Activity Outline
FDA Grand Rounds: Quality Considerations for the Multi-Attribute Method (MAM) for Therapeutic Proteins
October 13, 2022
Virtual

Activity Coordinators:
Madison Hanson (Madison.Hanson@fda.hhs.gov), Rokhsareh Shahidzadeh (rokhsareh.shahidzadeh@fda.hhs.gov), Sharron Watson (Sharron.Watson@fda.hhs.gov)

Series Description
The FDA Grand Rounds is webcast monthly to highlight cutting-edge research underway across the agency and its impact on protecting and advancing public health. Each session features an FDA scientist presenting on a key public health challenge and how FDA is applying science to its regulatory activities.

Lecture Description
The multi-attribute method (MAM) is a liquid chromatography-mass spectrometry (LC-MS) based peptide mapping approach used for the identification and quantitation of product quality attributes (PQAs) in therapeutic proteins. Within the Center for Drug Evaluation and Research (CDER), the Emerging Technology Program (ETP) has assessed the use of MAM in quality control environments and laboratory resources have been developed to improve the FDA's understanding of the approach.

References
- Multi-Attribute Method for Quality Control of Therapeutic Proteins. Sarah Rogstad, Haoheng Yan, Xiaoshi Wang, David Powers, Kurt Brorson, Bazarragchaa Damdinsuren, and Sau Lee. Analytical Chemistry 2019 91 (22), 14170-14177. DOI: 10.1021/acs.analchem.9b03808

Series Objectives
- Discuss the research conducted at the FDA
- Explain how FDA science impacts public health

Learning Objectives After completion of this activity, the participant will be able to:
- Discuss how the LC-MS based multi-attribute method can be used for quality control of therapeutic proteins.
- Discuss how the multi-attribute method can detect multiple product quality attributes or critical quality attributes within a single LC-MS run.
- Discuss the key considerations for implementation of the multi-attribute method, including risk assessment, method validation, new peak detection, and conventional method comparisons.

Target Audience
This activity is intended for physicians, pharmacists, nurses, and other scientists within the agency external scientific communities.

Agenda

Lecture 1 October 13, 2022

TIME	TOPIC	SPEAKER
12:00 - 1:00 PM EDT	Quality Considerations for the Multi-Attribute Method (MAM) for Therapeutic Proteins	Sarah Rogstad, PhD Frances Namuswe, PhD

Continuing Education Accreditation

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INTERPROFESSIONAL CONTINUING EDUCATION

In support of improving patient care, FDA Center for Drug Evaluation and Research is jointly accredited by the Accreditation Council for Continuing Medical Education (ACCME), the Accreditation Council for Pharmacy Education (ACPE), and the American Nurses Credentialing Center (ANCC) to provide continuing education for the healthcare team.

IPCE CREDIT™

This activity was planned by and for the healthcare team, and learners will receive 1 Interprofessional Continuing Education (IPCE) credit(s) for learning and change.

CME

FDA Center for Drug Evaluation and Research designates this live activity for a maximum of 1.00 *AMA PRA Category 1 Credit(s)™*. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

CPE

This knowledge-based activity has been assigned ACPE Universal Activity Number JA0002895-0000-22-006-L04-P for 1.00 contact hour(s).

CNE

FDA Center for Drug Evaluation and Research designates this activity for 1.00 contact hour(s).

Requirements for Receiving CE Credit
Physicians, pharmacists, nurses, and those claiming non-physician CME: participants must attest to their attendance and complete the final activity evaluation via the CE Portal (ceportal.fda.gov). For multi-day activities, participants must attest to their attendance and complete the faculty evaluation each day. Final activity evaluations must be completed within two weeks after the activity - no exceptions.

Attention Pharmacists and Pharmacy Techs: Failure to provide your correct NABP AND Date of Birth information, in the required format, may result in the loss of credit for this activity. NABP profile number should be the 6-7 digit profile number assigned by the CPE Monitor and your birth date should be in the MMDD format (e.g. 0721) Do not provide your pharmacy license number. Please click the "My Account" tab and then navigate to "Edit Contact Information" to verify that your information is correct.

Important Note regarding completion of evaluations and receiving credit
Attendees have 14 days from the last day of the activity to log in, complete the required evaluation(s) and attest to your attendance to claim credit.Physicians and nurses may then view/print statement of credit. Pharmacists should log into the CPE monitor 8 weeks after the last session of the activity to obtain their CE credit.

Disclosure

Faculty
- Namuswe, Frances, PhD, Lead Chemist, Office of Biotechnology Products, OPQ, CDER - nothing to disclose
- Rogstad, Sarah, PhD, Senior Scientific Advisor, US FDA - nothing to disclose

Planning Committee
- Dinatale, Miriam, DO, Team Leader, Food and Drug Administration - nothing to disclose
- Pfundt, Tiffany, PharmD, Senior Advisor, HHS/ASPR - nothing to disclose
- Wheelock, Leslie, RN, MS, Director, OSPD, FDA, OC, OCS, OSPD - nothing to disclose

CE Consultation and Accreditation Team
- Bueide, Rachel E., MPhil, Training Specialist, FDA/CDER/OEP/DLOD - nothing to disclose
- Zawalick, Karen, CE Team Leader, FDA/CDER/OEP/DLOD - nothing to disclose

Any relationship shown above in italics has been divested within the last 24 months and is therefore considered mitigated.
All relevant financial relationships have been mitigated.

Registration Fee and Refunds
Registration is complimentary, therefore refunds are not applicable.