A door to the future

Personalised oral pharmaceutical dosage forms via mass-customisation manufacturing

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Managing the administration of multiple medications comprises an important part of global healthcare. Present pharmaceutical products do not easily allow for regimen adherence by patients or dosage customisation by physicians. A novel technology is being developed to provide personalised fully-variable oral combination dosage forms.

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Today's medication management challenges

Polypharmacy – the daily administration of multiple medications for chronic therapy – presents global problems. For many patients, it means a difficult and confusing process with numerous bottles of medicines and often allocation into pill-boxes with multiple compartments. Complex regimens lead to non-adherence issues and drug mix-ups, especially in elderly patients where multi-chronic conditions are common. The challenges associated with the medication allocation and administration processes are of much concern to healthcare providers and family members.

Also, physicians wish to easily account for physiological characteristics by prescribing precise customised doses, especially for drugs with low therapeutic indices and unique efficacy profiles – such as, cardiovascular and hormone replacement therapy. Physicians are concerned when patients must subdivide tablets to obtain the correct dosage.

Present products do not meet these needs and situations such as the following occur: "Are you sure that you took the small white pill and not the large white pill this morning?" asked of an elderly patient or the instructions from a physician that read "Take one and three-quarter tablets three times a day." Such incidents should not occur in our technological era.

Recent attempts to simplify cardiovascular therapy regimens have involved developing "polypills" containing several drugs such as statins, ACE inhibitors, beta-blockers and aspirin. However, these are fixed combination products and inflexible in drug composition and dosage. An alternative to the tablets and capsules devised in the mid-20th century is needed.

Devising a 21st century solution

P&C Pharma has designed a novel technology which for the first time will manufacture fully variable oral combination medication products.

MAESTRA Formulation Technology™ is designed to consolidate and advance the technologies by which oral dosage forms are manufactured and delivered. It will allow physicians to customise drug therapy while maintaining high quality and at a cost that is comparable to that of the corresponding generics.

This system will provide a patient with the precise required dosage of medications for each administration. All of the needed medications are combined and packaged into a minimum number of capsules – preferably one. As a line extension, it has the option of providing the medications in a vial for reconstitution into a single-dose flavoured liquid. The system allows for full flexibility in medication composition and dosage strength to fit each patient's needs. Each dose – capsule or vial – will be packaged in its individual sachet, labelled with the appropriate information, and tracked via a barcode. The sachets can be colour-coded to easily differentiate the day's dosing periods – morning, afternoon, evening, and bedtime. The sachets required for the prescription period will be consolidated, boxed, and shipped to the patient's residence. The technology accounts for issues of bioavailability and stability.

Combines four technologies:

- Information management and software design for the management of the prescription requests.
- Industrial automation and material handling.
- Drug microparticulate formulations bioequivalent to marketed products.
- The precise automated filling of small quantities of microparticulates to weight [1].

A transformative technology for cost-effectively producing pharmaceutical formulations. It is the first technology designed for „just-in-time" manufacture of pharmaceutical products. In contrast to present manufacturing procedures, MAESTRA™ employs fewer unit operations, total quality control for each manufactured unit and is also better for the environment as there is no more waste from expired products. The technology is designed to control costs while increasing the quality of the manufactured products. Patents have already been granted in the US. and Japan and applications are under review in other countries.

1 Mettler-Toledo's technology, Quantos Dosing System, is being evaluated for this application.

Seeking Partners

Patients' & Consumers' Pharma (www.pandcpharma.com) is a U.S. based entrepreneurial company developing novel technologies to provide customised human and veterinary pharmaceutical products. The company is seeking partners to co-develop its two inventions, MAESTRA Formulation Technology™ and INSTA Compounding System™.

Development & commercialisation strategy

We have three key goals associated with the development:

- Technology: The required technology subcomponents are available through well-established global corporations with proven expertise in their fields. The technologies will have to be adapted to the needs of the system. However, we believe this to be a very attainable objective.
- Regulatory: MAESTRA™ represents a new manufacturing approach for pharmaceutical products. Approval pathways will have to be developed via collaborative discussions with regulatory agencies.
- Commercialisation: We intend to partner with a suitable global company to develop a worldwide commercialisation pathway .

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Fig 1. MAESTRA Formulation Technology™ Combining Expertise for Innovative Manufacturing