTIVES (Please list three. May be continued with an attachment)**At the end of the session, the participant will be able to:* |
| *1.* Define Point-of-Care (POC) Testing |
| *2.* Differentiate between waived and non-waived (i.e. moderately complex) POC tests |
| *3.* Gain a basic understanding of FDA clearance processes for POC tests |
| *PROGRAM TIME TABLE* |
| *Begin time\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ End time\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*  |
| *Break(s)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Lunch\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*  |
| *CONTACT HOURS PROPOSED: \_\_\_\_\_\_\_\_\_* | *CONTACT HOURS: \_\_\_\_\_\_\_\_ per Committee (for Office Use Only)* |

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|  | Professional Acknowledgment for Continuing EducationSPEAKER INFORMATION FORM Not all blanks need to be completed. |

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| Name: Tamara Pinkney |
| Current Position: Scientific Reviewer |
| Business Address: 10903 New Hampshire Avenue |
| City, State, Zip: Silver Spring, MD 20993 |
| Phone: (301)796-6182 Email: Tamara.Pinkney@fda.hhs.gov |
| Area of expertise: *In Vitro* Diagnostic Hematology Devices |
| Credentials: Bachelor of Science in Biology Board Certified Medical Technologist |
| Certifications/Agency: MT (ASCP) |
| Relevant Experience pertaining to the topic to be presented (papers, presentations, publications):* Lead Reviewer of the recently cleared Sysmex XW-100 Automated Hematology Analyzer for CLIA Waived Use
* Speaker at AMDM Annual Meeting (April, 2018). Presented on the topic, *FDA Considerations of CLIA Waiver Submissions for a First to Market Product: Sysmex XW-100*
* Member of OIR POCT Harmonization Group
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Information for a program Introduction: |

**Tamara Pinkney** is a Scientific Reviewer in the Hematology Branch of the Division of Immunology and Hematology Devices in FDA’s Office of *In Vitro* Diagnostics and Radiological Health (OIR) where she reviews a variety of medical devices and assays for hematological, coagulation, and evaluation of other body fluids. Ms. Pinkney joined the FDA in 2015 with 10 years of clinical laboratory experience, including expertise in hematology and urinalysis testing. She served as a lead technologist in the Hematology laboratory at Walter Reed National Military Medical Center. Prior to her time at Walter Reed, Ms. Pinkney worked as a generalist in the Core laboratory at Palmetto Health Baptist. Ms. Pinkney is an ASCP certified Medical Technologist and holds a BS in Biology from the University of SC, Columbia and a Certificate of Completion from Palmetto Health Baptist School of Medical Technology.