POSTER 2

DM² Platform II
Development of an Automated Microscale Manufacturing System for Oral Solid Dosage Forms

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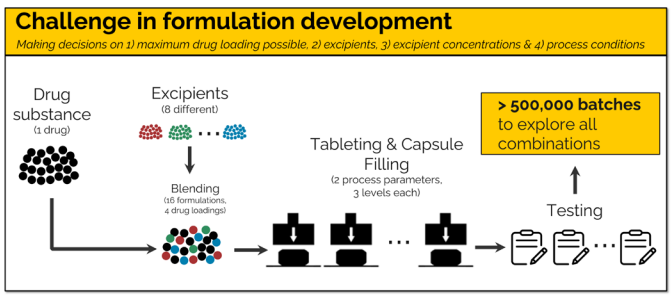
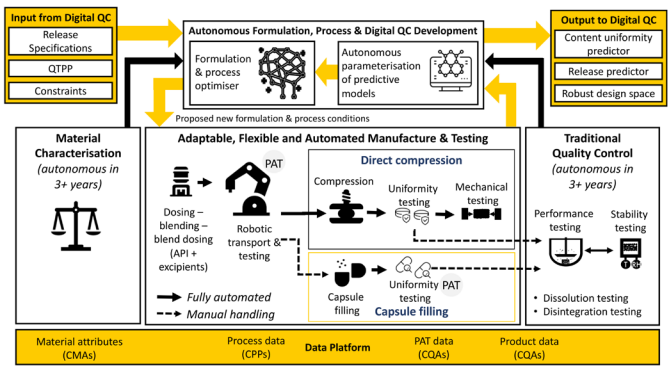
Introduction to DM² Platform II

This platform aims to create a unique autonomous microscale drug product manufacturing and testing system to select formulation and process parameters that result in a stable product with desired critical quality attributes.

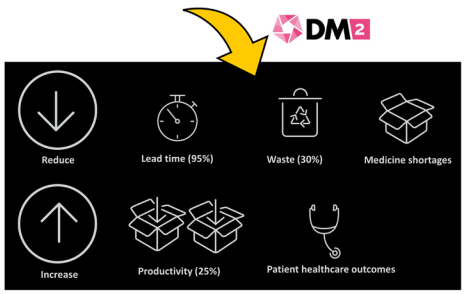




The number of experiments increases drastically with the number of excipients, drug loadings and process conditions that need to be explored to find the optimal formulation and process settings.

Integrating industrial digital technologies (IDTs) with innovative pharmaceutical process technologies will de-risk and accelerate drug product manufacture, reducing experiments and dramatically reducing development time and raw material/solvents use by 60%, whilst achieving CQA objectives by self-optimized formulation and process conditions. The platform is co-developed and co-delivered with industry partners focusing on 1) tablets (via direct compression) and 2) capsules (via powder fill).

The initial aim of this platform is to deliver an automated microscale batch manufacturing system that can eliminate waste while preparing tablet batches of < 10 g per batch and < 50 tablets per batch.



The Microscale Tablet Manufacturing System

The goal is to produce a system which can be run autonomously with user input limited to the filling of excipient and drug substance hoppers. This system will revolve around the use of fully autonomous devices controlled through a supervisory control system linked physically using a collaborative robot (cobot).

The tableting line will consist of:

- Powder dosing and blending will be performed using a novel DEC Group system.
- Blend content uniformity and homogeneity testing will be performed by a Viavi MicroNIR
- The powder transport will be done by a Kuka LBR iiwa 14 r820 cobot.
- Tableting will be done using a Styl'One Nano from Medelpharm
- Tablet testing will be done by a Sotax AT50

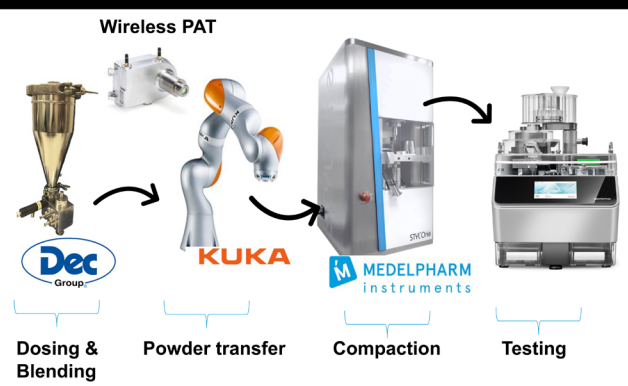


Figure 1: Schematic of microscale tableting manufacturing system.

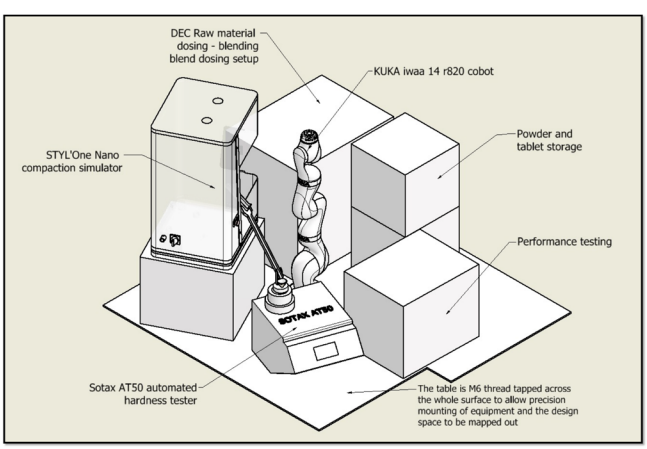


Figure 3: 3D visualization of the table top tableting setup. The sizes of the dosing and blending setup, powder and tablet storage, and performance testing stations have been estimated to give an overall representations of the space that the setup will cover.

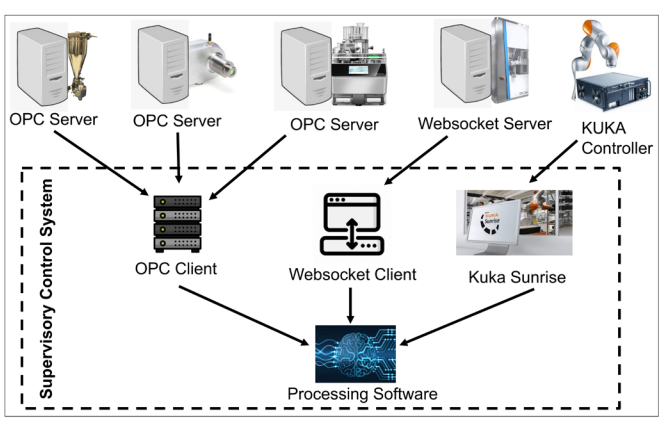


Figure 2: Hardware block diagram showing the communication protocol between the IDTs, the manufacturing technologies and the supervisory control system.

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