

Vial Adapter Combination Product Case Study

Product

- Vial Adapter Combination product
- Ongoing sales

Issue

- Design verification study for Mix2Vial® device per customer intended use
 - Testing to be performed in cGMP environment

Resolution

- Perform Three-Year Study
- Report to be used for FDA 510(k) submission
- Created, validated and executed test methods to meet specific needs for regulatory submissions



Mix2Vial® Device
rapid transfer of
liquid to powder
(under vacuum)