Joint Conference on
8th International Conference and Exhibition on Pharmaceutical Regulatory Affairs and IPR
&
8th International Conference and Exhibition on Pharma Audit, GMP, GCP & Quality Control

	SCIENTIFIC PROGRAM
8:30-9:30	REGISTRATIONS
9:30-10:00	OPENING CEREMONY
	KEYNOTE FORUM
10:00-10:05	INTRODUCTION
10:05-10:50	Title: A Blueprint for Outsourcing Audits of Approved GxP Validations
	Michael D Spangler, Spangler Consulting LLC, USA
10:50-11:35	Title: Quality Management and Quality Audit According to GxP/GMP Requirements
	Eleonora Babayants, Galaxy Consulting, USA
	GROUP DISCUSSIONS
	PANEL DISCUSSION
	Networking Refreshment 11:35-11:55
	SESSION INTRODUCTION

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	Session: Good Manufacturing Practices: The Gap within Current GMP Guidelines (cGMP) & GxP in Pharmaceuticals Good Clinical Practices & Good Laboratory Practices| Validation| Quality Control | Quality Assurance |Regulatory Communications and Submissions |Impact of Brexit on Regulatory Framework |Regulatory Communications and Submissions Regulatory Requirements for Pharmaceuticals
	Session Chair: Eleonora Babayants, Galaxy Consulting, USA
	Session Co-Chair: Joel Finkle, ACUTA LLC, Marlborough, MA USA
	PLENARY SESSIONS
11:55-12:20	**Title: Continuous Reactions and the FDA**
	Aysu Yurdasiper Erdem, Ego University, Izmir, Turkey
12:20-12:45	**Title: Accelerating patient access to medicines in Africa**
	OumKaltoum Lahlou, MERCK, Morocco
12:45-13:10	**Title: Crisis of Quality Management**
	Raminder Pal Singh, Ursapharm Arzneimittel gmbh, Germany
	PANEL DISCUSSION
	Networking Lunch 13:10-14:30
	KEYNOTE FORUM

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14:30-15:15	**Title: A Personal History of Regulatory Submissions Technology**
	Joel Finkle, ACUTA LLC, Marlborough, MA USA
15:15-16:00	**Title: Pharma Regulatory Affairs As Well As Importance Of ISO 9001:2015, ISO 14001:2004, ISO 18001:2007 Standards And Related Audits For Quality Pharma Products**
	Manalapan R, RVS College of Pharmaceutical Sciences, India
	SPECIAL SESSIONS
16:00-16:25	**Title: Planning for and Complying with the IDMP Standard for Europe**
	Joel Finkle, ACUTA LLC, Marlborough, MA USA
16:25-17:25	**Title: GxP/GMP and its Consequences for Documentation and Information Technology Systems**
	Eleonora Babayants, Galaxy Consulting, USA
	PANEL DISCUSSION
	Networking Refreshment 17:25-17:45
	VIDEO PRESENTATIONS
17:45 -18:10	**Title: Navigating Government Healthcare Reforms and their impact in USA, Europe, Turkey & Emerging Markets**

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	Yavuz Selim SILAY , ICG (Istanbul Consulting Group), Turkey
18:10-18:35	**Title: Regulatory Affairs**
	Syed Abid Hassan, Jamjoom Pharmaceuticals Company, Kingdom of Saudi Arabia
	PANEL DISCUSSION
	Day 1 Closes
	DAY 2
	KEYNOTE FORUM
8:30-8:35	**INTRODUCTION**
8:35-9:20	**Title: Maximizing the Impact of Strong Compliance Audits**
	Jennifer Lopez, Director, Metrics, USA
9:20-10:05	**Title: Investigations, RCA, CAPA, and why "Human Error" is not the true root of the problem**
	Joe Helmstetler, Rhizo Sciences, USA
	PANEL DISCUSSION
	Networking Refreshment 10:05-10:25
	SESSION INTRODUCTION

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	Session: Regulatory Affairs | Current Regulations and Quality Standards | Regulatory Challenges for Medical Devices | Regulatory Affairs in Pharmacovigilance | Quality Control| Quality Assurance | Quality Assurance Audits in Pharma Industries | Quality Management System in Testing Laboratories
	Session Chair: Teginder Singh, Johnson & Johnson, USA
	Session Co-Chair: Joe Helmstetler, Rhizo Sciences, USA
	PLENARY SESSIONS
10:25-11:50	**Title: The Status of Diabetes in Guyana, it's Herbal and Synthetic Drug Treatments**
	Raymond C. Jagessar, University of Guyana, Guyana
11:50-11:15	**Title: Risk Based Manufacture of Pharmaceutical Products**
	Muhammad Naeem, Indus Pharma (Pvt.) Ltd., Pakistan
11:15-11:40	**Title: Quality Risk Management: Quality Control Perspective**
	Prof JA Kolawole, University of Jos. Jos Nigeria
11:40-12:05	**Title: Antimicrobial Activity Of The Uncombined And Combined Aqueous Extract Of Phyllanthus Acidus, Sphagneticola Trilobata Leaves And Doliocarpus Dentatus's Bark Against Human Pathogenic Microorganism In The Absence And Presence Of Zn2+ Cations**
	Raymond C. Jagessar, University of Guyana, Guyana

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	Network Lunch: 12:05-13:05
13:05-13:30	**Title: The impact of the Global regulatory agencies expectations and Its impact on small and Medium Business Units of Indian Pharmaceutical industrial progress and the Role of Software in reaching the Global regulatory Expectations**
	Dr. Sagaram.Sudhakar, Wollega University, Ethiopia
	Key Note Forum
13:30-14:15	**Title: Good Manufacturing Practices For Sterile Pharmaceutical Products**
	Rashid Mahmood, SURGE Laboratories Private Limited Pakistan
	Video Presentations
14:15-14:35	**Title: Medical Device**
	Syed Abid Hassan, Jamjoom Pharmaceuticals Company, Kingdom of Saudi Arabia
	Panel Discussions
	Day 2 Closes