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

August, 3rd to 5th, 2015 – São Paulo/SP

2015 Program Chair
Rafael Barrientos, Ph.D.
Eurofarma Laboratórios S.A.
Opening session

Mike Lee, PhD – Milestone Development Services
Rafael Barrientos, PhD – Eurofarma Laboratórios S.A.
CPSA Vision

CPSA - Clinical and Pharmaceutical Solutions through Analysis represents a broad vision to promote new technologies and solutions across disciplines and forge global paths for education and training.

World-Class Programs
Unique focus on industrial issues and needs featuring internationally recognized scientists and premier research.

Thinking Big!
Provide an ideal environment to benchmark a strategy or capture an epiphany. Big ideas, creativity and involvement are openly encouraged. Imagination needed!

Diversity and Study Abroad
Promote interdisciplinary education, training and career development on a global level with unique focus on young scientists and students.

Technological Rigor
Support the highest level of technology evaluation to assist professionals with the identification of practical considerations to perform an analysis that meet specific regulations such as FDA or CLIA with the highest level of performance (accuracy, sensitivity, throughput, cost).

Interaction and Relationships
Facilitate the growing interest in industrial research with special events dedicated to promoting a collegial atmosphere and fostering friendship.

CPSA is User Friendly!

www.cpsa-brasil.com
Global Community

Langhorne, PA USA
São Paulo, Brazil
Shanghai, China
Is there a “pathway” or trail to follow for Innovation?

The History of a Telephone Pole...
Clinical & Pharmaceutical Solutions through Analysis
August 3 – 5, 2015 São Paulo, Brazil

Where Technology and Solutions Meet
Clinical & Pharmaceutical Solutions through Analysis
August 3 – 5, 2015    São Paulo, Brazil

Where Technology and Solutions Meet
How to be inserted into the Innovation way?

Creating an Innovation Platform
Four corner Innovation Platform for Pharmaceutical Industry
Why Brazil is moving toward Innovation in Pharmaceutical market?

Are we prepared for Innovation?
**TOTAL PHARMACEUTICAL MARKET FORECAST**

<table>
<thead>
<tr>
<th>Year</th>
<th>Global Sales (US$Bn)</th>
<th>Global Growth (%)</th>
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<tbody>
<tr>
<td>2009</td>
<td>770</td>
<td>4%</td>
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<tr>
<td>2010</td>
<td>820</td>
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<td>2011</td>
<td>870</td>
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<td>2012</td>
<td>920</td>
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<td>2013</td>
<td>970</td>
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<td>2014</td>
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<tr>
<td>2015</td>
<td>1,070</td>
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<tr>
<td>2016</td>
<td>1,120</td>
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<tr>
<td>2017</td>
<td>1,170</td>
<td>12%</td>
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<tr>
<td>2018</td>
<td>1,220</td>
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<tr>
<td>2019</td>
<td>1,270</td>
<td>14%</td>
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**PHARMERING MARKETS EVOLUTION**

- **2009-2019: Pharmerging Markets Sales Dynamics**
- **Sales (US$Bn)**
  - Total: 1,270
  - Brasil: 309
  - Mexico: 200
  - Russia: 114
  - India: 72
  - Brazil: 45
  - Other Pharmerging: 40

**50% of Top 20 are pharmering**

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**Pharmerging Markets by 2019**

- **BRASIL**: 54% (22.0% CAGR)
- **MÉXICO**: 18% (7.2% CAGR)
- **ARGENTINA**: 8% (3.3% CAGR)
- **AM CENTRAL**: 5% (2.1% CAGR)
- **COLOMBIA**: 4.5% (1.8% CAGR)
- **CHILE**: 4% (1.5% CAGR)
- **EQUADOR**: 3% (1.1% CAGR)
- **PERU**: 2% (0.9% CAGR)
- **VENEZUELA**: 1% (0.6% CAGR)
- **URUGUAY**: 0.2% (12.0% CAGR)

*Where Technology and Solutions Meet*
NEW LIFECYCLES FOR INNOVATIVE DRUGS

New small molecule lifecycle? (e.g. incivox launched October 2011, discontinued August 2014, Sovaldi already trending down after Dec 2013 launch)

Loss of exclusivity

Golden age biologic drug i.e. Remicade, 16 years from launch to mature market biosimilars

Future biologic drug lifecycle?: eroded by biosimilars at increasing rates, under pressure from new innovative competition

Typical small molecule drug lifecycle (Lipitor, Plavix)

Time from launch in a developed market

Sales
How the Innovation in Pharmaceutical Industry is doing in Brazil?

- **Radical**
  - NCE (herbal medicines)
- **Incremental**
  - FDC
  - New Pharmaceutical Technology
- **Licensing**
  - Patented molecules
- **Biosimilars**
  - Orygen and Bionovis
  - Companies with specific pipelines
Scientific Program

Official language: English (no simultaneous translation)
Specific discussions could be done in Portuguese
Vendor and Poster Session
Sponsored Lunch
Traditional Soccer & Barbecue
Every session should consider:

- “Think global, act local”
- “Working together, progressing together”
- “CPSA is a meeting of friends speaking on science”
- “Informal forum for debating on relevant issues for pharmaceutical development”
- “English as universal language”
Distinguished Plenary Lecturers

Nathan Yates
University of Pittsburgh
Pittsburgh, Pennsylvania  USA

Differential Mass Spectrometry – Proteomics Applications in Basic, Translational, and Clinical Research

Shane Needham
Alturas Analytics
Moscow, Idaho  USA

Analytical Technology: From the Analytical Chemistry Bench Straight Results to Patients–Is This Really True?
Day 1 (Aug, 4th)

- Opening session
- Plenary Lecture
  - “A global overview on biomarkers, large molecules and proteomics” – Prof. Nathan Yates (University of Pittsburg)
- Session 1
  - “Fixed Drug Combination (FDC): BA/BE, pharmaceutical equivalence and regulatory updates” – Maurício Magalhães (EMS)
- Sponsored Lunch by Sciex
- Session 2
  - “Clinical trials in Brazil: regulatory updates and challenges” – Carlos Kieffer (GC2)
- Session 3
  - “New drug release and pharmaceutical process technologies: an overview” – Prof. Gabriel Araújo (University of São Paulo)
- Poster & Vendor session / Cocktail
  - Daniel Lebre - CEMSA & Shane Needham - Alturas Analytics
Day 2 (Aug, 5th)

- **Plenary Lecture**
  - “Analytical technology: From the analytical chemistry bench straight results to physicians: is this really true?” – Shane Needham (Alturas Analytics)
- **Session 4**
  - “Biosimilars: where are we and where are we going” – Vanda Magalhães (Eurofarma Laboratórios S.A.)
- **Sponsored Lunch by Agilent**
- **Session 5**
  - “Drug discovery: are we prepared for that?” – Gabriela Barreiro (Eurofarma Laboratórios S.A.)
- **Session 6**
  - “Personalize medicine with better diagnoses, better treatment through innovative analytical methods” – Daniel Lebre (CEMSA) & Dulce Casarini (Federal University of São Paulo)
- **Closing session**
- **Traditional Soccer & Barbecue (CPSA Brasil 2015)**
  - CEMSA & Peak Scientific
Thank you and welcome to CPSA Brasil 2015!