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A Divya et al., J Develop Drugs 2015, 4:4
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Process validation and its regulatory requirements according to USFDA, ICH, GHTF

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Validation is one of the important steps in achieving and maintaining the quality of the final product. Validation of the individual steps of the process is called process validation. Process validation's main objective continues to be the generation of a process which yields a product which means meeting its predetermined quality criteria. It is an important component in design, prototyping and manufacturing process and once, if done correctly, that can save a considerable amount of time, money and resource. End product testing by itself does not guarantee the quality of the product. Therefore, quality assurance techniques must be used to build the quality into the product at every step and not just tested for at the end. Process validation performs this task of building the quality into the product at every step. FDA had release various guidelines for process validation. These guidelines incorporate principles and approaches that all manufactures can use to validate manufacturing process. FDA considers appropriate elements of process validation for the manufacturing of human and animal drugs, biological products, including active pharmaceutical ingredients and applicability to manufacturing (including servicing and installation) process for medical devices. Specific recommendation for verification of design output and design validation is included in the GHTF document covering design control. Process validation also emphasizes the role of objective measures and statistical tools and analyses and emphasizes knowledge, detection, and control of variability and gives assurance on consistent of quality/productivity throughout life cycle of product.

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