

A SYSTEMS-BASED APPROACH TO DIGITAL DESIGN AND OPERATION IN THE FORMULATION OF PHARMACEUTICALS

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The formulation of drug products (e.g. tablets) requires the properties of the active pharmaceutical ingredient (API) particle and the excipients to be optimised along with the manufacturing process, to ensure that the requirements for product performance, stability and manufacturability are met.

Digital Design combines research insight and qualitative and quantitative mechanistic modelling to provide links between raw materials, manufacturing processes and product performance to deliver the needs of the patient. Work carried out under a major UK-based design, manufacture and supply chain collaboration has defined a system for Digital Design and Operation for drug products and their manufacturing processes. Through a dedicated technical facilitation process, the members of the ADDoPT (Advanced Digital Design of Pharmaceutical Therapeutics) consortium have developed an Information Flow for digital design and manufacture of formulated drug products.

ADDoPT partners have worked both to advance the current state of the art in process modelling and control for pharmaceutical processes, and to combine and integrate these developments using a systems framework-based approach. The process encompassed: identification of current best practice and areas for development through interviews with industrial partners; definition of the requirements for the Information Flow; and generation of an architecture for a Digital Design Guide for Pharmaceutical Manufacture capable of meeting these requirements.

The Information Flow has been implemented as an interactive flowchart. Using E-Learning software has facilitated the layering of information from high level overview down to increased depth and detail, and provides a web-enabled output, ideal for dissemination. The generic information flow developed is a template upon which individual organisational needs can be customised, and similar digital information flows will be applicable outside the pharma sector.

