

## How does quality impact business success

**Sunita Sharma**

Ocimum Bio Solutions, USA

How does quality impact business success? The subject of quality for a business or organization must be understood before it can be determined if it is important. The purpose of business is to attract customers and make a profit. This requires the ability to retain the customers they have and allure in new ones. One of the characteristics important to customers is quality. This cannot be denied in that those who have a great reputation and good customer service flourish in today's economy. The question to be answered is how businesses focus on quality principles and do they have quality high on their objectives/policy in their operational plan.

### Biography

Sunita Sharma has completed her Ph.D in Molecular Biology and Biochemistry from University of Lucknow, in Lucknow, India. She was granted the Rockefeller Foundation Post-doctoral fellowship and earned a high rank in University of Pennsylvania School of Medicine, Philadelphia, PA. She has a nice blend of academia, USA Government (NIH and FDA) and BioPharmaceuticals. She has worked in many reputed Universities in USA (Thomas Jefferson University, Temple University in Philadelphia, PA) and National Institute of Health in DC. She has worked as Senior Quality professional in Amgen and GlaxoSmithKline pharmaceuticals. She is the Director and Site-Head of Quality, Regulatory and Compliance of Gene Logic, an Ocimum Biosolutions Company, global integrated genomic services company. She has published several papers in reputed journals. She has been honored and awarded in Who's Who in America 2012.

sunita\_sharma27@hotmail.com

## Impurity and its regulatory requirement

**Surendra Pandey**

Symchem Research Labs Pvt Limited, India

Impurities in active pharmaceutical ingredients (APIs) and in pharmaceutical products is a main issue reviewed both during the assessment of registration files (CTD) and during GMP inspections. Due to the importance and complexity of stability issues this subject is covered directly and indirectly by many regulatory guidelines.

The impurity present in the finish product is due to various operations carried out during their manufacturing. There are various ways to characterize the impurities during the drug development process. Impurities present in the Finish products are Residual solvents, Genotoxic impurities, Heavy metals impurities, and Organic impurity. There are specifications from ICH/USP/B.P/E.P. requirement for Impurities Profiling.

The presentation will cover following topics

1. Classification of Impurities
2. Process responsible for presence of impurity in finish product
3. Types of impurity
4. Organic Impurities
5. Inorganic Impurities
6. Solvents
7. Genotoxic impurity
8. Cash study of Impurity with chemical structure of one API.

### Biography

Surendra Pandey has completed his Ph.D from UDCT Mumbai. For last 20 years he is pursued his research carrier in process development and drug discovery. He has filled two DMF while pursuing his industrial Process Development carrier. He has filled 13 patents on New Chemical entities (NCEs) during his carrier at Drug Discovery. Presently working with SYMCHEM, the industry is engaged in the synthesis of IMURITY and synthesized/isolated more than 100 impurities.

spandey@symchem.com