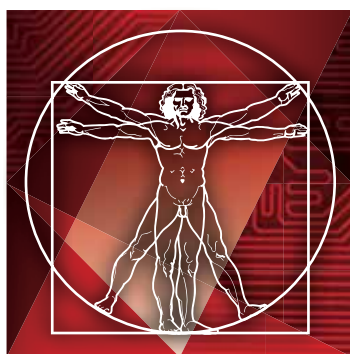


August 29-31, 2016

San Diego, CA



3D | Drug Discovery & Development Tissue Models

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Toxicology, Safety & Target Validation

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Director & Head WW Animal
Research Strategy

GSK



Adrian Roth

Head of Mechanistic Safety

Hoffman La Roche



Kristin Fabre

Microphysiological Systems
Development & Implementation Lead

AstraZeneca



Danilo Tagle

Associate Director
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Donna Mendrick

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 3D Tissue Models: Drug Discovery & Development

Researched & Developed by:



Welcome to 3D Tissue Models 2016

Validating the True Utility of 3D Tissue Models Within Drug Discovery & Development

With the promise of faster, more accurate compound screening and greater predictability of safety and efficacy than ever before, 3D tissue models will transform our approach to toxicology, drug metabolism, and PK/PD.

But can they live up to the hype? Can we ever really model the full complexity of the human body *ex vivo*?

3D Tissue Models 2016 is designed to tackle critical questions about the true utility and limitations of 3D tissue models in pharmaceutical development.

Hosting top decision makers from industry and academia, this unique summit will provide you with a collaborative platform to share and tackle your key drug development, biological and commercial challenges.

The case-study driven agenda and data centric approach will reveal the practical applications of these technologies, going beyond the science of tissue engineering.

Discover how leading pharmaceutical companies deploy organ-on-a-chip, organoid and other stem cell derived tissue technologies in drug discovery, toxicology, systems pharmacology and DMPK applications - to expedite discovery and translation to clinical research.

“Strong program, great speakers and a genuine focus on identifying solutions.”

Novartis
Past Attendee, Hanson Wade Event

Top 10 Reasons to Attend 3D Tissue Models 2016:

- 1 Identify the practical applications and true utility** of 3D microphysiological models to maximize the discovery and development of drugs within translational and pre-clinical research
- 2 Unlock the trapped potential of 3D microphysiological models** to reduce attrition rates within drug discovery and development
- 3 Elucidate bio-computational strategies utilizing complex 3D systems** to increase predictability and translatability to the clinic
- 4 Engage with your peers across industry and academia** over 2 days of interactive networking sessions to tackle your common biological and commercial challenges
- 5 Secure funding for your organization** by understanding what needs to be realized from a commercial standpoint to facilitate market success and fuel further investment
- 6 Validate targets and better predict toxicology** prior to animal screening to reduce late stage failures
- 7 Discover how 3D models can optimize efficacy and DMPK predictions** throughout the drug discovery & development process
- 8 Learn how industry are creating novel strategies utilizing 3D cell cultures** to improve predictability and translatability of early discoveries
- 9 Anticipate the evolving regulatory landscape** facing the use of complex 3D models to ensure that you are up to date with the latest discussions from the FDA and worldwide
- 10 Harness the latest developments in *in vitro* imaging protocols** to achieve non-invasive readouts

Speakers



Brian Berridge
Senior GSK Fellow;
Head, WW Animal Research
Strategy
GSK



Adrian Roth
Head of Mechanistic
Safety
Hoffman La Roche

“Excellent panel of speakers
providing a comprehensive
overview of the field.”

Vertex Pharmaceuticals,
Past Attendee, Hanson Wade Event



Kristin Fabre
Microphysiological
Systems Development &
Implementation Lead
AstraZeneca



Danilo Tagle
Associate Director for
Special Initiatives
NIH/NCATS



John Wikswo Gordon
A. Cain University
Professor; Director
VIIBRE



D. Lansing Taylor
Allegheny Foundation
Professor of
Computational & Systems
Biology & Director
**University of Pittsburgh
Drug Discovery Institute**



Dinah Misner
Senior Scientist,
Investigative Toxicology
Genentech



Shane Horman
Research Investigator III
**Genomics Institute of the
Novartis Research
Foundation**



Donna Mendrick
Associate Director,
Regulatory Activities
FDA/NCTR



Jeetendra Eswaraka
Director Pre-Clinical &
Attending Veterinarian
Amgen



Joan Nichols
Professor Internal Medicine
& Associate Director
**Galveston National
Laboratory, UTMB**



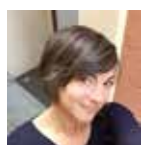
Mark Donowitz
LeBoff Professor of
Medicine & Physiology
**Johns Hopkins
University School of
Medicine**



Will Proctor
Scientist, Investigative
Toxicology
Genentech



Murat Cirit
Director, Translational
Systems Pharmacology
**Massachusetts Institute
of Technology**



Gina Yanocho
Senior Principal
Scientist, Investigative
Toxicology, DSRD
Pfizer



Jinping Gan
Senior Principle
Scientist
Bristol-Myers Squibb



Jean-Louis Klein
Manager & Leader of the
Human Disease Relevant
Model Flagship
GSK



Jonathan Himmelfarb
Professor of Medicine
& Director, Kidney
Research Institute
**University of
Washington**



Monicah Otieno
Scientific Director,
Mechanistic & Investigative
Toxicology, Preclinical
Development & Safety
**Janssen Pharmaceuticals
(Johnson & Johnson)**

“It exceeded my expectations.
The talks were high quality
and the interaction among
participants was excellent.”

Genentech,
Past Attendee, Hanson Wade Event

“The difference between this event and others is that this allows us to
exchange ideas with those with whom we share many common challenges.”

Abbvie,
Past Attendee, Hanson Wade Event

Conference Day One | Tuesday, August 30, 2016

8.00 Chairman's Opening Remarks



Brian Berridge,
Director & Head WW
Animal Research
Strategy, **GSK**

8.10 Driving the Adoption of Innovative Pre-Clinical Designs: Advanced Cellular Models in Drug Development Today & Tomorrow

- Highlighting key research and case studies that opened the flood gates for 3D platforms R&D
- Evaluating the current 'state of the art' to determine what is possible with organoids and tissue chips, and what needs further development
- Establishing a roadmap to achieve wide-scale adoption of human tissue models and the 3R's in drug discovery and development
- Addressing what needs to be realized from a commercial standpoint to further facilitate market success and fuel greater investment
- Perspectives on new opportunities and challenges in this exciting and emerging space to accelerate progress



Adrian Roth, Head of
Mechanistic Safety,
Hoffman La Roche

8.40 Panel Discussion: Qualifying the Use of 3D Microphysiological Systems in Drug Discovery & Development - Defining a Role for 3D Human Tissue Models Within Industry

- Assessing the current utility and limitations of tissue chips and organoids, and their potential in the discovery of next generation therapies
- Justifying risk: Where do we envisage this technology heading and what can these systems never do? Will microphysiological platforms live up to their hype or are they already being over-sold?
- Is the goal to achieve the 3R's of animal models? Or are we adding other tools to the drug development kit?
- What advances have been made in 3D cell culturing for high throughput drug screening?
- Where in the context of discovery and toxicology can complex 3D models be used?
- What needs to be demonstrated to investors who are looking to fund the space?



Brian Berridge,
Director & Head WW
Animal Research
Strategy, **GSK**



Dinah Misner,
Senior Scientist,
Investigative
Toxicology,
Genentech



Kristin Fabre,
Microphysiological
Systems Development
& Implementation
Lead, **AstraZeneca**

9.25 Creating the Environment to Drive Innovation: The Roadmap to Acceptance

- Addressing the context of use for microphysiological systems as a critical factor in achieving success within industry
- An insight into how we can begin to bridge the gap between industry early adopters and the mainstream
- Exploring the lessons learned from CDER's Drug Development Tools Qualification Programs to encourage innovation in drug development



Donna Mendrick,
Assistant Director,
Regulatory Activities,
FDA/NCTR

9.55 Morning Refreshments & Speed Networking

10.55 Harnessing Phenotypic & Target Based Screening for 3D Models to Increase Translatability During the Drug Development Process

- Understanding how to overcome late stage failures by adopting novel screening strategies using complex 3D platforms in HTS environments
- Utilizing organotypic systems to better enable targeting and modulation of intended mechanisms
- Employing novel technologies to translate better performing drug candidate selection early on



Shane Horman,
Research Investigator
III, **Genomics Institute
of the Novartis
Research Foundation**

11.25	Assessing the Untapped Potential of 3D Organ Chips to Enhance Target Biology & Safety Investigation - Identifying strategies utilizing these chips to advance our understanding of target biology - Addressing issues surrounding utility, complexity and context of use through illustrative case studies from industry - Elucidating the opportunities for chip models within neuroscience, immuno-oncology, and pancreatology to enhance target biology and safety investigations	 Jeetendra Eswaraka , Director Pre-Clinical & Attending Veterinarian, Amgen
11.55	Complex 3D Systems for the Study of Drug Elimination & Drug Induced Nephrotoxicity - Identifying robust models of the human kidney utilizing an <i>in vitro</i> 3D modular microphysiological system to better predict drug excretion - Developing more predictable renal handling of xenobiotics, as well as assessing the response to kidney injury from endogenous and exogenous intoxicants	 Jonathan Himmelfarb , Professor of Medicine & Director, Kidney Research Institute, University of Washington
12.25	Using Complex 3D Systems for Studying Drug Metabolism Pharmacokinetics & Dynamics (DMPK) - Evaluate advances in 3D culture systems for DMPK applications - Better predict human PK resulting from drug metabolism and transport mediated clearance - Leverage 3D systems to study bile acid homeostasis, ADC disposition, and species difference in biotransformation and toxicity	 Jinping Gan , Senior Principle Scientist, Bristol-Myers Squibb
12.55	Networking Lunch	
13.55	Panel Discussion: Debating Approaches to Validating 3D Microphysiological Systems as Predictive Models of Drug Safety & Efficacy – The Path to Verification & Regulatory Acceptance - What constitutes a validated model from an industry standpoint? - Applying complex models to the translational and pre-clinical landscape to increase the confidence rationale of drug targets - Employing smart compound libraries to begin standardizing models across the board - Acknowledging the importance of dosimetry and identifying how we translate toxicity to and from complex systems - How do we scale microphysiological systems for use in high throughput screening? - How do we overcome issues surrounding cell maturity and the mitigating heterogeneity of differentiated cells? - What are the requirements from regulatory agencies to help facilitate further success?	 Adrian Roth , Head of Mechanistic Safety, Hoffman La Roche  Donna Mendrick , Assistant Director, Regulatory Activities, FDA/NCTR  D. Lansing Taylor , Director, University of Pittsburgh Drug Discovery Institute
14.40	Predict the Predictability of Pre-Clinical Models - Designing Approaches to Validate 3D Models for Toxicity Screening - Addressing the lack of efficacy and toxicity in current pre-clinical studies - Identifying 3D systems as more efficient pre-clinical models for predicting drug effects in patients - Evaluating the translational capability of 3D pre-clinical models to patients and illustrating unique approaches to validating human primary cell based models	 Jean-Louis Klein , Manager & Leader of the Human Disease Relevant Model Flagship, GSK
15.10	High Throughput Strategies Using 3D Microphysiological Systems to Better Identify Hepatotoxicity - Showcasing how best to use the models as predictive tools and technologies to better identify hepatotoxicity - Assessing strategies for generating kinetic fingerprints of cells to identify on target effects of drugs - Understanding how high-content kinetic imaging and high-throughput studies can be utilized with 3D tissue models	 Will Proctor , Scientist, Investigative Toxicology, Genentech  Dinah Misner , Senior Scientist, Investigative Toxicology, Genentech

16.10 **Using Systems Pharmacology to Identify Predictive Responses Within 3D Tissue Models to Enhance the Drug Discovery Process**

- Generate innovative approaches to better predict human physiological responses during the drug discovery process
- Learn to deploy quantitative bio-analytics with 3D platforms to identify robust, reliable *in vitro* strategies for disease modeling and secondary pharmacology
- Utilize 3D data analysis to distinguish the effect of tissue organization on cell behaviour



D. Lansing Taylor,
Allegheny Foundation
Professor, Director,
**University of Pittsburgh
Drug Discovery
Institute**

16.40 **Using 3D Cultures to Model GI Epithelial Barrier Integrity for Both Toxicity & Efficacy Studies to Identify & Clarify Translational Endpoints**

- Reviewing the current landscape for use of organoids and other 3D cultures within drug screening and safety for GI studies
- Addressing the hurdles for implementing 3D models of the GI tract within industry
- Showcasing unique strategies utilizing GI organoids to enhance the drug discovery and development process



Gina Yanochko, Senior
Principle Scientist,
Investigative Toxicology,
DSRD, **Pfizer**

17.10 **Breakout Roundtable Discussion:**

This session will enable open and interactive discussions to help you maximize the current pre-competitive environment by tapping into the wealth of experience and expertise in the room. Shape the debate and build collaborative partnerships to tackle current drug development, biological and commercial challenges on the following topics:



17.55 **Close of Day One**

■ ■ This conference was of outstanding value. First class presentations, great opportunity for networking and perfect logistics! ■ ■

AstraZeneca,
Past Attendee, Hanson Wade Event

Conference Day Two | Wednesday, August 31, 2016

8.00 Chairman's Opening Remarks



Adrian Roth, Head of Mechanistic Safety, **Hoffman La Roche**

8.10 Use of 3D Tissue Models for Pre-Animal Screening & to Improve Clinical Translation

- Strategic positioning of 3D tissue models to progressively improve the translation of pre-clinical modeling to clinical outcomes
- Understanding the challenges of *in vitro* to *in vivo* extrapolation in animals or human patients
- Pathways-based modeling to bridge the *in vitro in vivo* gap and enable a less animal-dependent future with 3D tissue models
- Aligning 3D tissue platforms from bench to bedside utilizing translational biomarkers



Brian Berridge, Director & Head WW Animal Research Strategy, **GSK**

8.40 iPSc Derived Human Enteroid Models as Platforms for Defining Drug Absorption from the GI Track, Metabolism, Toxicity & Interactions with Other Organs

- Establish methods to generate indefinite *ex vivo* primary epithelial mini-intestines to better represent *in vivo* like behaviour and to enhance system predictability
- Explore the translational applications of complex enteroid models within diarrhoeal disease and other host-pathogen interactions



Mark Donowitz, LeBoff Professor of Medicine & Physiology, **Johns Hopkins University School of Medicine**

9.10 Target Validation & Lead Optimization – Integrating 3D Mini Guts to Validate Targets

- Developing flexible strategies with 3D tissue cultures to maximize predictability and translatability of early discoveries to lower attrition rates
- Evaluating new approaches for understanding cross species differences during drug development
- Addressing the level of complexity required for functional analysis of intended targets



Kristin Fabre, Microphysiological Systems Development & Implementation Lead, **AstraZeneca**

9.40 The NIH Program on Tissues-on-Chips for Drug Screening, Safety & Efficacy Testing: Progress & Future Plans

- Innovative and collaborative partnerships to help drive the development of tissue chip technology
- Identifying current efforts towards the validation and standardization of tissue chip technology
- Addressing predictive efficacy testing using tissue chips to better inform the pipeline



Danilo Tagle, Associate Director for Special Initiatives, **NIH/NCATS**

10.10 Morning Refreshments & Networking

10.40 Incorporating Complex 3D Micro-Engineered Models to Understand Lung Fibrosis

- Understanding the need for more complex and physiologically relevant models to accurately represent respiratory diseases
- Mimicking mechanical stress and micro-injuries to better represent disease pathogenesis
- Identifying the potential of organotypic systems for improved parallelization of coupled organs to define the functional processing of drugs



Joan Nichols, Professor Internal Medicine & Associate Director, **Galveston National Laboratory, UTMB**

11.10 **Application of a Lung-Thrombosis Chip Model for Pre-Clinical Safety Assessment**

- Showcasing a Lung Thrombosis model addressing safety liabilities in drug discovery and development, and gaining insights into the mechanism of action
- Introducing pathophysiological conditions to the Lung-on-Chip design by incorporating features essential for coagulation
- Developing functional endpoints for detection of thrombosis e.g. fibrin clots
- Assessing and validating the platform's utility for de-risking safety issues by harnessing tool molecules known to cause thrombosis



Monicah Otieno,
Scientific Director,
Mechanistic &
Investigative
Toxicology,
Pre-clinical
Development & Safety
**Janssen
Pharmaceuticals
(Johnson & Johnson)**

11.40 ***In vitro* Modeling of the Blood Brain Barrier Using Complex 3D Models**

- Using cross channel microfluidics integrated with neurovascular models to produce simple and scalable brain barrier models
- Trade-offs between simplicity and realism: Evaluating transwell, parallel channels, parallel sheets, and vascularized 3D models in modulating and validating the blood brain barrier in health and disease
- Identifying the latest advances in modeling the blood brain barrier: Multiculture vs. organotypic systems



John Wikswo, Gordon
A. Cain University
Professor; Director,
VIBRE

12.10 **Networking Lunch**

13.10 **Panel Discussion: Balancing Complexity vs. Functionality – The Best Approaches to Designing & Engineering 3D Tissue Platforms**

- Weighing up the cost per data point against the importance of throughput
- How simple should a complex 3D system be?
- Determining the maturity levels of cells from fetal to adult phenotypes
- How best to relate the output of the microphysiological systems to physiological measurements to ensure that you are fully replicating the key features
- How do we cut through the “noise”: Addressing the mitigating heterogeneity in cell populations following cell differentiation
- Assessing the need for newer and better biomaterials to represent the *in vivo* microenvironment
- Moving away from diffusion towards perfusion: Keeping high cell densities alive in small volumes and eventually overcoming the costs of long term perfusion



Shane Horman,
Research Investigator
III, **Genomics Institute
of the Novartis
Research Foundation**



John Wikswo,
Director, **VIBRE**



Jean-Louis Klein,
Manager & Leader of
the Human Disease
Relevant Model
Flagship, **GSK**

13.55 **The Human Physiome-on-a-Chip: Merging Tissue Engineering & Systems Pharmacology**

- Recapitulate clinical pharmacology in microphysiological systems (MPS) to achieve greater *in vitro in vivo* translation
- Deploy Quantitative Systems Pharmacology (QSP) approaches to multi-MPS interactome to better predict *in vivo* responses during the drug discovery process



Murat Cirit, Director,
Translational Systems
Pharmacology,
**Massachusetts
Institute of
Technology**

14.25 **Afternoon Refreshments & Networking**

“Very invigorating conference! Bringing a group of like minded people together to share common stories.”

Eli Lilly
Past Attendee, Hanson Wade Event

15.00 **Mastermind Discussion: Lowering the Barriers to Entry for Pharma: Adoption, Implementation & Automation**

- How do big pharma need to adapt their understanding of classical discovery and development to the micro-engineered tissue systems?
- How create a path forward for pharma and microphysiological systems within drug development?
- Building a pre-competitive culture - how best to set up and run "innovation" groups to harness 3D systems?
- What are big pharma looking for when deciding who to partner with? Have the first movers got an uncatchable advantage?
- How can the big pharma "machine" be best used to accelerate microphysiological platforms to the next level?
- What key scientific breakthroughs are needed to further accelerate the adoption of microphysiological systems?
- What role should big pharma play to help commercialize the field?
- How do we build manufacturing processes into intellectual property conversations?
- What regulatory conversations need to take place to further advance microengineered tissues development?
- Should we be using biotech or building in house as we move to more relevant models?



Jeetendra Eswaraka,
Director Pre-Clinical & Attending Veterinarian, **Amgen**



Adrian Roth,
Head of Mechanistic Safety, **Hoffman La Roche**



Kristin Fabre,
Microphysiological Systems Development & Implementation Lead, **AstraZeneca**



Danilo Tagle,
Associate Director for Special Initiatives, **NIH/NCATS**

15.45 **Chairman's Closing Remarks**

16.00 **End of Day Two & Close of Conference**

“A fantastic event both in terms of the science and the networking opportunities.”

Roche
Past Attendee, Hanson Wade Event



Act today to reserve your place at 3D Tissue Models 2016

Register online at: 3d-tissuemodels.com/register

Workshop A: Hands on with Organ-on-a-chip

Date: August 29, 2016 | Time: 9am - 12am

Join industry leaders for an in depth analysis of how best to approach and develop microfluidic devices for their use within industry. This workshop will help you **realize the unlimited potential of engineered tissue models** for replicating organ system signalling and dynamics.

Leave this workshop with:

- A greater understanding of the key challenges facing the development of microfluidic systems and how to overcome them
- An in depth insight into how to model, test and control these biological systems using allometric, biochemical and functional scaling
- Knowledge of how best to achieve non-invasive readouts with the latest advances in imaging and sensor technologies



Workshop leader

John Wikswo

Gordon A. Cain University
Professor; Director

VIIBRE



Workshop B: Drug MPK Master Class

Date: August 29, 2016 | Time: 1pm - 4pm

DMPK is essential to the drug discovery process as identification of active drug metabolites and drug-drug interactions are attributed with a large percentage of drug failures. Largely due to their over simplicity and lack of physiological relevance, the poor pharmacokinetic profile of current 2D *in vitro* models falls short for DMPK study. A paradigm shift is required towards the next generation of *in vitro* models for DMPK.

With their greater physiological relevance and more *in vivo* like characteristics, this workshop will give you an in depth insight into **how best to utilize complex 3D models for DMPK research to help you reduce failure and attrition rates.**

Leave this workshop with:

- Novel approaches with increased predictiveness for metabolite identification and enzyme mapping
- An insight into how more complex systems will enable you to predict the *in vivo* clearance of some compounds
- Strategies to address issues of non-specific binding in 3D models utilizing bio-materials with high absorption properties



Workshop leader

Jinping Gan

Senior Principle Scientist
Bristol-Myers Squibb

Sponsorship Opportunities

Do you have a product or solution utilizing 3D constructs such as 3D model design, microfluidic development, bio-printing, iPS cells and more that can be applied to optimize drug discovery?

3D Tissue Models 2016 will host top decision makers from leading pharma and biotech companies seeking to use these technologies to accelerate validation of target molecules, expedite time to the clinic, and reduce attrition rates and the cost to bring drugs to market.

Throughout the two day conference, you will have the opportunity to present to and personally interact with stakeholders throughout the field including translational, pre-clinical, MPK, drug safety and efficacy experts trying to integrate and implement these technologies.

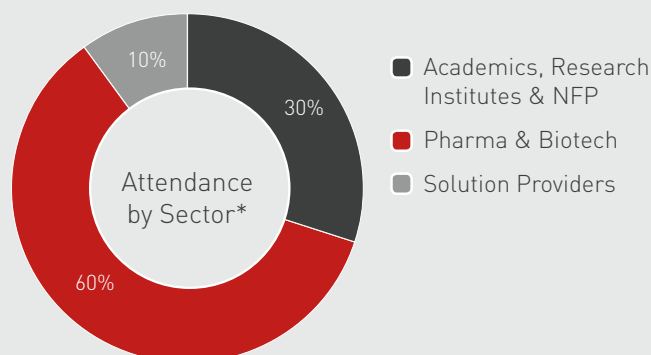
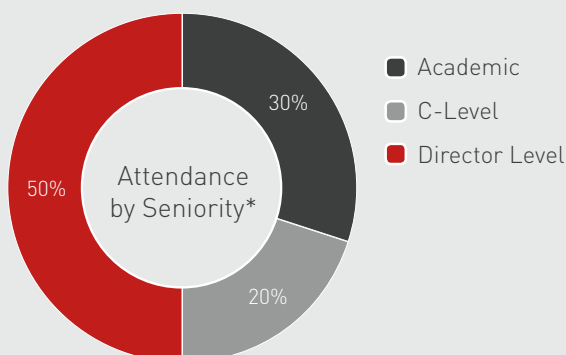
Sponsor 3D Tissue Models 2016 to:

- Educate industry leaders about what can be achieved with microphysiological systems
- Access this nascent market and establish your credibility as a trusted partner within industry
- Discover what pharma wants out of this technology, and how your solutions will be utilized to advance the field

■ Perfect networking opportunities with true value. Great meeting with decision makers and scientists mixing well. ■

TMO,
Past Attendee, Hanson Wade Event

Audience Breakdown



*Expected attendees for 2016 based on recent industry research

Become a Sponsor

Contact

Mo Langhi

Commercial Manager

Tel: +1 212 537 5898

Email: sponsor@hansonwade.com



Venue

Hotel Karlan

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San Diego, CA 92129

www.hotelkarlan.com

Please note: Overnight accommodation and travel are not included in the registration fee.



“A very useful and informative meeting. I’m looking forward to attending future events”

Pfizer
Past Attendee,
Hanson Wade Event

Pricing

Industry	Register & Pay before Friday June 24, 2016	Register & Pay before Friday July 22, 2016	Standard Price
Conference + 2 Workshops	\$3297 (save \$800)	\$3497 (save \$600)	\$3797 (save \$300)
Conference + 1 Workshop	\$2698 (save \$700)	\$2898 (save \$500)	\$3198 (save \$200)
Conference Only	\$2199 (save \$500)	\$2399 (save \$300)	\$2699
Workshops (each)	\$699		

Vendor	Register & Pay before Friday June 24, 2016	Register & Pay before Friday July 22, 2016	Standard Prices
Conference + 2 Workshops	\$4197 (save \$600)	\$4297 (save \$500)	\$4397 (save \$400)
Conference + 1 Workshop	\$3498 (save \$400)	\$3598 (save \$300)	\$3698 (save \$200)
Conference Only	\$2799 (save \$200)	\$2899 (save \$100)	\$2999
Workshops (each)	\$899		

*Academics are entitled to a 40% discount off the Industry Pricing (Please note: No further discounts are applicable)

Register

www.3d-tissuemodels.com/register

Tel: +1 212 537 5898

Email: register@hansonwade.com

Mail:

Hanson Wade
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London, SW1W 0AU

Team Discounts*

- **10% discount** – 3 delegates
- **15% discount** – 4 delegates
- **20% discount** – 5 or more delegates

Please note that discounts are only valid when three or more delegates from one company book and pay at the same time.

Terms & Conditions

Full payment is due on registration. Cancellation and Substitution Policy: Cancellations must be received in writing. If the cancellation is received more than 14 days before the conference attendees will receive a full credit to a future conference. Cancellations received 14 days or less (including the fourteenth day) prior to the conference will be liable for the full fee. A substitution from the same organization can be made at any time.

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