November 12-14, 2013 DoubleTree by Hilton Hotel Chicago-North Shore, IL, USA

GMP in pharmaceutical industries: The failures and their investigation

Lokesh Kumar Gupta Lupin Limited, India

Good manufacturing practices (GMP) are the back-bone of any pharmaceutical industry to ensure the production of intended quality drug substances or drug products. In-view of involved processes, machines, operations, infrastructure and systems, certain failures cannot be ruled out which are likely to be occurred. However, these can be minimized by suitable precautions and following GMP guidelines/practices. In most of the cases, observations in different type of inspections, around the globe, are linked with inappropriate investigation of failures or precursors of failures, which results into repeated failures. It is also a point to be noted that, prodigiously, in majority of cases, the emphasis is there to follow GMP but comparatively less efforts are being devoted to investigate the previous observation/failure and keep on place the suitable "Corrective And Preventive Actions (CAPA)".

It is a great need, to elaborate feasibility of failures common in pharmaceutical industries, their proper end to end investigation and CAPA with suitable technical rationales. The present article has been profusely focused to demonstrate the pharmaceutical failures, their heedful investigation, in best possible ingenuity.

Biography

Lokesh Kumar Gupta completed his Ph.D. at the age of 25 years from Delhi University, India and has postdoctoral exposure of about 10 years with leading pharmaceutical companies, in the area of "Analytical Research and Development". Presently, he is working with Lupin Limited as senior manager (ADL) and actively engaged to develop analytical technology and its commercialization. He has published more than 42 research papers in reputed journals of chemistry and serving as an active reviewer for different journals. In addition to that he is fellow member of several scientific bodies. He has also been awarded with Young Scientist Award, twice and several more honors.

lokeshgupta@lupinpharma.com