

New platform for the design and manufacture of patient-centric pharmaceuticals

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It has long been known that giving the same medication to multiple individuals does not have the same effect on each one. For the last six decades, pharmacotherapy has been based on subjecting every individual patient to the same dosing regimen, while the different degree of therapy success among them has been regarded as an expected “fact of life.” However, biomedical advances in the last twenty years have made revealed the underlying reasons for, and made it possible to objectively assess, the variability in therapy response among individuals. These developments have triggered the era of Patient-Centric and Personalized Medicine, which poses a game-changing challenge to pharmaceutical manufacturing. Simply put, existing pharmaceutical manufacturing methods were not conceived, nor are suitable for tailor-made therapy, that is, pharmaceuticals customized to the needs of specific group of patients or individuals.

We present a new platform for the design and manufacture of oral dosage forms (*pills*), developed to satisfy the patient-tailored (or subpopulation-tailored) requirements of personalized medicine. The approach is a paradigm shift, whereby pills are conceived as Integrated Systems, rather than as traditional compacts of powder blends. The new dosage forms (“3D Pills”) are assembled in modular form from prefabricated components, where each component performs a specific pharmaceutical function. The 3D Pills are assembled as 3D stacks of the prefabricated components in a fashion analogous to the manufacture of 3D Integrated Circuits. Each prefabricated component is a polymer composite wafer, whose particular function in the assembly is determined by the type of material embedded with the polymer (active pharmaceutical ingredient, solubilizer, disintegrant, absorption enhancer, pH modifier, ID/anti-counterfeiting element, etc.). The Integrated Systems approach to manufacturing makes it comparatively (to traditional manufacturing) a simple task to add or refine performance attributes of the pill, and/or quality related attributes to the dosage form by incorporation of additional/different functional composite wafers. The 3D Pill concept is patient-centered, such that precise dose adjustment, as well as drug release characteristics, can be achieved within the same platform, in order to meet the therapy requirements of the individual patient. The Integrated Systems approach to pharmaceutical manufacturing is suitable for just-in-time (JIT) manufacturing for individual patients, and scalable to (larger) patient sub-populations of indeterminate size.