

Abstract



## QbD - Compliance need or Cognizance of Science

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## Abstract:

Quality by Design – New paradigm in Pharmaceutical Product Life Cycle.

QbD has stirred pharma world w.r.t. new product filings and compliance. Enforcement of QbD in pharmaceutical development and continuing with product life cycle management has brought out an increased no of 483s to the no of manufacturers including giant pharma companies. And also decreased no of approvals after QbD enforcement. In this era of competition, quality has been given prime magnitude; failure to meet such quality allied goals produces massive shift of company in share of market. Recent past years have witnessed this through no of 483s to big pharma giants. "Quality could be planned and most of quality deficit arises in the way process is planned and developed", this thought gives foundation to the concept of quality by design (QbD).

## Biography:

Nitin M Kadam, a known International Technical Speaker and Global QbD Expert. He brings his passion in Pharmacy Profession in research & development, to teach, to guide/consult the pharmacy community as ethical pharmacy professional. He have a professional experience of teaching, technology transfer.



## **Recent Publications:**

- 1. Flament T, Bigot A, Chaigne B. Pulmonary manifestations of Sjogren's syndrome. Eur
- 2. Ito I, Nagai S, Kitaichi M, et al. Pulmonary manifestations of primary Sjogren's
- 3. Ramos-Casals M, Brito-Zerón P, Bombardieri S On behalf of the EULAR
- 4. B. Crestani, S. Schneider, H. Adle-Biassete. Pulmonary involvement in Sjogren's
- 5. Deprettere AJ, Van Acker KJ, De Clerck LS, Docx MK, Stevens WJ, Van Bever HP.

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