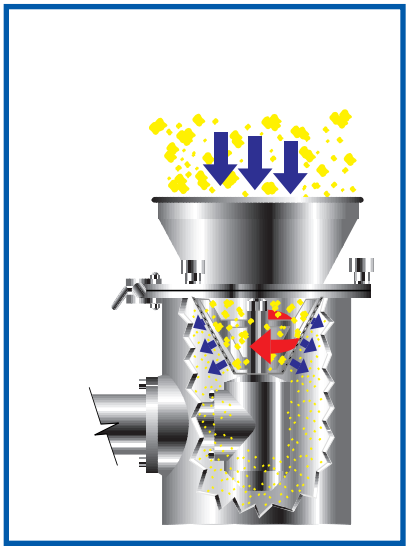
# Quadro® Comil®

## Sizing of Parenteral (Injectable) Drug Powder

### Background / Requirement

A large multinational pharmaceutical corporation approached Quadro with an application to size sterile, freeze dried (lyophilized), pharmaceutical powders. The sterile powders are then placed into sterile vials for use as an injectable dosage form (parenteral). The product in the vials is stable for a long period of time as it is freeze dried, sterile and sealed under vacuum. When it is time to use the drug, a solvent (such as water) is added by syringe to the vial and the vial is shaken to dissolve the powder within. The resulting suspension or solution is then withdrawn from the vial by syringe and injected directly into the patients blood stream. It is important that the powder in the vial be of a lump free and uniform particle size to facilitate suspension or dissolution and to provide the required maximum particle size to suit the needle and application used. For this a size reduction step is required between freeze drying and the filling of the vials. The parenteral nature of this product requires that aseptic (sterile) conditions be maintained throughout the manufacturing process. Our client was not pleased with the aseptic qualities of competitive size reduction mills. Knowing Quadro's reputation for client driven innovation they approached us in the hopes of developing a suitable size reduction mill for this very specialized application. The prototype was developed years ago as a joint engineering effort between Quadro and multinational pharmaceutical corporations.



### Comil® Performance

By working closely with the client, Quadro developed the "ULTRA SANITARY" MODEL "Z" STERILIZABLE COMIL®. The Z Comil® is polished to an ultra sanitary finish and can be sterilized by autoclave, steam in place, or with hydrogen peroxide gas. The Z unit is equipped with our unique "CENTRIFUGAL SEAL" to prevent cross contamination between batches which can arise from many competitive mills. The spindle assembly can be equipped with sanitary mechanical seals if running under high temperatures is required and can be offered as a CERTIFIED PRESSURE VESSEL should steam in place pressures warrant. The removable head can easily disassemble for autoclave sterilization. The new Z design operates as and offers all of the advantages of the standard Comil® while incorporating many unique and innovative options that satisfy the most stringent of sterilization and aseptic processing specifications.

### Summary

Several multinational pharmaceutical corporations have installed the Z Comil® in similar applications since the first prototype was developed in 1990. With each successful installation Quadro has improved the basic Z design and has added even more unique features as options to broaden the Z Comil® sphere of capabilities. Consult Quadro for more detailed technical bulletins on sterilizable Comils®.



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