G Sundar, J Develop Drugs 2015, 4:4
http://dx.doi.org/10.4172/2329-6631.C1.011

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## Effective GMP audits for APIs and formulation in pharma companies

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The independent third-party GMP audit is to evaluate GMP compliance status of the manufacturer in accordance with the current GMP requirements set forth in 21 CFR Part 210 & 211 ICH Q7 and EU GMP with its interpretations. The compliance status will be evaluated in terms of quality compliance with respect to all the six systems and hardware, software, and personnel. All deficiencies identified during the cGMP audits will be noted in the audit report with gap analysis and proposed corrective actions. A pharmaceutical auditing plan may include CAPA on:

- Documentation and Record Control
- Verification of data integrity and its control measures
- Manufacturing Process and Equipment
- Training
- Validation and Qualification

While the purpose of all audits is the same, the elements and steps involved in the audit process may differ depending on the type of audit required and its applied regulation standards. Any pharmaceutical manufacturing company must be able to prove that it does so with absolute reliability, under optimal secure conditions, and with extreme uniformity to allow for exact reproduction. Therefore, all manufacturing equipment and processes must be qualified and validated to ensure performance.

### Biography

Sundar Ganesan has completed his MSc Chemistry from Annamali University and qualified as GxP compliance person with 22 years of rich experience. He is the Director of PharQA Complaince Services, a premier GxP consultancy service organization. He has published more than 20 papers in reputed journals and has been serving as an Editorial Board Member of repute.

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