

TO WHOM SO EVER IT MAY CONCERN

Mr. Kalpesh Vaghela, CEO of "Infra Control Systems" had given training at Sentiss Pharma Pvt. Ltd, Nalagarh (H.P) premises on 03 and 04th Feb. 2016.

Training subjects during the two days training program discussed were

Why Validation and Benefits.
Role of FDA
Computer Systems Validation Deliverables.
Basics of 21 CFR part 11 Compliance
GAMP5
Risk Assessment
Annex 11
Data Integrity
Advance 21 CFR part 11 Compliance.

The training was concise, to the point with practical examples and helped us to clear many doubts. The trainer is energetic and has through knowledge of the subject.

We wish him all the best.

For Sentiss Pharma

QAMead

Deepika Chowsla

Sentiss Pharma Private Limited (Formerly known as Promed Exports Private Limited)



To Whomsoever it may concern

This is to certify that Mr. Kalpesh Vaghela, CEO Infra Control Systems was engaged in Sentiss Pharma Pvt. Ltd. for the following assignments:

- Computer System Validation (CSV) of ERP Microsoft Dynamics
- Lab Instrument validation of Analytical Department (AD) Lab

This was a massive task and ICS team did a commendable job in understanding the exact requirements from users and mapping them for preparing and executing validation documents. They considered GAMP 5 and 21 CFR Part 11 guidelines in various scripts and tested it successfully along with our team members. The team worked under superior guidance of Mr. Kalpesh Vaghela to meet tight timelines and organizational objectives. Their experienced team lead and validation team members prepared all validation documents and accomplished this task well in time to make our system compliant as per regulatory requirements.

On behalf of Sentiss Pharma, I wish them all the best in all their future endeavors and projects. I hope that they will keep on helping us in future assignments and keep on guiding us in validation projects.

Dalveer Singh

Head IT (Deputy General Manager)

Sentiss Pharma Pvt. Ltd.

Tel: +91-11-26863503 Fax: +91-11-26968517