



KRUPANIDHI COLLEGE OF PHARMACY, Bangalore
11 March 2017

To,

The Registrar,
Rajiv Gandhi University of Health Sciences,
4th 'T' Block, Jayanagar,
Bangalore – 560 041.

Forwarded by,
The Principal,
Krupanidhi College of Pharmacy,
Bangalore.

Sub: Submission of the report of QbDCON - National Conference on Recent Developments, Practical and Regulatory Aspects of Quality by Design was organized by Department of Quality Assurance, Krupanidhi College of Pharmacy, Bangalore.

Respected Sir,

With reference to the letter, **RGU/GEN/FA-172/2014-15**, from the RGUHS, a one day workshop on **QbDCON - National Conference on Recent Developments, Practical and Regulatory Aspects of Quality by Design** was organized by Department of Quality Assurance, Krupanidhi College of Pharmacy, Bangalore co sponsored by Rajiv Gandhi University of Health Sciences, Karnataka . The report of the programme, details of participants, Utilization certificate and CD containing photographs of the programme are here by attached for your reference. I request you to kindly go through the details and make the payment for the sanctioned amount.

Thanking you,

Yours sincerely,

Convener of the event

Chandramouli R,
Prof & HoD, Dept. of Quality Assurance,
Krupanidhi College of Pharmacy, Bangalore

Forwarded through

Dr. Ramn Dang,
Patron QbDCON & Principal,
Krupanidhi College of Pharmacy, Bangalore

Enclosures:

(1) Report of the programme (2) Details of participants, list of registered participants and list of attended participants (3) Utilization certificate with all the bills related to the workshop (4) CD (5) Feedback forms collected from the participants.


PRINCIPAL
Krupanidhi College of Pharmacy
Chikkabellandur, Carmelaram Post,
Varthur Hobli, Bangalore - 560 035



A report on the proceedings of:

QbDCON - NATIONAL CONFERENCE ON RECENT DEVELOPMENTS, PRACTICAL AND REGULATORY ASPECTS OF QUALITY BY DESIGN

QbDCON - National Conference on Recent Developments, Practical and Regulatory Aspects of Quality by Design was organized by Department of Quality Assurance, Krupanidhi College of Pharmacy, Bangalore on Saturday, 11 March 2017 between 9.15 am to 5.10 pm.

QbDCON was sponsored by **Rajiv Gandhi University of health Sciences, Karnataka** and the event was partnered by **Center for Pharmaceutical Professional Advancement, Krupanidhi College of Pharmacy**. **M/s. Vienni Training & Consulting LLC, Bangalore** were the training partners of this event.

A total of 59 delegates from 9 colleges and 2 states registered for the event. The delegates catered to were from faculty, research scholars and also students pursuing M Pharma.

The **QbDCON** was inaugurated by Dr. Raman Dang the Patron of this event in the presence of Prof. Prkasah V Mallya, Director, Center for Pharmaceutical Professional Advancement and all invited the resource persons. The deliberations commenced from 9.30 am and went on till lunch at 12.45 pm.

The Hands on training sessions commenced from 1.40 pm and the delegates were trained on 2 real life case studies. (For more information please refer to the appended agenda of **QbDCON**).

The Valediction of the event commenced from 4.45 pm and went on till 5.10 pm. The delegates were presented with participation certificates and the volunteers of this event were awarded certificates of appreciation. Prof. Chandramouli R, LOC Convener of **QbDCON** proposed a vote of thanks.

The feedback given by the participants of the **QbDCON** were as follows: all the 3 lecture sessions and 2 hands on training session envisaged were either graded as "Excellent or Good" on an overall 3 point scale feedback by the delegates.

The Objectives and the agenda of **QbDCON** is presented overleaf.

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Objectives:

- Give specific regulatory guidance on Quality by Design (QbD) and Pharmaceutical product development on QbD
- Statistical and computing aspects of QbD
- Training in pharmaceutical product development within QbD framework
- Hands on training on DOE with specific pharmaceutical developmental examples.

Agenda of QbD CON:

- Each 1 hr Session was planned as a PowerPoint® talk/ Demonstration session using *Minitab 17™*, *JMP 11™*. (45 – 50 mins of talk followed by 10 – 15 mins of Q&A).
- The start of each session was interspersed by a speaker intro and a brief resume of the speaker and his relevance to the domain of QbD.

Sl #	Time	Speaker(s)	Topic	Expected Learning outcomes
1	08.30 onwards – Registration, collecting kit, conference ID.			
2	9.15 – 9.30	Prof. Prakash V Mallya Dr. Raman Dang	Inauguration speech Dr.Raman Dang, CPPA concept Presentation by Prof. Prakash V Mallya	
3	9.30 – 10.30	Chandramouli R Prof. & HoD, Dept. of QA, KCP +919663134578	QbD & ICH Q8 – Q10 guidelines explained, Introduction to regulatory & statistical basis of QbD	<ol style="list-style-type: none"> 1. To understand the basis of QbD 2. ICH guidelines associated with QbD 3. To understand the regulatory implications of QbD 4. To understand about the statistical basis of QbD
4	10.30 – 11.30	Dr. KLK Paranjyothy Eminent Pharmaceutical Consultant +919483883007	Product Development and registration within QbD framework	<ol style="list-style-type: none"> 1. Overview of Planning and developing product within QbD framework 2. QbD Product registration guidelines 3. ANDA provisions concerning QbD
5	11.30 – 11.40	Tea Break -1		
6	11.30 – 12.30	Chandramouli R Prof. & HoD, Dept. of QA, KCP	Introduction to Computing resources in QbD	<ol style="list-style-type: none"> 1. Software programs and packages Available for QbD /

		+919663134578		DOE 2. Scope and application of Major Software titles 3. Introduction to <i>Minitab & JMP</i> software suites
7	12.30 – 13.20	Lunch & Networking break		
8	13.20 – 13.30	Setting up for lecture - demonstration sessions		
9	13.30 – 14.20	Sachin Mundade Asst. Vice President Strides Shasun +919008778888	<i>Case study 1:</i> Development of a Solid Oral Dosage Form with QbD Framework to match the QTPP Demo tool: Minitab/ JMP	1. Planning Formulation development 2. Screening the formulation for CQA, QTPP 3. Defining the Design space 4. Optimizing the formulation
10	14.30 – 15.30	Vishal Sharma & Ivy Louis Directors, Vienni Training & Consultancy LLP +919845762740 +919986821045	<i>Case Study 2:</i> Development of parenteral Dosage Form with QbD Framework to match the QTPP Demo tool: Minitab/ JMP	1. Development of a sterile biopharmaceutical product, challenges 2. Product development and scaleup within QbD framework – its advantages 3. Product compliance to norms
11	15.30 – 15.40	Tea break 2		
12	15.40 – 16.20	Q&A on case studies, Panel Discussion Panelists: Prof PV Mallya, Dr KLK Paranjyothy, Vishal Sharma, Ivy Louis, Sachin Mundade, Chandramouli R		
13	16.20 – 16.45	Feedback taking, Valediction collection of certificates and Vote of Thanks.		



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**Rajiv Gandhi University of
Health Sciences, Karnataka**



**Association of Pharmaceutical
Teachers of India**

Certificate

This is to certify that **Dr. KUNTAL DAS**, Krupanidhi College of Pharmacy has completed the **Short Course in Educational Methodology** in the Ninth Cohort from **Jan, 2017 to April, 2017**. This program was jointly conducted by **Rajiv Gandhi University of Health Sciences, Karnataka** and **Association of Pharmaceutical Teachers of India**.

Dr. Munir Ahmed R.
Chief Faculty &

Director-College Development Council

Dr. Raman Dang
Secretary - APTI

Programme Convener & Co-ordinator

Dr. C.M. Noor Mansoor K.A.S
Registrar

Dr. K.S. Ravindranath
Vice-Chancellor