



INSTITUTE OF MEDICINE

OF THE NATIONAL ACADEMIES

USP Heavy Metals Testing Methodologies Workshop

August 26–27, 2008

National Academy of Sciences Lecture Room
2100 C Street, NW
Washington, DC

WORKSHOP AGENDA

Tuesday, August 26

Introduction to the Workshop

Welcome to The National Academies and the Institute of Medicine

Judith A. Salerno, MD, MS

Executive Officer, Institute of Medicine, US National Academy of Sciences

Conduct of the workshop

Joseph V. Rodricks, PhD

Chair, Workshop Planning Committee; Founding Principal, ENVIRON International

Charge to the workshop speakers and observers

Darrell Abernethy, MD, PhD

Chief Science Officer, US Pharmacopeia

Overview of USP <231>

Nancy S. Lewen

Principal Scientist, Analytical Research & Development, Bristol-Myers Squibb Company

Session I – Which Metals and Why are We Concerned with Them?

Michael Wierer, PhD, Moderator

member, Workshop Planning Committee;

Deputy Head, European Pharmacopoeia Department,

European Directorate for the Quality of Medicines & HealthCare, Council of Europe

Metals in health care products of natural origins

Lothar Kabelitz, PhD

Managing Director, PhytoLab GmbH & Co. KG (ret.)

Metals in active pharmaceutical ingredients and excipients

Michael Türck, PhD

Director, Organic Analytical laboratories, Merck KGaA Darmstadt

Observed levels of metals in drug products

Matthew W. Borer, PhD

Research Advisor, Eli Lilly and Company

Priorities for toxicological risk assessment for metals in health care products

Bruce A. Fowler, PhD

Assistant Director for Science, Division of Toxicology, Agency for Toxic Substances and Disease Registry,
US Department of Health and Human Services

lunch break



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Session II – Risk Assessment and Limit Setting

Monica Nordberg, PhD, Moderator

member, Workshop Planning Committee;

Professor of Hygiene/Environmental Medicine, Institute of Environmental Medicine, Karolinska Institutet

Risk assessment for metals and the establishment of tolerable intakes

P. Michael Bolger, PhD, DABT

Chief, Risk Assessment Staff, Center for Food Safety and Applied Nutrition, US Food and Drug Administration

European approach taken in the CHMP guideline on specification limits for residues of catalysts or metal reagents

Roland Frötschl, PhD

Genetic toxicologist, Federal Institute for Drugs and Medical Devices BfArM, Bonn

Converting acceptable intakes to concentrations in products

Vasilios H. (Bill) Frankos, PhD

Director, Division of Dietary Supplement Programs, US Food and Drug Administration

Panel discussion – First day's speakers

Moderators to be named

Reception, *The Great Hall of the National Academy of Sciences*

Wednesday, August 27

Brief welcome and overview of the workshop

Joseph V. Rodricks, PhD

Chair, Workshop Planning Committee; Founding Principal, ENVIRON

Session III – Modifying Factors for Risk Assessment

Douglas M. Templeton, PhD, MD, Moderator

member, Workshop Planning Committee;

Professor of Laboratory Medicine and Pathobiology, University of Toronto

Importance of chemical species

Robert Yokel, PhD

Professor, Department of Pharmaceutical Sciences, University of Kentucky

Bioavailability

Curtis D. Klaassen, PhD

Distinguished Professor and Chair, Department of Pharmacology, Toxicology & Therapeutics, Kansas University Medical Center

Metal-Metal interactions

Lauren Zeise, PhD

Chief of Reproductive and Cancer Hazard Assessment, California Environmental Protection Agency, Office of Environmental Health Hazard Assessment

lunch break



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Session IV – Measurements

R. Kenneth Marcus, PhD, Moderator
member, Workshop Planning Committee;
Professor of Analytical Chemistry, Clemson University

Reliable measures relative to acceptable limits

Gregory C. Turk, PhD
Leader, Inorganic Chemistry Metrology Group, National Institute of Standards and Technology, US
Department of Commerce

Total elemental analysis

Ramon M. Barnes, PhD
Professor Emeritus of Chemistry, University of Massachusetts at Amherst; Director, University Research
Institute for Analytical Chemistry

Sample preparation issues

David Barclay, PhD
Analytical Product Manager, CEM Corporation

Reference materials

Ralph Sturgeon, PhD
Group Leader, Chemical Metrology, National Research Council of Canada

State of the art in chemical species

Michael Sperling, PhD
Chief Managing Director of the European Virtual Institute for Speciation Analysis (EVISA)

Workshop Wrap-up

Joseph V. Rodricks, PhD, Moderator
Chair, Workshop Planning Committee;
Founding Principal, ENVIRON International

Roundtable discussion among planning committee members, workshop presenters, and observers

Workshop adjourns