



Welcome to **Montréal!**  
Bienvenue à **Montréal!**

## STP 36th Annual Symposium Musculoskeletal System

June 24–29, 2017 | Montréal Convention Centre | Palais des congrès de Montréal | Montréal, Québec, Canada

### Saturday, June 24

#### NTP Satellite Symposium: Pathology Potpourri

9:00 AM–4:30 PM

**Chair:** Susan A. Elmore, MS, DVM, DABT, FIATP, DACVP, NTP and NIEHS, Research Triangle Park, NC

The object of this interactive symposium is to provide continuing education on interpreting pathology slides, to generate lively and productive conversation, and to have a good time. During each talk, the speakers will project a series of images of lesions on one screen with a choice of diagnoses/answers on a separate screen. The members of the audience will then vote using wireless keypads and the results will be displayed on the screen. Time is allowed for discussion after each voting session.

### Sunday, 25 June

#### CE 1 (Sunday AM)

8:00 AM–12:00 Noon

##### Impact of Age on the Stage-Aware Assessment of Reproductive Tract

**Co-Chairs:** Karen Regan, DVM, DACVP, DABT, Regan Path Tox Services, Inc, Ashland, OH; and Karyn Colman, BVetMed, MRCVS, Novartis, East Hanover, NJ

The evaluation of the reproductive system in the context of toxicological pathology requires a good understanding of the normal physiology and morphology of the reproductive organs. Stage-aware assessment of the reproductive organs can provide important information on the potential of toxicity of a compound in the early steps of the drug development. However, the reproductive organs undergo major morphological and physiological changes from birth to senescence, and therefore the interpretation of reproductive morphological alternation and/or pathology sometimes becomes complex. This interactive course presents the different aspects of reproductive toxicological pathology that pathologists will face during the various phases of drug development, from challenges in juvenile and immature animals to changes associated with senescence, with emphasis on the stage-aware assessments of male and female reproductive organs in typical laboratory animal species (rodents, dogs, and NHP).

8:00 AM–8:40 AM

##### Stage-Aware Assessment in Adult (Sexually Mature) Males

Claudine Tremblay, DVM, MSc, DACVP, Charles River Laboratories, Montréal, Quebec, Canada

8:40 AM–9:20 AM

##### Stage-Aware Assessment in Adult (Sexually Mature) Females

Karyn Colman, BVetMed, MRCVS, Novartis, East Hanover, NJ

9:20 AM–10:00 AM

##### Maturity and the Assessment of Male Reproductive Toxicologic Effects in Large Animal Species

Katharine Whitney, DVM, PhD, DACVP, Abbvie, North Chicago, IL

10:00 AM–10:30 AM

##### Break

10:30 AM–11:15 AM

##### Immaturity, Adolescence, and Puberty: Interpretation of Female Reproductive System in Nonrodents (Dog and NHP)

Justin Vidal, DVM, PhD, MPI Research, Mattawan, MI

11:15 AM–12:00 Noon

##### Early Senescence in Female Rodents: Recognizing and Interpreting the Changes in Preclinical Studies

Karen Regan, DVM, DACVP, DABT, Regan Path Tox Services, Inc, Ashland, OH

#### CE 2 (Sunday AM)

8:00 AM–12:00 Noon

##### Current Practices and Challenges in Method Validation

**Co-Chairs:** Florence Poitout, DVM, DACVP, DECVP, Charles River, Montréal, Quebec, Canada; and Mehrdad Ameri, DVM, MS, PhD, DACVP, GlaxoSmithKline, King of Prussia, PA

This course will address current practices, problems, and future directions of method validation, and a review of current regulatory requirements for clinical and preclinical biomarker validation. It will focus on non-traditional instrumentations such as Multiplex ligand binding assays now used to support many stages of drug development, but with unique challenges, compared to single-plexed assays that necessitate various adjustments for validation and sample analysis. Quantitative mass spectrometry validation may also be challenging as this technology is now an integral part of operations in a growing number of clinical pathology laboratories and could certainly gain more space in drug development and preclinical toxicology testing. Pitfalls and challenges encountered in the validation of biomarkers and flow cytometry assays in support of large molecule (biologics) in different species will be presented. The current preclinical safety biomarker qualification process and the role of pathologists and clinical pathologists will be reviewed; from the use of shared histopathology lexicons and blinded vs. open histopathology evaluation, study design, data interpretation, and data curation for statistical evaluation. Emphasis will be placed on the complementary roles of the anatomic pathologist in the phenotypic anchoring of safety biomarker changes, and that of the clinical pathologist for understanding pathophysiological and analytical aspects unique to each novel biomarker.

8:00 AM–8:45 AM

##### Challenges in Quantitative Mass Spectrometry Assay Validations

Simon Lavallee, BSc, Charles River, Montréal, Quebec, Canada

8:45 AM–9:30 AM **Challenges in Quantitative Mass Spectrometry Assay Validations**  
Jennifer Colangelo, PhD, Pfizer, Groton, CT

9:30 AM–10:00 AM **Break**

10:00 AM–10:30 AM **Strategies and Pitfalls in Biological Biomarker Validations**  
Adam Aulbach, DVM, DACVP, MPI Research, Mattawan, MI

10:30 AM–11:15 AM **Validation Challenges in Flow Cytometry**  
Marie-Soleil Piché, PhD, Charles River, Montréal, Quebec, Canada

11:15 AM–12:00 Noon **The Role of Anatomic and Clinical Pathologists in Biomarker Qualification**  
Danielle Ennulat, DVM, PhD, GlaxoSmithKline, King of Prussia, PA

 **CE 3 (Sunday PM)**

1:30 PM–5:30 PM

**Tissue-Based Image Analysis**

**Co-Chairs:** Jean-Rene Galarneau, DVM, MSc, DACVP, Novartis, Cambridge, MA; Marielle Odin, DVM, DVSc, RochePharma, Basel, Switzerland; and Sasmita Mishra, DVM, MS, PhD, DACVP, AbbVie, Lake Villa, IL

Digital pathology is in the process of revolutionizing the way pathologists conduct their art. Quantitative image analysis is a rapidly evolving area of digital pathology. The quantification of histological features on photomicrographs is not a new concept but it used to be cumbersome, resource intensive, and limited to specialists and specialized laboratories. However, recent technological advances like highly efficient automated whole slide digitizer (scanner) systems, innovative image analysis platforms, and the emergence of pathologist-friendly image annotation and analysis systems means that quantitation of features on histological digital images will become more and more prominent in our daily professional life. There is a plethora of potential use for quantitative image analysis in pathology including confirmation of equivocal findings noted by a pathologist, increasing the sensitivity of features detection, quantification of signal intensity, improving efficiency, etc. There is no denying that quantitative image analysis is part of the future of pathology but there are also numerous potential pitfalls when trying to estimate volumetric features from a few 2D sections. This continuing education session on quantitative image analysis will offer a broad overview of the field, a hands-on toxicologic pathologist's experience with image analysis, a talk on how to apply basic stereology principle in order to avoid biases in image analysis, and finally, a reflection on the future of image analysis in the toxicologic pathology field.

1:30 PM–2:20 PM **Pathology through Pixels: Where We Are, Where We Need to Be**  
Robert Dunstan, DVM, PhD, DACVP, AbbVie, North Chicago, IL

2:20 PM–3:10 PM **An Investigative Toxicologic Pathologist's Experiences with Whole Slide Image Analysis**  
Chandra Saravanan, DVM, MS, PhD, DACVP, Novartis, Cambridge, MA

3:10 PM–3:45 PM **Break**

3:45 PM–4:35 PM **Reducing Bias in Image Analysis Data by Applying Stereological Principles**  
Danielle Brown, DVM, MS, DACVP, DABT, Charles River, Durham, NC

4:35 PM–5:25 PM **Image Analysis Solutions to Drive Investigative Pathology**  
Vanessa Schumacher, DVM, MS, DACVP, DABT, Roche Innovation Center, Basel, Switzerland

5:25 PM–5:30 PM **Panel Discussion**

 **CE 4 (Sunday PM)**

1:30 PM–5:30 PM

**What You Always Wanted to Know About Immunotoxicology in Pharmaceutical Development...but Were Afraid to Ask**

*Sponsored by the American College of Toxicology (ACT)*

**Co-Chairs:** L. Peyton Myers, PhD, US FDA, Silver Spring, MD; and Michael Holsapple, PhD, ATS, Michigan State University, East Lansing, MI

As evidenced by ICH S8, M3(R2), as well as S6(R1) Guidelines, the immune system has long been an important target in pharmaceutical development. Because of this attention, the science behind safety risks associated with the immune system has evolved, resulting in attention on immunotoxicology assessment tools. In recent years, as more pharmaceuticals are targeting specific immune targets, more immunotoxicology tools have been applied. This course will provide an overview of some of the most important immunotoxicology drug development platforms. Dr. Holsapple will set the stage by briefly reviewing ICH Guidelines and current paradigms in immunotoxicology. The next talks by recognized leaders in Immunotoxicology will focus on three important platforms. All of these talks will highlight how the data derived from these platforms are used to inform, highlighting strengths and limitations. Dr. Lebec will consider the application of immunophenotyping to safety assessment. Dr. Holsapple will describe the utility of the T-dependent antibody response (TDAR) as the "gold standard" in immunotoxicology. Dr. Rao will address the dichotomy of the role of cytokines, as "friend or foe." The final talk by Dr. Myers will provide a regulatory perspective on immunotoxicology, including trends in immunotoxicology assessment for recent US FDA approvals.

1:30 PM–2:10 PM **Studies Setting the Stage: What You Always Wanted to Know About Immunotoxicology**  
Michael Holsapple, PhD, ATS, Michigan State University, East Lansing, MI

2:10 PM–2:50 PM **Immunophenotyping: Application to Safety Assessment**  
Herve Lebec, PharmD, PhD, DABT, Amgen Inc., South San Francisco, CA

2:50 PM–3:20 PM **The "Gold Standard": Utility of the T-Dependent Antibody Response**  
Michael Holsapple, PhD, ATS, Michigan State University, East Lansing, MI

3:20 PM–3:50 PM **Break**

3:50 PM–4:30 PM **Cytokines: Friend or Foe?**  
Gautham Rao, PhD, DABT, Genentech Inc., South San Francisco, CA

4:30 PM–5:30 PM **Immunotoxicology, Regulatory Perspective**  
L. Peyton Myers, PhD, US FDA, Silver Spring, MD

## Monday, June 26

8:00 AM–8:10 AM

### Symposium Welcome

8:10 AM–9:00 AM

### Keynote Address: Overview of Bone/ Muscle Specific Analyses with a Focus on Histology

*Cathy Carlson, DVM, PhD, DACVP, University of  
Minnesota, St. Paul, MN*

## Session 1

9:00 AM–12:00 Noon

### Toolbox for the Evaluation of the Musculoskeletal System

**Co-Chairs:** *Jacquelin Jolette, DVM, MSc, Charles River Laboratories,  
Senneville, Quebec, Canada; and Theresa Boulineau, DVM, MS,  
DACVP, Livingston, NJ*

The musculoskeletal system is often a *bête noire* for diagnostic and experimental pathologists. To effectively tackle this system, this session will provide an overview of available tools that can be used to uncover changes in bones and muscles. The first two presentations will focus on familiar histopathology tools including case studies in addition to also exploring other approaches such as bone biomarkers, biomechanical testing, histomorphometry, and various imaging tools that can characterize effects at the organ, tissue, and cell levels. The third presentation will highlight nomenclature changes from the recently published INHAND bone and joint publication and the rationale for these changes. Finally, we will explore species, age, and anatomic considerations regarding evaluation of the skeleton that are relevant for preclinical study design.

9:00 AM–9:05 AM

### Introduction

*Jacquelin Jolette, DVM, MSc, Charles River  
Laboratories, Senneville, Quebec, Canada; and  
Theresa Boulineau, DVM, MS, DACVP,  
Livingston, NJ*

9:05 AM–9:50 AM

### Bone Toolbox: Biomarkers, Biomechanics, Imaging Tools, Histomorphometry

*Aurore Varela, DVM, MSc, DABT, Charles River  
Montréal, Montréal, Quebec, Canada*

9:50 AM–10:20 AM

### Break

10:20 AM–11:05 AM

### Diagnostic Criteria for Bone and Joint Lesions: Using INHAND Nomenclature

*John Vahle, DVM, PhD, DACVP, Eli Lilly &  
Company, Indianapolis, IN*

11:05 AM–11:50 AM

### Differences in Bone over Time

*Matthew R. Allen, PhD, Indiana University  
School of Medicine, Indianapolis, IN*

11:50 AM–12:00 Noon

### Panel Discussion

## Career Development Lunchtime Series

Monday, June 26

12:30 PM–1:30 PM

### STP Special Interest Groups: Role and Relevance for Your Toxicologic Pathology Career

**Chair:** *Brent Walling, DVM, PhD, DACVP, Charles River Laboratories,  
Medina, OH*

This session will include a panel of members of the Society of Toxicologic Pathology (STP) that are also members of one or more Special Interest Groups (SIG) talking about their experiences with SIGs. Topics of discussion may include what leads/has led to the formation of SIGs, how SIGs contribute to the strategic plans of the STP and the field of toxicologic pathology, how do individual members of SIGs contribute to the missions of SIGs, and/or what role(s) SIGs may have in the careers of toxicologic pathologists. The goal of the panel discussion will be to familiarize STP members with the SIGs and their contributions to the STP and toxicologic pathology and how joining one or more SIG can be mutually beneficial to the toxicologic pathologist and the SIGs of interest.

## Session 2

1:30 PM–5:00 PM

### Bone Therapeutics: Safety Considerations

**Co-Chairs:** *Rogely Boyce, DVM, PhD, DACVP, Amgen, Clay, WV; and  
Chris Jerome, BVetMed, PhD, Wake Health, Winston-Salem, NC*

The first presentation will be an overview of a major regulatory requirement in the nonclinical filing package for bone therapeutics, studies designed to assess the impact of an agent on bone quality. While relatively few bone therapeutics are currently under development, the experience with those previously developed can inform the evaluation of bone safety classes. Two presentations will focus on safety issues associated with classes of drugs whose primary mechanism of action is inhibition of bone resorption. An overview of safety issues that have been identified largely through clinical experience will be followed by a discussion of typical findings associated with this class of agents in general and reproductive toxicology studies will be reviewed, highlighting INHAND nomenclature. Similarly, safety and regulatory issues associated with classes of drugs whose primary mechanism of action is stimulation of bone formation, known broadly as bone anabolic agents will be presented, with a major focus on carcinogenicity risk assessment. The final pair of presentations will be an introduction to a rapidly evolving area in bone therapeutics, treatment of rare genetic bone diseases, and the development challenges associated with these indications and novel therapeutic modalities.

1:30 PM–1:35 PM

### Introduction

*Rogely Boyce, DVM, PhD, DACVP, Amgen,  
Clay, WV*

1:35 PM–2:10 PM

### Regulatory Requirements for Assessment of Bone Safety

*Michael Ominsky, PhD, Radius Health, Inc.,  
Waltham, MA*

2:10 PM–2:45 PM

### Antiresorptives Safety Concerns—Clinical Perspective

*Jacques P. Brown, MD, FRCPC, Laval University,  
Montréal, Quebec, Canada*

2:45 PM–3:00 PM

### Antiresorptives—Toxicology Perspective

*Rogely Boyce, DVM, PhD, DACVP, Amgen,  
Clay, WV*

3:00 PM–3:30 PM

### Break

- 3:30 PM–4:10 PM **Anabolics—Potential Safety Concerns**  
*Luc Chouinard, DVM, DACVP, Charles River Montréal, Senneville, Quebec, Canada*
- 4:10 PM–4:45 PM **Therapeutics for Rare Bone Diseases—Clinical Perspective**  
*Frank Rauch, MD, McGill University, Montréal, Quebec, Canada*
- 4:45 PM–5:00 PM **Rare Bone Disease—Toxicology Perspective**  
*Rogely Boyce, DVM, PhD, DACVP, Amgen, Clay, WV*

## Mystery Bone, Joint and Musculoskeletal Pathology Session

7:00 PM–9:00 PM

**Co-Chairs:** *Stacey Fossey, DVM, PhD, DACVP, DABT, AbbVie, Worcester, MA; Timothy LaBranch, DVM, PhD, DACVP, Blueprint Medicines, Cambridge, MA; and Kathryn E. Gropp, DVM, PhD, DACVP, Pfizer, Groton, CT*

This session will provide attendees with the opportunity to expand their knowledge through focused histopathology case review. Cases will be available for review online prior to the STP annual meeting to foster discussion during the face-to-face session in Montréal. Case materials are being sought to span the breadth of spontaneous and induced disease, with contemporary target-based toxicities highlighted.

**Tuesday, June 27**

### Session 3

8:00 AM–12:00 Noon

#### Unintended Pharmacologic Effects on Bone

**Co-Chairs:** *James Hartke, DVM, PhD, DACVP, Celgene Corporation, San Diego, CA; Jairo Nunes, DVM, MSc, PhD, DACVP, Takeda Pharmaceuticals, Cambridge, MA; and Stacey Fossey, DVM, PhD, DACVP, DABT, AbbVie, Worcester, MA*

Bone is a metabolically active tissue and undergoes changes in structure and composition as a result of direct and indirect pharmacologic activity in toxicology studies. Examples of molecular pathways (WNT, IHH, VEGF) and bone findings will be presented with emphasis on describing the pathogenesis and how the basic biology was altered in the growth plate, metaphysis, trabecular bone, and bone marrow. The impact of the findings along with de-risking strategies will be discussed.

- 8:00 AM–8:05 AM **Introduction**  
*James Hartke, DVM, PhD, DACVP, Celgene Corporation, San Diego, CA; Jairo Nunes, DVM, MSc, PhD, DACVP, Takeda Pharmaceuticals, Cambridge, MA; and Stacey Fossey, DVM, PhD, DACVP, DABT, AbbVie, Worcester, MA*
- 8:05 AM–8:50 AM **Wnt Pathway and Bone**  
*Alexander G. Robling, PhD, Indiana University, Indianapolis, IN*
- 8:50 AM–9:25 AM **Physis in Crisis**  
*Kendall Frazier, DVM, PhD, DACVP, DABT, GlaxoSmithKline, King of Prussia, PA*

9:25 AM–9:45 AM

**Student Speaker**

9:45 AM–10:15 AM

**Break**

10:15 AM–10:35 AM

#### IHH Pathway and Premature Growth Plate Closure

*Melissa Schutten, DVM, PhD, DACVP, Genentech, South San Francisco, CA*

10:35 AM–10:55 AM

#### VEGF-Related Growth Plate Changes

*Anne M. Ryan, DVM, PhD, DACVP, Pfizer Inc, Groton, CT*

10:55 AM–11:15 AM

#### Effects on Trabecular Bone in the Metaphysis

*Kathryn E. Gropp, DVM, PhD, DACVP, Pfizer, Groton, CT*

11:15 AM–11:50 AM

#### Bone Findings Secondary to Anti-Neoplastic Compounds: Marrow Hematopoietic, Bone, and Cytokine Cross-Talk

*Lise Loberg, PhD, DABT, Abbvie, North Chicago, IL*

11:50 AM–12:00 Noon

#### Closing Remarks

*James Hartke, DVM, PhD, DACVP, Celgene Corporation, San Diego, CA; Jairo Nunes, DVM, MSc, PhD, DACVP, Takeda Pharmaceuticals, Cambridge, MA; and Stacey Fossey, DVM, PhD, DACVP, DABT, AbbVie, Worcester, MA*

Afternoon

**Free Time**

**Wednesday, June 28**

### Session 4

8:00 AM–12:00 Noon

#### Bone As an Endocrine Organ

**Co-Chairs:** *Susan Y. Smith, MSc, Charles River Laboratories, Senneville, Quebec, Canada; and Dana B. Walker, DVM, DACVP, MS, PhD, Novartis Institute of Biomedical Research, Cambridge, MA*

The objective of this session is to highlight developments in the evolving role of the skeleton as an endocrine organ, and its relevance in toxicology evaluations as part of a whole-body, systems biology approach to drug safety assessment. Evidence to date is convincing that at least two hormones known to be produced by the skeleton: osteocalcin and FGF23, are involved respectively in energy metabolism, and mineral homeostasis and metabolism. Research indicates that an imbalance in these critical functions has pathophysiological ramifications affecting the function of major organ systems. Speakers in this session are experts in their domain and will present state-of-the-art talks on the role of bone in energy metabolism, the central and peripheral nervous system, and our current understanding of the actions of FGF23; the session will conclude with a talk on the immunoskeletal interface to highlight how this relationship can impact physiological and pathological function of bone.

8:00 AM–8:05 AM

#### Introduction

*Susan Y. Smith, MSc, Charles River Laboratories, Senneville, Québec, Canada*

8:05 AM–8:55 AM

#### Energy Metabolism of Bone

*Clifford J. Rosen, MD, Maine Medical Center Research Institute, Scarborough, ME*

8:55 AM–9:45 AM	<b>Bone and the Nervous System</b> <i>Paul Baldock, PhD, Garvan Institute of Medical Research, Sydney, Australia</i>
9:45 AM–10:15 AM	<b>Break</b>
10:15 AM–11:05 AM	<b>Pleiotropic Actions of FGF23</b> <i>Reinhold Erben, Univ.-Prof., Dr.med, Dr.med. vet., University of Veterinary Medicine, Vienna, Austria</i>
11:05 AM–11:55 AM	<b>Bone and the Immune System</b> <i>M. Neale Weitzmann, PhD, Atlanta Department of Veterans Affairs Medical Center, Atlanta, GA</i>
11:55 AM–12:00 Noon	<b>Closing Remarks</b> <i>Dana B. Walker, DVM, DACVP, MS, PhD, Novartis Institute of Biomedical Research, Cambridge, MA</i>

**IATP Lunchtime Session**

Wednesday, June 28  
12:30 PM–1:30 PM

**Nanotechnology Reflections: Understanding the Toxicologic Pathology of Nanoscale Interactions**

**Co-Chairs:** *Darlene Dixon, DVM, PhD, DACVP, FIATP, NIEHS/NTP, Research Triangle Park, NC; and Robert R. Maronpot, DVM, MS, MPH, Maronpot Consulting, LLC, Raleigh, NC*

**Speaker:** *Ann F. Hubbs, DVM, PhD, CDC/NIOSH/HELD Morgantown, WV.*

**Session 5**

1:30 PM–5:00 PM

**Structural Approaches to Bone & Joint Repair**

**Co-Chairs:** *Lyn Wancket, DVM, PhD, DACVP, NAMS, Ottawa Hills, OH; and Timothy LaBranch, DVM, PhD, DACVP, Blueprint Medicines, Cambridge, MA*

Repair of bone and joint tissue is a unique endeavor for two reasons. First, structural integrity is key to restoring normal function. Second, essential to this repair is a combination of both organic and inorganic tissue components, each with their own discrete role to play. This session will cover methods and models used to evaluate novel approaches for repairing bones and joints. The first talk will provide an overview of bone and joint devices, with an emphasis on preclinical and clinical evaluations of implant sites. The next presentation will show an example of *ex vivo* tissue engineering as a therapeutic option for arthritis. The third talk will compare the benefits and limitations of different animal models of joint damage and repair. Finally, the session will conclude with an overview of the unique standards and guidances that steer approval of these novel bone and joint treatments.

1:30 PM–2:15 PM	<b>Bone and Joint Devices: Evaluating Repair from the Ground (Substance) Up</b> <i>Lyn Wancket, DVM, PhD, DACVP, NAMS, Ottawa Hills, OH</i>
2:15 PM–3:00 PM	<b>Biologic Joint Repair Strategies</b> <i>Keiichi Kuroki, DVM, PhD, DACVP, University of Missouri, Columbia, MO</i>
3:00 PM–3:30 PM	<b>Break</b>

3:30 PM–4:15 PM	<b>Animal Models of Joint Damage and Repair</b> <i>Timothy LaBranch, DVM, PhD, DACVP, Blueprint Medicines, Cambridge, MA</i>
4:15 PM–5:00 PM	<b>Regulatory Considerations for Medical Devices</b> <i>Karen Manhart, VMD, ANP, DACVP, US FDA, Silver Spring, MD</i>

**Thursday, June 29****Session 6**

8:00 AM–12:00 Noon

**Evaluation of Skeletal Muscle**

**Co-Chairs:** *Wendell P. Davis, DVM, DACVP, Charles River Laboratories, Sherbrooke, Quebec, Canada; and Stephane Thibault, DVM, DACVP, DABT, Pfizer Inc., San Diego, CA*

The symposium's final scientific session will focus on the skeletal muscle and begin with a review of the basic toolbox for evaluating skeletal muscle in toxicology studies including specimen collection & orientation, species differences, and common background findings. Commonly used histochemical stains and other specialized approaches utilized in the evaluation of skeletal muscle will be discussed. The second presentation will provide an overview of the classic skeletal muscle biomarkers and current commercially available assays and conclude with an update on the status of the FDA working groups' qualification efforts and discussion of case studies analyzing the performance of biomarker assays in drug development. The next presentation will focus on Sarcopenia and highlight the importance of health issues associated with aging in the worldwide population. Key mechanisms currently implicated in the pathophysiology and progression of this condition will also be discussed, as well as the current controversies and future directions in the field of Sarcopenia research. The final presentation will include a review of several animal models of muscular dystrophy and utilize Duchenne's muscular dystrophy to illustrate some emerging image analysis tools being employed to mitigate the challenge of providing quantitative clinical biomarker data in patients.

8:00 AM–8:05 AM	<b>Introduction</b> <i>Wendell P. Davis, DVM, DACVP, Charles River Laboratories, Sherbrooke, Quebec, Canada; and Stephane Thibault, DVM, DACVP, DABT, Pfizer Inc., San Diego, CA</i>
8:05 AM–8:50 AM	<b>Skeletal Muscle Toolbox (Comparative Anatomy, Histology, IHC, TEM)</b> <i>Kathryn E. Gropp, DVM, PhD, DACVP, Pfizer Inc., Groton, CT</i>
8:50 AM–9:40 AM	<b>Overview of Biomarkers for Skeletal Muscle Injury in Rats</b> <i>Richard A. Goldstein, DVM, Pfizer Inc., Groton, CT</i>
9:40 AM–10:00 AM	<b>Student Speaker</b>
10:00 AM–10:25 AM	<b>Break</b>
10:25 AM–11:15 AM	<b>Models of Accelerated Sarcopenia</b> <i>Thomas W. Buford, PhD, University of Florida, Gainesville, FL</i>
11:15 AM–12:00 Noon	<b>Muscular Dystrophy: Biomarker Quantification and Drug Development</b> <i>Kristin Wilson, DVM, PhD, DACVP, Flagship Biosciences, Westminster, CO</i>
12:00 Noon	<b>Meeting Adjourned</b>