



Approved Certificate Course in  
**QUALITY BY DESIGN APPROACH FOR FORMULATION DEVELOPMENT**  
Under JEEVAN SHIKSHAN ABHIYAN

**About Course:**

The course outlines a new and proven approach to pharmaceutical product development which is now being rolled out across the pharmaceutical industry internationally. This innovative approach is based on the application of product and process understanding underpinned by a systematic methodology which can enable pharmaceutical companies to ensure that quality is built into the product. Familiarity with Quality by Design is essential for scientists working in the pharmaceutical industry

**Objectives:**

- 1) To understand the fundamental principles of QbD, current regulatory requirements, DoE, relationship between QbD and PAT tools
- 2) To get the practical approach of application of QbD principles in formulation development

**Course Contents:**

**Unit I: 04 hours**

**Introduction to Quality by Design (QbD)**

Fundamentals of Quality by design, Steps involved in QbD, Key aspects of QbD, Tools of QbD.

**Unit II: 04 hours**

**Global regulatory perspectives on Quality by Design**

Regulatory perspectives on QbD, ICH Q8, Q9 and Q10 guidelines.

**Unit III: 08 hours**

**Design of Experiments (DoE) in pharmaceutical product and process optimization**

Fundamentals of experimental designs, Selection of experimental designs, Screening designs, Optimization designs, DoE considerations in QbD.

**Unit IV: 04 hours**

**PAT tools for implementation of Quality by Design**

Relationship between QbD and Process Analytical Technology (PAT), In-line, on-line, at-line analysis through PAT. .

**Unit V: 10 hours**

**Quality by Design approach for formulation development: Case Study**

Case study of formulation development through QbD paradigm. Identification of QTPP, CQA, Risk assessment, DoE with focus on critical material and process attributes.

**Course duration: 30 h**

**Course fee: 1000/-**

**Course credit: 02**

**Who can apply?**

Students studying in degree, PG, research scholars and Faculty

**Link for registration:**

<https://forms.gle/i6xJAMwFCnjVwnpm9>

**Last day to register:**

24/06/2022

**Conducted by: Priyadarshini J.L College of Pharmacy, Electronic Zone Building, MIDC, Hingna Road, Nagpur -440016**

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