Lothar Hartmann, 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

Pharmaceutical quality system

Lothar Hartmann
Crucell, Switzerland

Often the thesis is thrown into the discussions that our industry does not need to implement a Pharmaceutical Quality System (PQS) - we already apply to GMP. But, are we operating efficiently? Can we meet all the GMP standards when we continue to work as in the past? Probably not. The International Conference on Harmonisation (ICH) has addressed the increasing complexity of our business to be compliant by issuing the ICH Q10 Guideline called "Pharmaceutical Quality System". An effective PQS is the foundation for successful manufacturers.

The implementation of a Pharmaceutical Quality System is an enormous effort where most of the departments of a company are involved in. It involves a cultural change in how we think about our business: away from the departmental silo thinking towards a process orientation approach. The solid knowledge of our processes is key for being in compliance with regulations and to demonstrate inspection readiness.

The implementation of a Pharmaceutical Quality System according to ICH Q10 throughout the product lifecycle facilitates continual improvement. In addition we will benefit from winning time, improved quality and reduced costs.

About 10 years ago the 'New York Times' has blamed the pharmaceutical industry that their (manufacturing) processes are less robust than those from the potato chips manufacturers. We now have the tool in our hand to demonstrate that this is not true. Let's start to implement Pharmaceutical Quality Systems.

lothar.hartmann@jentges.com