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Abstract

R&D Formulation, Naari Pharmaceuticals Private Limited, India.

Nitin M Kadam

Pharmacy community as ethical pharmacy professional

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).

Quality, today's integral part of pharmaceutical development and buzz word to Pharma. But, "Quality has Quality Only if Its Quality is Qualified" (own statement). Quality is actually having "Design Driven Origin". Quality cannot be accomplished fully by traditional "trial and error" methodology as there are many constraints. These constraints created need of effective, efficient, systematic, more science-based paradigm worldwide that we called as QbD (Quality by Design). QbD, a buzz word in current pharma world which covers ultimate Product Life Cycle and emphasizes mainly on "Built-in Quality" of pharmaceutical products.

QbD emphasize the development of pharmaceutical product based on sound scientific principles which accelerates the progress of formulation development by the virtue of keen knowledge and science-based brain storming leads to precise Quality process and product. This systematic science-based approach leads to smooth development-regulatory review-approval interface and manufacturing-compliance-review interface.

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, formulation development, Technical consultation, new industrial project establishment. Audit approvals of global regulatory

bodies. Experienced and holded Key Positions as Chief R&D Formulations and Technology Transfer operations in Piramal Health Care R&D

Center, Mumbai. As General Manager R&D in T&T Pharma Care Pvt Ltd and worked with Microlabs, Ipca Laboratories, Wockhard, Cipla-Medica, Shadow Pharma Venture, Currently holding Lead R&D Formulations with Naari Pharma (Strides / Tenshi group Company) for 505 b 2, ANDAs for US, EU, Canada, AUS, ASIAN, ROW, MCC, GCC, etc.

He addressed more than 35 International / National Conferences by CPhI, UBM, SLECTBIO, UBS Transformance, PharmaElite etc. Delivered talks on QbD, Research & Development, Regulatory Affairs,Compliance,Qualityetc.

Publication of speakers:

- Smith and Sara HD: Orphan Drug Development: Incentives under the Orphan Drug Act. Senior Theses, Trinity College, Hartford, CT 2015.
- https://www.fda.gov/downloads/ForIndustry/DevelopingProductsforRareDiseasesConditions/HowtoapplyforOrphanProductDesignation/FINAL Orphan Drug Designation Plan.
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