



GMP compliance strategies:

Preparation of regulatory inspections

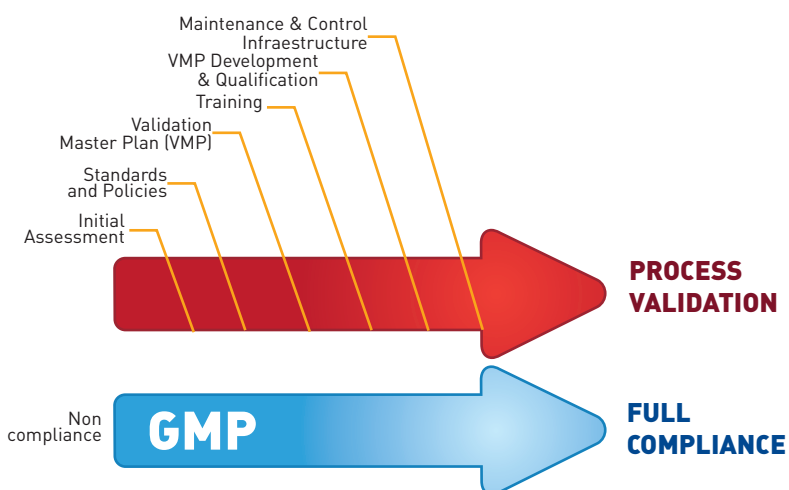
Today, many companies should face up to situations new to them in having to deal with new business opportunities: the development of a new product, opening a new market in foreign countries, an agreement with a large company for a global scale business,...

This entails the necessity of complying with new regulations that the company never encountered, simply because that need didn't exist before.

The opening to the EU and US markets involves full compliance to the applicable cGMP and the subsequent audits and regulatory inspections for approval of the intended activities.

The experience TDV has gained in such cases, for both primary and secondary manufacturing, has provided a methodology capable of producing, in a reasonable time and resources frame, an infrastructure for GMP compliance, able to successfully meet the requirements of the future audit or inspection.

- GMP Audit and Assessment
- Implementation of Action Plans
- Preparation of regulatory inspections (EU, FDA) and external audits
- Quality System improvement: development of policies and procedures
- Customised, area-specific training



For further information about GMP compliance strategies, please contact:
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