

FRI, SEP 9 AT 8:00 AM

SÃO PAULO, BRAZIL

Regulatory Innovations: FDA and ANVISA Compliance Trends

WHO SHOULD ATTEND?

LEADERS FROM THE INDUSTRY SUCH AS:

QA | COMPLIANCE | MANUFACTURING | LABORATORY OPERATIONS

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| 8:00 - 9:00 AM | Registration, Coffee & Networking - 1 hr. |
| 9:00 - 9:10 AM | Welcome Dr. Nelson dos Santos Júnior, SINDUSFARMA - 10 min. |
| 9:10 - 9:20 AM | Opening Remarks on Innovation and Compliance Dr. Lauro D. Moretto, President, Academia Nacional de Farmácia - 10 min. |
| 9:20 - 9:40 AM | Agenda, Objectives and Recognitions Elizabeth Plaza, Founder & Chairwoman, Pharma-Bio Serv - 20 min. |

REGULATORY TRACK

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| 9:40 - 10:10 AM | Single Audits Program for Medical Devices and Expectations for API's (Pre-Recorded Presentation) Kimberly A. Trautman, Executive Vice President, Medical Device International Services at NSF International, Former FDA - 30 min. |
| 10:10 - 10:25 AM | Coffee Break & Networking - 15 min. |
| 10:25 - 11:10 AM | Drug Products ANVISA Approach Dr. José Carlos Magalhães da Silva Moutinho - Director of Coordination, ANVISA - 45 min. |
| 11:10 - 11:40 AM | FDA Overseas: Current Issues Regarding FDA's Evolving Approach to Global Regulation Scott Gottlieb, Former FDA Deputy Commissioner for Medical and Scientific Affairs - 30 min. |

INDUSTRY TRACK

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| 11:40 - 12:00 PM | Design of Facilities to comply with Global Health Authorities Eng. Luis Merle, CMA Architects & Engineers LLP - 20 min. |
| 12:00 - 1:30 PM | Lunch Recess - 1.5 hr. |
| 1:30 - 2:00 PM | Trends on FDA Compliance: Registrations, ICH Q11 and ICH Q12 Magaly Aham, US RAC, VP of Compliance, Pharma-Bio Serv - 30 min. |
| 2:00 - 2:30 PM | Trends on FDA Compliance: Quality Metrics and Continued Process Verification (CPV) Elizabeth Plaza, Founder & Chairwoman, Pharma-Bio Serv - 30 min. |
| 2:30 - 3:00 PM | Coffee Break & Networking - 30 min. |
| 3:00 - 3:30 PM | Inspection Trends and Industry Experience with FDA and ANVISA Dr. Fernando Otero, Executive Director Operations Management, MSD, SP Brazil - 30 min. |
| 3:30 - 4:00 PM | The Benefits of Single Audits and Rational New Challenges Dhalia Gutemberg, M. Sc., Technical Consultant, Camara Brasileira de Diagnostico Laboratorial - 30 min. |
| 4:00 - 4:30 PM | The Role of INCQS in the Quality Control of Biologics and Biotechnological Medicines / Eduardo Chaves Leal, Director of Fiocruz, Oswaldo Cruz Foundation, National Institute for Quality Control in Health - 30 min. |

JOINT PANEL

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| 4:30- 5:00 PM | Successful Inspections and Product Approvals Panel Discussion: FDA, ANVISA, Industry Speakers and Q & A's - 30 min. |
| 5:00 PM | Networking |