



Global Bio-India 2019 Road Show – Pune | 12 Nov 2019 Theme - Going Global with your Med-Tech Innovations

This Road Show intended to publicize the Global Bio-India Summit 2019, took place in Aerocity Delhi from 21 to 23 November 2019. This Road Show was focused on understanding regulatory and market requirements for commercializing med-tech products (Medical Devices and In-vitro Diagnostics) globally (EU, USA, Japan, Mexico, Canada and Australia). Sessions as part of this the event were focused on the Medical Device Single Audit Program (MDSAP) mechanism to enable entry in Australia, Mexico, Canada, Japan and the United States markets and EU regulations for In-vitro Diagnostics. Sessions were also included insights into market entry decision making, knowledge of sales and marketing channels, mechanisms to establish connects with importers and challenges likely faced in global markets.





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Session on **EU Regulations for In-vitro Diagnostics** was taken by Lakshman Balajepalli, Head, Quality and Regulator, RAS Lifesciences Pvt Ltd. A Master of Sciences (Biochemistry) from a prestigious medical school in India. Over 28 years' experience in Life sciences industry (IVD and Human vaccines) which includes in over 20 years in IVD industry in R&D, manufacturing, QC, QA , Regulatory as well as of 8+ years' experience in process development, QA of human vaccines. Highly experienced in Regulatory, QMS including ISO 13485, ISO 9001, ISO 15189 systems. Faced many WHO and GMP audits. Was Consultant to overseas Biotech company for QMS. Has extensive experience in Indian MDR and QA as well as in EU IVDR, EU-MDR.



Taking Medtech products Global: Focus on Medical Device Single Audit Program which was a second session discussed by Dr Anita Joshi and highlighted the possibilities for the startups. Dr. Anita Joshi External Resource Auditor, BSI Group India Pvt. Ltd. An exciting career spanning around 18+ years in Biotech industry and 10 years in academics (NIV and Pune University). Cross functional experience of working with more than 80 organizations till date since 2001. Publications: 26 till date. Esteemed Companies I worked for include: BSI India, Thermo Fisher Scientific, Merck Millipore, Lonza India, Span Diagnostics Ltd, Advanced Enzyme Technologies, etc. I am an external resource auditor with BSI - (British Stds Institution) as an auditor and trainer for ISO 13485; MDSAP; trainer for CE marking ie IVDR.



Mr Ravi Sarangapani spoke on the tips and ideas for **Entering Overseas Markets: A Staged Approach**. Mr. Ravi Sarangapani Consultant Medical Devices Product Development Mr. Ravi previously held senior positions for Sushrut / Adler in Product Development, Sales and Marketing, Regulatory affairs. He is an accomplished professional with over 25 years in the medical device industry encompassing leadership roles in New Product Development, Quality Management and Regulatory affairs, Marketing, Sales and Business Development. Mr. Ravi has proven track record of managing the new product development process from conceptualization and market analysis through development, risk management, pre-clinical evaluation, verification and validation, test marketing to commercialization. Outstanding communication talents with proven ability to build and lead highly efficient teams, train technical professionals and to convey complex concepts in understandable terms. Especially skilled at problem analysis and resolution, strategic planning and budget controls. Strong background of interactions with Key Opinion Leaders, customers and trade channels throughout Asia, Middle East, Africa and some areas of Europe.



The Road show was closed with the enlightening panel discussion moderated by Dr Premnath V, who pointed out the questions from MedTech eco-system to the expert panelists.







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(12th Nov 2019) Global Bio - India 2019 Road Show - Pune					
Evaluation Results					
Category	Avg (Max-Min) Count				
Section 1 - Event		Rating Scale			
Overall Satisfaction with Event	6.8(5,7)16	1	Bad	2	Well below average
Satisfaction with Content	6.1(4,7)16	3	Below ave	4	Average
Satisfaction with Speakers/mentors etc	6.5(5,7)15	5	Good	6	Very Good
Satisfaction with srtructure,design and pace of event	6.3(5,7)16	7	Excellent		
Satisfaction with networking opportunities	6.2(5,7)16				
satisfaction with event logistics,arrangements	6.2(5,7)16				
Please Provide the following information					
You are a:			You became know of this event via:		
Student	9	E-mail		5	
Entreprenuer	2	Social Media		2	
Employed	4	Advt		6	
Other	1	Other		2	
Not mentioned	1	Not mentioned		2	
Please Provide any other suggestions,comments etc here					
The focus should have been more on global bio India 2019 and its importance. It was too brief and the presentation could have					
Hi Quality Resource Personnel ! Thank you!					
Please email me the entire study material on findkieron@gmail.com					