Scientific Issues in Assessing the Similarity of Follow-on Protein Products
December 12 – 14, 2005

AGENDA
Day 1: December 12, 2005

Monday, December 12, 2005 7:00 AM – 7:00 PM

7:00 - 8:30 AM	**Registration and Continental Breakfast** Grand Ballroom Foyer F – Second Floor
8:30 – 9:00	INTRODUCTION AND GOALS OF THE WORKSHOP
	Welcoming Remarks ***Rashid Shaikh,*** New York Academy of Sciences
	Current Regulatory Directions ***Keith Webber***, FDA
	Meeting Goals and Agenda ***Emily Shacter***, FDA
9:00 AM – 5:30 PM	**SESSION I: ANALYTICAL TECHNIQUES TO EXAMINE MOLECULAR HETEROGENEITY OF ACTIVE INGREDIENT: COMPARISONS, STRENGTHS AND WEAKNESSES**
	Primary Structure Session Moderator: ***David Bunk***, NIST
9:00 - 9:15	Overview of Primary Structure and Related Issues ***David Bunk,*** NIST
9:15 - 9:45	Comparative Analysis of Post-Translationally Modified Peptides and Proteins by Mass Spectrometry: New Technology and Applications ***Donald F. Hunt***, University of Virginia
9:45 - 10:15	Chromatography Techniques ***William Hancock****, Northeastern Univversity*
10:15 - 10:45	**Coffee Break**
10:45 - 11:15	Fourier Transform MS ***Jonathan Amster***, University of Georgia
11:15 - 11:45	Towards a Goal of Automated Glycoproteomic Analysis ***Vernon Reinhold***, University of New Hampshire
11:45 AM - 12:30 PM	**Panel Discussion** Panel Moderator: ***Barry Cherney***, FDA
12:30 - 2:00	**Lunch Service** **Secondary and Tertiary Structure** Session Moderator: ***Blair Fraser***, FDA

2:00 - 2:20	Overview and Issues ***Russ Middaugh,*** University of Kansas
2:20 - 2:45	NMR ***Daron Freedberg***, FDA
2:45 - 3:10	Spectroscopic Techniques -FTIR, Fluorescence, Other – For Secondary Structure Analysis ***Keith A. Oberg***, Medical Research Products – A
3:10 - 3:35	Spectroscopic Techniques for Tertiary Structure Analysis ***Curtis Meuse***, NIST
3:35 - 4:00	**Coffee Break**
4:00 - 4:25	Thermodynamic Characterization of Protein Pharmaceutical Products by Calorimetry ***Frederick P. Schwarz***, NIST
4:25 - 4:50	Surface Hydrophobicity/HIC ***Steve Cramer***, Rensselaer Polytechnic Institute
4:50 - 5:30	**Panel Discussion** Panel Moderators: ***Daron Freedberg***, FDA and ***Curtis Meuse***, NIST
5:30 – 7:00	**Wine and Cheese Reception** Legends Ballroom – Second Floor

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AGENDA
Day 2: December 13, 2005

Tuesday, December 13, 2005 7:30 AM – 5:45 PM

7:30 - 8:30 AM	**Registration and Continental Breakfast** Grand Ballroom Foyer F – Second Floor
8:30 – 12:00 Noon	**SESSION I CONTINUED**
	Protein-Protein Interactions- Quaternary Structure Session Moderator: ***Amy Rosenberg***, FDA
8:30 - 8:45	Overview and Related Issues ***Amy Rosenberg,*** FDA
8:45 - 9:05	Critical Factors Governing Aggregation of Proteins in Aqueous Solution ***John F. Carpenter***, University of Colorado Health Sciences Center
9:05 - 9:25	Field Flow Fractionation (FFF) in Protein Purification and Characterization ***Karin D. Caldwell***, Uppsala University, Sweden
9:25 - 9:45	Light Scattering as a Tool for Assessing Protein Aggregates ***Ewa Folta-Stogniew***, Yale University
9:45 - 10:05	Imaging Proteins Using Atomic Force Microscopy ***Roger E. Marchant***, Case Western Reserve University
10:05 - 10:30	**Coffee Break**
10:30 - 10:50	Uses of Analytical Ultracentrifugation ***Thomas M. Laue***, University of New Hampshire
10:50 - 11:10	Mass Spectrometry of Higher Order Protein Structures ***Igor A. Kaltashov***, University of Massachusetts at Amherst
11:10 - 12:00 Noon	**Panel Discussion** Panel Moderator: ***Barry Cherney*****,** FDA
12:00 - 1:30	**Lunch Service**
1:30 - 3:30	**SESSION II: EFFECT OF THE MANUFACTURING PROCESS ON THE PRODUCT** Session Moderator: ***Stephen Moore***, FDA
1:30 - 1:50	Product Definition by Process Design ***Charles L. Cooney***, Massachusetts Institute of Technology
1:50 - 2:10	Chromatography ***Erik Fernandez***, University of Virginia
2:10 - 2:30	Effects of the Bioreactor Environment on Product Quality ***Sarah W. Harcum***, Clemson University

2:30 - 2:50	Renaturation and Folding ***Francois Baneyx***, University of Washington
2:50 - 3:30	**Panel Discussion** Panel Moderator: ***Kurt Brorson***, FDA
3:30 - 4:00	**Coffee Break**
4:00 - 5:45	**SESSION III: IMPURITIES AND CONTAMINANTS** Session Moderator: ***Andrew Chang***, FDA
4:00 - 4:20	Overview – What Types of Impurities are of Concern and Why Impurities Matter? ***Kathleen Clouse***, FDA
4:20 - 4:40	Proteomics Approaches ***Timothy D. Veenstra***, SAIC-Frederick, Inc.
4:40 - 5:00	Immunological Techniques ***Nadine M. Ritter***, The Biologics Consulting Group, LLC
5:00 - 5:45	**Panel Discussion** Panel Moderator: ***Andrew Chang***, FDA

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AGENDA
Day 3: December 14, 2005

Wednesday, December 14, 2005 7:30 AM – 4:00 PM

7:30 - 8:30 AM	**Registration and Continental Breakfast** Grand Ballroom Foyer F – Second Floor
8:30 - 11:30	**SESSION IV: BIOASSAYS AND POTENCY** Session Moderator: ***Marjorie Shapiro***, FDA
8:30 - 9:00	Overview ***Steven Kozlowski***, FDA
9:00 - 9:25	**Case Studies** **Example 1**: Enzyme Assays - Single Function vs. Pleiotropy ***Laureen Little***, Bioquality
9:25 - 9:50	**Example 2**: Binding Assays Versus Functional Bioassays ***C Jane Robinson***, National Institute for Biological Standards and Control, United Kingdom
9:50 - 10:15	**Coffee Break**
10:15 - 10:40	**Example 3:** Challenges to Assaying Protein Concentration ***David Bunk***, NIST
10:40 - 11:30	**Panel Discussion** Panel Moderator: ***Steven Kozlowski***, FDA
11:30 AM - 1:00 PM	**Lunch Service**
1:00 - 1:45	**SESSION V: ASSESSING SIMILARITY OF ACTIVE INGREDIENTS** Session Moderator: ***Emily Shacter***, FDA
1:00 - 1:15	Overview of Issues ***Emily Shacter***, FDA
1:15 - 1:45	Challenges in Developing Reference Materials for Biotech Products ***Adrian Francis Bristow***, National Institute for Biological Standards and Control, United Kingdom
1:45 – 3:15	**Roundtable Discussion** How to Compare Products/Proteins in the Absence of Reference Standards Moderator: ***Emily Shacter***, FDA
3:15 - 3:45	Workshop Wrap-Up ***Emily Shacter***, FDA
3:45 – 4:00	Closing Remarks ***Steven Kozlowski***, FDA