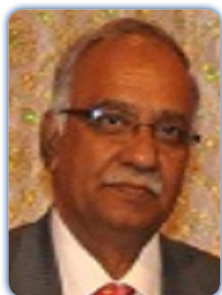


2nd International Conference and Exhibition on

PHARMACEUTICAL DEVELOPMENT AND TECHNOLOGY

May 11-12, 2018 Osaka, Japan



Saeed Qureshi

Pharmacomechanics, Canada

The scientific basis of defining quality pharmaceutical products and their assessment

It is important to note that patients and consumers need drugs or medicines but buy products such as tablet or capsule. In this respect, one must first clearly differentiate between the two drugs or medicines from products. The capability of releasing or delivery of the drugs from the products as expected then becomes a quality attribute of the products from a patient's perspective. A formal or regulatory recognition of this critical quality attribute (CQA) is lacking at present, at least in a measurable terms which causes significant hurdles in developing and manufacturing of the pharmaceutical products. This presentation explains scientific rationale for defining the CQA for pharmaceutical products so that the development process for such products becomes effective, objective and efficient. Unlike the current practices and requirements, which lack scientific basis, the approach or technique for the assessment of quality, thus CQA, must be product independent for an unbiased assessment. Such a product independent evaluation approach is not only a scientific requirement but will hugely simplify product evaluations thus their development and manufacturing. Considering solid oral dosage forms (tablet/capsule) as an example, a new and simple approach based on a universal drug dissolution test will be presented for monitoring CQA. Scientific validity, simplicity and superiority of such an approach in comparison with the current practices will be highlighted.

Biography

Saeed Qureshi has extensive working experience as a Research Scientist, with a regulatory agency (Health Canada). He is an internationally known expert on the subject and maintains a full command in the areas of drug dissolution testing, pharmacokinetics, biopharmaceutics and analytical chemistry as related to animal and human studies for developing and evaluating pharmaceutical products. He has extensively published in peer-reviewed journals and given numerous national and international presentations on the subject.

principal@pharmacomechanics.com**Notes:**