

# Case Study

Pharma Automated Powder Dosing Solutions



## Purchase Justification – for the Quantos Powder Dosing System

This is a memorandum from a fast growing US company that operates very successfully in contract Pharmaceutical development and manufacturing. This internal justification document explains the benefits of Quantos, especially with respect to safety, and assisted them in the purchase of two automated powder dosing systems. If you are required to submit a similar purchase justification and are interested in receiving a complete copy of this document to assist your internal process, please contact your local Quantos representative.

### Pharma & Contract Research and Manufacturing Companies

Class II to V regulated compounds  
Analytical Laboratories



Quantos QB1 with Autosampler QS30

METTLER TOLEDO

## "Benefits for potent product testing

■ Containment processes (Matrix) and the equipment associated with them, are necessary parts of the business of handling potent API's. The need for anticipation, recognition, evaluation, and control of environmental factors that arise in and from the workplace that may result in injury, illness, impairment, or that may in any way affect the well-being of workers are critical. The value of effective containment systems (Quantos Powder Dosing System) has become even more apparent at "Company A" since the recognition of our customers' increasing need for potent product development and manufacturing and our decision to pursue this business in a major way. Of the four basic responsibilities of the Containment Matrix previously mentioned - anticipation, recognition, evaluation, and control - the first two require a fundamental knowledge of toxicology, epidemiology, and other sciences which extend the ability of the scientist to control highly hazardous processes and materials. The other two deals with what are considered being the critical role isolation management program. These includes:

1. The evaluation of the magnitude of potential exposures, primarily of workers and other members of the organization.
2. The strategies, facilities, and work practices necessary to ensure adequate control of such exposures to potentially hazardous material in the work environment.

The system will enhance the ability of the analytical team members to operate in a safe manner along with providing controls on work processes. This balance is one with unique containment features that ensures a successful weighing of products with isolation to the scientist/chemist. This would be a great investment in the containment program/strategies here at the Company A along with exceptional weighing analysis/outcomes. The unique dosing head provides a closed system for weighing powders and solid drug substances. This allows the users a second barrier of protection against potent compounds. Once the dosing head is loaded, the users only place the dosing head on the balance and weigh samples directly into the flasks for testing. This unique design will reduce the number of repeat analyses due to analyst weighing error. The design also adds a second level of protection against potential analyst weighing errors when the glove box is used for analyses involving potent compounds. This unit can be placed inside of a hood where the unit will perform the weighing and eliminate analyst weighing errors while providing an additional protection barrier. Once the dosing heads are loaded, the containers can be stored inside of the hood where they are not removed until testing of the project is completed.

### Benefits for DEA Regulated Compounds

■ Company A works on Class II to V regulated compounds. The current process for weighing a regulated compound within the analytical laboratories involves the analyst

and a witness to verify the amount dispensed. As stated before, the dosing head container stores the compounds for weighing. Since each dosing head is equipped with the RFID, each dosing head is unique to a sample. The information that is stored on the chip can be used to track the consumption of compounds. These RFID's can be locked and only changed by appropriate personnel. This capability will provide a useful tool for sample management in that the dispensing of controlled substances for analytical testing can be less time consuming and easier to trace. The added value of weighing directly into the preparation vessel and elimination of sample loss provides an added level of security for controlled substances. The time involved in weighing and witnessing controlled substance will also be reduced allowing for more efficient testing.

### Summary

■ The Quantos Powder Dosing System will provide a great benefit for the analytical laboratories. These benefits include more efficient weighing, a reduction in the number of repeat analyses due to weighing errors, added protection for analyses involving potent compounds, and an increase in efficiency for dispensing and weighing of controlled substances. The reduction in repeat analyses and the time saved for weighing samples will offset the initial costs of these units. Reference standards can also be converted to this weighing system and improve the overall efficiency of testing in the analytical laboratories."

► [www.mt.com/quantos](http://www.mt.com/quantos)

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