Certified Life Science QbD Specialist

13-17 November 2017 I 9am – 5pm
IMU Main Campus, Bukit Jalil, Malaysia

SYNOPSIS

The pharmaceutical Quality by Design (QbD) is a systematic approach to development that begins with predefined objectives and emphasizes product and process understanding and process control, based on sound science and quality risk management. Quality by Design (QbD) is emerging to enhance the assurance of safe, effective drug supply to the consumer, and also offers promise to significantly improve manufacturing quality performance

Quality means fitness for intended use. Pharmaceutical quality refers to product free of contamination and reproducibly delivers the therapeutic benefit promised in the label to the consumer. The Quality of the pharmaceutical product can be evaluated by in vivo or in vitro performance tests. Quality by design assures in vitro product specifications correlates well with in vivo product performance. “Hence Quality by design relate to Product Performance”.

There are various benefits for Pharmaceutical Industry to adopt the principles of QbD, these include: Better understanding of the process, less batch failure, more efficient and effective control of change which will lead to better return on investment / cost savings. Another implicit opportunity of an enhanced QbD approach to pharmaceutical industry is that it paves the way for more flexible regulatory approaches.

Course Highlights
The participants get a chance to work in small groups on various pharmaceutical dosage forms to apply the theory to practice.

What You Will Learn

- Understand why QbD came into existence & it’s benefits.
- Know where you currently stand?
- Understand QbD role in Drug Product Development & Analytical Method Development
- Know PAT measures that already exist with you & start making meaningful use of those PAT measures.
- Understand QTTP & CQA’s & how to link them.
- How to arrive at Risk Priority Number
- Do an effective risk assessment
- Understand what is univariate & multivariate design
- Understand the overall design of experiments
- How to plan effective CAPA & monitor it?
- Learn about the role of development QA
- How to analyse the data generated by DoE ?
- How to make the QbD report & how to file it?

Prerequisite

Interest in QbD knowledge and desire to acquire better conceptual understanding in this area. Technical background in Science at Diploma or Degree level would be desirable.

Course Methodology

The participants are first taught the theories in classroom setting with the aid of slides and other training aids. The concepts are then re-enforced through exercises and examples of how the theories are applied in real-life

Course Structure

1) Introduction	2) Current Regulatory Scenario	3) Understand ICH Q8 & ICH Q11	4) FDA's Guidance on PAT	5) QbD Process Step 1: Setting QTPP (Quality Target Product Profile)
• Why QbD? • Historical Background • Advantages to the customer & company	• Regulatory Observations • End Quality VS Built in Quality • Current regulatory expectation on QbD implementation for developing & developed world	• Contents • Steps described • Role of PAT	• What is PAT • You have it but probably you don't know it • Must for QbD	• Workshop with case studies (internal & external) software use • Prior Knowledge Management (Literature Survey) • Understand QTPP • Setting QTPP for your product
6) QbD Process Step 2: Setting CQA's (Critical Quality Attributes)	**7) QbD Process Step 3: Initial Risk Assessment**	**8) QbD Process Step 4: Design of Experiments**	**9) QbD Process Step 5: Design Space Determination**	**10) QbD Process Step 6: Control Strategy & Life Cycle Management**
• Knowledge base for generic product • Linking material attributes to CQA's • Linking CPP's (critical process parameters) to CQA's	• Risk Management principles as per ICH Q9 • FMEA: A good predictive risk management tool • Risk related to product characterisation & development	• Univariate & multivariate experiments • Data feeding to the computer • Output Data Analysis	• Analysis of the output • Arrive at the design space • Changes in the design space	• Definition • Risk based approach • Understand product & process • Continuous Process & Method Verification • Correct & Preventive Actions (CAPA)
11) Development QA	**12) Regulatory Submissions**	**13) Drug Product Development**		
• Why DQA? • Role of DQA • GLP/GMP requirements for R&D	• How to submit QbD information? • What to submit • Extent of submission	• Actual Case Study from start to finish • Practical for companies own project: Start to finish • How to make a report?		

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Who Should Attend

Members of the following departments may attend:

- Analytical Development
- Research & Development
- Formulation Development
- Quality Assurance
- Regulatory Affairs
- Quality Control
- Validation

Course Instructor

Vijay Kshirsagar

Vijay Kshirsagar is an accomplished Quality, Regulatory & Analytical professional with about 40 years of rich experience of working for highly reputed Indian & Multinational Pharmaceutical firms. Till April 2013, he worked for Unichem for about 7 years as Executive Vice President responsible for Corporate Quality, Regulatory, Analytical Research, Bioanalytical services based in Mumbai.
Thereafter he continues to be associated with Unichem as Advisor on Quality & Regulatory matters. He is also a Technical Advisor to 3 more companies including 2 leading Chinese companies. Prior to Unichem he worked for Ranbaxy, Sun , Lupin, IPCA, German Remedies & Tata Pharma in various senior positions like Director-Quality , GM-Quality . He has successfully represented his company in US and UK courts regarding IP related matters (Para IV filings)

Vijay has led from front for successful completion of several regulatory inspections by US FDA, MHRA, EDQM, ANVISA, WHO, TGA etc. both for Drug Products & API's. He has been a frequent trainer in India & abroad having spoken on wide range of topics including cGMP/ GLP/ PQS/QRM/Validations (Process, AMV, Cleaning, Microbiological) /QbD/Dissolution/ Stability/. Handling Regulatory Queries/Investigations/CAPA/Auditing/Documentation/EM etc.

He is the President of 'Society for Pharmaceutical Dissolution Science' right from its beginning.He is also working on the board of Directors of ISPE-India. IDMA has conferred upon him an 'Outstanding Analyst Award 2011' for his contribution towards pharmaceutical analysis. In 2015,he has been awarded by USP, India office, for his contribution to USP's Stakeholders Forum. He has also published articles on topics like OOS, QbD & cGMP in reputed journals/books. His chapter on 'OOS Investigations' is a reference material being a part of the book for Pharmacy students. Guideline written by him on CAPA is published by IDMA. He is M.Sc. By Research in Organoanalytical Chemistry from Mumbai University. He has a good Microbiological background too having done his graduation with Microbiology as a principle subject.

Post retirement, he has formed his own Pharma Consultancy called TRAC offering specialized services globally, for cGMP Training, Regulatory Filings, Auditing & Compliance. His current clients include reputed Pharma/API companies based in India, China, US, Europe, Turkey, Jordon,Bangladesh, Malaysia, Indonesia & Middle East countries. As a consultant, he has helped number of companies to get their first time/renewed US FDA, EU & PICS approvals. He is also advising some companies for their remediation plans to revive their regulatory approvals.

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