

# CDSA Newsletter

Issue 5

April 2016

Clinical Development Services Agency

Dear Reader,

It is the beginning of a new financial year and a year for CDSA to leap forward in an expanded mode. Now that, all of us have understood the new regulations, amendments, orders and circulars, the Indian and multinational pharmaceutical companies should start conducting their clinical trial and slowly bring back the old glory, jobs and business.

CDSA, with increased budget, additional employees, new business initiatives and Promasys installed in validated and secured environment, is geared up to cater larger network of innovators.

The training program for EC members on current regulatory requirements has touched up on 1700 participants across 14 cities over 17 months. Finally, in FY16 CDSA conducted 21 training programs (17 last year), enhancing the knowledge of 1906 participants from 536 institutions with 233 faculty. The Clinical and Medical departments are all set to take on the GLSE study forward.

We have great challenges and great opportunities ahead. Hope to have a prosperous financial year for all.

*Sudhakar Bangera*  
COO & Program Director



## Check it Out

ICMED - country's first indigenously developed quality assurance system for India manufactured medical devices.

<http://qcin.org/pdf/Certification%20Standards/OCI%20AIMED%20Medical%20Devices%20Requirements%20for%20CBs.pdf>

Govt of India has banned 344 FDC drugs under Section 26A of drugs & cosmetic act and rules.

[http://cdsco.nic.in/writereaddata/SO%20705\(E\)%20TO%201048\(E\)%20DATED%2010-03-2016.pdf](http://cdsco.nic.in/writereaddata/SO%20705(E)%20TO%201048(E)%20DATED%2010-03-2016.pdf)

IBM has launched IBM Health Corps. It is a global corporate citizenship program, to help tackle public health challenges by working with health organizations around the world.

<http://www.eweek.com/it-management/ibm-launches-global-public-health-effort.html>

Dengvaxia, world's first dengue vaccine is awarded "The vaccine Breakthrough of 2016"

[http://www.indiaonline.com/article/news-sector-pharma-healthcare/first-dengue-vaccine-dengvaxia-awarded-the-vaccine-breakthrough-of-2016-116032800020\\_1.html](http://www.indiaonline.com/article/news-sector-pharma-healthcare/first-dengue-vaccine-dengvaxia-awarded-the-vaccine-breakthrough-of-2016-116032800020_1.html)

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# Trainings and Programme Conducted by CDSA

Sucheta Banerjee Kurundkar & Neha Mishra

## Touching lives

This year we touched close to two thousand lives through our twenty one programs that involved two hundred and thirty faculty members across nine cities in India. A drop in the ocean indeed but a baby step towards reaching you.

We believe that it is always better to hear from the 'horse's mouth' as a result, we walk an extra mile to get the experts for you. CDSA is blissfully supported by CDSCO. Both the Regulatory Workshop on "Phytopharmaceuticals" and "Medical Devices & in vitro Diagnostic Kits" were held at CDSCO Offices at Mumbai and Chennai respectively. Without the sincere support and help of the Deputy Drug Controllers, Dr. Bangarurajan and Dr. Manivannan this was a distant dream. This program was made unique by providing a rare opportunity to all participants (innovators, start-ups, SMEs) to interact directly with the current regulators and clarify doubts, seek guidance on one to one basis. This entire regulatory series is steered and supported by BIRAC, Govt. of India.

## Invest in Yourself

It is well said that investing in yourself may be the most profitable investment you ever make. This year I, Sucheta Banerjee Kurundkar thought of turning this into practice, I invested a week on pursuing 'Management of Training' at Institute of Secretariat Training & Management, Dept. of Personnel & Training, Govt. of India. I am blessed to be in an organization which encouraged this, valued it and supported this wholeheartedly. How many among us do this at our Institute? Help and encourage our colleagues and team members to embark on a learning journey. Do we seldom realize it's after effects? If we do today, we will reap its benefits tomorrow.



*Dear CDSA Team,  
Thank you for the wonderful training we had at Chennai. Hope to see many more trainings conducted at your end.*

*Divya Ganapathy  
Participant, BIRAC CDSA Regulatory Workshop on Medical Devices & in vitro Diagnostic Kits Program (Feb 24, 2016), CDSCO, Chennai*

*Thanks for the link and my heartiest congratulations to the team on conducting such value added programs.*

*Dr Gulrez Tyebkhan  
Participant, BIRAC CDSA Regulatory Workshop on Phytopharmaceuticals Program (Jan 12, 2016), CDSCO, Mumbai*

*On behalf of PSG Centre for Research & Bioethics and PSGIMSR, I sincerely thank the CDSA team for organizing a wonderful program at our Institute.*

*Participants from PSG told me that they found the sessions very useful.*

*It was a pleasure meeting you all. Look forward to more collaborative programs in future.*

*Dr. Sudha Ramalingam  
Local Organizing Secretary & Faculty, EC Program (Jan 19-20, 2016) at PSGIMSR, Coimbatore*

# Down The Memory Lane

Sucheta Banerjee Kurundkar & Neha Mishra



BIRAC - CDSA Regulatory Workshop on Emerging Needs & Regulations Phytopharmaceuticals, CDSCO Mumbai (Jan 12, 2016)



Current Regulatory Requirements for Members of Institutional Ethics Committees (Awareness Program) at PSGIMSR, Coimbatore (Jan 19-20, 2016)



250+ participants accommodate in a frame at Rustom Choksi Auditorium for Good Clinical Practice (GCP) (An Awareness Program) at Tata Memorial Hospital, Mumbai (Feb 16, 2016)



Group Discussion among the Participant groups on different Case Studies at Current Regulatory Requirements For Member of IEC at Tata Memorial Hospital, Mumbai (Feb 17-18, 2016)



Regulatory Workshop on Current Regulation on Medical Devices & in vitro Diagnostic Kits at CDSCO, Chennai (Feb 24, 2016)

*Let me take this opportunity to thank CDSA for inviting me to this important meeting. It was one of the best conducted meetings with good academic discussions emanating from the talks and active participation of the participants. The senior faculty of CDSA and the team need to be complimented on the success of this awareness program.*

*Congratulations once again & thanks for keeping me a part of this important event.  
Dr. Lalita Savardekar, Faculty, EC Program (Feb 17-18, 2016) at Tata Memorial Hospital, Mumbai*



## Upcoming Programs

No.	Dates	Training Title	Venue
1	Mar 31 – Jun 04, 2016	Bioethics Certificate Course 2016 (Manipal University and CDSA Collaboration Program)	Online Course with 3 Contact Sessions at Manipal University, Manipal
2	April 11, 2016	Webinar on Study Designs in Clinical Research	Online, 11:00 AM - 12:00 PM
3	April 27, 2016	Current Ethical & Regulatory Requirements for Clinical Trials (An Awareness Program)	Tata Medical Center, Kolkata
4	April 28, 2016	Good Clinical Practice (An Awareness Program)	
5	May 07-08, 2016	Research Methodology	Andaman & Nicobar Islands Institute of Medical Sciences, Port Blair
6	May 09, 2016	Good Clinical Practice (An Awareness Program)	
7	May 10, 2016	Current Ethical & Regulatory Requirements for Clinical Trials (An Awareness Program)	
8	May 17-19, 2016	Laboratory Quality Management System in Biotherapeutics	National Institute of Biologicals, Noida
9	June 14-16, 2016	Laboratory Quality Management System in Vaccines	
10	June 28-30, 2016	Research Methodology	ICGEB, New Delhi

## Employee's Corner

CDSA participated in "THSTI Games Tournament" held in Feb 2016



Three Legged Race



Lemon Race (Team D)



Kho Kho (Team B)



CDSA welcomes "Lauren" as a new addition to Ligi's (Study Monitor for GLSE Study) family.