



Need of the hours is Training to staff on Data Integrity, 21 CFR part 11 Compliance and Computer Systems validation. If they are trained fir why , what and when ? They help design better system, help perform better Review and approval mechanism.

We can help you train your staff in best possible way to compliance. Cost per person is the lowest and Training is world class. We can organize two to four days class room session as per your choice. Most big and Medium Life science and IT companies are booking slots of multiple Training.

Specialized training on Why Validation ? GAMP, 21 CFR Part 11, CSV, Data Integrity & Risk Assessment for your Staff. Basics to Advance.

Why CEOs have to study Data Integrity and 21 CFR part 11 Compliance as well as Software Validation.

After studying market Cap of IPCA, Wockhardt, Zydus, Dr Reddy's and Sun following is the conclusion

Zydus Lost heavily in Market cap after warning

IPCA stock prices are down since long

Lupin Lost 400 Rs per share on adverse news of FDA

Natco lost 85 Rs in a day per share

Wockhardt Lost heavily.

Cadila Pharma in remediation mode at Ankleshwar Plant.

Emcure has adverse effect.

SUN Also Loss huge amount

Dr Reddy's Lost Rs 1400 per share in a week resulting in a great loss of market cap.

Selmer Research and GVK Bio things are real shock.

Cost of Remediation action, Production loss is separate so Cost of Non Compliance is very high.

About us.

More than 10 year dedicated work in Software validation - Training and 30 experience with Automation. Our working style and full dedication has made us a leading consultant in Software validation over a period of time. We can safeguard our customers in Data Integrity, 21 CFR part 11 Compliance, Risk Assessment, GAMP5, Annex 11, Computer Systems Validation and many more areas by imparting good training. We let you know Why Validation is needed? How it is linked to growth of each Employee and the company. How each employee can help in Patient Safety, Product Quality and Data Integrity as individual and jointly with the company.

Without proactive compliance, 21 cfr part 11 training as well as good implementation, good risk assessment and Gamp5 knowledge, pharma Company stock price will tumble for sure.

Careful evaluation of software validation consultants and machine supplier is a must with Vendor audit for category 4 and 5 as per Risk Assessment. They realise that cost based evaluation can close the shutter of the pharmaceutical company or the consultant can not support (expertise issue). Software validation consultant- Data Integrity - compliance trainer (Inhouse or External) is your heart and mind. Select and use them carefully. Good consultants

are getting over booked. Once you loose the contract with a good consultant , new contract always comes at a premium.

I strongly suggest following

Now so many pharma company Started realizing importance of good Software validation consultant. Consultant charges are only 2-5% and get you 100% more in earning. They safeguard your data, process and Quality. They train your people too.

All pharma company MD, CEO, CIO, CFO should meet with CEO of Good Software validation company and make a good bond so they are always protected.

All Limited Companies should have one independent director who is expert in Software Validation and Data Integrity. Having such independent Director post itself will increase pharma company market cap by few hundred crores. If he starts working the profit will multiply 10 to 1000 times in future.

Special Training program devised for the pharma people to get the insight of Why Validation ?

FDA Role

Why Validation?

Benefits of Validation

GAMP5

21 CFR part 11 compliance

Annex 11

Data integrity

Computer Systems Validation Deliverables

Risk Assessment

Teaching in most easy and understandable way. 10 years of dedicated experience of CSV given during this 2-4 days training. Please wrote to infraics@yahoo.com or call 9825047998

We are glad to quote for the training to your Senior, middle and junior management staff at different plant location on Quality aspect like Data Integrity, GAMP5, 21 CFR Part 11 compliance, Computer Systems Validation, ICH Q9 Risk Assessment and benefit of Quality production. We are a leading quality consulting firm with a goal to benefit Indian company achieve excellence in regulatory compliance. We work in India, China, USA, France, Iceland, Muscat and many other part of the world. We work with No.1 Automation company of the world Emerson Process management China, No 1 Raman Spectrometer Company of

**Japan Horiba Scientific, No.1 Retail Pharma chain of Muscat - Muscat Pharmaceuticals,
Morton Groves in USA.**

One has to join this session sooner than later. The price is also kept attractive and you can have more people joining the course and per person cost will work out very economical and no travelling cost and time involved as we come to your site.

We have been taking training at China, Muscat, India and IT companies Like MphesiS, and HCL Technologies, Clinigene (Biocon Group Company) for their Global Pharma Account team. We have also trained team of Alembic (Multiple Session) , Cipla, Sentiss Pharma, Scitech Laboratories, Naproad Life Sciences, Piramal Glass, Watson, UCB, Dr. Reddys' Lab, Emerson Process Technologies, Lupin, Glenmark, S Kant Health Care, Medispray, Alkem, Nootan Pharma, Sun Pharma, Piramal Health Care, J B Chemicals, Aventis, Degin Medical Devices, and Many More..

Even Open to all training conducted at locations like Mumbai, Chandigarh and Hyderabad where people from all company jointly took the training.

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