PSG ANNUAL CONFERENCE 2016

40+ YEARS

Recent Advances in Pharmaceuticals, Medical Devices & Biosimilars

TUESDAY, MAY 10, 2016

Paramount Conference & Event Venue
Woodbridge, ON

Presented By:

Pharmaceutical Sciences Group (PSG)
WWW.PSG.CA

PSG Annual Conference 2016

Recent Advances in Pharmaceuticals, Medical Devices & Biosimilars

The 44th annual Pharmaceutical Symposium and Exhibition is the largest event of the year proudly hosted by PSG. Conference attendees will be able to gather information from top Health Industry experts who will discuss the latest advances in the area of Pharmaceuticals, Medical Devices, Biosimilars, Data Integrity, API Inspections, and new technologies related to Solid Dosage Forms. This exciting symposium and exhibition will feature leading specialists from Health Canada as well as Canadian and U.S. international experts in the Pharmaceutical Life Science Industry.

We are delighted to welcome Bikash Chatterjee, President and Chief Science Officer of Pharmatech Associates (U.S.A.) as Keynote Speaker. Mr. Chatterjee has over 30 years of experience in the pharmaceutical, biosciences, medical device/diagnostic and nutraceutical/ dietary supplement industries and will be discussing the exciting topic of “Next Generation Gene Sequencing & Drug Therapy”. This is a presentation not to be missed.

Overall, the Symposium also provides an excellent opportunity to network with business colleagues, Health Canada, and senior Pharmaceutical Industry officials throughout the day. Laboratory instrumentation suppliers, contractual quality service providers and regulatory compliance consulting groups have been invited to participate in the exhibition, which is a free area open to the public. We hope to see you all at this informative and engaging event.

CONFERENCE SCHEDULE AT A GLANCE

Registration & Breakfast:	8:00 am - 9:00 am
Symposium Presentations:	9:00 am - 4:30 pm
Exhibition Hall:	8:00 am - 3:30 pm

VIEW THE CONFERENCE LIVE ONLINE!

PSG is allowing attendees from all over the world to participate in the conference! This is an exciting opportunity to join us, regardless of your geographic location. Questions should be submitted to the PSG Office **before** the event by clicking here.

Please click here to register for the online stream of the conference for the low cost of $149 + HST.

PSG Annual Conference 2016

EXHIBITION

Free to the Public

Open from 8:00 am - 3:30 pm

The exhibition hall gives you the opportunity to visit with the following exhibitors and learn more about the services that they provide. This is an excellent opportunity to interact directly with representatives and mingle with your fellow colleagues. There is no registration or fee required to attend this area so all are welcome!

2016 Exhibitors Include:

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PSG Annual Conference agenda

8:00 am - 9:00 am	Continental Breakfast & Registration	
9:00 am - 9:05 am	Welcome & Introductions	
9:05 am - 9:45 am 	**Bikash Chatterjee** President and Chief Science Officer, Pharmatech Associates	**Keynote Address:** **The Challenge & Promise of Next Generation Gene Sequencing & Drug Therapy** In the years since the first complete human genome sequence was reported, there has been a rapid development of technologies to facilitate high-throughput sequence analysis of DNA (termed "next-generation" sequencing) or NGS. These novel approaches to DNA sequencing offer the promise of complete genomic analysis at a cost feasible for routine clinical diagnostics. The emergence of targeted therapies in oncology, for example, brings an increased need for companion diagnostic tests. Next-generation sequencing (NGS) is an ideal solution to transform the tumor profiling paradigm from a series of single gene tests to a multi-analyte approach to delivering precision oncology. The ability to deliver a comprehensive set of the actionable and emerging biomarkers relevant to cancer drug development for example, has the potential to forever change the approach and effectiveness of oncology health care and others dramatically. This presentation will describe the evolution of NGS systems from the early Sanger chemistry of the 1970's to today's multi-analyte NGS systems being groomed to provide targetd information for disease state intervention. The presentation will also discuss some of the regulatory and compliance challenges that emerge as the product moves from a Research-Use-Only system, regulated under general controls to one which is regulated as a medical device.
Q & A SESSION WITH BIKASH CHATTERJEE: 5-10 MINUTES CLICK HERE TO SUBMIT YOUR QUESTION		
9:50 am -10:30 am 	**Dr. Jian Wang** Chief, Clinical Evaluation Division - Haematology/ Oncology, Centre for Evaluation of Radiopharmaceu-ticals & Biotherapeutics Biologics & Genetic Therapies Directorate HPFB, Health Canada	**Clinical Study for SEBs (Biosimilars): Sensitive Study Population and Study Endpoint** The purpose of the clinical studies, including PK/PD, efficacy and safety studies, is to confirm comparable clinical performance of the SEB (Subsequent Entry Biologics) and the reference product. The extent and nature of the clinical studies to be performed depend on the level of evidence obtained in the previous comparative steps, such as the robustness of the physicochemical, biological and in vitro/in vivo non-clinical data. In order to demonstrate that the two products are comparable from the clinical perspective, it is important that both clinical study population and study endpoint are sensitive to detect clinically meaningful differences between the two products.
Q & A SESSION WITH JIAN WANG: 5-10 MINUTES CLICK HERE TO SUBMIT YOUR QUESTION		
10:35 am - 11:05 am	Morning Break - Vendor Exhibit Area Open	

Conference Also Available Online!

AGENDA (CONTINUED)

11:05 am -11:45 pm 	**Kimberly A. Trautman** Executive Vice President Medical Device International Services NSF Health Sciences, a division of NSF International	**Medical Device Single Audit Program (MDSAP) – Overview and Update** Learn about the Medical Device Single Audit Program (MDSAP) and how Australia's TGA, Brazil's ANVISA, Canada's HC, Japan's PMDA, and the United States' FDA will implement the program moving from the pilot to the operational phase in January 2017. Learn how the EU Commission, the WHO IVD Prequalification Program and other emerging regulators are participating and utilizing parts of MDSAP. Understand where you can find MDSAP information now and as the program moves forward.
Q & A SESSION WITH KIMBERLY TRAUTMAN: 5-10 MINUTES CLICK HERE TO SUBMIT YOUR QUESTION		
12:00 pm - 1:30 pm	Hot Buffet Lunch - Vendor Exhibit Area Open	
1:30 pm - 2:10 pm 	**Vincent Tong** Compliance Officer, Inspectorate Program, Health Canada	**API Inspections** The Food and Drug Regulations were amended in November 2013 to incorporate the regulation of active pharmaceutical ingredients (API). Since the regulations came into force, the initial phase of licensing and inspection has been underway. This presentation will also address new API Regulations, new revised API Inspection Programs, upcoming changes to API Compliance, and major compliance issues and possible solutions.
Q & A SESSION WITH VINCENT TONG: 5-10 MINUTES CLICK HERE TO SUBMIT YOUR QUESTION		
2:15 pm - 2:55 pm 	**Raju Raghavan** Regional Regulatory Compliance & Enforcement Officer, Inspectorate Program, Health Canada	**Data Integrity in the Lab and Beyond** The expectation that information about a drug product's quality, safety and efficacy be scientifically sound is not new. Collecting accurate data and reporting all data for consideration in batch release decisions is critical to this objective. To achieve it, controls should be in place to ensure complete and accurate reporting, and there should be verification that these controls are effective. One key objective of any company's Pharmaceutical Quality System should be to prevent and detect issues with data integrity, in the lab and in any area handling critical GMP data. This presentation will look at: Health Canada's expectations for data integrity, aligned with the Food & Drug Regulations and guidelines set by other Regulatory Authorities; observations cited in cases where those expectations were not met; upcoming revisions to the GMP Guidance Document, GUI-0001.
Q & A SESSION WITH RAJU RAGHAVAN: 5-10 MINUTES CLICK HERE TO SUBMIT YOUR QUESTION		
3:00 pm - 3:30 pm	Afternoon Break - Vendor Exhibit Area Open	

Conference Also Available Online!

AGENDA (CONTINUED)

3:30 pm - 4:10 pm 	**Dr. Herman C. Lam** CEO, Powder Pharma Coating Inc.	**Electrostatic Dry Powder Coating Technology for Solid Pharmaceutical Dosage Forms** Recent advances in electrostatic dry powder coating (EDPC) on organic substrates suggest that EDPC may become the next generation of coating technology for pharmaceutical and nutraceutical products. EDPC is an environmentally friendly technology that involves electrostatic deposition of charged ultrafine (pharmaceutically acceptable) coating materials on tablets or pellets inside a grounded (conventional) pan coater. It is an enabling technology that can be applied to the formulation and manufacturing of a wide range of immediate as well as modified release tablet or pellet products. Electrostatic dry powder coating and its applications for taste masking, enteric (delayed) release and extended release of drugs will be discussed in the presentation.
Q & A SESSION WITH HERMAN LAM: 5-10 MINUTES CLICK HERE TO SUBMIT YOUR QUESTION		
4:15 pm	Closing Remarks	

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PSG Member :	$350 + $45.50 HST = $395.50
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Academia: (University/College Professor)	$200 + $26 HST = $226.00
Student:	$99 + $12.87 HST = $111.87
NEW Web-Conferencing : (Includes Certificate & Course Notes)	$149 + $19.37 HST = $168.37

All registration fees except web conferencing include: continental breakfast, break refreshments, hot lunch, certificate of attendance, and course notes.

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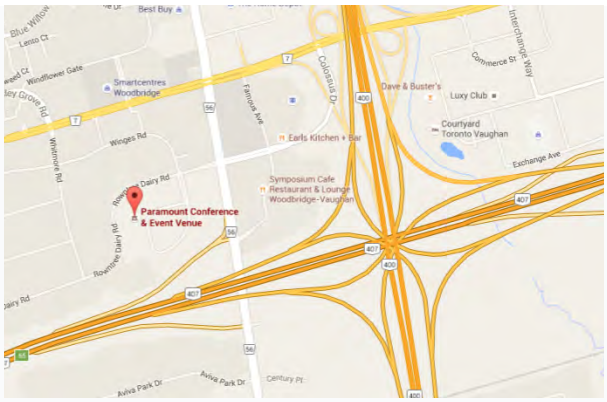
Login & Register Online CLICK HERE

Call 416-649-7782 or 1-877-PSG-2077

CONFERENCE LOCATION:

Paramount Conference & Event Venue
222 Rowntree Dairy Rd
Woodbridge, ON, L4L 9T2
(905) 326-3000



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Pharmaceutical Sciences Group (PSG)
4646 Dufferin Street, Unit 6, Toronto, ON, M3H 5S4
Tel: 416-649-7782 Fax: 416-649-7725
Website: www.psg.ca Email: info@psg.ca