Kalam Institute of Health Technology

(Department of Biotechnology, Government of India Project)

Formative Industry leaders Research institutes Start-up partners Technology Meet (FIRST)

Minutes of the Meeting

Date(s): 21st – 22nd August, 2017

Venue: Auditorium

Objective: The main objective of the meeting is to discuss the core technologies involved in manufacturing of medical devices, to identify the critical components and explore the opportunities of doing relevant research and development to ensure that manufacturing can be done in India in future related to the prioritized medical devices.

Lead by: **Dr. Jitendar Sharma**, Executive Director, Kalam Institute of Health Technology

Participants:

1. Ms. Sonia Gandhi, Senior Manager, BIRAC
2. Mr. Kannan Neelakanta, Director, New Product Development, Cura Healthcare (P) Ltd.
3. Mr. V. Sashi Kumar, Founder & Managing Director, Phoenix Medical Systems (P) Ltd.
4. Mr. Satish Kumar M, Director, India Operations, TriMedx India (P) Ltd.
5. Mr. R.N. Sundar, Senior Technology Manager, TriMedx India (P) Ltd.
6. Mr. Subhas Punja, Managing Director, Robonik India (P) Ltd.
7. Mr. Prakash Vaidya, Robonik India (P) Ltd.
8. Mr. Gaurav Agarwal, CEO - Innvolution Imaging, Innvolution India (P) Ltd.
9. Dr. Suresh Kuppuswamy, Vice President, Skanray Technologies (P) Ltd.
10. Mr. Srikanth Bobbili, Service Engineer, Resmed India (P) Ltd.
11. Dr. A. K. Dutta, Excel Matrix Biological Devices (P) Ltd.
12. Ms. Ranjna C Dutta, Excel Matrix Biological Devices (P) Ltd.
13. Mr. Hitesh Priyavadan Shah, CEO, Shaili Endoscopy

14. Mr. Nirmal Poddar, President – Instruments, Transasia
15. Mr. Moinuddin Shaikh, Founder & Promoter, MS Enterprises
16. Mr. Akhil Gupta, Marketing Manager, Genes2Me
17. Mr. Vinod KR Sharma, Senior GM R&D, Poly Medicure Ltd.
18. Mr. Ajay Chadha, CEO, Lab Engineers India
19. Dr. Nirmala Marutirao Balwalli, Consultant, Renalyx Healthcare systems (P) Ltd.
20. Mr. Sushant Banerji, CEO, OrthoTech
21. Mr. Hardik Shah, Senior Manager, Sharma Orthopedics India (P) Ltd.
22. Dr. Inderjeet Singh, Executive Director, Advanced MedTech Solutions (P) Ltd.
23. Mr. Radu Gogoana, Head - Ambio Personal Cooling, Padmini VNA Mechatronics (P) Ltd.
24. Mr. Vijay Sharma, Owner, Life Force
25. Dr. Arun Shastry, Chief Scientific Officer, Hanugen Therapeutics (P) Ltd.
26. Mr. Sarath S Nair, Scientist/Engineer-D, BMT Wing, SCTIMST
27. Ms. Suman Kapur, Senior Professor, HOD Biological Sciences, BITS Pilani
28. Prof. Siva Sankara Sai S, Dean, Faculty of Sciences, SSSIHL
29. Dr. Sai Muthukumar, Assistant Professor, Dept of Physics, SSSIHL
30. Dr. Rupesh Ghyar, Sr. Executive Officer BETiC Lab, IIT Bombay

From KIHT:

31. Ms. Sushmitha R. C, Consultant, Regulatory Affairs, Knowledge partner
32. Mrs.Y. Madhuri, Fellow
33. Nitin Bharadwaj, Vice President
34. Mr. Amareesh, Senior Technical Officer
35. Mr. Kingshuk Poddar, Senior Technical Officer
36. Mr. Gokul Krishna, Technical officer
37. Mr. Ekram Galeti, Technical officer
38. Mr. P. Harikanth, Technical officer

From AMTZ:

39. Ms. P.L. Harika, Fellow
40. Dr. M. Anburajan, Senior Manager
41. Mr. M. Santhosh Kumar, Senior Manager
42. Mr. P. Srinivasa, Senior Manager
43. Mr. N. Ramakrishnan, Senior Manager
44. Mr. C.V. J. Shastry, Senior Manager
45. Dr. Sandeep Patnaik, Manager
46. Mr. Ch. Avinash, Manager

Instrument Segment	Identified Critical Components which can be approached for R&D grants	Required Facility	Additional comments
Bio-Chemistry (6 verticals in the product segment Clinical diagnostics. Product segments overlap over times. Eg. HPV is a microbial as well as genetics)	1. Biochemistry, fluorescence reagents	• Reagents calibration and evaluation facility	• Clinical diagnostics are dependent on Elisa and similar techniques. No standard hardware, highly dependent on modality and custom based applications. Most imports are from China. • Immunofluorescence and western blotting techniques are not prevalent
	2. Blood gas analyzers (Non-invasive Near IR measurement similar to SPO2)		• MATEK is making blood gas analyzers
	3. Flow sensor based blood gas detector should have an upper cap		
	4. Electrolyte analyzer		• CGCRI, IICT Hyderabad makes electrochemical equipment. • One company in Hyderabad Making Electrolyte Analyzer
	5. Electrodes development (Na and K)		
	6. Membranes (with longer life)	• Membrane testing facility • Precision manufacturing facility	• Membranes are manufactured by Ross Siemens and Medika • SCTIMST and ISRO have precision manufacturing facility
	7. Hyper spectral Imaging		• Emerging technology like Hyper Spectral Imaging is looked for improved insurance claims.
	8. Antigen Antibody reagents and Imaging (no reliable procurement company in India)		

	9. Automated staining (for eliminate human error) 10. ELISA strips 11. Cuvettes (single crystal non jointed glass and disposable plastic: quartz is not required as clinical spectrophotometric measurements are not in the UV range)		● No manufacturing companies in India ● HHV Bangalore can be referred for plastic cuvette ● IICT Pune makes ion selector. ● Govt. has National Diagnosis program
Immunology	12. Immunology reagents		● No Indian manufacturers
Hematology	13. Cytometric Glass 14. Flow Cytometer (Light source (Halogen) and detector)		● No Indian manufacturers
Histopathology	15. Rapid test kits 16. Cellular imaging and testing	Micro machining facility for integration of LOC(Lab On a Chip)	● Tropical diseases ● For cancer diagnostics and hereditary diseases like Beta thalassemia and cystic fibrosis
Molecular Biology - Genetics	17. Microscopic lens 18. Micro positioners (with resolution of 1-2 microns)		● Saint Gobain leading global manufacturer of lens.

	19. Whole Slide Scanners 20. Actuators (between 2 cells) 21. DICOM Compatibility (Additive manufacturing ready) 22. Micro Arrays 23. Mass Arrays 24. Gene Arrays 25. Micro sequencers for genetics 26. Fluorescence nucleotides 27. Mass spectrometer (preferred over next generation sequencing) 28. HLA typing with respect to luminex based sequencing	Integration and automation facility for Whole slide scanner	
Certification Regime: **FDA > BIS > CE** (also China CE) NAB (National Accreditation Board) is asking for 100 % specificity and sensitivity			
IMAGING **(X-Ray, C-Arm, CT & Catheterization Lab.)**	29. Tubes (In a Day format like GE, Non glass based and universal fitting x-ray tubes) 30. Glass and Vacuum brazing	• Tube manufacturing and screening facility • Commercial integration facility for flat panel detectors	• No Indian parallel authority like atomic energy for X-ray. • RRCAT, Indore is making tubes • CURA made India's first OEM x-ray tube

	31. Medical grade display monitors (pixel testing) 32. Liquid Crystals 33. Rotating Anode (gears, should reach 11000 rpm in 2-3 sec without lubricant) 34. Target anode (Beryllium, Rhodium is present, Molybdenum with tungsten coating is emerging technology) 35. High Frequency Generator 36. Bi directional couplers 37. Image optimization software 38. Phantoms for radiation imaging 39. Bearings technology for rotating anode with high precision 40. Bearing less rotating anode 41. 16 bit dynamic flat panel detectors	• Fumigation testing, pixel testing (A+ and A grade) facility	• 48 Hours fumigation test and 0.19 micron pixel size for display monitors (AMTZ can consider pixel testing) • ICG Bangalore has fluorescent coating facility • CGCRI Kolkata is making refractory materials • Above 15 KV and 200 KHz without noise and heat • Phantoms of different sizes, weights and densities • Flat panel detectors are not manufactured in India

	42. TFT arrays		• No TFT detector manufacturers in India
	43. Static detectors		• Static detectors are making in India by BHEL
	44. Transformer for 16 slice 150 KW CT		• Non-sparking transformer for preserving resolution
	45. Appropriate transformer oil which supports up to 2 million hit units		
	46. Collimators		• RALCO is making 1st class industrial collimators. Refine its technology to make medical collimator
	47. Data Acquisition System		
	48. Detector Array		• Rejection ratio is 25 - 35%. GE, Philips are manufacturing. Not preferred unless the mass production of about 10000 units
	49. CCD image sensor		
	50. Backlit CMOS sensors (Cheaper)		
	51. Scintillators	• Chip integration facility	
	52. Fluorescence filters (C-Arm)	• Integration facility for scintillators	
	53. Slip rings (CT)		• Slip rings are manufactured in Chennai

Catheters	54. Dilatation Balloon soldering to catheter 55. Catheters for catheterization lab 56. Hydrophilic coating on polymer catheters for endoscopy 57. Intravenous tubes 58. Promoting standards for ovine based transplants	• Precision and homogeneity testing facility • Micro machine molding • Marking, necking, Etching facility	• 100 – 200 micron Nitinol extrusion facility is available with defense laboratories • Standardization in terms of size and fitting is required
Ultrasound	59. Piezoelectric crystals 60. Phased array crystals 61. Fan beam forming technology (with respect to Tissue Heat Index) 62. Wireless ultrasound probes 63. Cable based transducers 64. Fetal Doppler 65. Image processing 66. Cardio Tacho Graph		• Everything is imported • OMS, Aloka, Toshiba companies are pioneers ultrasound equipment manufacturing • Beam forming technology is available with Fraunhofer Institute, Germany • CTG is great advantage for remote monitoring. SATWA is manufacturing wearable ultrasound for routine examinations

Neonatal Equipment	67. Incubators and warmers 68. Medical grade nitric oxide for NICU 69. Paramagnetic based sensors for FIO_2 monitoring 70. IR based $ETCO_2$ monitoring 71. Non-invasive Bilirubin measurement 72. Neonatal MRI 73. Trans Cranial Doppler		• Johnson & Johnson is making incubator and warmer. Very limited manufacturers • Nitrous Oxide as calibration gas is used, need to define as a drug and define its standards. • Non-invasive patient monitoring technology is available with MASIMO Corporation. • No Indian manufacturers • IR has diverse applications but many restrictions. ICI(Infrared Cameras Inc.) is making IR sensors • Similar to SPO_2 • Neonatal MRI should be compatible with other tubing, amplitude EEG and life support
Ventilators	74. High Frequency ventilators 75. Respiratory sensors		• For Neonates (high frequency(>12 Hz) and low volume based ventilators • STAAN, Coimbatore is making ventilators and other devices • PRICOL holding patents with ventilators

	76. compliance monitoring 77. FEV monitoring 78. O_2 sensors(with increased life) 79. Disinfecting tubes 80. Long Catheters 81. Oxygenator for Heart Lung Machine 82. Humidifier	Ceramic coating, anti-microbial coating facility for respiratory tubes Medical grade extrusion facility for tubing	• Different sized tubing leads to disturbed calibration. standardization is required. • Padmini VNA Mechatronics company is currently working to manufacture heart lung machine
Renal	83. Hollow fiber concentrator for dialyzer 84. HME filter 85. Anti-bacterial filters 86. 10mm tubing CAPD, promotion of CAPD	Dialyzer reprocessing, Membrane pressure testing facility Electro spinning facility	• Renalyx is working on water minimization techniques by recycling the dialect. • Nipro Ahmedabad and 3M working on hollow fibers • High flux dialyzers are considered for manufacturing

	87. Continuous Renal Replacement Therapy (CRRT) circuits		
Sutures & Scaffolds	88. Bio absorbable and non-absorbable sutures 89. Synthetic sutures 90. Hernia mesh 91. Light Prolene mesh 92. Nano based assembly of cellular matrix	• Biomaterial testing facility • Extrusion and controlled braiding facility • Electro spinning facility • 3D Bio printer(Collagen, Cell pat, Polymers, Biomaterials)	• Braiding technology is available with SITRA(South India Textile Research Association) • Ambala Advanced Micro Devices company are making membranes and filters
Non Cardiac Implants	93. Uncemented hip joints 94. Titanium for knee and hip implants 95. Spinal implants 96. 316 LVM 97. Ceramic rod 98. Medical grade polymer UHMWP(Ultra High Molecular Weight Polyethylene) 99. Bone glue 100. Bone cement (Poly methyl Methacrylate) 101. Dental implants	• Powder coating facility • Porous Titanium coating facility • Cold extrusion facility • Titanium rods extrusion and heat treatment facility • 316 LVM technology facility • Ceramic implants molding facility	• Importing almost all of the implants and its raw materials • DentCare company is making dental implants

Endoscopy	102. Optics and electronics 103. Lens 104. LED Lights 105. Cold source 106. Polymer catheters for guide wire 107. Hydrophobic and hydrophilic filters	● Dicing system facility ● Nitinol extrusion and bending facility for endoscopy tubing ● Instrument automation	
Muscular Dystrophy treatment	108. Axon skipping method for muscular dystrophy 109. Dystrophin protein 110. Oligonucleotide, monomer, Amitide synthesis	● Industrial scale commercial synthesis facility for Antigen Oligonucleotides	