

Role of process controls in mitigating the risk associated with manufacturing of biosimilars

Indu Javeri
CuriRx Inc., USA

This presentation addresses the basic requirement of having process controls based on analytical characterization and formulation and process development that would not only allow for mitigating the risk associated with manufacturing but also allow for product with quality, safety and efficacy similar to the reference product.

Biography

Indu Javeri is Innovative and results-driven leader focused on achieving exceptional results in highly competitive environments that demand continuous improvement. Experienced in driving product, process improvements, and customer service improvement while building partnerships with key business decision makers. Consistently increases production, reduces operating costs, and improves product quality. Areas of expertise in CGMP regulatory compliance, Formulation/lyophilization, Process Optimization, Project Management, Research and Development, Budgeting/Forecasting, Customer Relations Supply Chain Management, Productivity Improvement Quality Improvement Planning, Operational and Strategic Planning, Disaster Recovery Program. Known for building and motivating teams, as well as instituting metric systems for accountability.

ijaveri@curirx.com