

WORKSHOP ANNOUNCEMENT & PROGRAM

The Phyto-Engineering Research Center

The Role of Public-Private Partnerships



The University of California at Davis, Tuskegee University, Texas A&M, and the University of Louisville, are leading an effort to create a multi-center program on phyto-engineering, bringing together engineering and biological sciences at academic institutions together with industry and national and regional stakeholders to develop next-generation integrated systems for biomanufacturing novel products using plant-based platforms.

To help focus the scope of PERC, we are organizing a two-day workshop with leaders in the field of plant-made pharmaceuticals (PMP) to define priority areas and unmet needs. The ultimate goal of the workshop is to transform the rather fragmented efforts that characterize PMP today, into a mainstream, standardized product development and manufacturing continuum that can hold its own with the existing biotechnology industry.

The workshop will take place at the **UC Davis campus on April 7 and 8, 2016**. Dr. Charlie Arntzen, Regents' Professor at Arizona State University's Center for Infectious Diseases and Vaccinology, and Robert Erwin, President of iBio, Inc will be keynote speakers at the conference.

We believe that this gathering is timely and necessary for the further development of PMP. Although biology has made notable inroads in establishing workable expression systems in selected hosts, to date the engineering sciences have played mostly a supportive role and as a result, there exists little standardization of methods, materials and analytics, with each lab or group largely following their own course. Outside of biology, we have borrowed rather than innovated in PMP, and the scarcity of products heading towards the marketplace is one consequence of this disconnect. We hope to focus on areas where plants/cells have a competitive advantage over traditional expression/manufacturing systems. This includes for example, rapid production of personalized therapeutics, products for food and feed safety, sub-unit vaccines, nano-vaccines and nano-therapeutics based on plant-viral scaffolds, and other synergistic opportunities involving process sciences and biology.

We know that economically produced products with novel or superior features will drive this field. Therefore, in addition to PMP leaders, we plan to hear from the established bio/pharma players on how PMPs could be melded into their business/product plans, as well as from regulators who must adapt guidelines to cope with rapidly changing scientific advances. Industry participation is part of the PERC model, so industry (user) input is key. Training a future workforce to be cognizant of all these factors and competent to implement SOPs field-wide is also part of PERC's mission. The key themes to be covered at the workshop include:

- **Establishing a mainstream PMP industry – challenges and solutions.** Selecting ideal product targets; expression system and plant host options; cultured cell vs whole plant biosynthesis; downstream processes; expectations and limitations of the platform (what works, what doesn't); perspectives from established bio/pharma companies.
- **Integrating biological processes and engineering systems.** Advantages of a multidisciplinary approach to integrate life sciences and engineering disciplines; engineered system solutions; technical and knowledge barriers; priority research thrusts; demonstration projects and test beds for new technologies.
- **Creating and nurturing an innovation ecosystem.** Synergy among academia, industry, and regional economic centers; roles of funding institutions, regulatory agencies, policy makers and charitable foundations in creating and sustaining innovation; societal impact, development of ethical technical solutions, public outreach for technology understanding and acceptance.
- **Developing tomorrow's workforce to support the growing PMP industry.** Educational training programs, pre-college and college levels; role of industry, internships, job creation; impact on national competitiveness and regional economies.

The ultimate goal of this workshop is to stimulate dialogue and cooperation among disparate disciplines and interests for the purpose of implementing a field-wide, coordinated effort to bring PMP platforms into the mainstream of biotechnology and biomanufacturing, for the benefit of all stakeholders.



WORKSHOP PROGRAM

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Wednesday, April 6, 2016 (Hyatt Place Hotel at UC Davis)

6:30 — 8:30 pm **Informal Welcome Reception for Invitees**

DAY 1 **Thursday, April 7, 2016 (UC Davis Memorial Union, Room 210 MU II)**

7:30 — 8:00 am **Continental Breakfast**

8:00 — 8:20 am Welcome and Introductory Remarks by [Harris Lewin](#), Vice Chancellor for Research, UC Davis, and [Jennifer Curtis](#), Dean, College of Engineering, UC Davis

8:20 — 8:45 am Introductions (all). Overview of the PERC Workshop ([Karen McDonald](#)) and using the cloud-based sharing tool for presentations throughout the workshop ([Somen Nandi](#))

SESSION 1 **POSITIONING PLANT-MADE PHARMACEUTICALS FOR MAINSTREAM INDUSTRIAL BIOMANUFACTURING: OVERVIEW OF PMP RESEARCH, EDUCATIONAL, INNOVATION AND OUTREACH PROGRAMS AT ACADEMIC PARTNERS (Moderator: [Ray Rodriguez](#))**

8:45 — 9:15 am University of California, Davis – [Karen McDonald](#)

9:15 — 9:45 am University of Louisville – [Kenneth Palmer](#)

9:45 — 10:00 am **Short Break**

10:00 — 10:30 am Texas A&M University – [Zivko Nikolov](#)

10:30 — 11:00 am Tuskegee University – [Deloris Alexander](#)

11:00 — 11:15 am Arizona State University – [Qiang \(Shawn\) Chen](#)

11:15 — 11:30 am University of Massachusetts – [Sergey Savinov](#)

11:30 — 11:45 am Colorado State University – [Christie Peebles](#)

11:45 am — Noon Touro University – [Alison McCormick](#)

Noon — 12:15 pm OCRP, University of Louisville – [Nobuyuki \(Nobi\) Matoba](#)

12:15 — 1:15 pm **Networking Lunch at Memorial Union, Garrison Room/MU Patio**

1:15 — 1:30 pm Welcome – [Linda Katehi](#), Chancellor, UC Davis (to be confirmed)



SESSION 2 STRATEGIES TO ACHIEVE TECHNICAL AND MARKET SUCCESS (Moderator: Daniel Tusé)

- 1:30 — 1:45 pm ICON Genetics / DENKA, Germany – [Victor Klimyuk](#), General Manager
- 1:45 — 2:00 pm Mapp Biopharmaceutical, Inc – [Michael Pauly](#), CSO
- 2:00 — 2:15 pm Medicago Inc, Canada – [Marc-André D'Aoust](#), Vice President Research and Innovation
- 2:15 — 2:30 pm Nomad Bioscience GmbH, Germany – [Yuri Gleba](#), CEO
- 2:30 — 3:00 pm Break**
- 3:00 — 3:15 pm Planet Biotechnology Inc, USA – [Keith Wycoff](#), Director of Research
- 3:15 — 3:30 pm PlantForm Corp, Canada – [Don Stewart](#), President and CEO
- 3:30 — 3:45 pm Protalix Ltd – [Yoseph Shaaltiel](#), Executive Vice President, R&D
- 3:45 — 4:00 pm Short Break**
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SESSION 3 TOOLS AND SERVICES FOR PRODUCT DEVELOPMENT AND MANUFACTURING (Moderator: Somen Nandi)

- 4:00 — 4:15 pm iBio CMO, USA – [Sylvain Marcel](#), Senior Scientist
- 4:15 — 4:30 pm Novici Biotech LLC, USA – Molecular Evolution Technologies – [Hal Padgett](#), CEO
- 4:30 — 4:45 pm Intelligen Inc, USA – Technoeconomic Modeling Software – [Demetri Petrides](#), President
- 4:45 — 5:00 pm Osaka University, Japan – Glycan Characterization and Modification – [Kazuhiro Fujiyama](#), Professor
- 5:00 — 5:15 pm University of Tokyo, Japan – Controlled Environment Agriculture Technology for PMP Production Systems – [Ryo Matsuda](#), Associate Professor
- 5:15 — 6:30 pm Break**
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6:30 — 7:30 pm Reception and Dinner, Memorial Union Patio and 210 MU II

- 7:30 — 7:45 pm Remarks by Prof. [Gurdev Khush](#) on PMP & Introduction of Prof. Charles Arntzen
- 7:45 — 8:30 pm Keynote Address by [Dr. Charles Arntzen](#) – *“Lessons Learned from the Development of Plant-Manufactured ZMapp™ as an Ebola Therapeutic”*
- 8:30 — 8:45 pm Concluding remarks by Ray Rodriguez, Executive Director, Global HealthShare, UC Davis
Conclusion of Workshop Day 1
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DAY 2 Friday, April 8, 2016 (UC Davis Memorial Union, Room 210 MU II)

7:30 — 7:55 am Continental Breakfast

- 7:55 — 8:00 am Opening Remarks – Recap of Day 1 and Agenda for Day 2 – Karen McDonald
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SESSION 4 REGULATORY PATHWAYS FOR SPECIALTY BIOLOGICS (Moderator: Daniel Tusé)

- 8:00 — 8:20 am Regulatory Pathway for Biodefense Agents – [Barbara Solow](#), Senior Vice President, Vaccine and Therapeutics Development and Procurement, Emergent BioSolutions
- 8:20 — 8:40 am Regulatory Pathways at FDA for Food Ingredients Produced in Genetically Engineered Plants – [Patrick Cournoyer](#), Consumer Safety Officer, CFSAN, FDA
- 8:40 — 9:00 am Regulatory Issues Impacting Products Intended for Animals (Drugs and Feed) – [Kristi Smedley](#), VP and Owner, CFR Services Inc

SESSION 5	INTERNATIONAL NEEDS AND OPPORTUNITIES FOR PLANT MADE PHARMACEUTICALS (Moderator: Somen Nandi)
9:00 — 9:20 am	University of Cape Town, South Africa – Ed Rybicki
9:20 — 9:40 am	Council for Scientific and Industrial Research (CSIR), South Africa – Tsepo Tsekoa/Rachel Chikwamba
9:40 — 10:00 am	UC Davis School of Veterinary Medicine – James Cullor
10:00 — 10:15 am	Short Break

SESSION 6	LESSONS LEARNED FROM ESTABLISHED PRODUCTION PLATFORMS AND PHARMA-PMP COMPANY ALLIANCES (Moderator: Karen McDonald)
10:15 — 10:30 am	Bayer Pharma AG – John Butler , Manager, Global External Innovation and Alliances
10:30 — 10:45 am	Genentech, Inc – Ting-Kuo Huang , Sr. Engineer
10:45 — 11:00 am	Keck Graduate Institute, Bioprocessing Program — Matthew S. Croughan , Founding Professor
11:00 — 11:15 am	Protalix Biotherapeutics – William Taylor , Vice President, Business Development

SESSION 7	VISIONING & INNOVATION SESSIONS*: All Participants
11:15 — 11:30 am	Orientation to Innovation Sessions – Karen McDonald
11:30 — 12 Noon	Establishing a Mainstream PMP Industry – Challenges and Plausible Solutions (Moderators: R. Barry Holtz & Somen Nandi)
12:00 — 1:15 pm	Networking Lunch at Memorial Union, Garrison Room/MU Patio
1:15 — 1:45 pm	Developing Tomorrow’s Workforce to Support the Growing PMP Industry (Moderators: Deloris Alexander & Jean VanderGheynst)
1:45 — 2:15 pm	Integrating Biological Processes and Engineering Systems: (Moderators Zivko Nikolov & Karen McDonald)
2:15 — 2:45 pm	Creating and Nurturing an Innovation Ecosystem (Moderators: Kenneth Palmer & Daniel Tusé)
2:45 — 3:00 pm	Short Break
3:00 — 3:30 pm	Updates by Innovation Session Moderators; Discussion (Coordinator: Denneal Jamison-McClung)

Networking and Tours of UC Davis Facilities

3:30 — 5:30 pm	Networking and/or tour of selected UC Davis facilities (e.g. Robert Mondavi Institute for Food and Wine Science, RMI LEED Platinum Pilot Facilities, and others as requested in advance on the registration form)
5:30 — 6:30 pm	Reception and Dinner (RMI Sensory Theater Lobby and Patio)
6:30 — 6:45 pm	Remarks by Prof. Karen McDonald on PMP & Introduction of Dr. Robert Erwin
6:45 — 7:30 pm	Keynote Address by Robert L. Erwin , President, iBio Inc – <i>“Scientific Progress vs Commercial Progress: Why is it Taking so Long to Make Plant Biotech Relevant to the Broader Pharmaceutical World?”</i>
7:30 — 7:45 pm	Questions and Discussion
7:45 pm	Workshop Adjournment; Concluding Remarks by Karen McDonald

***Visioning & Innovation Sessions** are fun and fast-paced group exercises designed to facilitate dialogue and stimulate “out of the box” thinking to define plausible solutions to complex problems, such as those faced by the nascent PMP industry and global health disparities.

Saturday, April 9, 2016 – PERC University Partners, Affiliates, International Collaborators & Leadership Team Only, Conference Room 1111, Plant Reproductive Biology Building (directions will be provided at the workshop)

8:00 — 10:00 am Wrap-Up of PERC Workshop and Planning of White Paper (includes Continental Breakfast)

A Few Logistics

Direction to Hyatt Place Hotel, UC Davis: <http://ucdavis.place.hyatt.com/en/hotel/home.html>

Directions to Memorial Union, UC Davis: <http://tinyurl.com/zyd7ulr>

Directions to Robert Mondavi Institute: <http://robertmondaviinstitute.ucdavis.edu/about/map-and-direction>

For out of town guests and invitees, local organizers will organize the travel between the hotels in advance. So please feel free to contact any of the following if you have any questions or special requests.

PERC Local Organizing Committee, University of California at Davis

Karen A. McDonald, kamcdonald@ucdavis.edu

Somen Nandi, snandi@ucdavis.edu

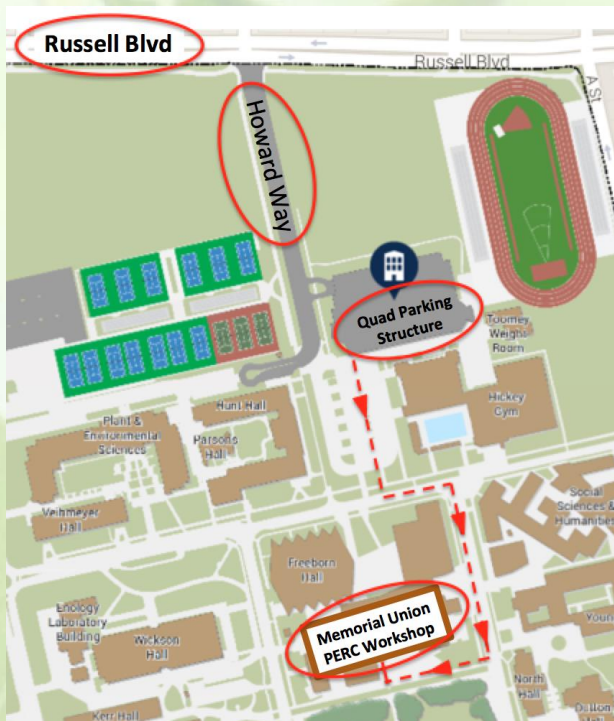
Denneal Jamison-McClung, dsjamison@ucdavis.edu

Raymond Rodriguez, rrodriguez@ucdavis.edu

Daniel Tusé, daniel@dt-cg.com

Parking

Local guests and invitees who are driving to campus can find daily parking for \$9 at (1) the Quad parking structure (on Howard Way, just off Russell Blvd), north of the **Memorial Union** where the workshop will be held (**map at left; short walk - follow arrows**), and (2) lots P1 or P2 just East of the **Robert Mondavi Institute for Wine and Food Science** for Friday April 8 evening events (tour and dinner; **map at right**). The visitor-parking pass will allow you to park in any visitor-designated lot on campus throughout the day.



Acknowledgment

The PERC Local Organizing Committee would like to thank the UC Davis Office of Research, College of Engineering and Department of Chemical Engineering, for sponsoring this workshop, as well as Tuskegee University, University of Louisville and Texas A&M University for supporting participation by their faculty.