



## **KMSCL Institute for Drug Studies(KIDS)**

Kerala State Pharmacy Council Building, Public Health Lab Campus, Red  
Cross Road, Thiruvananthapuram- KERALA. 695035

Web: [www.kmscl.kerala.gov.in](http://www.kmscl.kerala.gov.in), Email: [kidskmscl@gmail.com](mailto:kidskmscl@gmail.com), Phone: 0471 24777353

**KIDS/ PROJECT/4- Notification**

**Dated May 23, 2013**

**Study Title:**

**"THE QUALITY CONTROL SYSTEM OF THE DRUGS ANALYSED BY THE  
EMPANELLED LABORATORIES"**

**Last date for applying to join the Research Team: 31<sup>st</sup> May 2013**

**Date of starting the Study: 5<sup>th</sup> June 2013**

**Last date for completing the study: 1<sup>st</sup> July 2013**

**Study Sponsor:** Kerala Medical Services Corporation Limited.

**Project Supervisor:** Dr.K.G. Revikumar , Director, KIDS

Email: [kg.revikumar@gmail.com](mailto:kg.revikumar@gmail.com)

Contact no: 0471-2475028, 2570347

**Study Coordinator:** NithishShyاملal V K

Email: [nithishvk@gmail.com](mailto:nithishvk@gmail.com)

**Contact Number:** 09809952363

### **Aim& Objectives**

Aim of the study is to analyze and evaluate the quality control system of drugs used in government health care institutions of the state of Kerala .

The objectives of the study are:-

1. To study the quality control management system of KMSCL from its inception to till date
2. To study, analyze and report quality related issues of drugs in health care institutions of Kerala.
3. To conduct case studies on medicine quality related issues occurred in Kerala like the incidents of supply of spurious medicines in Nilambur Taluk hospital.
4. To identify and suggest measures to prevent the supply and availability of counterfeit /spurious/ adulterated/ substandard drugs to government hospitals.
5. To critically evaluate Quality control mechanism of drug testing lab( Drugs control department )of Kerala and suggest measures to improve the same.
6. To evaluate and monitor quality related parameters of drugs during testing.
7. To conduct SWOT analysis of Quality control arrangements of various laboratories empanelled with KMSCL for analyzing the quality of procured drugs.
8. To find out how to utilize the services of post graduate pharmacy colleges and other laboratories in the state for quality control of medicines.

## How to conduct the study?

For this study 'Quality' includes quality of the item, its packing, labeling, packaging and other related aspects. Every product/ item should comply with the quality tests specified in official monographs, apart from that they are supposed to maintain the quality parameters for containers, packing materials etc. Every proposed packaging system should be shown to be suitable for its intended use, transportation and storage. The packing should adequately protect the dosage form, compatible with the dosage form and should be composed of materials that are considered safe for use with the dosage form and the route of administration. Label should have name of product with strength and specifications, batch/lot no.mfg/exp date, name of manufacturer, quantity etc.

The present study entitled "the quality control system of the drugs analysed by the empanelled laboratories" can be conducted as an analytical/ experimental/ observational interview based/case study oriented or in any other suitable manner decided by the individual Research Team.

About 5- 8 Research teams will be constituted for this study in Kerala and outside. The teams will study the quality control system of drugs and the process. Each team will have at least of 1 Research fellow and 3- 4 research associates. The team will be constituted jointly by the Research Fellow/s and the Study Coordinator.

Once the team is constituted and approved by KIDS Director, each team have to submit a proposal to KIDS within 5 days specifying the study methodology including how and where they plan to conduct the study and other aspects. If the team need additional support to prepare the proposal, they can contact the Study Coordinator who will extent required help and support .

Once the proposal is accepted by KIDS, the team shall conduct the study within the stipulated time in the specified manner. The study Coordinator will provide a model data collection form and a semi-structured questionnaire which can be used by the Research team for finalizing their workplan to interview the authorized persons of Quality control departments of KMSCL, pharmacists and store superintendent of the government hospitals, laboratories which are empanelled to KMSCL and government drug testing laboratories of Kerala ( *This is not a compulsory provision as the team can opt for better methods based on the local situation.*)Each team is at liberty to include their suggestions and modify/ add more questions.

During the study the teams can make use of the standard operating procedures and quality manuals followed by KMSCL. Apart from these resources, scholars can utilize the previous documented data regarding quality control system of KMSCL, Govt. reports, various monographs used for quality control testing, Good laboratory practice guidelines, audiovisual media, news

papers, books, journals, research reports, magazines, manuals, and similar publications on quality control system of drugs.

The teams can take pictures/ video graph of the interview, study sites, medicines labeling etc wherever possible. The study can be conducted as per the convenience of the team on specified times but should be completed within the specified date shown in the notification.

### **Procedure of making the Report**

Each team has to make a Report based on their study focusing on the Aim and Objectives notified within the time incorporating photos, pictures, tables, charts etc. wherever needed. The report, duly filled questionnaire/data collection forms/ report sheets etc. have to be scanned and sent to the study coordinator ([nithishvk@gmail.com](mailto:nithishvk@gmail.com)), with a copy to KIDS ([kidskmacl@gmail.com](mailto:kidskmacl@gmail.com)) within 24 hours of completing the study.

The obtained data and findings from each study site will be further evaluated, combined, collated and published as a report at KMSCL Institute for Drug Studies with due recognition to each contributors.

Each team may submit their study report to the Coordinator before the last date notified. Completion of the work within a short time will make the team effective and such teams will be appreciated. This will also help to put the team included in priority teams list of KIDS.

### **Role of the study coordinator.**

The study coordinator will clear the doubts of the Research Fellows and Research Associates related to the study topic. He/ she will provide additional guidance wherever required.

### **What the team members will get out of the study?**

- All participants will get certificates from KIDS acknowledging their participation in the study.
- In the study report published by KIDS, the names of all participants will be shown and the document will be published in the website also.
- The actual expenses for the study like local travel, phone, photocopy, email, food expenses etc. will be reimbursed to each team after submitting their study report.
- After evaluating all the study reports of this study one team will be selected as the best team by a Committee of KIDS.
- The best team for the Project will be selected based on their performance, contribution of newer ideas and concepts, innovative approach, extent of involvement in the study, writing skill and other similar parameters. Every year the best team of each project will be given awards and certificates.

**All Communications can be made through email.**