2ND ANNUAL SYMPOSIUM
Clinical & Pharmaceutical Solutions through Analysis
Where Technology and Solutions Meet

On The Way to Innovation: Pharmaceutical/Analytical Technology, Regulation and Knowledge Management

August 3 - 5, 2015
Club Transatlântico
São Paulo

MEETING PROGRAM
GC-2’s specialty: results.

Precise, continually updated information is directly related to the efficiency of the best products and services. In order to fully meet its clients’ expectations in pharmaceutical and biotechnological research and development, GC-2 structures projects and proposes the most appropriate laboratory solutions, focusing on management and effective results. This is how GC-2 facilitates safe, profitable decisions, guaranteeing the success of your investment. After all, what impact will the wrong scientific research have on the success of your investment?

Focus Areas

LABORATORY SOLUTIONS

The GC-2 business model is based on control and management of the laboratory process, founded on specialized R&D knowledge. For this reason, GC-2 works with structured clinical laboratories with different specialty area focuses. GC-2 provides central laboratory solutions that strictly follow certified quality control programs and comply with best scientific practices. GC-2’s services are built on the foundation of detailed knowledge specific to laboratory and research processes gained through the accumulated experience of its professional team over many years.

- Pre-implementation support for projects
  - Feasibility studies
  - Project-scope consulting
  - Project development and write-up
- Results with Flag and Delta-Flag customized for each protocol
- Approval and management of laboratories for specialized requirements
- Implementation and validation of tests on demand
- Harmonization of laboratory methodologies and assays
- Post-analytic advisory services: clinical laboratory interpretation

PROJECT MANAGEMENT

GC-2 is the first company with exclusive knowledge of management and control of research laboratory processes for pre-clinical and clinical stages.

With a computer system developed especially for integrated information management, GC-2 provides the client and researchers pre-defined levels of access so they can monitor all research in real time by accessing results and management reports. This not only streamlines decision making, but also considerably increases research and investment safety margins.

- Support when implementing protocols and trials
  - Dedicated system set up
  - Training for each protocol or trial
  - Specific laboratory manual for each project
- Pre-clinical and clinical development project management
- Network structuring and management
- Post-installation support
  - Query management
  - Laboratory monitoring
  - Delivery of results through web portal or data transfer
- Technical support for pre-clinical and clinical regulatory stages
August 4, 2015

Dear Colleagues:

On behalf of the organizing committee and our sponsors, it is our pleasure to welcome you to the 2nd annual Brazilian Symposium on Clinical and Pharmaceutical Solutions through Analysis (CPSA BRASIL 2015). Our meeting and related events will feature lively discussions, memorable interactions, and the open sharing of real-world experiences that focus on the unique challenges facing the modern analytical laboratory, regulations and knowledge management.

The goal of CPSA BRASIL is to provide timely, in-depth reviews of innovative technology and emerging practices through open discussion of industry related issues and needs. Our intent is to feature scientific leaders within diversified symposia and sponsored events specially designed to be highly interactive where professionals can openly share their experiences and visions in a collegial setting – where technology and solutions meet… where together we progress!

We are delighted to feature two outstanding plenary speakers. On Tuesday, Professor Nathan Yates of the University of Pittsburgh will deliver a Plenary Lecture on “Differential Mass Spectrometry – Proteomics Applications in Basic, Translational and Clinical Research.” Our Plenary Lecture on Wednesday will feature Dr. Shane Needham of Alturas Analytics who will share his recent innovations and work on “Analytical Technology: From the Analytical Chemistry Bench Straight Results to Patients – Is This Really True?” Both Nathan and Shane have made significant contributions to the field ranging from quantitative proteomics to regulated bioanalysis; from fundamentals of HPLC to novel technologies for nanospray and microspray LC/MS. The combination of such diverse interests, impact, and lessons learned will provide unique perspectives, and certainly, continue to inspire future applications.

Our hope is that you will actively participate, interact, and share ideas during the event. Creativity and imagination have been key ingredients to making CPSA meetings a memorable experience all over the world. In this way, a genuine passion for the analytical sciences can lead to personal growth as well as opportunities to significantly impact the field through participation and leadership.

Special thanks go to the sponsors of this unique event. In particular, we wish to thank both SCIEX and Agilent Technologies for giving this meeting life. Muito obrigado! All CPSA sponsors share the passion and commitment for both innovative technologies and the acceleration of product development.

Enjoy the annual meeting – where technology and solutions meet… where together we progress!

Sincerely,

Mike S. Lee, Ph.D.
CPSA Founder

Rafael Barrientos
CPSA BRASIL 2015 Program Chair
2015 ORGANIZING COMMITTEE

PROGRAM CHAIR
Rafael Barrientos
Eurofarma Laboratórios S.A.

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University of São Paulo

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Naidong Weng
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Nathan Yates
University of Pittsburgh

LOGISTICS & MANAGEMENT

Communications & Media
Martin Steel
McKinley Scientific

Carla Marshall-Waggett
New Objective

Management & Correspondence
Mike Lee
Milestone Development Services
The CPSA annual symposium is made possible by the broad-based support of industry sponsors. The passion for the analytical sciences and the accelerated discovery and development of pharmaceuticals is shared by each sponsor. As a result, the event is dedicated to promoting awareness and understanding of the issues and needs associated with research and development in the hopes of inspiring significant advances in the field.

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PRE-CONFERENCE WORKSHOPS

Monday  August 3

EMERGING TRENDS (AND CHALLENGES!) ON PHARMACEUTICAL ANALYSIS

LOCATION: Sindusfarma

Sponsored by SCIEX

8:00 AM - 8:30 AM  Registration and Reception

8:30 AM - 9:00 AM  Keynote Address: Introduction to Mass Spectrometry
  Mike Lee, Milestone Development Services

9:00 AM - 10:00 AM  Mass Spectrometry Method Development
  Renato Romano, U.S. Pharmacopeia

10:00 AM - 10:30 AM  Break

10:30 AM - 12:00 PM  BioBA Solution: Biologics Bioanalysis Made Easy
  Alana Figueiredo, SCIEX

12:00 PM - 1:30 PM  Lunch

1:30 PM - 4:30 PM  New Challenges of Pharma Companies on Product Analysis CRO
  Leonardo Teixeira, ICF

  Impurities Profiling Analysis: The Power of the ImpurityPilot Software
  Helio Martins, SCIEX

  Regulatory Affairs Overview
  David Abramovitz, SCIEX

4:30 PM - 4:45 PM  Closing Ceremonies
  Mike Lee, Milestone Development Services

START GROWING SCIENTIFIC BUSINESS

LOCATION: Trabulsi Auditorium
Institute of Biomedical Sciences (Building III)
University of São Paulo, Av. Prof. Lineu Prestes, 2415
Cidade Universitária, Butantã, São Paulo
SP - CEP 05508-000

8:00 AM - 8:30 AM  Registration and Reception

8:30 AM - 12:00 PM  Scientific Business Development Overview
  Shane Needham, Alturas Analytics

  Brazilian Scientific Business Scenario
  Daniel Lebre, CEMSA

  Scientific Business Strategy
  Fernando Haaland, Labtec

  Marketing & Communication Plan
  Marcia Metran, CEMSA

12:00 PM - 1:15 PM  Lunch

1:15 PM - 5:15 PM  Dealing with Scientific Business Units
  Renato Abreu, SCIEX

  Scientific Business Lab Infrastructure
  Marcelo Coelho, PEAK

  The Spark Approach
  Julio Ferreira, ICB/USP

  Patents in Brazil: Recent Developments and Future Perspectives
  Caio Rodrigues, Magellan-IP

  The Role of Technology Transfer in The Development of the Scientific Business: The IPEN Scenario
  Anderson Zanardi Freitas, IPEN/NIT

5:15 PM  Closing Ceremony
O que acontece nos laboratórios torna-se parte de nossas vidas.

Desenvolvimento de medicamentos inovadores que nos tornam mais saudáveis. Controle de Qualidade para os alimentos que comemos, as bebidas que bebemos e a água de que dependemos. Soluções para a segurança de plásticos, polímeros e materiais sintéticos que se tornam as roupas que vestimos, os brinquedos com que nossas crianças brincam. Diagnóstico precoce e tratamento de doenças. Padrões elevados para um ambiente mais limpo.

Tudo isso começa com a tecnologia analítica da Waters – e a ciência do que é possível.

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Several key performance attributes are required for essential overall performance. While each may be independent of the other, the coordinated control of these parameters is essential to improving your overall analysis.

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We need this to be **easy to use**... But we don’t want to give up any **performance**."

*Nathan Yates*  
*University of Pittsburgh*

**High-performance**  
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*Shane Needham*  
*Alturas Analytics*
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McKinley Scientific transforms the business of global outsourcing in the pharmaceutical and clinical life sciences by providing both standard and customized leasing options as a tool to efficient equipment management.

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More Information:
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TUESDAY, AUGUST 4

8:30 AM – 9:00 AM
OPENING REMARKS
Welcome
Mike Lee, Milestone Development Services
Objectives, Format, and Opening Remarks
Rafael Barrientos, Eurofarm Laboratórios S.A.

9:00 AM -10:00 AM
PLENARY LECTURE
Differential Mass Spectrometry – Proteomics Applications in Basic, Translational, and Clinical Research
Nathan A. Yates, University of Pittsburgh

10:30 AM - 12:00 PM
SYMPOSIUM SESSION
Fixed Drug Combination (FDC):
BA/BE, Pharmaceutical Equivalence and Regulatory Updates
Chair: Maurício Magalhães, EMS

▶ ANVISA Guidelines for FDC
Gustavo Santos, CETER/ANVISA

▶ Statistical Approach for FDC Clinical Assays
Marcelo Angelo da Costa, CETER/ANVISA

▶ CRO Perspective
Leonardo Teixeira, ICF

12:15 PM – 1:15 PM
SPONSORED LUNCH & ROUNDTABLE EVENT
Sponsored by SCIEX

▶ Validation of LC/MS Instruments for Part 11 Compliance - How To Migrate to An Integrated Compliance Strategy for Your Lab
Dave Abramowitz, SCIEX
PROGRAM AGENDA

Tuesday  August 4

1:30 PM – 3:00 PM  SYMPOSIUM SESSION

Clinical Trials in Brazil: Regulatory Updates and Challenges
Chair: Carlos Kiffer, GC2

► Pharmaceutical Industry Perspective
Renato Peimonte Ribeiro, Libbs Farmacêutica Ltda.

► Class Association Perspective
Anna Paula Ruenis, ABRACRO

► CRO Perspective
José Emílio S. Neto, Icon Clinical Research

3:00 PM - 3:30 PM  BREAK / ROUNDTABLES

3:30 PM - 5:00 PM  SYMPOSIUM SESSION

New Drug Release and Pharmaceutical Process Technologies: An Overview
Chair: Gabriel Araújo, University of São Paulo

► Scientific & Technological Perspective
Luis Alexandre Pedro de Freitas, University of São Paulo

► Industry Perspective
Miller Nunes de Freitas, Libbs Farmacêutica Ltda.

► Regulatory Perspective
Natalia Bellan, Inteligência Sanitária

5:00 PM - 6:00 PM  POSTER & VENDOR SESSION

18th Annual Symposium on Clinical & Pharmaceutical Solutions through Analysis

Make plans now to attend CPSA 2015! This annual meeting began in 1998 and has evolved into the premier industry-led event dedicated to promoting awareness of issues and needs associated with research and development.

Short Courses • Symposia • Roundtables • Poster Session
Vendor Session • Exhibition • Workshops
Colloquium Series • Charity Events

October 5 - 8, 2015
Sheraton Bucks County Hotel
Langhorne, PA

Where Technology and Solutions Meet
7:30 AM - 8:30 AM REGISTRATION & CONTINENTAL BREAKFAST

8:30 AM – 9:30 AM PLENARY LECTURE
Analytical Technology: From the Analytical Chemistry Bench Straight Results to Patients: Is This Really True?
Shane Needham, Alturas Analytics

9:30 AM – 10:00 AM BREAK & ROUNDTABLES

10:00 AM - 11:30 AM SYMPOSIUM SESSION
Biosimilars: Where Are We and Where Are We Going?
Chair: Vanda Magalhaes, Eurofarma

- Present Brazilian Regulatory Scenario and Trends
  Marcelo Moreira, ANVISA
- How far should a comparability exercise goes?
  Priscila Scheinberg, Orygen
- Are Switching Studies Necessary for Interchangeability?
  Maritê Faria, Amgem

11:45 AM – 12:45 PM SPONSORED LUNCH & ROUNDTABLE EVENT
Sponsored by Agilent Technologies

- Agilent LC-MS Solutions for Biopharma
  Maurício Ribeiro Marques, Agilent Technologies
- Metabolomic studies in a Brazilian population - Use of GC/MS for Metabolite Phenotype Characterization
  Gabriela Venturini, University of São Paulo

1:00 PM – 2:30 PM SYMPOSIUM SESSION
Drug Discovery: Are We Prepared for That?
Chair: Gabriela Barreiro, Eurofarma

- Advances in natural-product-based screening from Brazilian Biomes
  Cristina Dislich Ropke, Phytobios
- The Role of Academia in Drug Discovery
  Lidia Moreira Lima, UFRJ
- The Role of Information Technology in the Development of New Drugs
  Cristina Mendes, INPI
PROGRAM AGENDA

Wednesday August 5

2:30 PM – 3:00 PM BREAK & ROUNDTABLES

3:00 PM - 4:30 PM SYMPOSIUM SESSION

Personalize Medicine with Better Diagnoses, Better Treatment Through Innovative Analytical Methods
Chairs: Daniel Lebre, CEMSA and Dulce Casarini, UNIFESP

➤ Therapeutic Imunosuppressor Monitoring using Dried Blood Spot and LC-MS/MS
  Daniel Lebre, CEMSA

➤ Clinical Biomarkers
  Dulce Casarin, UNIFESP

➤ Application of Directed Proteomics in Clinical Biochemistry
  Valdemir Melechco Carvalho, Fleury

4:30 PM - 5:00 PM WRAP-UP & ADJOURN

Rafael Barrientos, Eurofarma Laboratórios S.A.
Mike Lee, Milestone Development Services

6:00 PM FOOTBALL & BARBECUE

Sponsored by CEMSA & Peak Scientific

Innovative Approaches to Reduce Attrition and Predict Clinical Outcomes

7th Annual Shanghai Symposium on Clinical & Pharmaceutical Solutions through Analysis

Make plans now to attend CPSA Shanghai 2016! This annual meeting is evolving into the premier industry-led event dedicated to promoting awareness of issues and needs associated with global research and development.

Short Courses • Symposia • Roundtables
Expo • Workshops • Student & Innovator Awards

April 20 - 22, 2016
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