



GxP in Research & Development

Technology Transfer

Quality by Design (QbD), ICH Q8

Technology Transfer
ICH Q8 development models
Process Analytical Technology (PAT)
GMP in Pharmaceutical Development
Development Reports
Expert Reports

Research and Development areas were in the past traditionally excluded from the “regulatory envelop”, since it strictly applied to the production environment with regard to GMP compliance.

However, an increasing requirement for the application of GXP (GMP, GLP, GCP) principles to the complete Product Life Cycle has been driven by FDA’s ‘riskbased-approach’ initiative, and especially by the more recent guidances subsequently developed from it: ICH Q8, Q9, Q10 and Process Analytical Technology (PAT),...

Concepts such as Quality by Design (QbD) apply from the early development stages. Sound scientific criteria applied to evaluate results and data contribute to the product and process knowledge, which is the key to providing, and proving, the necessary control of the process and the consistent quality of the product.

Before going to the production plant, the manufacturing process should be understood in depth, including its Critical Process Parameters (CPP). This knowledge gives the ability to drive improvements within what is considered the Design Space without potentially affecting the quality of the product.

This, in turn, leads to the optimization of the process without the need for revalidation or regulatory prior approval.

TDV provides experience in R&D projects for:

- Solid, semi-solid and liquid dosage forms
- Active Pharmaceutical Ingredients (API’s)
- Sterile and aseptic manufacturing
- Biotechnology
- Process Analytical Technology (PAT)

For further information about
GxP in R&D and
Technology Transfer, please contact:
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