Enhanced access and affordability of high quality and Stable Supply of medicines

Krishna Sekhar Akkineni
Senior Vice President- Operations Abu Dhabi- UAE

Abstract:
Robust Product Development.

From a patient compliance perspective, the dosage forms to have a clear and acceptable preference and several char- acteristics need to be considered while developing the drug product's formulation. The formulation development can be considered as an amalgamation and incorporation of core concepts in chemistry, pharmacokinetics, engineering tech- nologies, and manufacturing practices to produce a product that is bioavailable, stable, manufacturable, and economical- ly feasible to ensure affordable, high quality medicines with stable supplies.

Robust Product Registration

The drug product registration process involves the compila- tion of the information in the form of investigational new drug submissions or new drug applications for final registra- tion. The robust product registration process refers to formu- late the strategy for interacting with the regulatory authorities in various countries as well as the tactics of securing responses to questions dealing with submissions and maintaining com- munication post registration.

The drug regulatory affairs are involved with nearly every as- pect of drug development through to commercialization and involved in post commercialization activities. For example, activities that involve an expansion of information to modify a current label on a marketed product, submissions for new indications, or new formulations and post marketing surveil- lance of safety (pharmacovigilance) arepartofregulatory.

Sound scaleup and commercialization

In an engineering environment, experiments are often con- ducted to explore, estimate, or confirm. These experiments become the basis for ensuring quality of the product as the process is scaled-up. The formulators should realize the re- strictions that scale-up and tech transfer places on their prod- uct and should proactively work with their manufacturing team to address these limitations.

Biography:
A.K.Sekhar is a postgraduate in Pharmacy Operations by train- ing from BITS, Pilani. He has been a senior Pharma Industry professional for over 30 years in Operations, Strategy, Quality and Regulatory Affairs. He has risen from ranks and has been instrumental in setting up International Quality standard plants from the green field Phase in large reputed Pharma companies like Krebs, Torrent, Lupin, Oman Pharma, Eisai India, Apotex, Jubilant and Neopharma.

Publication of speakers:

1. Pan, Nan & Qin, Jiaohua & Tan, Yun & Xiang, Xuyu & Hou, Guimin. (2020). A video coverless information hiding algorithm based on semantic segmentation. EURASIP Jour- nal on Image and Video Processing. 2020. 10.1186/s13640- 020-00512-8.
2. Wang, Ze & Chen, Mingzhi & Yang, Yu & Lei, Min & Dong, Zhexuan. (2020). Joint multi-domain feature learning for image steganalysis based on CNN. EURASIP Journal on Image and Video Processing. 2020. 10.1186/s13640-020- 00513-7.
3. Wang,Huaqi & Qian, Zhenxing & Feng, Guorui & Zhang, Xinpeng. (2020). Defeating data hiding in social networks using generative adversarial network. EURASIP Journal on Image and Video Processing. 2020. 10.1186/s13640-020-00518-2.
4. Sahu, Aditya Kumar & Swain, Gandharba. (2020). Revers- ible Image Steganography Using Dual-Layer LSB Matching. Sensing andImaging.21.10.1007/s11220-019-0262-y.