

GMP compliance organisation and policies:

Quality Risk Management (ICH Q9)
Pharmaceutical Quality System (ICH Q10)



Organisational GMP Assessment
Improvement Plans Risk Management
Policies and Procedures
Implementation and assessment
of Phtil Qlit St Pharmaceutical
Quality Systems.

Since FDA's initiative in year 2002: 'cGMPs for the 21st Century - A Risk-Based Approach' many things have changed dramatically in the pharmaceutical business to better approach GMP compliance in its original and essential objective: to protect patient's health.

These changes have expanded to the pharmaceutical industry worldwide through the ICH 'globalisation' of the original initiative and the resulting guidelines: ICH Q8, Q9 and Q10.

The application of ICH guidelines to the pharmaceutical business processes can integrate, in the most effective way, the GMP compliance needs with the business objectives of the company.

The implementation of a versatile and practical risk management policy together with a Quality System pursuing the continual improvement and a robust organisation in order to 'manage the exception' should be the enablers of the new approach.

The large experience of TDV, working for many years closely to the organisational areas in the pharmaceutical companies to improve the overall GMP compliance profile can provide an unparalleled knowledge infrastructure and 'GMP culture' to the best implementation of the current concepts leading GMP compliance.