

# Combination Drug/Medical Device

Emerging Combination Drug/Medical Device products now being developed require a new approach to process and facility design. Guidance from the newly formed FDA Office of Combination Products, as well as CDRH, CBER and CDER now govern product and facility design from the earliest stages of development through product approval, launch and routine manufacturing.

## Planning and Design

Adding to current combination product regulatory challenges are the new high potency pharmaceutical compounds typically in use that require specialized containment systems and processing strategies. Design of new clean rooms must take into account current and future potent chemical compounds and cleaning chemicals, as well as how equipment will be operated and maintained. From R&D labs and pilot plants to full scale facilities, potent pharmaceutical compound processing suites require integrated planning and design. For the downstream low temperature sterilization processes (ethylene oxide, electron beam or gamma radiation) often required for Medical Device or Drug Device sterilization, the overall integration of process equipment with facility HVAC and clean utility systems is critical. CRB can advise and lead your project team in meeting special clean room requirements. A reliable upstream process with well-engineered systems and appropriate redundancies will make the final product sterilization process more robust and your process yields higher.



CRB has experience in these emerging combination technologies and can lead your design and process development effort. Our goal is to provide you with the specialized expertise now needed for combination products equipment and facilities.



# COMBINATION DRUG/MEDICAL DEVICE

## Combination Product Regulatory Strategy Planning

- Drug/Device Equipment Commissioning and Validation Master Plan Guidance
- Product Design History File/Drug Development Report Impacts
- Combination Product cGMP Reviews and New Processing Trends

## Potent Compound Processing and Containment

- Isolators and Closed Isolator Feed Systems
- Closed Solution Mixing Reactor Systems
- Misting Showers and Accidental Spill Containment
- Walk-in Processing Hoods and Containment Systems

## Customized Drug/Device Process Equipment and Layouts

- Precision Drug Spraying Technologies
- Vacuum Drying Processes
- Parylene Coating Processes
- In Process and Final Packaging Lines
- CIP Systems
- 3D CAD Process Layouts
- Computerized Process Simulation
- Plant Material and Personnel Flow Analysis
- Lean Manufacturing/De-bottlenecking

## Drug/Medical Device Analytical Laboratories

- High Purity RO/DI, USP, WFI Water Systems
- Specialty Bulk and Bottled Gas Systems (Nitrogen, Hydrogen, Helium, Oxygen, Argon, Carbon Dioxide)
- Clean Compressed Air and Lab Vacuum Systems
- Low Vibration Instrumentation Areas
- Solvent Hazards Minimization Per 2008 IBC L Occupancy Requirements

## Specialized Electrical Power, Control and Data Systems

- Uninterrupted and Emergency Power System Design
- Building Control and Automation Planning and Philosophy
- Critical Equipment Monitoring (Refrigerators, Freezers, Stability Chambers)
- Electronic Batch Records and Manufacturing Execution Systems (MES)

