

# The 3<sup>rd</sup> Brazil-Japan Seminar of Regulations on Pharmaceuticals and Medical Devices

Date: October 4<sup>th</sup>, 2016, 9:00 to 18:00

Venue: Auditorium Hotel NOVOTEL Jaraguá, Rua Martins Fontes 71 - Bela Vista

Number of participants: 170

Hosted by ANVISA, MHLW/PMDA/JETRO

Supported by Industry of Pharmaceuticals and Medical Device

Brazil: INTERFARMA/ SINDUSFARMA/ ABIMO/ABIMED

Japan: Japan Pharmaceutical Manufacturers Association (JPMA) /Japan Medical Device Industry

	Sessions
9:00 - 10:00	<b>Opening Remarks</b> <ul style="list-style-type: none"> <li>• Dr. Jarbas Barbosa, Director President, ANVISA</li> <li>• Mr. Takahiro Nakamae, Consul-General of Japan in São Paulo</li> <li>• Mr. Yoshihiko Sano, MHLW</li> <li>• Dr. Takao Yamori, Executive Director, PMDA</li> <li>• Mr. Atsushi Okubo, JETRO São Paulo</li> <li>• Mr. Masayuki Suzuki, Terumo Medical do Brasil (Representative of JFMDA )</li> <li>• Mr. Jofre Moraes, ABIMO (Representative of Brazilian Industry)</li> </ul>
10:00 - 10:30	<b>Recent Update since last symposium</b> Moderator - Lilian Cunha <ul style="list-style-type: none"> <li>• Yoshihiko Sano, MHLW</li> <li>• Patricia Tagliari, ANVISA</li> </ul>
10:30 - 11:30	<b>Enhancing Review Efficiency of Pharmaceuticals and Medical Devices (Regulatory Convergence)</b> <ul style="list-style-type: none"> <li>• Efforts on the Japanese side PMDA - Mr. Naoyuki Yasuda</li> <li>• Enhancing marketing authorization of drugs and medical devices in accordance to the international best practices ANVISA - Balbiana Sampaio Oliveira</li> </ul> Question & Answer
11:30 - 11:45	Coffee Break
11:45 - 12:45	<b>Enhancing Review Efficiency of Pharmaceuticals and Medical Devices (Regulatory Convergence )</b> <b>[Pharmaceuticals]</b> <ul style="list-style-type: none"> <li>• Proposal from Japanese industry - Takeshi Shigihara - JPMA</li> <li>• Proposal from Brazilian industry - Rosana Mastellaro -- Sindusfarma</li> </ul> <b>[Medical Devices ]</b> <ul style="list-style-type: none"> <li>• Proposal from Japanese industry - Kotaro Ichikawa - Nihon Kohden do Brasil</li> <li>• Proposal from Brazilian industry - Angelica Marques - ABIMED</li> </ul> Panel Discussion

12:45 - 13:45	Lunch Time
13:45 - 14:45	<b>Strengthening cooperation between industry and regulator, request from industry</b> <ul style="list-style-type: none"> <li>Japanese industry's activities in Brazil Ms. Kiyo Tsujimoto, JETRO São Paulo</li> <li>Brazilian industry's activities for international convergence Dr. Antonio Britto - INTERFARMA</li> </ul> Q&A
14:45 - 15:45	<b>Quality Certification on Medical Devices (QMS) and Pharmaceuticals</b> <p>Moderator - Cleber Ferreira - ANVISA</p> <ul style="list-style-type: none"> <li>PMDA - Recent Trends Ms. Naoko Sato, PMDA</li> <li>ANVISA - Results of MDSAP Mr. Fabio Quintino, ANVISA</li> <li>Proposal from Brazilian Industry Joffre Moraes - ABIMO</li> </ul> Panel Discussion
15:55 - 16:10	Coffee Break
16:10 - 17:10	<b>Cooperation on Pharmacopoeia and others</b> <p>Moderator - Mr. Yoshihiko Sano - MHLW</p> <ul style="list-style-type: none"> <li>Japanese Pharmacopoeia Dr. Naoyuki Yabana, PMDA</li> <li>Brazilian Pharmacopoeia Mr. Varley Sousa , ANVISA</li> <li>Proposal from Brazilian Industry Jair Calixto - Sindusfarma</li> </ul> Panel Discussion
17:10 - 17:30	<b>Closing Remarks</b> <p>ANVISA Ms. Patricia Tagliari PMDA Dr. Takao Yamori</p>

For registration, please access: [www.jetro.go.jp/brazil](http://www.jetro.go.jp/brazil)