Sponsored session

It is 60 minutes session supported by cooperate company. Registration is necessary to attend a session with showing “Registration” icon on the program.

Registrations has been started from June 12. We are looking forward to have many accesses. When you make a reservation, disclosure of personal information will be required. Please register from our website below;
Website: http://jsot2020.jp/contents_en/program.html

Sponsored session 1  June 29 (Mon) 13:10 - 14:10  Track 3  Registration

Developing high-throughput organ-on-a-chip tissue models for drug discovery and unlocking their full potential using high-content imaging

Speaker : Chiwan Chiang (Field application scientist, MIMETAS BV)
Mitsunari Yamaguchi (Product Manager, Molecular Devices Japan)

Chair : Yoko Ejiri (CEO, MIMETAS Japan)

Sponsored by : MIMETAS Japan / Molecular Devices

Overview

Organ-on-a-Chip technology is a new paradigm in drug testing. The aim of this technology is to raise the physiological relevance of traditional cell culture by combining it with microfluidic techniques. Organs-on-a-Chip are 3D tissues that capture the complexity of in vivo tissues including 3D morphology, extracellular matrix embedment, multiple cell types, vascular structure and perfusion flow. Incorporating these technologies in a microplate format enables increased throughput in high content imaging systems.

In this presentation, experts from MIMETAS and Molecular Devices will introduce the culture and interrogation of complex 3D tissues, such as liver, kidney, gut and brain tissue. The tissues are grown in the OrganoPlate®, an in vitro cell culture microplate platform that allows culturing of over 40 tissues in parallel. The tissues are embedded in an extracellular matrix gel and comprise both stromal tissue, blood vessel structures as well as epithelial barriers. We will show examples of Organ-on-a-Chip tissues for use in disease modeling and drug safety testing and will present the new OrganoPlate® Graft, which allows vascularization of spheroids, organoids and PDX explants, and offers a powerful solution for the study of angiogenesis, an important focus for cancer therapeutics.

These complex 3D tissue cultures can be interrogated in a high-throughput manner using powerful cellular imaging systems. Molecular Device’s ImageXpress® Micro Confocal High-Content Imaging System features unique confocal technology which can capture high quality images of whole organisms, thick tissues, 2D and 3D models, and cellular or intracellular events with high-throughput. With newly unveiled high-resolution water immersion lens and unprecedentedly flexible auto focus function even suitable for complex plate design as seen in OrganoPlate®, the System play a vital role in the development and analysis of 3D tissue models, such as those built on the OrganoPlate® platform.

Sponsored session 2  June 29 (Mon) 13:10 - 14:10  Track 4  Registration

Functionalization of cells by three-dimensional culture for usage in drug discovery

Speaker : Nobuhiko Kojima (Graduate School of Nanobioscience, Yokohama City University)

Chair : Shinsuke Aoyama (Drug Development Solutions Sales Office, SEKISUI MEDICAL CO., LTD.)

Sponsored by : SEKISUI MEDICAL CO., LTD.

Overview

In order to evaluate the toxicity of drug candidates, Microphysiological System (MPS) have received widespread attention. MPS is a highly physiological culture system for human cells that mimics a living organ and is expected to solve the problem of species differences in preclinical studies. Currently, MPS is actively developed in terms of materials, structures, and processing methods, but research on cell processing is also essential. In this session, we will introduce the technology for designing multicellular spheroids, as well as specific efforts to develop a contract research using multicellular spheroid consists of primary human hepatocytes.
Immunogenicity Testing using High sensitivity Single Molecule Counting Technology SMC -AstraZeneca Case

Speaker : Ayako Yamada (Merck Ltd. Life Science Commercial Marketing)
Sponsored by : Merck Ltd.

Overview

Drug immunogenicity and the detection of anti-drug antibodies (ADA) have an important role in the drug discovery process for potential new therapeutics. Single Molecule Counting (SMC™) immunoassay technology can support all phases of immunogenicity testing using the SMCxPRO™ high-sensitivity instrument for low-level protein detection. One of SMC™ advantages is high sensitivity down to pg/mL detection for low-affinity ADA. All ADA subtypes can be detected including IgM and IgE and tolerance to high drug concentrations in sample is well tolerated. We will also introduce the ADA assay application developed by AstraZeneca and Merck.

The Path to Successful FDA Regulatory Review - Pharmacology and Toxicology

Speaker : Chris Sheth, PhD (Senior Consultant, Aclairo Pharmaceutical Development Group)
Chair : Kenjie Amemiya, PhD, DABT (Vice President Safety Assessment, Aclairo Pharmaceutical Development Group)
Sponsored by : Aclairo Pharmaceutical Development Group

Overview

Drug developers from around the world need to interact with the United States Food and Drug Administration (FDA) for authorization to transport investigational agents across state lines (the basis for the Investigational New Drug application [IND]), to initiate and conduct clinical trials in human subjects in the US, and to gain regulatory Agency approval (New Drug Application / Biologics License Application) to market their product(s) within the country. This presentation will provide a guide to working with the FDA all throughout the drug development process. The presenter will discuss the organization of the FDA, into Centers, Offices and review Divisions. Various submission types will be discussed, along with how the submissions are assigned and reviewed within the FDA Divisions, and what to expect in return from the FDA. The presentation will also include information about the assistance available to drug developers through the use of expert consultants, with a particular focus on aspects related to the pharmacology and toxicology of new drugs and biologics.

Physiologically relevant tissue models for drug discovery and safety evaluations

Speaker : Remko van Vught (Business development Director, MIMETAS BV)
Chair : Yoko Ejiri (CEO, MIMETAS Japan)
Sponsored by : MIMETAS Japan K.K.

Overview

Organ-on-a-chip technology is a new paradigm in enhanced, 3D tissue culture. The field builds on almost 29 years of developments in microfluidic and associated microfabrication techniques on the one hand and an urge towards ever more physiologically relevant cell and tissue culture approaches on the other hand. Application of microengineering techniques in cell culture enables structured co-culture, 3D culture, the use of flow and associated shear stress and application of controlled gradients.

MIMETAS develops a commercially available platform based on a microtiter plate format that harbors up to 96 chips and enables perfused 3D co-culture in a membrane-free manner. The OrganoPlate® facilitates growth of tubules and blood vessels under continuous flow of medium, it allows engineering of organ complexity without usage of artificial membranes. The OrganoPlate® is fully compatible with liquid handling equipment and high-content readers and is easily adopted by end-users. In this presentation, we will introduce culture of relevant 3D tissues, discuss methods for analysis of tissue morphology, function and viability, and highlight recent advances in gut, kidney and vasculature models for use in drug discovery and safety evaluations.
① Validation of the high-throughput assay using human iPSC-derived cardiomyocytes to assess cardiotoxic compounds under the CiPA initiative

Speaker: Panida Lertkiatmongkol, Ph.D. (Senior Scientist and Group Leader, Eurofins Discovery)
Chair: David (Haiyang) Wei, Ph.D. (Director, Drug Discovery Partnerships, Eurofins Discovery)

② Screening Approaches for Reducing Attrition Due to Drug-induced Liver Injury (DILI) Early in Drug Discovery

Speaker: Yong Zhao, Ph.D. (Director of In Vitro Toxicology Services, Eurofins Discovery)
Chair: Michael D. Mitchell (Business Area Manager, Eurofins Discovery)

Sponsored by: Eurofins Discovery

Overview

① Drug-induced QT interval prolongation and Torsades de Pointes (TdP) arrhythmias are the leading causes for compound attrition during drug development. To assess potential cardiotoxicity of compounds, Comprehensive in vitro Proarrhythmia Assay (CiPA) is a cardiac safety testing paradigm that includes in vitro assays using human induced pluripotent stem cell derived cardiomyocytes (hiPSC-CM). To adopt CiPA paradigm, we developed a high-throughput hiPSC-CM assay using calcium-sensitive dyes detected by high-speed imaging platform, the FLIPR® Penta. Our assay can provide an in vitro drug-induced proarrhythmia assessment and strengthen pharmacological safety profiles of drug candidates.

② Drug-induced liver injury (DILI) is a leading cause of drug failures in clinical trials and the major reason for drug withdrawals. It is very challenging to predict DILI because the causes of DILI are multifactorial. We will discuss a set of in vitro assays that tackle the challenges of in vitro hepatotoxicity assessment; the utilization of a portfolio of cell-based in vitro assays that assess mitochondrial dysfunction, toxic effect by reactive metabolites, induction of reactive oxygen species and cholestasis; and the major cell types that are used in in vitro hepatotoxicity screening.

Sponsored session 7 June 30 (Tue) 13:00 - 14:00 Track 3 Registration

Use of Immunohistochemistry in Development and Safety Assessment of Cell and Gene Therapies

Speaker: Shari A. Price, PhD, DABT (Senior Research Pathologist, Immunopathology, Pathology Associates, Charles River Frederick)
Chair: Hiroyuki Minami (Charles River Laboratories Japan, Inc.)
Sponsored by: Charles River

Overview

Immunohistochemistry can provide a powerful tool for assessing the safety and functionality of cell and gene therapies. Various immunohistochemical stains can be used to localize cell and gene therapy candidates in tissues in safety/toxicity study animal models and provide tissue, cellular, and subcellular context for the biodistribution and persistence of these drug candidates over time. In addition, other stains can be used to provide additional information about proliferation, tumorigenicity, or other tissue/protein expression changes resulting from administration of these drugs.
**Overview**

The Organization for Economic Cooperative Development (OECD) provides guidance for the assessment potential risks associated with existing and newly developed chemicals that may alter normal functioning of endocrine systems. In this session, we discuss in vitro systems that are required for testing in safety assessment of the endocrine disruption system with a focus on the NIS (Natrium Iodide Symporter) inhibition assay that is part of the required in vitro tests.

**Overview**

Efforts on hematology or biochemistry tests in Non-clinical field

(Japanese only)

**Overview**

Gene therapy products are actively researched and developed innovative medical treatment both in Japan and overseas. However, the characteristics of gene therapy products are different from those of pharmaceuticals and medical devices, also different from cell derived tissue-engineered medical products which are classified in the same regenerative medicine category. Non-clinical safety evaluation of gene therapy products requires flexible, rational and case-by-case responses based on their characteristics. In this session, we will provide an outline of non-clinical safety studies of gene therapy products and our capabilities.

**Overview**

The recent growth in data availability for chemical structures, bioactivities as well as adverse events and toxicology, is becoming more important for predictive modelling in toxicology. This talk will focus on Elsevier’s projects using large data sets from different sources to support various areas of drug safety. The projects include a modelling for DILI (drug-induced liver injury) risks with the FDA that can be used at the preclinical stage, developing a tool to assess a safety margin for early prediction of secondary pharmacology risk and adverse events, such as drug-induced depression.
Joint Session for Advanced Safety Research:

(1) ZeTox: Predicting teratogenesis through zebrafish screenings  
Speaker: Jana Iscla (Business Developer Manager, ZeClinics)

(2) Outline and Evaluation for Inhalation Toxicity  
Speaker: Tomoki Fukuyama (D.V.M, Ph.D, Senior Assistant Professor, Pharmacology Laboratory, Azabu University School of Veterinary Medicine)

(3) Outlines and future perspectives on the TK6 micronucleus assay  
Speaker: Tadashi Imamura (B.Hyg., M.T., Study Director, Ina Research Inc.)

Sponsored by: Ina Research Inc.

Overview

- Availability of efficacy/safety studies using zebrafishes
- Requirements and key points for inhalation toxicity study design

Navigating SEND Requirements & The Role of Technical Rejection Criteria

Speaker: Audrey Walker (Director, Data and Report Delivery Services, Charles River Montreal)
Chair: Masamichi Kaminishi (Charles River Laboratories Japan, Inc.)

Sponsored by: Charles River

Overview

The topics to be discussed will be the scope of SEND, the mandatory timelines including the technical rejection criteria, how to navigate the SEND requirements and industry sponsor awareness.
Sponsor hospitality room

You will have a hospitality space instead of exhibition booth. Participants will visit there freely and have a face-to-face communication in virtual space.

As an incentive to visit, the secretariat will present a gift to 150 participants by lot.

June 29 (Mon) 9:00 - 17:00  Sponsor channel 1

Sponsored by : Shin Nippon Biomedical Laboratories, Ltd.

Shin Nippon Biomedical Laboratories (SNBL), was founded in Kagoshima as Japan’s first contract research organization in 1957. Since then, SNBL has steadily expanded and innovated to become a global business that works in the pre-clinical research, clinical pharmacology research, pharmacokinetics and analysis, clinical trial, and other industries. SNBL is striving toward globalization and expanded from Japan into North America, Europe, and other parts of Asia.

We are waiting for your access to each session.

June 29 (Mon) 11:00 - 13:00  Sponsor channel 2

Sponsored by : Sumika Chemical Analysis Service, Ltd.

Sumika Chemical Analysis Service, Ltd. open ‘Sponsor Hospitality Room’ between 11:00 and 13:00 June 29 (Monday) as a company exhibition. We plan to introduce our technology and performance, mainly in terms of "methods for evaluating the tumorigenicity of regenerative medicine products", "cardiac ion channel evaluation using an auto-patch clamp system", and "biomarker measurement service". Please connect Sponsor channel 2 to participate.

Furthermore, we will also hold a web seminar on July 22, 10:00 to 17:00 (Japanese only). For more information, please check our homepage: https://www.scas.co.jp/latest-updates/event/jsot2020.html.

June 29 (Mon) 11:00 - 13:00  Sponsor channel 3

Sponsored by : Ushio Inc.

We offer a microfluidic cell culture plate, CEP PLATE™ jointly developed with Kyoto University.

CEP PLATE™ is
-made of medical-grade cycloolefin polymer, so that it is compatible with fluorescent observation.
-suitable for in vitro screening, as it complies with Microplate Standard.

Our MPS product is manufactured by Photobonding®, a glue/solvent free bonding technology, so that we can offer a "clean" plate that is not affected by elution of impurities.

If you face any troubles in your assays, please do not hesitate to contact us or make a request at https://www.photobonding.com/. We can propose a chip design/evaluation protocol to meet your needs!

June 29 (Mon) 13:00 - 15:00  Sponsor channel 2

Sponsored by : FUJITSU KYUSHU SYSTEMS LIMITED

June 29 (Mon) 13:00 - 15:00  Sponsor channel 3

Sponsored by : Instem Japan K.K.

The headquarter of Instem Japan is in UK and provide toxicology data collection system(Provantis), Genetox study(Micronucleus study, Comet Assay, AMES etc) data collection and management system as well as SEND solutions. Our products are GLP compliance and it provides by cloud environment. Half of our clients have chosen cloud and it is under GLP compliance. We also provide SEND data conversion service, consultation, and Target Safety Assessment. We acquired Leadscope last year and now our solution expands ICH M7 compliance and provides in-Silico solutions. Please feel free to contact us.
June 29 (Mon) 15:00 - 17:00  

**Sponsor channel 2**

**Sponsored by: MIMETAS Japan / Molecular Devices**

MIMETAS B.V. is a biotech venture company incorporated in 2013 based in Leiden, Netherlands. Mimetas Japan Ltd. in Tokyo in July 2018. We develop and sell practical Organ-on-a-Chip (vital function chips) models for drug discovery and toxicological research. The Organ-on-a-Chip of MIMETAS can accurately reproduce the functions of internal body organs using human-derived cultured cells on a USB flash memory-sized polymer microchip.

Molecular Devices provides our customers with innovative bioanalytical solutions for protein and cell biology in life science research, pharmaceutical and biotherapeutic development. We introduce ImageXpress® Micro Confocal High-Content Imaging System which features unique confocal technology enabling you to capture high quality images of whole organisms, thick tissues, 2D and 3D models, and cellular or intracellular events with high-throughput.

June 29 (Mon) 15:00 - 17:00  

**Sponsor channel 3**

**Sponsored by: SEKISUI MEDICAL CO., LTD.**

June 30 (Tue) 9:00 - 17:00  

**Sponsor channel 1**

**Sponsored by: Shin Nippon Biomedical Laboratories, Ltd.**

Shin Nippon Biomedical Laboratories (SNBL), was founded in Kagoshima as Japan’s first contract research organization in 1957. Since then, SNBL has steadily expanded and innovated to become a global business that works in the pre-clinical research, clinical pharmacology research, pharmacokinetics and analysis, clinical trial, and other industries. SNBL is striving toward globalization and expanded from Japan into North America, Europe, and other parts of Asia.

We are waiting for your access to each session.

June 30 (Tue) 11:00 - 15:00  

**Sponsor channel 2**

**Sponsored by: FUJITSU KYUSHU SYSTEMS LIMITED**

June 30 (Tue) 11:00 - 13:00  

**Sponsor channel 3**

**Sponsored by: Nihon Bioresearch Inc.**

We conduct about 400 studies per year as a non-clinical GLP-compliant facility for studies of drugs, medical appliances, and regeneration medical products.

We focus on safety studies using minipigs. We also perform efficacy studies for evaluation using immune deficiency model and renal failure model. We prepare animal models to meet individual requirements.

Evaluation using immune deficiency model and evaluation using bacteria and virus in our BSL-II lab. are also available. Recently, we started in vitro skin irritation studies and cell-based assays. You can see our study list on the web (https://www.nbr.co.jp/). We look forward to receiving your inquiry.

June 30 (Tue) 13:00 - 15:00  

**Sponsor channel 3**

**Sponsored by: Ushio Inc.**

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The Japan Society of Quality Assurance (JSQA) is a general incorporated association consisting of members involved in quality and Quality Assurance in medicines, medical devices, agricultural chemicals, chemical substances, foods, veterinary medicines, feed additives, etc. Established by GLP personnel in 1992, GCP started in 1995, GQP/GVP/GPSP activities related to post-marketing started in 2006, and now we handle quality and QA from non-clinical to clinical and post-marketing. The GLP Subcommittee regularly hosts educational courses such as GLP basic training. In addition, we have conducted the GLP-QAP registration test to judge the ability as an expert in reliability assurance work, and have registered successful applicants as “GLP-QAP registrations”.

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We offer one-stop services tailored to customer needs, from the development of pharmaceuticals, medical devices and regenerative medicine products to practical applications. The topics for this year are doubling the capacity of small animal studies, and the expansion of immunodeficiency animal breeding area. Simultaneously, the existing facility was renovated to be a facility dedicated to safety pharmacology for dogs, monkeys, and pigs. In the hospitality channel, we will introduce new facilities such as the new animal research building, as well as a detailed explanation by the presenters about the 4 posters of JSOT. We look forward to your participation.

The headquarter of Instem Japan is in UK and provide toxicology data collection system(Provantis), Genetox study(Micronucleus study, Comet Assay, AMES etc) data collection and management system as well as SEND solutions. Our products are GLP compliance and it provides by cloud environment. Half of our clients have chosen cloud and it is under GLP compliance. We also provide SEND data conversion service, consultation, and Target Safety Assessment. We acquired Leadscope last year and now our solution expands ICH M7 compliance and provides in-Silico solutions. Please feel free to contact us.
Sponsored by : Nikon Corporation

Do you want automatic cell imaging unit in order to evaluate toxicity efficiently? Nikon would provide “BioPipeline LIVE” that consist of inverted microscope “Ti2-E” and CO2 incubator. It’s possible to culture stably and evaluate multiple samples. In addition, it’s important to make full use of live-cell imaging technology for evaluating the condition of cultured cells. Nikon developed “BioStationCT”, “BioStudio-T/mini/mw” for live-cell imaging, “CL-quant Add-on Modules” for image analysis. We could provide the best cell evaluation solution, and support for toxicology.

Sponsored by : Ushio Inc.

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Sponsored by : JAPAN NUS CO., LTD.
### Web advertisement in break time

Three minutes before each scientific session advertisement will be streamed.

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