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Process Validation

D & D Consulting LLC provides world class process validation services to pharmaceutical and biotech companies. Our consultants have performed process validation for a wide range of systems. We offer a high quality standard for the following service areas:

- **Active Pharmaceutical Ingredients**
- **Biotechnology**
- **Blood Facilities**
- **Liquid and Solid Dosage**
- **Medical Devices/Diagnostics**
- **Parenteral and Sterile Facilities**
- **Vaccine Manufacturers**



Process Validation provides documented evidence that a manufacturing process utilized consistently produces a product meeting predetermined specifications. The process validation approach assesses critical unit operations at each step of the process, as governed by Critical Process Parameters (CPP's) and Critical Quality Attributes (CQA's). CPP's are those processing variables, which must be maintained in order to produce material consistently meeting quality characteristics. CQA's are predefined acceptance limits that ensure the potency, safety and purity of the final product.

Today, many companies have an incomplete/lack robust methods, and/or rationale to address process validation, and are therefore seeking D & D Consulting to help them develop/improve their process validation methods and procedures.