

NEWSLETTER

Volume 1

Issue 1 - Chennai

October 2019

LEARN UNLEARN RELEARN

Continuing Laboratory Professional Education Programme

IMMUNOASSAY TESTING - NEW ANSWERS TO OLD QUESTIONS



Lamp lighting ceremony: From L to R :- Dr. V K Ramadesikan, Dr. C N Srinivas, Dr. R Dhananjayan, Dr. Thuthi Mohan, Dr. S. Danalakshmi, Dr.Sowmya, Mr. Roy Zhong, Mr. Benny Joseph
September 7, 2019 - Saturday, Hotel Taj Coromandel, Chennai. From 6:00pm to 8:30pm



Diagnostic Care & Trading Pvt.Ltd
That Cares you all....

In this Edition

About the Program

Program Anchors

Industry Education Initiative -
Partners

Opening Remarks

Splendid Snibe

Challenges in Immunoassays &
Case Study

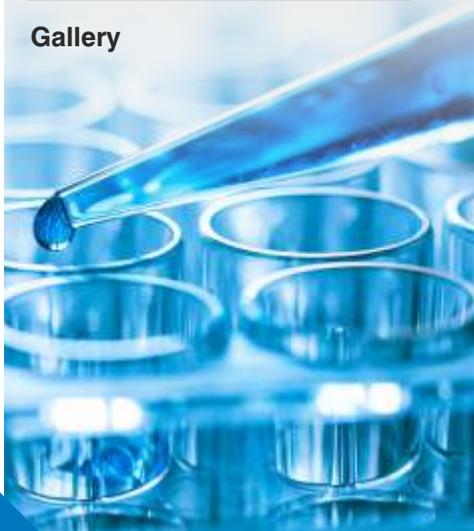
Open Forum on Immuno Assay
Testing -An Unconference
Session

Case study

Special Immuno Assay Markers
in Maglumi

Vote of Thanks

Gallery



About the Program

The objective of this initiative is to share knowledge with Lab Medicine Professionals and Lab Owners about the advancements and new solutions that are available in “Immunoassay” Diagnostics Testing space.

World over the shift in healthcare is happening towards using highly disruptive, innovative solutions which can help in faster diagnosis and delivery of healthcare solutions at affordable pricing. This session focused on discussing about the opportunities and challenges in Immunoassay Testing. The Session had around 100 participants and was attended by Laboratory Medicine Professionals — Pathologists, Microbiologists, Biochemists & Lab Owners from various parts of the country.

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Program Anchors



Prof. Dr. C.N. Srinivas, CNS as he is fondly known, is a highly acclaimed speaker and teacher, He graduated in Medicine from Bangalore University with 10 gold medals, is a pathology gold medalist PG from University of Madras and DipNB with a gold medal as well from New Delhi. He trained under Dr. John Gerlach, President of ASHI, with a Fellowship in Molecular Diagnostics and Transplantation Immunology. Prof. Srinivas has over 26 years of experience in Laboratory Medicine, Pathology and Transplantation Immunology, he is the first to initiate state-of-the-art clinical lab, especially world class Immunology and Molecular diagnostics, into South India bringing Multiplex technology to Clinics. Having revolutionized this field, he is aptly regarded as “**Father of Urine Automation**” in India. He is also NABL (ISO 15189:2012) Technical Assessor & NABH Med Lab Lead Assessor, CAP-LAP Inspector & WHO Trainer for GCLP & Lab QMS.



Dr. V.K. Ramadesikan, is a doyen in the field of Medical lab medicine, Lab management and Total Quality Management in clinical lab. After 3 decades of outstanding service in Tamil Nadu Government Health sector, 2 decades of which were in top medical teaching institutes, he is now a full time Senior Consultant in Clinical Biochemistry. His unmatched technical acumen is nicely complemented by his exemplary expertise in Quality Management Systems. He has facilitated more than 100 labs for NABL & CAP Accreditation in the past 17 years in TN, Karnataka & AP states. His accomplishments also involve guiding hospitals, blood banks & Imaging centers for NABH accreditation. He is NABL Technical Assessor for Clinical Biochemistry since Feb 2016. His vast experience, excellence, teaching skill and down-to-earth personality make him a much sought-after speaker at leading conferences and workshops.

National Partner



Shenzhen New Industries Biomedical Engineering Co., Ltd. (known as Snibe) is located in Hi-tech Industrial Park, Nanshan District of Shenzhen, China, founded in December 1995.

Snibe is a bio-medical company specialized in clinical laboratory instruments and in vitro diagnostic reagents. Snibe has formed a strong team of professionals: Reagents R & D and production center, Instruments R & D and production center, Sales & Marketing center.

Since MAGLUMI (brand for Snibe Products) series of products entered domestic market, they are highly recognised by the end users - hospitals and labs, though they are a recent entrant to the market. Now there are more than 3000 hospitals using the MAGLUMI CLIA System in domestic CHINA. They had established cooperation relationship in more than 144 countries and regions. Snibe has become operational in the Indian market with strong Sales and Support teams by engaging direct teams as well as through strong network of distributors, Channel partners across India.

Regional Partner



Diagnostic Care & Trading (DCT) P Ltd headed by Adarsh Krishnan is the exclusive Distributor for Snibe Products in Tamilnadu. Team DCT has been in the distribution for Diagnostic Solutions for more than a decade and has strong Sales and Support Team across Tamilnadu. The combined Sales and Support team strength of Snibe as well as its exclusive Distributors helps in meeting customer needs faster and delivering solutions on a fast track mode.

Knowledge Partner



Healthcare Events is a platform created for sharing knowledge among all players in the healthcare industry. Healthcare Events identifies the changing needs of the industry and the evolution taking place within and without the industry that would have an impact on the healthcare businesses. Initiatives are created to bring together professionals from the various fields. Knowledge dissemination is achieved through Discussion Forums, Meet Ups, Round Table Meets, Conferences, Unconferences etc. The focus is on maximum knowledge exchange.

Opening Remarks



Dr V.K.Ramadesikan,

M.D., Senior Consultant,
Sundaram Medical Foundation,
Dr Rangarajan Memorial Hospital, Chennai

Dr. Ramadesikan welcomed the gathering and briefed on how Immunoassay has evolved considerably since the discovery of Radioimmunoassay for Insulin by Berson and Yalow in 1959. Emil von Behring with Shibasaburo Kitasato conducted pioneering experiments that demonstrated some natural defense mechanism against the then recently discovered bacteria that cause diphtheria and tetanus. Behring was awarded the first Nobel Prize in Physiology or Medicine in 1901. Since then science of immunoassay has grown by leaps and bounds. Immunoassay has now pervaded all fields of laboratory medicine particularly histopathology, immunohistochemistry and even other fields like veterinary science and food sciences.

Key takeaways from the session:

The first immunoassay was described by Berson and Yalow in 1959. Since its introduction, immunoassays have evolved considerably. Today, immunoassays play a prominent role in the analysis of many clinical laboratory analytes such as proteins, hormones, drugs, and nucleic acids.



Splendid Snibe - Mr Roy Zhong,

Snibe Diagnostics India P Ltd

Shenzhen New Industries Biomedical Engineering Co. Ltd. (Snibe Co. Ltd.) was established in 1995 by a group of university professors and scientists in Shenzhen, China. Snibe is a bio-medical company specializing in clinical laboratory instruments and in vitro diagnostic reagents. It officially launched the fully automated Chemiluminescence Immunoassay system and reagents in 2010. The top and largest labs in France, Italy, Portugal, Estonia, East Europe,

Opening Remarks

Poland, Ukraine are using Snibe systems, very satisfactorily. In India, currently they have 800 Maglumi installations in SRL Diagnostics, Apollo, Metropolis, Neuberg, Hi-Tech, and many other reference labs, and the company is further aiming to grow to 3000 installations.

Key takeaways from the session:

Every person and every company should have a dream, this is Snibe's dream story – it's a leading player in Chemiluminescence Immunoassay for 24 years with presence in 144 countries and 11,000 units. Snibe is the only Chinese Chemiluminescence Immunoassay brand that has US FDA approval for both instruments and reagents.

Maglumi Chemiluminescence Immunoassay system has 160 assays available and more parameters are to be added.



Speaker - Dr C.N.Srinivas,

Director, Dept of Laboratory Medicine,
Head, Transplantation Immunology and
Molecular Diagnostics,
MIOT International, Chennai

When it comes to immunoassay it is important to understand what methodology will be good for our specific cases and whether we have any interferences. Interference is a substance which either processes itself or does not process itself but alters the assay result. They are of 2 types – Exogenous that are introduced into the patient specimen like collection tube components, fibrin clot, and Endogenous that are present in the patient's own sample, like heterophilic antibodies, Biotin vitamin supplements. FDA conveys to IVD manufacturers that kit pack inserts should carry warning about Biotin interferences if any. Patients may be on varying dosage of Biotin and generally such information does not trickle to lab. Why we worry about Biotin interferences is because they can act as both competitive and non competitive immunoassays.

Key takeaways from the session:

Of current interest are interferences being seen in immunoassays with regard to Biotin Biotin sales are always on the rise, FDA gives an alert to all manufacturers to validate in their lab whether Biotin interferes with the assay, and if so, to disclose in the kit pack

Know the what, when, how, where and who of interferences

Most important quality goal should be to accept the total allowable error which should not be altered.

Open Forum on Immunoassay Testing -An Unconference Session

Anchors – **Dr V.K.Ramadesikan**, M.D., Sr. Consultant, Sundaram Medical Foundation, Dr Rangarajan Memorial Hospital, Chennai,

Dr C.N.Srinivas, Director, Dept of Laboratory Medicine, Head, Transplantation Immunology and Molecular Diagnostics, MIOT International, Chennai

Panelists - **Dr Sowmya**, M.D. Professor of Biochemistry, Sri Ramachandra Medical College Hospital & Research Institute, Chennai,

Dr.Thuthi Mohan, M.D. Professor of Biochemistry, ESI Medical College & Research Institute, Chennai,

Dr Danalakshmi, Sr Consultant & Head – Biochemistry, Apollo Hospitals, Greames Road, Chennai



Immunoassay is an interesting science and has an enigma to it. Harmonization is yet to be a reality in immunoassay, there are different calibrators with different traceability across platforms. When it comes to vaccines and therapeutics, when tested for hormones, do these antibodies interfere with immunoassays? Whether it will produce interference depends on what is the type of antibody used in the assay, what is the amount of antibody present and if there is any interference then whether it is clinically significant. Besides Biotin, there are many more interferences which we are yet to know more about. Also there is the effect on assays commonly seen in cases of TSH.

Interesting experiences:

- On routine screening for a patient in her 1st trimester, TSH was abnormally low, clinical history showed she was on mouse monoclonal antibodies maintenance for non-Hodgkin's lymphoma.
- A patient tested at midnight for HCV antibodies came positive in alpha based technology, when cross-checked with CMI came negative. In the morning, when testing was repeated with the same alpha system, result was a clean negative. In the lab, generally the 3 sets for HBV, HIV, HCV are kept open, the strip is put in and SPR is added. When SPR of HBsAg was mistakenly kept in the HCV strip, that

was the problem, hence the false positive. SPR is coated with monoclonal antibodies.

- Anti-CCP is a marker for Rheumatoid Arthritis, when you get an anti-CCP more than 200, even if patient has not asked, run a HIV test, surprisingly the test will be positive.
- Antibodies released from placenta interfere with anti-TPO and TSH values
- B12 does interfere with assay, if any value more than 1000 or 1500 patient is mostly on supplements
- Random sampling can be done for thyroid tests, food does not interfere, just TSH should not be tested in evenings. Circadian rhythm must be kept in mind. It is important to remember global references are done on fasting so compare oranges with oranges. Follow the same procedure for a patient. If there is food intake, lipaemia may be there
- Do not order for Thyroid test for in-patients

Key takeaways from the session:

- Standardization is yet to be a reality in immunoassay, there are different calibrators with different traceability across platforms, till today there are only 165 measurands in the clinical labs are standardized
- In assays, when there are discordant values, communication with clinicians is key
- IVIG has half life of 21 days, so consultants should not order any immunoassay based testing for 21 days, in oncology based cases don't order for a follow up serum protein electrophoresis because you will get false elevation of IGG which can be mis reported as recurrence
- Immunization as in cases of pneumococcal vaccines and HBV vaccines does have an interference effect

Case Study

Speaker - Dr. R. Dhananjayan,

Consultant & Head, Dept of Biochemistry,
Apollo Speciality Hospitals, Vanagaram, Chennai



It is a novel idea to include clinicians in future such events because complaints from clinicians like values are not co-relating with diagnosis, test results are unsatisfactory, even if the lab's calibration and quality systems are in place, are being commonly seen. A 55 year old female was admitted to psychiatry dept. with depression and neurological problems, thyroxine level

was elevated but no symptoms of thyrotoxicosis. She was diagnosed and treated for anemia with B12. On follow up, another physician who was unaware of her history, stopped the medications. Her condition worsened, she was put on the regimen again and she improved. In this case unwarranted cessation of therapy led to worsening of neurological abnormalities.

Key takeaways from the session:

Important to bear in mind frequently reported misconceptions and misbeliefs of vitamin B12 deficiency like you do not have B12 deficiency because you do not have anemia

Do not do total Vitamin B12, only active Vitamin B12 is recommended because it is a more superior marker

More than Vitamin D, testing Vitamin B12 is more beneficial, particularly for 20-30 years age group

Special Immunoassay Markers in Maglumi

Speaker - Mr. Benny Joseph,

Marketing & Technical Director, Snibe India P Ltd



Maglumi is Snibe's Chemiluminescence Immunoassay system, a major player in the global manufacturing field. There are special immunoassays parameters available only on Maglumi making it a unique and versatile system. Maglumi offers 5 markers as a minimally invasive tool for Hepatic Fibrosis. It has 4 markers offering 99% sensitivity

specificity to identify Type I Diabetes. H-FABP is a more sensitive marker of cardiac damage in early AMI detection. Lp-PLA2 is a supporting tool for angiogram in cardiovascular cases, available only on Maglumi. Maglumi offers easy, automated system for Direct Renin, a rare test but beneficial in management of hypertension. Maglumi also offers good fertility markers.

Key takeaways from the session:

- Maglumi offers the world's largest menu of 164 parameters, CLIA parameters more relevant for India eg Dengue, Malaria, Leptospirosis, chikungunya are to be introduced
- Maglumi is a fully operated system, traceability is readily available
- If any marker can identify AMI within 2 hrs, then the treatment is much easier than later diagnosis
- Maglumi offers reverse T3 which is not offered in any other Chemiluminescence platform

Vote of Thanks

Mr. Adarsh Krishnan,

Director, DCT



Mr. Adarsh Krishnan extended a huge thank you to all participants, organizers and supporters who made this immunoassay testing meet a success. Today quicker, precise diagnosis and treatment is becoming the norm, advancements and new solutions in immunoassay diagnostic testing is bound to have a great impact. In a special mention, he expressed his gratitude to the event's stalwart anchors Dr. V.K. Ramadesikan and Dr. C.N. Srinivas for their lively, engaging expertise that was an immensely valuable contribution to this event. He thanked Healthcare Events Team and Ms. Rama Venugopal for their untiring efforts that made this a spectacular, meaningful event that too at such a short time.

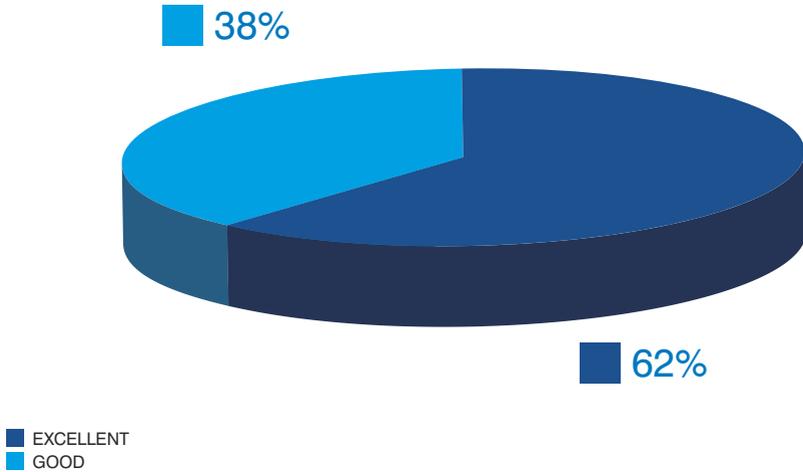
Audience Photos



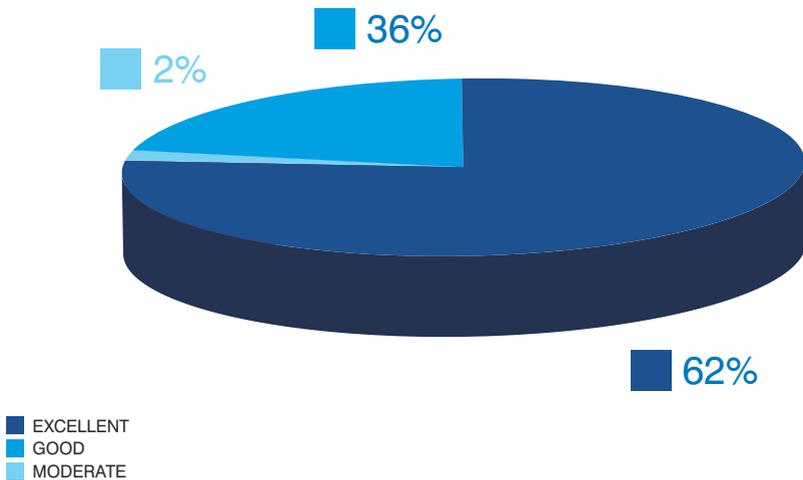
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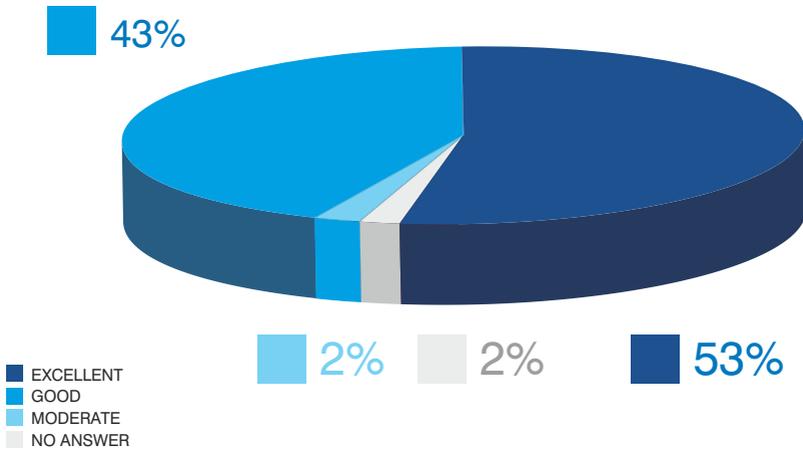
Overall Experience of the Conference



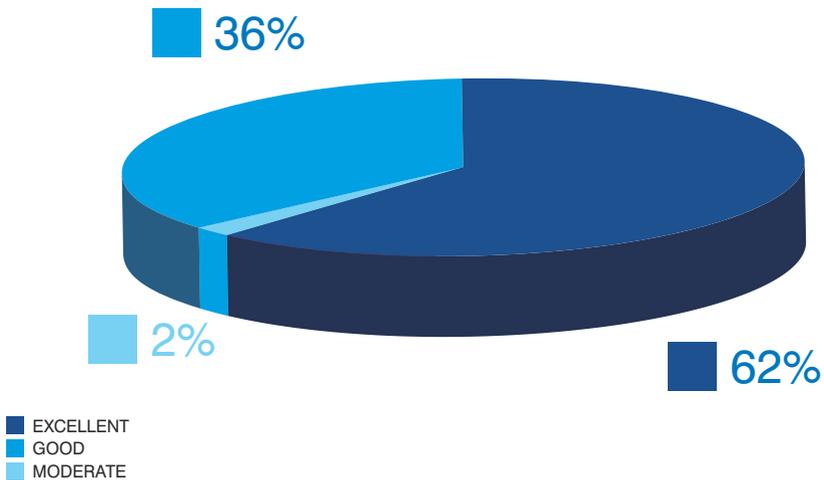
Informative & Beneficial



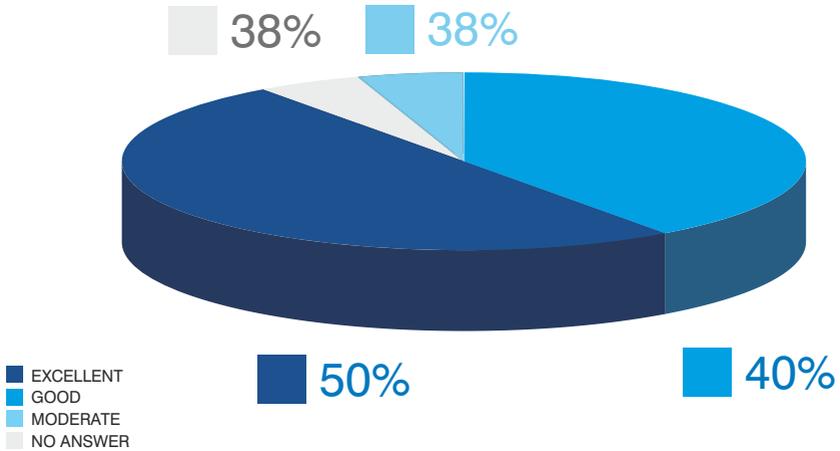
Overall Experience of the Conference



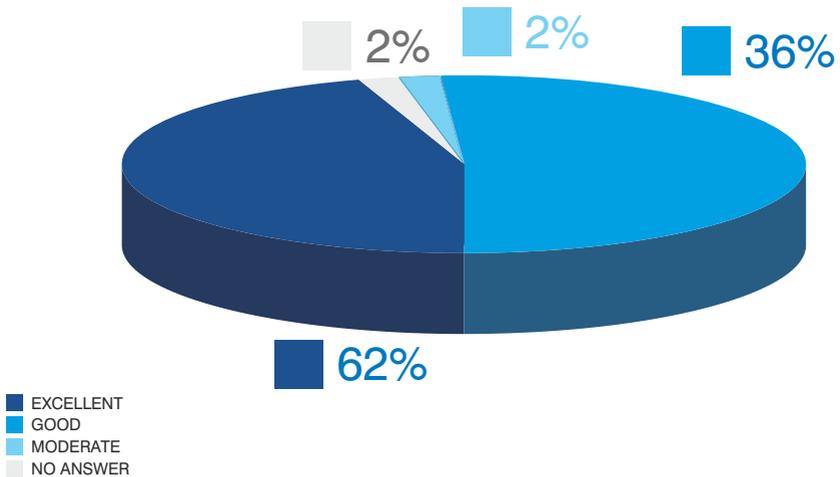
Quality of the Speakers or Panelists



Opportunity to interact and network with other participants



Venue



Program Feedback Corner from Industry

Dr. Anita Suryanarayan

Vice President Operations (India & Srilanka)
Metropolis Healthcare Limited



“

In the past few years we have felt a need for programs for lab professionals like this one, this event is a big knowledge sharing platform which has been created, bringing all of us together, it's like meeting old friends, people whom we know, and you can discuss your problems, discuss your issues. I would like to congratulate the team for this stupendous effort. This will go a long way in providing the best quality healthcare in all aspects to all the citizens of this country.

”

“

This was a great get together, laboratory professionals who are leaders gave an idea about the challenges the laboratories face with the immune assays. Such events are going to benefit not only the laboratory professionals but also the patients and the Healthcare Industry itself. Such events should be conducted on a regular basis so that we can include our own clinical group to understand what best we can do for the industry, how patient safety cannot be compromised, about standardization & harmonization, applying good laboratory practices, and keep open communications with clinicians.

”

Dr. C N Srinivas

Director, Department of Laboratory Medicine
MIOT International, Chennai



Dr. Danalakshmi

Sr. Consultant & Head -
Biochemistry, Apollo Hospitals,
Greames Road, Chennai



“

Such interactive sessions where experts come together to share their experiences are very important because you find that you get an answer to some unresolved queries which you would have been facing for a long time and also you would feel more confident to do your work in future because you get to know that you are not wrong in what you are doing presently. And it's a great knowledge sharing platform. We should have such sessions in future quite frequently so that it benefits everybody.

”

Dr. R Dhanajayan

Consultant & Head,
Department of Biochemistry
Apollo Speciality Hospitals, Vanagaram



“

Programs similar to this one are crucial as only through these people gather and share their knowledge, expert laboratory professionals are ready to give suggestions, share their research and experiences, what kind of errors they come across in their day to day activities, what are the latest innovations. So such programs should always happen regularly for the benefit of laboratory professionals, allied healthcare professionals and the society.

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“

It's a very nice program and it is very important to host such events where we have an opportunity to share our experiences and also learn. We should encourage such gatherings and such educational programs where we can come together, share our experience, learn new things and implement them in our organizations. I wish the team success and look forward to future events.

”

Dr. Sowmya

Professor of Biochemistry
Sri Ramachandra Medical College
Assistant Lab Director of
Sri Ramachandra Laboratory Services



Dr. Subramaniam

Executive Director, Regenix Super
Specialty Laboratories



“

I use Maglumi, the quality is good. They need to focus on supplying materials with same quality and consistency. Previously we had a problem with some quality issues especially in the cuvettes but now it's been looked into and I expect quality would be better. They have many parameters like collagen type 4, was beneficial for one of my PhD student's research. Liver fibrosis markers are excellent and I wish Snibe to bring better Chemiluminescence systems into Indian markets.

”

“

It is a great evening and the first for us at Snibe Diagnostics, India. We are proud to have this important knowledge sharing conference, we will strengthen our focus in Indian market, and have more such sessions. Thank you for all your support.

”

Roy Zhong

General Manager
Snibe Diagnostic, India



Lab Meet Newsletter

Compiled by Healthcare Events

Healthcare Events (HE) was formed to disseminate knowledge to the healthcare industry through multiple engagement modes. It identifies the changing needs and evolutions in the healthcare industry, brings together stakeholders and promotes growth through industry engagements, interactions and initiatives.

Knowledge is Power and Healthcare Events, as a Knowledge Partner, organises following engagements for Healthcare Industry - in collaboration with Industry, with the support of the industry & for the industry.

Expos	Market Research
B2B Meets	Round Table Meets
Conferences	Discussion Forums
News Letters	Buyer – Seller Meets
Market Survey	Business Directory Listing
Business Meets	Business Delegation Tours

All the above Engagements are either done Directly or in Collaboration with Industry Associations, Trade Bodies, Healthcare platforms or any other Institutional collaborations too. Events are attended by Medical Professionals, Healthcare Professionals, Business Owners, Operational Heads, Functional Head etc.

HE Team comprises of Healthcare Consultants with strong domain Knowledge and competencies to create stakeholder engagements based on market needs. Agile teams work together to add value to the engagements, which encourage and empower stakeholders to embrace changes to face the future format of healthcare delivery. Event attendance is limited and exclusive but the Knowledge Transfer is phenomenal.

News Letters are created for Knowledge dissemination and reach industry members across the country to share the best practices. In an era of digital focus, digital News Letters shall reach everyone through Social Media Channels too.

Same shall be made available on Healthcare Events website too for download - <http://events.healthcare/>



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