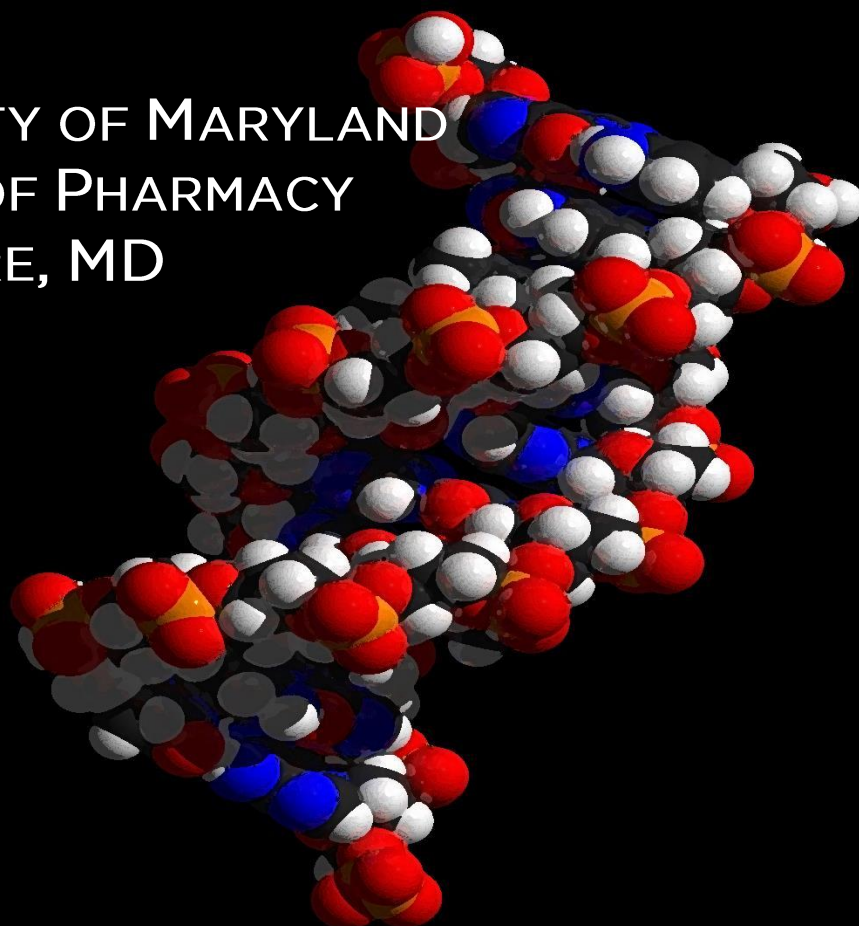


THE UNIVERSITY OF MARYLAND CENTER FOR EXCELLENCE IN REGULATORY
SCIENCE AND INNOVATION AND THE BIO- AND NANO-TECHNOLOGY CENTER AT
THE UNIVERSITY OF MARYLAND SCHOOL OF PHARMACY PRESENT:

PROTEIN AGGREGATION MEASUREMENT IN BIOTHERAPEUTICS: ESTABLISHED AND EMERGING TECHNIQUES

MONDAY, DECEMBER 5, 2016

UNIVERSITY OF MARYLAND
SCHOOL OF PHARMACY
BALTIMORE, MD



CONFERENCE AGENDA

TIME	ACTIVITY
8:00-8:30 a.m.	ATTENDEE ARRIVAL AND REGISTRATION
8:30-9:00 a.m.	WELCOME AND INTRODUCTION Natalie D. Eddington, PhD, FCP, FAAPS Dean and Professor University of Maryland School of Pharmacy Bruce Yu, PhD Professor of Pharmaceutical Sciences Director, Bio- and Nano-Technology Center University of Maryland School of Pharmacy Ewa Marszal, PhD Chemist Center for Biologics Evaluation and Research Food and Drug Administration
	SESSION 1: OVERVIEW OF REGULATORY CHALLENGES AND ANALYTICAL TECHNOLOGIES CHAIR: Rukman De Silva, PhD, Chemist, Division of Biotechnology Review and Research IV, FDA/CDER/OPQ/OBP
9:00-9:20 a.m.	SCIENTIFIC AND REGULATORY PERSPECTIVES ON MEASURING PROTEIN AGGREGATION OF BIOTECHNOLOGY PRODUCTS Ashutosh Rao, PhD Laboratory Chief CDER/OPQ/OBP/DBRIII Food and Drug Administration
9:20-9:40 a.m.	SUBMICRON PARTICLE CHARACTERIZATION AND BENCHMARKING UNDER BIOLOGICS LEADERSHIP GROUP OF THE IQ CONSORTIUM Mario Hubert, PhD Principal Scientist Bristol Myers Squibb
9:40-10:00 a.m.	CRITICAL EVALUATION OF THE EMERGING ANALYTICAL METHODS FOR CHARACTERIZATION OF SUB-VISIBLE PARTICLES Atanas Koulov, PhD Head, Analytical Development & QC Lonza AG
10:00-10:30 a.m.	PANEL DISCUSSION
10:30-11:00 a.m.	BREAK

SESSION 2: APPLICATIONS AND LIMITATIONS OF COMMON TECHNOLOGIES

CHAIR: Brian Lobo, PhD, Associate Director and Group Leader, Formulation Sciences Department, MedImmune/AstraZeneca

11:00-11:20 a.m.

SIZE EXCLUSION CHROMATOGRAPHY OF BIOLOGICALS: TRUTH OR FICTION?

Christina Vessely, PhD
Senior Consultant
Biologics Consulting

11:20-11:40 p.m.

PRACTICAL APPLICATION OF ANALYTICAL TOOLS FOR CHARACTERIZATION OF AN IMPURITY-RELATED PARTICLE FORMATION MECHANISM

Jared Bee, PhD
Senior Scientist
MedImmune

11:40-12:00 p.m.

GENERALIZED METHOD FOR SUBVISIBLE PARTICLES CLASSIFICATION AND COUNTING USING FLOW MICROSCOPY AND RANDOM FORESTS

Miguel Saggu, PhD
Scientist
Genentech

12:00-12:30 p.m.

PANEL DISCUSSION

12:30-1:30 p.m.

LUNCH

SESSION 3: OPTICAL TECHNIQUES – COUNTING AND CHARACTERIZATION

CHAIR: Dean Ripple, PhD, Leader, Bioprocess Measurements Group, National Institute of Standards and Technology

1:30-1:50 p.m.

HOLOGRAPHIC CHARACTERIZATION OF PROTEIN AGGREGATES

David Grier, PhD
Director, Center for Soft Matter Research
New York University

1:50-2:10 p.m.

ESTIMATION OF PROTEIN AGGREGATE DENSITY USING SEDIMENTATION COMBINED WITH MICRO-PARTICLE TRACKING

Richard Cavicchi, PhD
Physicist
National Institute of Standards and Technology

2:10-2:30 p.m.

ACHIEVING ABSOLUTE PARTICLE SIZING WITH FLOW CYTOMETRY

Reema Raghavendra, PhD
Scientist II
AbbVie

2:30-3:00 p.m.

PANEL DISCUSSION

3:00-3:30 p.m.

BREAK

SESSION 4: NMR AND MS TECHNIQUES

CHAIR: Thomas Spitznagel, PhD, Vice President of Development, Macrogenics

3:30-3:50 p.m.

APPLICATIONS OF NMR FOR ASSESSING THE HIGHER ORDER STRUCTURE OF PROTEIN THERAPEUTICS

David Keire, PhD

Acting Laboratory Chief
CDER/OPQ/OTR/DPA/PABI
Food and Drug Administration

3:50-4:10 p.m.

WATER NMR FOR PROTEIN AGGREGATION CHARACTERIZATION

Marc Taraban, PhD

Research Assistant Professor
Department of Pharmaceutical Sciences
University of Maryland School of Pharmacy

4:10-4:30 p.m.

CHARACTERIZATION OF AGGREGATION PROPENSITIES OF PROTEIN THERAPEUTICS BY HYDROGEN/DEUTERIUM EXCHANGE MASS SPECTROMETRY

Richard Y. Huang, PhD

Research Investigator II
Bristol Myers Squibb

4:30-5:00 p.m.

PANEL DISCUSSION