

## BIOMARKER DISCOVERY AND VALIDATION: FROM BENCH TO BEDSIDE

Mass spectrometry is at the core of a rapidly expanding worldwide effort to find clinically useful protein biomarkers in human tissues and body fluids. This effort involves major challenges in MS applied to protein discovery and in high-throughput validation of markers in large sample sets. This meeting is focused on these challenges and the status of efforts to demonstrate robust technologies supporting a biomarker pipeline from basic research through validation to clinical use.

Our goal is to critically evaluate current challenges in sample collection, sample processing, MS data collection and data analysis for biomarker discovery, and the requirements for validation of candidate markers. Our discussions will focus on developing an understanding of best practices in biomarker discovery and validation, what analytical and data analysis approaches are truly useful and robust, and what new methods on the horizon may deserve particular attention.

### FRIDAY, OCTOBER 14

**3:00 pm**    **Check-in**, *Asilomar Main Lobby*

**6:00 – 7:00 pm**    **Asilomar dinner for on-site lodgers**, *Crocker Dining Hall.*  
*Asilomar meal ticket required.*

Friday evening presenters should arrive in the Chapel at 6:30 pm to set up laptops.

**7:00 – 10:00 pm**    **Opening Session**, *Chapel*

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7:00 – 7:15 pm    **Steve Carr and Leigh Anderson**  
*Welcome and introductory remarks*

7:15 – 8:00 pm    **Lee Hartwell**; Fred Hutchinson Cancer Center, Seattle, WA  
*Rationale for Biomarkers in the Early Detection of Disease*

8:00 – 8:45 pm    **David Millington**; Duke University Medical Center, Durham, NC  
*The Success of MS in Screening for Inborn Errors of Metabolism*

8:45 – 9:15 pm    **POSTER PRESENTATIONS, 5 minutes each**

Poster #

2.    **Jeff Silva**, Waters Corporation
3.    **Trent Northen**, Biodesign Institute, Arizona
5.    **Gongyi Shi**, Bruker Daltonics
6.    **Mike Knierman**, Eli Lilly
12.    **Suzanne Miyamoto**, UC Davis

**9:15 – 10:00 pm**    **Poster Viewing and Reception**

**SATURDAY, OCTOBER 15**

**7:30 – 9:00 am** **Asilomar Breakfast** for on-site lodgers, *Crocker Dining Hall*.  
*Asilomar meal ticket required.*

Saturday morning presenters should arrive at 8:30 am to set up laptops.

**9:00 am – 12:00 pm** **Historical Perspective on Success and Challenges of Biomarker Discovery, Chapel**

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9:00 – 9:45 am **Leigh Anderson**; Plasma Proteome Institute, Washington, DC  
*Filling the Biomarker Pipeline: Overview and Historical Context*

9:45 – 10:30 am **Robert Gerszten**; MGH/HMS  
*The Biology and Clinical Importance of Markers in Cardiovascular Disease*

**10:30 – 10:45 am** **Coffee Break**

10:45 – 11:30 am **Marc Sabatine**; HMS  
*History, Utility, How They Got to Troponins, CRP, etc.*

11:30 – 12:00 pm **Scott Patterson**; Amgen  
*Biomarkers in Early Drug Development*

**12:00 - 2:00 pm** **Asilomar lunch, Crocker Dining Hall.** *Asilomar meal ticket required.*

## SATURDAY AFTERNOON

Saturday afternoon presenters should arrive at 1:30 pm to set up laptops.

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**2:00 – 5:30 pm    Sample Processing and Analytical Approaches for  
(Semi)Quantitative MS Analysis by Pattern and Identity**

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- 2:00 – 2:30 pm    **Ron Beavis**; Beavis Informatics Ltd.  
*The Role of Proteomics Data Repositories in Biomarker  
Discovery and Validation*
- 2:30 – 3:00 pm    **John Stults**, Jonathan Heller, and Shawn Becker; Predicant  
Biosciences  
*Discovery and Clinical Assay of Cancer Biomarkers Using a  
Microfluidic CE-MS System*
- 3:00- 3:30 pm    **Marty McIntosh**; Fred Hutchinson Cancer Center  
*Novel Software for LC-Pattern; Medical Value, Cost-benefit of  
Markers: Criteria for Sens./Specificity for Several Major  
Diseases and Subcategories of Cancer*
- 3:30 – 4:00 pm    **Matthias Uhlen**; AlbaNova University Center, Royal Institute of  
Technology Stockholm  
*Antibody-Based Proteomics for Human Tissue Profiling*
- 4:00 – 4:30 pm    POSTER PRESENTATIONS, 5 minutes each**  
Poster #
1.     **Chris Turck**, Max Planck Institute of Psychiatry,  
Munich
  9.     **Eunok Paek**, Univ. of Seoul
  10.    **Maribel Beaumont**, DNAX, Palo Alto
  11.    **John Crabb**, Cleveland Eye Clinic
  15.    **J. DeGreef**, Genologics
- 4:30 – 5:30 pm    Poster Viewing**
- 6:00 - 7:00 pm    Asilomar dinner for on-site lodgers, Crocker Dining Hall.  
Asilomar meal ticket required.**

## SATURDAY EVENING

Saturday evening presenters should arrive at 6:30 pm to set up laptops.

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### 7:00 – 8:30 pm Plenary Session, Chapel

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7:00 – 7:45 pm **Werner Zolg**; Roche Diagnostics, Pensburg, Germany  
*Lessons Learned in the Search of Biomarkers*

7:45 – 8:30 pm **David Ransohoff**; University of North Carolina  
*What Is Validation? Importance of Proper Study Design in Reducing Chance and Bias*

**8:30 – 10:00 pm** A Taste of Monterey Wine Tasting. *Seascape (in Crocker Dining Hall)*

Sponsored by

**Applied Biosystems**

**Bruker Daltonics**

**Thermo Electron**

**Waters**

## SUNDAY, OCTOBER 16

**7:30 – 9:00 am** **Asilomar Breakfast** for on-site lodgers, *Crocker Dining Hall*.  
*Asilomar meal ticket required.*  
Request a box lunch at entrance to Crocker Hall at breakfast if you wish to take lunch with you for the free afternoon.

Sunday morning presenters should arrive at 8:30 am to set up laptops.

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### **8:50 – 12:00 pm** **Advances in Technology and Applications, Chapel**

- 8:50 – 9:00 am Opening Remarks; Reminders
- 9:00 – 9:30 am **Greg Opiteck**; Caprion Pharmaceuticals  
*The Effect of Anti-Hypertensive Therapy on the Plasma Profile: Responders vs. Non-Responders and MOA-Specific Effects*
- 9:30 – 10:00 am **Mimi Roy**; PPD Biomarker Discovery Sciences  
*Toward CNS Lymphoma Biomarkers in Cerebral Spinal Fluid: Proteomic Expression Profiling and Validation*
- 10:00 – 10:30 am **Dick Smith**; PNNL  
*Mix of Technology and Applications*
- 10:30 – 10:45 am** **Coffee Break**
- 10:45 – 11:15 am **Jonathan (Baogang) Xu**; Vanderbilt University Medical Center  
*From Tissues to Cells: Combining Laser Capture Microdissection and MALDI Mass Spectrometry for Protein Biomarker Discovery*
- 11:15 – 12:00 pm **Catherine Costello**; Boston University Medical School  
*Proteomics Approaches for Identification of Hemoglobin Variants and their Posttranslational Modifications*
- 12:00 - 2:00 pm** **Asilomar lunch, Crocker Dining Hall.** *Asilomar meal ticket required.*

### **AFTERNOON FREE!**

If you ordered a box lunch at breakfast, pick it up at Crocker Hall.  
If you forgot to order a box lunch, just ask for your lunch “to go” when you go through the line.

## SUNDAY EVENING

Sunday evening presenters should arrive at 6:30 pm to set up laptops.

**7:00 – 9:00 pm**    **Novel Affinity-Based Depletion and Proteome Fractionation Methods, Chapel**

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- 7:00 – 7:30 pm    **Daniel W. Chan**; Johns Hopkins Medical Institutions.  
*Discovery of Cancer Biomarkers with Diagnostic Potentials*
- 7:30 – 8:00 pm    **Paul Tempst**; Memorial Sloan-Kettering Cancer Center  
*Serum Peptide Signatures of Solid Tumor Cancers using Bead-Based Sample Prep and MALDI*
- 8:00 – 8:30 pm    **Michael Gillette**, D.R. Mani, Jake Jaffe and Steven Carr; Broad Institute of MIT and Harvard University  
*The Role of Pattern in Biomarker Discovery*
- 8:30 – 9:00 pm    **Tobias Preckel**; Agilent Germany  
*Deep Mining of the Serum or Plasma Proteome using Off-Gel Electrophoresis Coupled to Abundant Protein Depletion and Multidimensional LC-MS/MS*
- 9:00 – 10:00 pm**    **Informal Gathering/Happy Hour, Seascope**  
Sponsored by **Advion Biosciences**

## MONDAY, OCTOBER 17

**7:30 – 9:00 am** **Asilomar Breakfast** for on-site lodgers, *Crocker Dining Hall*.  
*Asilomar meal ticket required.*

Monday morning presenters should arrive at 8:30 to set up laptops.

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### **9:00 am – 12:00 pm** **Advances in Technology and Applications, Continued, Chapel**

- 9:00 – 9:30 am **David Speicher**; Wistar Institute, Philadelphia  
*Discovery of Human Cancer Serological Biomarkers using Multi-Dimensional Protein Profiling and a Mouse Model System*
- 9:30 – 10:00 am **Hui Zhang**; Institute for Systems Biology, Seattle, WA  
*Detection of Prostate-derived Proteins in Blood via Glycopeptide Analysis Targeting Extracellular Subproteome*
- 10:00 – 10:30 am **Mandy Paulovich**; Fred Hutchinson Cancer Center  
*Peptide-Based Ab's for Enrichment of Target Proteins at Low Levels for MS-Based Quantification*
- 10:30 – 10:45 am** **Coffee Break**
- 10:45 – 11:15 am **Jiang Wu**; Wyeth Pharmaceuticals  
*Asthma Biomarker Discovery via Differential Proteomics Analysis of Bronchoalveolar Lavage Fluid*
- 11:15 – 11:45 am **Steven Carr**<sup>1</sup>, Michael Gillette<sup>1</sup>, Betty Chang<sup>1</sup>, Veronica Saenz-Vash, Terri Addona, Jacob Jaffe, Alice Shaw<sup>2</sup> and Tyler Jacks<sup>2</sup>;  
<sup>1</sup>Broad Institute of MIT and Harvard, <sup>2</sup>Department of Cancer Biology, MIT Broad Institute of MIT and Harvard  
*Biomarker Discovery and Validation in Proximal Fluids and Plasma by Proteomics: Application to Arthritis and Lung Cancer*
- 12:00 - 2:00 pm** **Asilomar lunch**, *Crocker Dining Hall*. *Asilomar meal ticket required.*

## MONDAY AFTERNOON

Monday afternoon presenters should arrive at 1:30 pm to set up laptops.

### **2:00- 5:00 pm MS and Antibody Methods for Preclinical Validation of Biomarker Candidates, Chapel**

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2:00 – 2:30 pm Sandra Steiner<sup>1</sup>, Karsten Kuhn<sup>1</sup>, Michael Sonnentag<sup>1</sup>, Harald Legner<sup>1</sup>, Peter Schmid<sup>1</sup>, Christian Baumann<sup>1</sup>, Jürgen Schäfer<sup>1</sup>, Marco Schärfke<sup>1</sup>, Jutta Korder<sup>1</sup>, Thorsten Prinz<sup>1</sup>, Manfred Wildt<sup>1</sup>, Stefan Kienle<sup>1</sup>, Malcolm Ward<sup>1</sup>, Christian Hamon<sup>2</sup>, Simon Lovestone<sup>2</sup>, **Josef Schwarz**<sup>2</sup>; <sup>1</sup>Proteome Sciences R&D; Frankfurt, Germany, <sup>2</sup>Institute of Psychiatry, King's College, London  
*Towards the Discovery and Validation of Plasma Biomarkers for Alzheimer's Disease using the qPST<sup>®</sup> Profiling Approach*

2:30 – 3:00 pm **Thomas Conrads**; National Cancer Institute at Frederick  
*Identification and Characterization of the Antiproliferative Factor from the Urine of Interstitial Cystitis Patients*

3:00 – 3:30 pm **Christie L Hunter**<sup>1</sup>, Gerald W. Becker<sup>2</sup>, Andrew Breite<sup>2</sup>, Leigh Anderson<sup>3</sup>; <sup>1</sup>Applied Biosystems, CA; <sup>2</sup>Roche Applied Science, IN; <sup>3</sup>The Plasma Proteome Institute, DC  
*Developing Peptide MRM-Based Assays for Cardiovascular Biomarker Proteins in Plasma Using a Hybrid Triple Quadrupole Linear Ion Trap Mass Spectrometer*

3:30 – 4:00 pm **Hanno Langen**; Roche, Basel, Switzerland  
*Discovery and Validation of Biomarkers using 2D-Gel Based Methods*

4:00 – 4:30 pm **Brian Haab**; Van Andel Research Center  
*Antibody Microarrays for the Discovery and Validation of Blood-Based Biomarkers*

### **4:30 – 5:00 pm POSTER PRESENTATIONS, 5 minutes each**

Poster #

4. **Ali Vaezzadeh**, Hochstrasser Group
7. **Bruno Domon**, ETH, Switzerland
8. **Peter Barker**, NIST
13. **Markus Hardt**, UCSF
14. **Wei-Jun Qian**, PNNL
16. **Luke V. Schneider**, Target Discovery, CA

### **5:00 – 6:00 pm Poster Viewing**

**6:30 pm Banquet** for all registrants and registered guests, *Seascape*  
Please go directly to the Seascape entrance, to the right (ocean side) of main entrance to Crocker Hall. Please bring your ticket.

**TUESDAY, OCTOBER 18**

**7:30 – 9:00 am** **Asilomar Breakfast** for on-site lodgers, *Crocker Dining Hall*.  
*Asilomar meal ticket required.*

**Depart at leisure**

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## POSTERS

Please set up Friday evening in the Chapel and remove at 5:30 PM on Monday

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1. **Chris Turck**, R. Landgraf, M. Kessler and S. Kroemer; Max Planck Institute of Psychiatry, Munich, Germany  
*Identification of Biomarkers in Mouse Models of Extremes in Trait Anxiety*
2. **Jeffrey C. Silva**, Richard Denny, Craig Dorschel, Guo-Zhong Li, Keith Richardson, Daniel B. Wall, Scott J. Geromanos; Waters Corporation, Core Technology/Proteomics, Milford, MA  
*Qualitative and Quantitative Analysis of E. coli by Time-Resolved Mass Spectrometry*
3. **Trent R. Northen** and Neal W. Woodbury; *The Biodesign Insitute at Arizona State University*  
*In situ Peptide Mass Fingerprinting of DNA Binding Protein and Sequencing of Peptides using High Site Density Hydrogel Microstructure Arrays*
4. **Vaezzadeh Ali R.**<sup>1</sup>, Zimmermann-Ivol Catherine G.<sup>1</sup>, Luxembourg Stefan L.<sup>3</sup>, Walther Daniel<sup>2</sup>, Scherl Alexander<sup>1</sup>, Appel Ron D.<sup>2</sup>, Heeren Ron M.A.<sup>3</sup>, Hochstrasser Denis F.<sup>1</sup>; <sup>1</sup>Biomedical Proteomics Research Group-BPRG, Geneva University Hospital, 1211 Geneva, Switzerland; <sup>2</sup>Swiss Institute of Bioinformatics, Geneva University, 1211 Geneva 4, Switzerland; <sup>3</sup>FOM-Institute for Atomic and Molecular Physics, Kruislaan 407, 1098 SJ Amsterdam, The Netherlands  
*The Molecular Scanner*
5. **G. Shi**<sup>1</sup>, G. Murphy<sup>2</sup>, C. Stephensen<sup>3</sup> and M. Shigenaga<sup>2</sup>; <sup>1</sup>Bruker Daltonics, Fremont, <sup>2</sup>Children's Hospital Oakland Research Institute, Oakland, <sup>3</sup>University of California, Davis  
*Clinical Proteomic Profile Analysis of Human Plasma from the REACH Project: Molecular Fingerprints Associated with Vitamin D Deficiency*
6. **Jesus A. Gutierrez**, Jill A. Dorocke, Michael D. Knierman, Valentina Gelfanova, Richard E. Higgs, Nicholas Lewin Koh, and John E. Hale; Eli Lilly and Company, Indianapolis, IN  
*Quantitative Determination of Peptides Using Matrix-Assisted Laser Desorption/Ionization Time-of-Flight Mass Spectrometry*
7. **Bruno Domon**, Markus Mueller and Ruedi Aebersold, ETH, Zurich, Switzerland  
*Requirements for Mass Spectrometry Data Analysis and Search Strategies, Databases and Repositories: Issues and Opportunities*
8. **Peter Barker**, *NIST*
9. **Eunok Paek**<sup>1</sup>, <sup>1</sup>Seungjin Na, <sup>2</sup>Sangtae Kim, <sup>3</sup>Ji Woong Sim, <sup>4</sup>Heejin Park and <sup>5</sup>Kong-Joo Lee; <sup>1</sup>University of Seoul, Seoul, Korea, <sup>2</sup>Hanyang University, Seoul, Korea, <sup>3</sup>Seoul National University, Seoul, Korea, <sup>4</sup>Hanyang University, Seoul, Korea, <sup>5</sup>Ewha Womans University, Seoul, Korea  
*A Scalable Approach to Identify Multiple Peptide Modifications from Tandem Mass Spectra*

10. Vega F., Bowman E., **Beaumont M.**; DNAX Corporation, Palo Alto, CA  
*2D-DIGE Profiling of Psoriasis Biomarkers in the Plasma of Psoriatic Patients*
11. **John W Crabb**<sup>1</sup>, J Gu<sup>1,2</sup>, X Gu<sup>1</sup>, JS Crabb<sup>1</sup>, E Bala<sup>1,3</sup>, G Sturgill<sup>3</sup>, E Simpson<sup>1</sup>, NL Peachey<sup>1,3</sup>, SA Hagstrom<sup>1</sup>, J Sears<sup>1</sup>, P Kaiser<sup>1</sup>, H Lewis<sup>1</sup>, S Yaniglos<sup>2,3</sup>, and RG Salomon<sup>2</sup>; <sup>1</sup>Cleveland Clinic Foundation; <sup>2</sup>Case Western Reserve University; and <sup>3</sup>Louis Stokes VA Medical Center, Cleveland, OH  
*Biomarker Discovery for Age-Related Macular Degeneration*
12. **Suzanne Miyamoto**<sup>1</sup>, Hyun Joo An<sup>2</sup>, Crystal Kirmiz<sup>2</sup>, Katherine S Lancaster<sup>2</sup>; Bensheng Li<sup>2</sup>, Hao Liu<sup>2</sup>, Helen Chew<sup>1</sup>, Gary Leiserowitz<sup>3</sup>, Ralph deVere White<sup>1</sup>, Kit S Lam<sup>1</sup> and Carlito B Lebrilla<sup>2</sup>; <sup>1</sup>UC Davis Cancer Center, Sacramento, CA; <sup>2</sup>UC Davis, Davis, CA; <sup>3</sup>UC Davis Medical Center, Sacramento, CA  
*Development of Glycan Serum Biomarkers for the Detection of Cancer*
13. **Markus Hardt**<sup>1</sup>, S.E. Dixon<sup>4</sup>, L.R. Thomas<sup>1</sup>, O. Miroshnychenko<sup>1</sup>, J. Sargent<sup>1</sup>, H.E. Witkowska<sup>1,4</sup>, S.C. Hall<sup>1,4</sup>, S. Fisher<sup>1,2,3,4</sup>; <sup>1</sup>Departments of Cell and Tissue Biology, <sup>2</sup>Anatomy and <sup>3</sup>Pharmaceutical Chemistry, <sup>4</sup>Biomolecular Resource Center Mass Spectrometry Facility, University of California San Francisco, San Francisco, CA  
*Targeted Sub-Proteomic Strategies Toward Human Salivary Biomarker Discovery: Endogenous Peptides, Metal-Ion Affinity and Diurnal Variation*
14. **Wei-Jun Qian**; PNNL, Richland, WA  
*Utilizing Chemical Fractionation Approaches and Quantitative Proteomics for High Dynamic Range Human Plasma Proteome Profiling*
15. M. Leung, **J. DeGreef**; GenoLogics Life Sciences Software Inc., Victoria, BC, Canada  
*A Collaborative Approach to Developing Proteomics Data Standards*
16. Hall, M.P., Wilson, J. P., and **Schneider, L.V.**; Target Discovery, Palo Alto, CA  
*Isotope-Differentiated Binding Energy Shift Tags (IDBEST™) in Biomarker Validation*

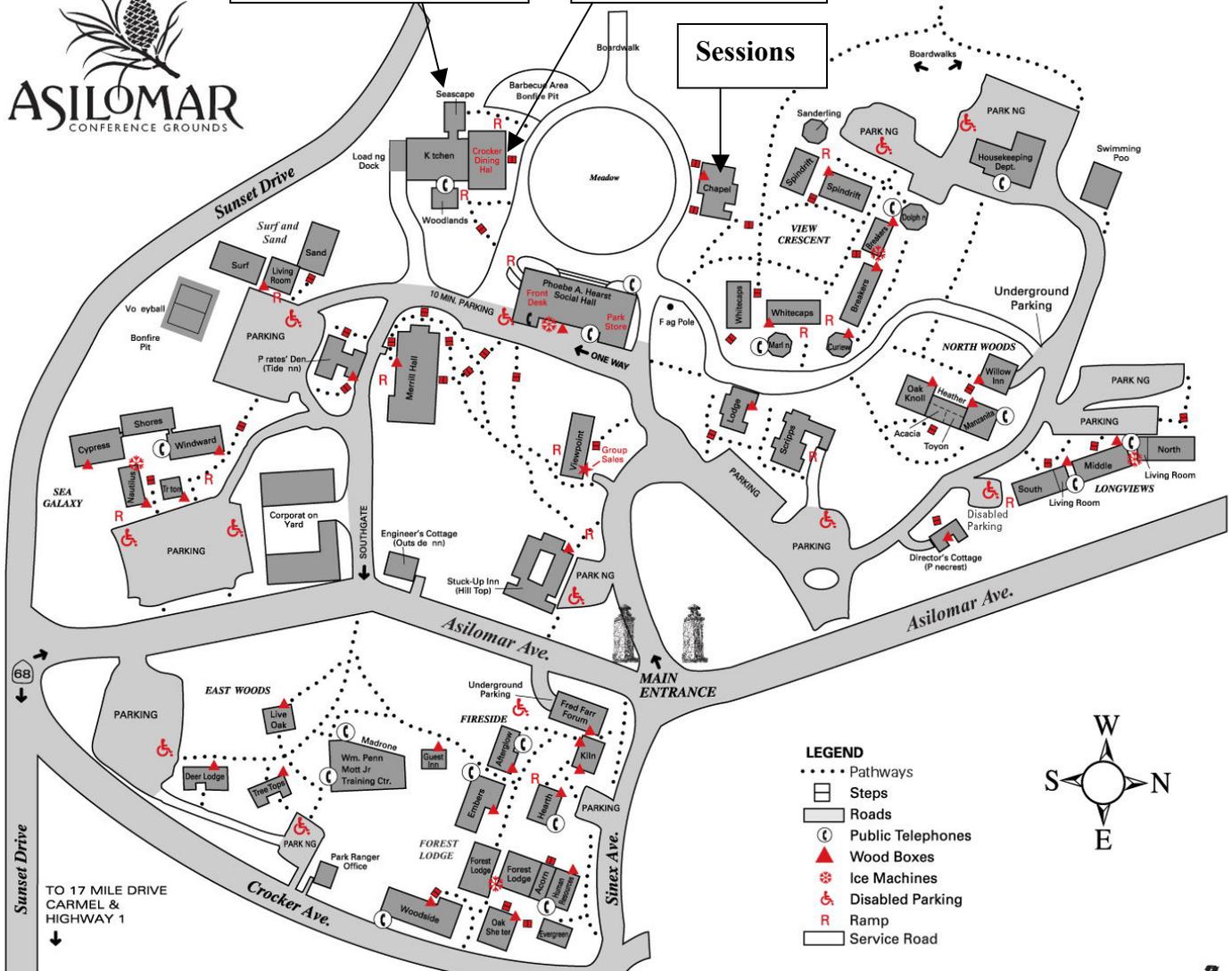
# MAP OF ASILOMAR



**Seascope –  
Receptions, Banquet**

**Crocker Dining  
Hall**

**Sessions**



- LEGEND**
- ..... Pathways
  - Steps
  - ▬ Roads
  - Ⓞ Public Telephones
  - ▲ Wood Boxes
  - ❄ Ice Machines
  - ♿ Disabled Parking
  - R Ramp
  - ▬ Service Road



TO 17 MILE DRIVE  
CARMEL &  
HIGHWAY 1

## MONTEREY BAY ATTRACTIONS

**The Monterey Peninsula is a perfect place** for a romantic weekend or exciting adventure. There are so many year-round activities, that you're limited only by your time and sense of adventure.

From historic adobes and landmarks to Fisherman's Wharf and the Monterey Bay Aquarium, Monterey has something for everyone. Visit Steinbeck's Cannery Row, Colton Hall and the Monterey Museum of Art. Stroll the recreational trail along the coast or see the wildlife close-up on a kayak adventure on the Bay.

When in Pacific Grove don't forget to check out the Monarch butterflies which make PG home for the winter, Asilomar State Beach, historic bed and breakfast inns, Lover's Point and the Pacific Grove Museum of Natural History.

Pebble Beach attractions include the 17-Mile Drive, Stillwater Cove, the Lone Cypress and an array of world-class golf courses and hotels.

Carmel Valley is home to many wineries, farms, ranches. And don't miss Big Sur with its Esalen Institute, Henry Miller Memorial Library, Point Sur Lighthouse, camping, hiking, beautiful redwood groves and excellent whale-watching.

Peninsula Attractions			
<b>Carmel Walks</b> <i>Stroll Thru Secret Pathways, Courtyards, Gardens &amp; Enchanting Fairytale Cottages</i>	P.O. Box 975	Carmel	(831) 642-2700
<b>Chris' Whale Watching &amp; Fishing Trips</b>	48 Fisherman's Wharf	Monterey	(831) 375-5951
<b>Fishermans Wharf</b>	140 W. Franklin St.	Monterey	(831) 649-6544
<b>Monterey Bay Aquarium</b>	886 Cannery Row	Monterey	(831) 648-4888
<b>Monterey Bay National Marine Sanctuary</b>	299 Foam St., Suite D	Monterey	(831) 647-4201
<b>Monterey Bay Scenic Tours</b> <i>A new premier "Multimedia" bus tour of the Monterey Peninsula! Hear the narration in your language!</i>	406 Calle Principal	Monterey	(831) 372- 6278
<b>Monterey Bay Whale Watch</b>	P.O. Box 52001	Pacific Grove	(831) 375-4658
<b>National Steinbeck Center</b>	One Main St.	Salinas	(831) 775-4725
<b>Pacific Yachting &amp; Sailing</b>	790 Mariner Park Way	Santa Cruz	(800) 374-2626
<b>Santa Cruz Beach Boardwalk</b>	400 Beach St.	Santa Cruz	(831) 423-5590