

Capsule Filling with QUANTOS

For clinical phase 0 & 1 trials

Application

In order to test toxicological effects of potential new pharmaceuticals, a wide range of trials is carried out. Phase 0 (human microdosing) and 1 trials are also known as first-in-human trials, with small numbers of patients (typically 20 to 80) that receive the API in small capsules. The application is similar to pre-clinical trials but the substances must have passed these successfully. All compounds need to be treated according to FDA regulations i.e. FDA approved contact surfaces and proven sterility. The duration of the study might be up to a year.

Challenge

The substances used are of a price of up to 2'500 €/g. Manual dosing takes about 2 to 3 minutes per dosing, overdosed samples are withdrawn. The goal is to automate a time consuming and repetitive work, keeping or even increasing the quality standards.

The solution with QUANTOS

The combination of the QB1 with the ErgoDisc is an ideal solution for this problem:

The operator can fill 15 capsules of small size (sizes 0, 1 and 2) into the ErgoDisc, mount this into QUANTOS and then dose the cap-

sules quickly by simply turning the disc in between the dosings. Therefore, reliable dosings at a fast speed can be achieved. To achieve sterile conditions, the ErgoDisc can be autoclaved and used in combination with the sterile dosing head QH075-BS. Regarding FDA approval, the certificates for all materials that are in contact with the substance are listed in the separate design qualification brochure. The LabX direct software and the protocol and label printers allow tracking of the dosed samples.



The QUANTOS solution and options

The list below shows the QUANTOS solution for the presented problem.
The recommended parts are the essential components; however, with the optional components the customer's requirements can be fully met

Recommended system



QUANTOS QB1 (including dosing unit, QD206DR balance, antistatic kit, Netcom kit, ethernet option, cable box and the EQ pac)



Sterile dosing head QH075-BS



ErgoDisc

Optional components



Label Printer CLP631



Protocol Printer RS-P25/QB1



LabX direct QUANTOS



Safety Enclosure QSE1



USB barcode / matrix scanner to track and match substances and targets

Mettler-Toledo AG

Laboratory & Weighing Technologies
BA Quantos Dosing Solutions
CH-8606 Greifensee

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Printed in Switzerland
GlobalMarCom Greifensee

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