Michele Luke Pruett, J Dev Drugs 2014, 3:3
http://dx.doi.org/10.4172/2329-6631.S1.009

OMICS Group Conferences
Accelerating Scientific Discovery

3rd International Summit on
GMP, GCP & Quality Control
September 25-26, 2014 Valencia Convention Centre, Spain

Best quality practices for biomedical research in drug development

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Despite the multi-billion dollar investment into pharmaceutical Research and Development, there has been a notable decline in productivity when one compares the sizable monetary input to the output of new approved medications available to patients. Although the basic scientific achievements are promising, we continue to see a huge number of drugs fail due to lack of efficacy. It has been suggested that the wrong drugs are being developed as a result of poor scientific principles being applied. It has been observed that there is a concerning lack of reproducibility in biomedical research. Non-regulated biomedical research lacks a common standard, the longstanding tradition of peer review of the results being considered the quality control. However modern biomedical research has become so complexthat peer review has a limited value today. In the interest of improving research practices, creating partnerships and increasingthe return on investment, a group has come together to discuss harmonizingthe standards for biomedical research. To date, an ASQ Technical Report has been published outlining the basic framework, simple requirements and concepts that incorporate quality into the very beginning of the development process. The goal of this endeavor: To speed up the discovery, delivery and commercialization of new drugs providing better choices of medicines for patients and delivering solutions for unmet medical needs.

Biography

Michele Luke Pruett began her foray into pharmaceutics in the Medicinal Chemistry department at the SUNY Buffalo School of Pharmacy. Over the span of her 20 plus years in the pharmaceutical world she has worked in Research & Development, lead Quality Control laboratories, managed Quality Assurance departments and helped remediate serious compliance issues. She believes that by teaching investigative skills, sharing the tools to develop meaningful quality and compliance metrics and engaging in discourse on the understanding of the governing regulations, how to implement appropriate systems and specific CAPA we can better the industry as a whole.

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