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ALLIANCE *for*  
NANOHEALTH

## AGENDA

# Scientific Workshop: FDA/ANH Nanotechnology Initiative *March 10-12th, 2008*

### Event Summary:

*The Alliance for NanoHealth (ANH) and the Food & Drug Administration (FDA) are co-sponsoring a scientific workshop being held in Houston, Texas on March 10-12th, 2008. This workshop, called the FDA-ANH Nanotechnology Initiative Scientific Workshop, is an invitation-only event dedicated to obtaining feedback from stakeholders in an attempt to identify key scientific and translational challenges in nanoengineered medical product development. In this regard, we have assembled ~50 key stakeholders from industry, Federal government, and academia. A main deliverable of this workshop will be the development and publication of a short list of existing translational gaps and the key elements that will be needed to bridge these gaps. It is hoped that by implementing joint projects, having these key elements, we can work with stakeholders to overcome R&D hurdles, inform regulatory review of nanoengineered biomedical products, and ultimately, benefit patients. The results of the Workshop will be made available in the public domain.*

**The University of Texas M.D. Anderson Cancer Center  
Frank E. Anderson Conference Hall (R11.1100)  
1515 Holcombe Blvd., Houston, Texas 77005**

Monday March 10, 2008  
(Workshop Session I)

11:00am	<b>Registration</b>
	<b>PLENARY KEYNOTE SESSION (Hickey Auditorium)</b>
12:00pm	<b>Plenary Keynote Introduction &amp; Welcome</b> <i>Mauro Ferrari, Ph.D., President, Alliance for NanoHealth</i>
12:30pm	<b>Keynote Speaker</b> <i>Norris E. Alderson, Ph.D., Associate Commissioner for Science, Office of the Commissioner, Food &amp; Drug Administration</i>
	<b>PANEL DISCUSSION (Hickey Auditorium)</b>
1:10pm	<b>Introduction to Panels</b> <i>Richard Canady, Ph.D., Senior Health Scientist, Office of the Commissioner, Food &amp; Drug Administration</i>
	<b>Nanoscale Material Review Perspectives: FDA</b>
1:20pm	<b>Presentation #1</b> <i>Nakissa Sadreih, Ph.D., Associate Director for Research Policy and Implementation, Center for Drug Evaluation and Research, U.S. Food &amp; Drug Administration</i>
1:40pm	<b>Presentation #2</b> <i>Jan Simak, Ph.D., Center for Biologics Evaluation and Research, U.S. Food &amp; Drug Administration</i>
2:00pm	<b>Presentation #3</b> <i>Subhas Malghan, Ph.D. Deputy Director, Office of Science and Engineering Laboratories, Center for Devices and Radiological Health, U.S. Food &amp; Drug Administration</i>
2:20pm	<b>Audience Questions to FDA Panel</b>
3:00pm	<b>Coffee Break</b>
	<b>Practical Experience with FDA Review Process for Nanotechnology</b>
3:15pm	<b>Presentation #1</b> <i>George Mills, M.D., M.B.A., Vice President, Medical Imaging Consulting Perceptive Informatics, /PAREXEL</i>
3:45pm	<b>Presentation #2</b> <i>Larry Tamarkin, Ph.D., President and CEO, CytImmune</i>
4:15pm	<b>Presentation #3</b> <i>Tony Huang, Ph.D., Vice President, Parenteral Technology Development, ALZA Corporation</i>
4:45pm	<b>Presentation #4</b> <i>Scott McNeil, Ph.D., Director, Nanotechnology Characterization Laboratory SAIC-Frederick, Inc., National Cancer Institute-Frederick, National Institutes of Health</i>
5:15pm	<b>Audience Questions to Panel</b>
6:00pm	<b>Close of Day-Invitation to Dinner</b> <i>Mauro Ferrari, Ph.D., President, Alliance for NanoHealth</i>
6:30pm	<b>Dinner: Tables Arranged by Breakouts (Conference Room 1, 2, 7 &amp; 8)</b>
8:30pm	<b>End of Day 1</b>

Tuesday March 11, 2008  
(Workshop Session I)

7:30am	<b>Breakfast</b>		
	<b>OPENING REMARKS (Hickey Auditorium)</b>		
8:00am	<b>Charge to Workshop Participants</b> <i>Wendy Sanhai, Ph.D., Senior Scientific Advisor, Office of the Commissioner, Food &amp; Drug Administration</i>		
	<b>BREAKOUT #1: PRECLINICAL (Conference Room #3)</b>	<b>BREAKOUT #2: CLINICAL (Conference Room #4)</b>	<b>BREAKOUT #3: MANUFACTURING (Conference Room #5)</b>
8:45am	<b>Overview</b> <b>Chairs:</b> <i>George Mills, M.D., M.B.A., Vice President, Medical Imaging Consulting, Perceptive Informatics, /PAREXEL</i>  <i>Abigail Jacobs, Ph.D., Associate Director for Pharmacology and Toxicology, Office of New Drugs, Food &amp; Drug Administration</i>	<b>Overview</b> <b>Chairs</b> <i>Mark Melkerson, Director, DGRND, Office of Device Evaluation, Food &amp; Drug Administration</i>  <i>David Feigal, M.D., Senior Vice President, Global Regulatory, Safety and Biometrics, Elan Pharmaceuticals</i>	<b>Overview</b> <b>Chairs</b> <i>Vicki Colvin, Ph.D., Professor of Chemistry and Professor of Chemical &amp; Biomolecular Engineering, Rice University</i>  <i>Nakissa Sadreih, Ph.D., Associate Director for Research Policy and Implementation, Center for Drug Evaluation and Research, U.S. Food &amp; Drug Administration</i>
9:00am	<b>Presentation #1</b> <i>Mark N. Milton, Ph.D., Vice President, Nonclinical Development, Tempo Pharmaceuticals Inc.</i>	<b>Presentation #1</b> <i>Gabriel Lopez-Berestein, M.D., Professor, Internist, Department of Experimental Therapeutics, The University of Texas M. D. Anderson Cancer Center</i>	<b>Presentation #1</b> <i>Neil P. Desai, Ph.D., Vice President, Research &amp; Development, Abraxis Bioscience Inc.</i>
9:30am	<b>Presentation #2</b> <i>Martin Philbert, Ph.D., Senior Associate Dean, School of Public Health, University of Michigan</i>	<b>Presentation #2</b> <i>Daniel C. Sullivan, M.D., Radiological Society of North America</i>	
10:00am	<b>Coffee Break</b>		
10:15am	<b>Identification of Top 2 or 3 Issues</b>	<b>Identification of Top 2 or 3 Issues</b>	<b>Identification of Top 2 or 3 Issues</b>
11:00pm	<b>Description of Top 2 or 3 Projects</b>	<b>Description of Top 2 or 3 Projects</b>	<b>Description of Top 2 or 3 Projects</b>
12:00pm	<b>Lunch (Conference Room 1, 2, 7 &amp; 8)</b>		
	<b>RETURN TO PLENARY (Hickey Auditorium)</b>		
1:30pm	<b>Breakout #1: Preclinical Presentation</b> <i>George Mills, M.D., M.B.A., Vice President, Medical Imaging Consulting, Perceptive Informatics, /PAREXEL</i>		
2:15pm	<b>Breakout #2: Clinical Presentation</b> <i>Mark Melkerson, Director, DGRND, Office of Device Evaluation, Food &amp; Drug Administration</i>		
3:00pm	<b>Breakout #3: Manufacturing Presentation</b> <i>Vicki Colvin, Ph.D., Professor of Chemistry and Professor of Chemical &amp; Biomolecular Engineering, Rice University</i>		
3:45pm	<b>Coffee Break</b>		
4:00pm	<b>PANEL DISCUSSION</b>		
	<b>Moderator:</b> <i>Richard Canady, Ph.D., Office of the Commissioner, Food &amp; Drug Administration</i>		
6:00pm	<b>Close of Day-Invitation to Dinner</b> <i>Mauro Ferrari, Ph.D., President, Alliance for NanoHealth</i>		
6:30pm	<b>Dinner (Conference Room 1, 2, 7 &amp; 8)</b>		
8:00pm	<b>End of Day 2</b>		



Wednesday March 12, 2008  
(Workshop Session II)

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8:00am

**Breakfast**

**OPENING REMARKS (Hickey Auditorium)**

8:30am

**Welcome & Introduction to Session II of Workshop**

*Mauro Ferrari, Ph.D., President, Alliance for NanoHealth*

9:00am

**Presentation of Top Projects**

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**Chairs:**

**Breakout #1: Preclinical Presentation**

*Abigail Jacobs, Ph.D., Associate Director for Pharmacology and Toxicology, Office of New Drugs, Food & Drug Administration*

**Breakout #2: Clinical Presentation**

*Mark Melkerson, Director, DGRND, Office of Device Evaluation, Food & Drug Administration*

**Breakout #3: Manufacturing Presentation**

*Vicki Colvin, Ph.D., Professor of Chemistry and Professor of Chemical & Biomolecular Engineering, Rice University*

10:30am

**Coffee Break**

10:45pm

**OPEN DISCUSSION**

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**Moderator:**

*Mauro Ferrari, Ph.D., President, Alliance for NanoHealth*

12:30pm

**Closing Remarks**

*Jason Sakamoto, Ph.D., Chief Operating Officer, Alliance for NanoHealth*

12:40pm

**Workshop Adjourned**

## Breakout Session Groups

	Preclinical	Clinical	Manufacturing
Co-Chair	George Q. Mills, M.D., M.B.A.	Mark N. Melkerson	Vicki Colvin, Ph.D.
Co-Chair	Abigail Jacobs, Ph.D.	David Feigal, M.D.	Nakissa Sadrieh, Ph.D.
Presenter	Mark N Milton, Ph.D.	Gabriel Lopez-Berestein, M.D.	Neil Desai, Ph.D.
Presenter	Martin Philbert, Ph.D.	Daniel C. Sullivan, M.D.	
Rapporteur	Paul C. Howard, Ph.D.	Daya Ranamukhaarachchi, Ph.D.	Katherine M Tyner, Ph.D.
Rapporteur	Chekesha S. Clingman, Ph.D.	Viju Bhadkamkar	
	Susan Blaney, M.D.	Mostafa Analoui, Ph.D.	James V.A. Abbey
	Ferdy Bremmer	Hugh C. Cannon	May G. Akrawi, Ph.D.
	Ai Lin Chun, Ph.D.	Diana Shu-Lian Chow, Ph.D.	Glenn Batchelder
	Jack Coats	Rabih O. Darouiche, M.D.	Stephen Barry, Ph.D.
	Dr. Roland A. Fleck	Bambi Grilley	R. Steven Conlan, Ph.D.
	Rogelio Sa Gaspar, Ph.D.	Placido Grino, M.D.	Anthony J. Elam
	Marco M. Gentile, Ph.D.	James C. Hamilton, M.D., M.B.A.	Dr. Gordon France
	David G. Gorenstein, Ph.D.	June Kaplow, Ph.D.	Stephen H. Friend, M.D., Ph.D.
	David Hobson, Ph.D.	Massoud Motamedi, Ph.D.	Randal K. Goodall, Ph.D.
	Maha Khaled, Ph.D.	Larry A. Nagahara, Ph.D.	Henry A. Havel, Ph.D.
	Amit Kulkarni, Ph.D.	J. Donald Payne	Tony Huang, Ph.D.
	Luigi Manzo, M.D.	Robert Powell, Pharm.D.	Annette T. Kolodzie, J.D., Ph.D.
	Kathleen Matthews, Ph.D.	Jan Simak, Ph.D.	Mark W. Shumbera
	Alexander J. (Sandy) McEwan, M.D.	Clifford Stephan, Ph.D.	Larry Tamarkin, Ph.D.
	Joseph Milone Ph.D.	Barbara Trautner, M.D.	Subhas G. Malghan, Ph.D.
	Sally Tinkle, Ph.D.	Jim Wright, Ph.D.	Sean Murdock
	Donald A. Tomalia, Ph.D.		John Weiner

Event Sponsored By:

