

4th International Summit on

GMP, GCP & Quality Control

October 26-28, 2015 Hyderabad, India

Overview of data integrity in the pharmaceutical laboratory and current regulatory challenges

Abhay Gupta

Novartis Healthcare Limited, India

In modern scenario GxP data integrity is critical to GMP requirement, patient safety, regulatory compliance, post approval submission and business success. Current days' regulatory authorities have highlighted concern in regions where the industries are rapidly growing especially in some Asian company. Data is all forms of raw, processed and recorded data, and associated records and documentation i.e., paper, digital/electronic, photographic/video and audio. Data integrity is transparent generation, acquisition, processing, evaluation, recording, reporting, protection and security of complete and accurate data, records and documentation. Data is generated in accordance with applicable GxP requirements that assure the reliability of data, records and documentation. Some of the macro root causes which erode data integrity are financial motivation, business pressure, organizational culture and working environment. Data integrity problem related to all GMP environments which mainly include quality assurance, quality control testing lab, product stability testing lab, validations, development labs, manufacturing packing and maintenance, engineering, etc. FDA has targeted India as a region that warrants close inspection and enforcement actions based on the following risk factors:

- India's pharmaceutical industry is relatively young and rapidly growing
- A major amount of API and FP generic drugs are sourced from India
- High rate of unacceptable inspection results

To control data integrity, it is necessary to develop a corporate ethics program that includes clear policy statement and expectation for employee conduct improvement. 'Health' of operating environment include

- Periodic trainings
- Disciplinary action against unethical practices
- Risk assessment for identifying gaps
- Company management should be committed to provide necessary training, resources, support and work culture.

abhay.gupta@novartis.com

Chemical and pharmaceutical analysis, stability and dissolution studies of drugs and medicines: Quality control of drugs and medicines

Edith Cristina Laignier Cazedey

Federal University of Bahia, Brazil

A lot of new drugs and medicines have an excellent pharmacokinetic/pharmacodynamic, effectiveness and many advantages. However, analytical methods for quantitative determination of them are not always available. It is known that poor quality of API and medicines are directly related to development of side effects and toxics events. Thus, it is important to develop efficient analytical methods for quality control of commercialized products. My research group works with development of analytical methods for qualitative analysis of drugs and medicines using UV/VIS/IR spectrophotometry, high performance liquid chromatography, thermal analysis, thin layer chromatography and other general methods for characterization of API and pharmaceutical forms. Analytical methods such as UV spectrophotometry, stability indicating high performance liquid chromatography and microbiological agar diffusion and turbidimetry are also developed and validated for quantitation of API and pharmaceutical forms. All validation parameters reach the requirements of the major guides and pharmacopoeias. The dissolution tests and dissolution kinetics are also developed. Stability studies of API and pharmaceutical forms are conducted to evaluate the susceptibility of them to acid, basic and neutral hydrolysis, oxidation and photolysis in acid, basic and neutral aqueous solutions, besides the photolysis and thermal degradation testes. Preliminary studies of accelerated stability and long-term stability are also performed. The degradation products are identified using liquid chromatography-mass spectrometry method.

cristalaignier@yahoo.com.br