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PREDiCT: 4th Annual 3D TISSUE MODELS

DISCOVERY & DEVELOPMENT

Enhancing the Predictive Success of Complex *In Vitro* Models for Drug Discovery and Development

Expert Speakers Include:



Suzanne Fitzpatrick
Senior Advisor for
Toxicology Center for
Food Safety & Applied
Nutrition
**U.S Food and Drug
Administration**



John Wikswo
Professor and Founding
Director
**Vanderbilt Institute
for Integrative
Biosystems Research
and Education
(VIIBRE)**



Will Proctor
Associate Director,
Investigative Toxicology
Genentech



Matthew Wagoner
Associate Director
- Mechanistic &
Investigative Toxicology
Takeda



Matthias Von Herrath
Vice President
Novo Nordisk



Matthew Lech
Senior Research
Scientist
Pfizer



Wen Kang
Principal Scientist
Merck



Joseph Charest
Program Manager
Draper



Fabian Zanella
Director of R&D
Stemonix

2019 Partners



PREDiCT: 4th Annual 3D Tissue Models Summit

Validate & Reproduce the Predictive Success of 3D Models

The **3D Tissue Models Summit** is back in 2019 with world-leading experts to address the key challenges in the preclinical industry. Hear from the latest case studies to deepen your understanding of validation methods and technical advancements that are driving drug development and disease modeling.

Join **120+ industry stakeholders** across the regulatory, pharma, biotech and academic landscape for effective cross-talk and interactive discussions. Discover how to apply the latest insight to enhance the predictive power of your therapeutic pipeline.

Hear what previous attendees have to say

“I thought the conference was very focused. It was time well spent. I learned a lot and had productive networking sessions”

Hicham Alaoui, Director, Biochemical & Cellular Pharmacology, **Genentech**
3D Tissue Models Attendee

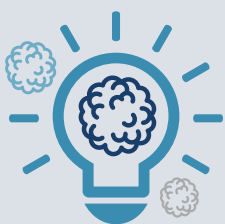
“The meeting was excellent. I was impressed with the array of highly relevant experts that were brought together to speak”

Andreas Baudy, Associate Principal Scientist, **Merck**
3D Tissue Models Attendee

“The 3D Tissue Models conference was a fantastic platform for industry and academics to come together and discuss how this field should and will move forward”

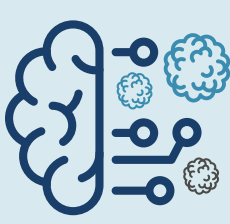
Nortis
3D Tissue Models 2016/2017 Attendee

5 Leading Institutions- Unmissable Case Studies



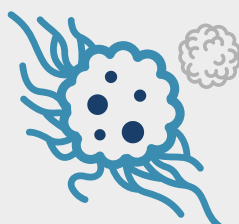
FDA Regulatory Insight

Hear **Suzanne Fitzpatrick** discuss the importance of context of use for model types and how defining a common language will assist in forming regulatory guidelines.



NIH Technology Advancements

Discover advances across the model continuum from high throughput Spheroid studies to **phenotypic machine learning** and **utilizing AI** to identify disease-relevant endpoints.



IQ Consortia Updates

Hear how **Genentech** and **Takeda** are defining organotypic standards for platform-specific models to increase reproducibility across the industry.



Tissue Chip Testing Centre Expertise

Discuss how drug discovery can be improved through applying **quantitative systems pharmacology** and maximising the impact of tissue-chip technology with **in vitro-in vivo translation**.



Roundtable Platform with PCRM and Industry Experts

An interactive discussion platform on the challenges of **cell sourcing**, tissue handling and the **3R's** following the latest modeling advances in the preclinical industry.

Your Expert Speakers



Suzanne Fitzpatrick
Senior Advisor for
Toxicology Center for
Food Safety & Applied
Nutrition
**U.S Food and Drug
Administration**



Matthew Wagoner
Associate Director
- Mechanistic &
Investigative Toxicology
Takeda



Steve Ferguson
Principal Scientist
**National Institute of
Environmental Health
Sciences (NIEHS)**



Will Proctor
Associate Director,
Investigative Toxicology
Genentech



Janine McCarthy
Research Specialist
**Physician's Committee
for Responsible
Medicine**



Lans Taylor
Director - Drug Discovery
Institute & Professor -
Allegheny Foundation
University of Pittsburgh



Murat Cirit
Director, Translational
Center & Tissue Chip
Technologies
MIT



Matthias Von Herrath
Vice President
Novo Nordisk



Yu-Chi Chen
Scientist
**National Institute of
Health Sciences (NIH)**



William Murphy
Drug Safety & Research
Evaluator
University of Wisconsin



Anshul Gupta
Principal Scientist -
Pharmacokinetics &
Drug Metabolism
Amgen



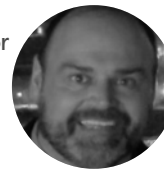
Bhushan Mahadik
Assistant Director of
Engineering & Complex
Tissues
University of Maryland



Matthew Lech
Senior Research Scientist
Pfizer



John Wikswo
Professor & Founding Director
**Vanderbilt Institute for
Integrative Biosystems
Research and Education
(VIIBRE)**



Richard Visconti
Principal Scientist
Celgene



Wen Kang
Principal Scientist
Merck



Szczepan Baran
Head of Emerging
Technologies
Novartis



Caghan Kizil
Group Leader
**Center for
Neurodegenerative
Diseases, Helmholtz
Association**



Regis Doyonnas
Associate Research
Fellow & Senior Principal
Scientist
Pfizer



Nathan Hotaling
Lead Data Scientist
**National Center
for Advancing
Translational Sciences
(NCATS)**



Sandra Engle
Director - Translational
Cell Sciences, Stem Cells
& Genomic Engineering
Biogen



Misti Ushio
CEO
Tara Biosystems



Joseph Charest
Program Manager
Draper



Fabian Zanella
Director of R&D
Stemonix



Janice Moser
Director of
Immunological Research
Sanofi Pasteur



Girija Goyal
Research Scientist
**Wyss Institute for
Biologically Inspired
Engineering**



**Prathap Kumar S.
Mahalingaiah**
Senior Scientist,
Investigative Toxicology
& Pathology
AbbVie

Workshop Day Wednesday September 4

Workshop A

08:30-11:00

3D Organoids: Defining & Validating Endpoints in Disease Modeling

Key Outcomes:

- Current state-of-the-art of 3D cultures: organoids and biomaterials
- The extent of disease modeling in 3D: multiple disease models
- Limitations and drawbacks as well as promises and advantages of 3D models
- Drug development in 3D - lead generation, optimization, efficacy, PK, and validation: where do we stand?
- What is the future of 3D cultures? What lies ahead?
- Regulatory and funding initiatives for 3D biology



Caghan Kizil

Group Leader

Center for Neurodegenerative Diseases, Helmholtz Association

Workshop B

12:00-2:30

Organ-on-Chip Masterclass

Key Outcomes:

- Key challenges of microfluidic systems and how to overcome them
- How multi-omic analytical chemistry can inform drug mechanism of action
- Depth of insight into how to model, interconnect, test and control biological systems with allometric, biochemical and/or functional scaling
- The commonalities and differences between organoids, tissue-chips, and organs-on-chips



John Wikswo

Professor & Founding Director

Vanderbilt Institute for Integrative Biosystems Research & Education (VIIBRE)

Workshop C

3:00-5:30

Quantitative Bright-Field Microscopy Combined with Artificial Neural Networks Predict Live Tissue Function

Key Outcomes:

- Validation of iPSC-derived retinal pigment epithelium cultured on biodegradable nanofiber scaffolds for use in a phase I clinical trial
- Next generation of the construct that is being developed in both the microfluidic system and the bioprinted system



Nathan Hotaling

Lead Data Scientist

National Center for Advancing Translational Sciences (NCATS)

Conference Day One

Thursday September 5

	8.20 Chair's Opening Remarks
Matthew Wagoner Associate Director - Mechanistic & Investigative Toxicology Takeda	8.30 IQ Consortium- Latest Developments & Challenges - Embedding the fundamentals of how 3D models have been utilized in the past 12 months and what are the latest challenges? - Exploring how defining organotypic standards within specific platforms can drive reproducibility - Future directions and objectives
Joseph Charest Program Manager Draper	9.00 Expertise Insight by Draper

9.30 Panel Discussion: Regulatory & Industry Cross Talk - What are the Next Steps?

- Insight into how collaborations between regulators, academics and companies are driving progress in 3D modeling
- Approaches to validating current MPS models
- Current requirements from the industry to improve model verification and success
- Discuss utilizing data exchange through smart compound libraries to assist with model standardisation



Suzanne Fitzpatrick
Senior Advisor for Toxicology
Center for Food Safety &
Applied Nutrition
**U.S Food and Drug
Administration**



Will Proctor
Associate Director,
Investigative Toxicology
Genentech



Matthew Wagoner
Associate Director -
Mechanistic & Investigative
Toxicology
Takeda

Fabian Zanella Director of R&D Stemonix	10.00 Expertise Insight by Stemonix
	10.30 Speed Networking
	11.00 Morning Refreshments

Discovery Track

Utilizing 3D models to Increase Target & Drug Discovery

11.30 Qualification & Implementation of Hepatic Spheroids to Support Drug Discovery

- Comprehensive evaluation and qualification of hepatic spheroid cultures for predicting clinical hepatotoxicity retrospectively
- Considerations for positioning hepatic spheroid assays during lead optimization and issue mitigation
- Advantages that 3D spheroid cultures have in relation to traditional 2D hepatic models

Will Proctor, Associate Director, Investigative Toxicology,
Genentech

Development Track

Evaluating the Predictive Outcomes from Current Models

11.30 A Toxicological Assessment of Drug Candidates in Multi-Species Ileal Organoids

- Comparing the toxicological responses in small intestinal organoids derived from mouse, dog, cynomolgus monkey, and human intestinal tissue
- Comparison with in vivo findings to discuss organoid predictability to infer GI effects in whole organisms

Richard Visconti, Principal Scientist, **Celgene**

12.00 Non-Alcoholic Fatty Liver Disease (NAFLD) Drug Discovery Through the Application of Quantitative Systems Pharmacology & Microphysiology Systems

- Advantages of applying both high throughput and biomimetic MPS for drug discovery
- Human liver biomimetic MPS disease model of NAFLD as key experimental/mechanistic model to identify drugs and drug combinations that halt/reverse disease phenotypes
- Inference of pathways of disease progression based on RNASeq of patient samples
- Computational prediction of drugs that target key pathways

Lans Taylor, Director - Drug Discovery Institute & Professor - Allegheny Foundation, **University of Pittsburgh**

12.00 Advanced Cellular Models for De-risking Drug-induced Liver Injury (DILI) in Pharmaceutical Development

- Benchmarking 2D and 3D liver models from an end user perspective
- Characterization and application of a micropatterned co-culture model (HepatoPac®) to inform on mechanisms of hepatotoxicity using a combination of molecular, metabolomics and imaging endpoints
- Model performance: robustness, stability, reproducibility – lessons learned

Wen Kang, Principal Scientist, **Merck**

12.30 Lunch

Screening Techniques to Increase Lead Optimization

1.30 High Throughput Cancer Spheroids for Drug Screening

- Insight into the establishing an effective screening compromise between complex matrix-based systems and 2D systems

Matthew Lech, Senior Research Scientist, **Pfizer**

2.00 Turning Inherently Variable Cell-Based Assays into Precision Tools for Drug Discovery in 3D - Case Reports from Islet & Liver

Issue: High variability of native pancreatic islets makes assay design complex and costly

Platform solution: Scalable formation of 3D microtissues and automation compatible assays
Re-aggregated human 3D Islets – characterization and functionality

Case study 1:

- Novel in vitro islet killing assay
- Detailed functional readouts in 3D
- Addition of external metabolic and immune stressors

Case study 2: Liver steatosis model using primary human cells and lipid loading

Outlook: From 3D static assays to 3D microtissue-based organ-on-a-chip devices under physiological flow conditions

Matthius Von Herrath, Vice President, **Novo Nordisk**

2.30 Presentation Title to Be Announced Shortly

Prathap Kumar S. Mahalingaiah, Senior Scientist, Investigative Toxicology & Pathology at **AbbVie**

3.00 Speaker Panel- Q & A Interactive Session

- Applying balance in spheroid studies of throughput with model complexity
- How to overcome spheroid clustering to increase collation of reliable results
- Insight into how quantitative systems pharmacology can assist to interpret data to improve in vitro to in vivo translation

Enhancing Translatability & Stability in Model Development

1.30 Phenotypic Machine Learning in High Content Imaging Screening with Organoids

- How to implement high-resolution 3D imaging assays for high-throughput screening
- How to answer disease relevant biology questions with 3D high content imaging assays
- How to develop a 3D analysis pipeline for HTS
- How to incorporate deep learning to high content image analysis pipeline for organoids

Yu-Chi Chen, Principal Scientist, **National Institute of Health Sciences (NIH)**

2.00 Utilizing 3D Cultures in the Blood Brain Barrier to Clarify Translational Endpoints

- Reviewing the current landscape on in vitro models of the neurovascular unit (NVU)
- What researchers might encounter as they move towards individualized tissue-chip models
- Addressing the hurdles and unique strategies to enhance and characterize 3D BBB/NVU models in health and disease

John Wikswo, Professor & Founding Director, **Vanderbilt Institute for Integrative Biosystems Research and Education (VIIBRE)**

2.30 Presentation Title to Be Confirmed

Misti Ushio, CEO, **Tara Biosystems**

2.45 Speaker Panel- Q & A Interactive Session

- How are complex growth media be utilized to generate large-scale cultures?
- Applying phenotypic screening to discriminate selective and off-target inhibitors in a physiologically relevant 3D culture setting

3.30 Afternoon Tea

4.00 Roundtable Debate: Interactive Sessions Discussing the Key Challenges within 3D Landscape

Decide between 2 in-depth roundtable discussions or choose a side and debate between the leading thinkers in the 3D modeling industry.

Human Tissue Sourcing & Handling

- Discussing the role of industry wide best practices for tissue handling guidelines to assist end users and increase tissue quality for 3D model systems
- Discussing the development of quality control metrics and minimum performance specifications to improve quality assurance
- Advantages and limitations of current tissue biobanks

Janine McCarthy, Research Specialist, **Physician's Committee for Responsible Medicine**

Future Prospects: 3D Models in Regenerative Medicine & Cell Therapy

- Utilising bio printing as a source of translatable tissues for regenerative medicine
- What are the current limitations and hurdles?
- What type of collaborations are needed with the industry to drive therapeutic success?

Bhushan Mahadik, Assistant Director of Engineering & Complex Tissues, **University of Maryland**

DEBATE- Accuracy of 3D Assays in Replacing In Vivo Models

- How will the industry adapt in light of increased assay predictability compared with in vivo models?
- What impact will this have on guidelines to produce Investigational New Drugs?

Regis Doyonnas, Associate Research Fellow & Principal Scientist, **Pfizer**

DEBATE: Biomimetic Environment and Improving In Vitro-In Vivo Translation

- What advancements are driving the success of bridging in vitro-in vivo translation gap?
- Challenges in replicating a biomimetic environment and increasing physiological relevancy

Murat Cirit, Director, Translational Center & Tissue-Chip Technologies, **MIT**



5.00 Moderator Feedback: Roundtable Discussions & In Vitro-In Vivo Debate Outcome

5.15 Chair's Closing Remarks



5.30 Poster Session

Continue to build your network during this interactive session presenting the latest data on 3D disease modelling, efficacy studies and target validation.

■ This was a great scientific meeting and networking opportunity. It brought together key players in the field to discuss important strategic issues of mutual interest ■

Brian Berridge, Associate Director,
National Toxicology Program
3D Tissue Models Past Attendee

Conference Day Two

Friday September 6

	8.20 Chair's Opening Remarks
Steve Ferguson Principal Scientist National Institute of Environmental Health Sciences (NIEHS)	8.30 NIH Insight: 3D Spheroid Models & High-Throughput Transcriptomics to Predict Human Liver Injury & Identify Pathways of Biological Response to Xenobiotic Exposures • Application of 3D HepaRG spheroids for the study of liver injury • Utilizing high-throughput transcriptomics to drive drug discovery • Benchmark concentration modeling • Metabolic activation • Drug analogue comparisons with varied clinical outcomes
Suzanne Fitzpatrick Senior Advisor for Toxicology Center for Food Safety & Applied Nutrition U.S Food and Drug Administration	9.00 FDA Regulatory Insight • Discussing the importance of context of use of alternative models • Defining a common language and terminology of key terms across the landscape for end users
Murat Cirit Director, Translational Center & Tissue Chip Technologies MIT	9.30 Tissue Chip Testing Centre (TCTC) Insight & Developments • Maximizing the impact of tissue-chip technologies with in vitro-in vivo translation (IVIVT) • Translational applications of tissue-chip technologies • Merging tissue-chip technologies with quantitative systems pharmacology (QSP), and machine learning (ML)

10.00 Panel Discussion: Balancing Functionality with Model Complexity

- How are current models defined as "fit for purpose"?
- The balance between physiological relevancy and throughput
- How cell heterogeneity in organoid models impacts the accuracy of readouts
- Improving biomaterials to increase stability for model microenvironment

Panel Discussion



Steve Ferguson
Deputy Director
National Institute of Environmental Health Sciences (NIEHS)



Murat Cirit
Director, Translational Center & Tissue Chip Technologies
MIT



John Wikswo
Professor & Director
Vanderbilt Institute for Integrative Biosystems Research and Education (VIIBRE)



Szczepan Baran
Head of Emerging Technologies
Novartis

10.30 Morning Refreshments

Discovery Track

Adaptive Technology Platforms to Drive 3D Model Drug Discovery

11.00 Utilizing iPSCs for Target Discovery in CNS

- Enabling the modeling of human diseases with patient derived neural cells
- Accelerating drug development for neurological diseases in parallel with iPSC-based technologies

Sandi Engle, Director - Translational Cell Sciences, Stem Cells & Genomic Engineering, **Biogen**

11.30 Gaining Insight into Mode of Action in Current 3D Models using DMPK & ADME Profiling

- Recapitulating the physiological and metabolic properties of the in vivo environment
- Utilizing the advantages for detection of drug induced toxicities over 2D systems
- Insight into biological context to deliver safe efficacious drugs

Anshul Gupta, Principal Scientist - Pharmacokinetics & Drug Metabolism, **Allergan**

12.00 Speaker Panel Q & A Interactive Session

- Discussing the cellular maturity and advantages of increasing lifespan in current models
- Evaluating cost vs functionality between simple and complex systems

Development Track

Digging Deeper into Current Models to Validate Design Criteria

11.00 Biomaterial & 3D Printing Approaches for Engineering a Vascularized Liver Tissue

- Development of a microbead-based biomaterial platform loaded with hepatic and endothelial cells
- 3D printed macrovasculature that drives angiogenesis and microvasculature development
- Evaluating the engineered tissue for key markers of liver function

Bhushan Mahadik, Assistant Director of Engineering & Complex Tissues, **University of Maryland**

11.30 Assessing the Importance of Microenvironment-Influencing Drug Response

- Evaluating how the extracellular matrix affects human tissue assembly and assay reproducibility

William Murphy, Drug Safety & Research Evaluator, **University of Wisconsin**

12.00 Speaker Panel Q & A Interactive Session

- How can we efficiently utilize the rich output of from 3D systems?
- What are the challenges in protocol to meet endpoints when utilizing single cell assays?

12.30 Lunch

Advancing Biomimetic Properties of Organ-on-Chip Technologies

Janice Moser
 Director of Immunological Research
Sanofi Pasteur

1.30 In Vitro MIMIC® Human Immune Evaluations: From the Cradle to the Grave

- Biomimetic model of the human immune system
- Insight into the Modular Immune In vitro Construct (MIMIC®) system to evaluate immunity elicited by vaccine candidates and other biological agents in a non-clinical/pre-clinical setting
- 4-gate analysis of the capacity of a test agent to trigger immunoreactogenicity, innate responses/APC activation, cellular immunity (T cell responses) and antibody production

Girija Goyal
 Research Scientist
Wyss Institute for Biologically Inspired Engineering

2.00 Recapitulating Clinical Responses with Human Organ Chips

- Key limitations of microfluidic systems
- A vascularized, mechanical mimicry organ on chip platform
- Case studies:
 - Role of mechanical forces in modeling lung disease
 - Role of microbiota in modeling enterohemorrhagic E. coli infection on the human intestine organ chip
 - Modeling the responses to influenza vaccination on the human lymph node chip

3.00 Speaker Panel Q&A Discussion

- Gaining insights into the latest developments of organ-on-chip technology
- What are the limitations of these systems?
- What hurdles are yet to be addressed?

3.30 Chair's Closing Remarks

3.45 Close of Conference

2019 Confirmed Partners

We unite the preclinical community and showcase the latest technological advances to support the therapeutic success of novel candidates.

The **PREDICT: 3D Tissue Models Summit** partners with leading Tissue Experts, Imaging Specialists and Modeling Providers to enhance the success of translatability and predictability in the preclinical industry.

Why Partner?



Network with world-leading industry experts from across the preclinical community to drive commercial success.



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Discover the latest Market Intelligence from the 3D tissue model industry.

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TARA Biosystems, Inc. provides predictive, in vitro human

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www.tarabiosystems.com



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AxoSim's Nerve-on-a-Chip technology predicts clinical

results from the benchtop, helping pharmaceutical companies develop safer and more effective drugs. Employing micro-engineering techniques and novel biomaterials, AxoSim has developed a 3D iPSC-based model which mimics living tissue in both form and function, enabling in vivo metrics from an in vitro platform. The Nerve-on-a-Chip platform delivers high-content data as a more accurate, less expensive, and faster alternative to animal testing.

www.axosim.com



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Xylyx Bio is harnessing the power of tissue-specific extracellular matrix for both cell culture and tissue regeneration applications. By bringing the native in-vivo environment to the in vitro setting, Xylyx Bio's tissue-specific ECM substrates support cell culture models that are significantly more predictive of human physiology, thus facilitating acceleration of drug discovery and development. We are committed to providing scientists with biomimetic solutions that transform the way biomedical research is conducted. From the very beginning, cells can be cultured in vitro but still studied in their natural environment – leading to better science and faster translation of results.

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www.advancedsolutions.com



Exhibition Partner

The SCREEN Group traces its history back 150 years to Ishida Kyokuzan Printing Works, a lithographic printing shop founded in Kyoto in 1868. In 1934, we succeeded in producing Japan's first photographic glass screens, eventually leading to our R&D division being spun off as an independent venture company in 1943 to become Dainippon Screen Mfg. Co., Ltd. Our corporate name actually originated with those first glass screens. As the SCREEN Group has grown, we have built our expertise in the areas of surface processing, direct imaging and image processing, developing them into our three core technologies. Working from this foundation, we have continued to target sustainable growth, including the development of new business opportunities, with a view to creating a strong and diversified corporate portfolio.

www.screen.co.jp/en

■ The depth of the discussion, and opportunities to hear perspectives from those leading the industry on developing 3D tissue models made this an exceptionally valuable meeting ■

Jana Stoudemire, Commercial Innovation Life Sciences Lead, **Center for the Advancement of Science in Space**

3D Tissue Models Past Attendee

Get Involved



Diane McKenna

Commercial Director

Tel: +1 508 869 4452

Email: diane.mckenna@hansonwade.com

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Solution Provider	Register & Pay before Friday June 7	Standard Prices
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Conference + 1 Workshop	\$3,298	\$3,898
Conference Only	\$2,799	\$3,399
Workshops (Each)	\$599	

Academic/Start-Up*	Register & Pay before Friday June 7	Standard Prices
Conference + 3 Workshops	\$2,296	\$2,796
Conference + 2 Workshops	\$2,097	\$2,597
Conference + 1 Workshop	\$1,698	\$2,198
Conference Only	\$1,299	\$1,799
Workshops (Each)	\$499	

*Academic and Start up pricing is subject to the organizer's approval. Please get in touch for more information.

VENUE

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Massachusetts, 02115, USA

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