RELEASING THE POTENTIAL:
How Novel Drug Delivery Technologies Can Deliver Competitive Advantage In The Solid Oral-dose Sector

POWERED BY:

Generics Bulletin
Pharma intelligence | informa

IN PARTNERSHIP WITH:

bddi

Novel delivery technologies and formulations have the potential to improve compliance, revolutionize drug manufacturing and let pharmaceutical firms optimize market positioning.

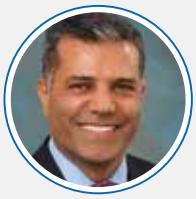
But identifying opportunities where such technologies can be applied calls for detailed market analysis and careful planning according to experts who took part in a Pharma Intelligence and BDD Pharma roundtable on *Releasing the potential: How novel drug-delivery technologies can deliver competitive advantage in the solid oral-dose sector* at CPhIWW in Madrid, Spain in October.

The panel was moderated by Aidan Fry, Executive Editor of Generics Bulletin.

Aidan Fry, Executive Editor,
Generics Bulletin

ROUNDTABLE PANEL

Professor Howard Stevens,
Chairman, BDD Pharma



Dr. Ali Rajabi-Siahboomi,
VP and Chief Scientific Officer,
Colorcon

Dr. Thekla Kurz, Head of
Pharmaceutical Development,
Stada

Cláudia Silva,
Chief Scientific Officer,
Bluepharma

Paul Tredwell,
VP Speciality Brands, Accord Healthcare

DELIVERY TECHNOLOGIES AND PATIENT CENTRICITY

Patient centricity is an obvious driver of interest in drug delivery technologies according to Professor Howard Stevens, BDD Pharma Chairman, who told attendees "patient convenience is very, very much in our philosophy."

He used the firm's OralogiK™ time-delayed technology as an example of an approach that directly benefits patients.

"With our technology you can take something at bedtime and then nothing happens until you design the release point to occur in the middle of the night, or just immediately prior to wake up."

Stevens added that the benefits of night time dosing include reduced side effects and a reduction in symptoms such as morning pain and stiffness before waking.

Patient centricity is also reshaping the wider industry according to Dr. Ali Rajabi-Siahboomi, VP and Chief Scientific Officer, Colorcon who said pharma firms are now seeking technologies that address issues like "swallowability".

"The acceptability of the dosage form for patients and age appropriate medication are really hot topics right now" he said, explaining that patient needs vary with age.

"On one side we have pediatric medicines that require a range of taste masking options and administration routes. Then on the other hand, we have drugs for elderly patients suffering conditions like Parkinson's or Alzheimer's for whom loss of muscle tone can result in difficulty swallowing.

To address this issue Colorcon recently launched a new film coating technology, Opadry® EZ, that dramatically improves tablet mobility, reducing the probability of sticking in the throat or esophagus."

Dr. Thekla Kurz, Head of Pharmaceutical Development at Stada, cited demand for products that comply with the requirements of religious groups and people who adhere to particular diets as a further example of how patient centricity is encouraging the drug industry to rethink delivery technologies.

"Presently most companies are cautious about presenting their pre-marketed products into an unknown drug delivery system. But we are seeing interest from people very early in the post-marketing phase, much earlier than I would ever had anticipated, wanting to have a product that may be marginally more complicated but most importantly, more effective than the product they may have originally developed."

BRANDED LIFE CYCLE MANAGEMENT

Life cycle management is another major driver of interest in delivery technology innovations according to Stevens, who said drug companies are not only keen to guard against competition, but anxious to add value to the choice of medicines at the disposal of physicians and subsequently in the interests of the patient.

He said, "It's about striking a balance between medical and commercial concerns."

"We go on the basis on some knowledge of what this company is about and we spend a fair amount of time looking at their products. What are they doing? What's their pipeline? What does it look like? Is there any way in which we can add value?"

"If I just look at the examples working with a few of our clients, several of them have said to us, 'Can you help us to address a complex pharmacokinetic challenge that will improve our medicine and help us bring more value to the market?' Using OralogiK™, we have the capability to combine an immediate release dose together with a delayed dose, some hours later, all in the same tablet. This generates a complex multiphasic release profile, which enhances the drugs PK profile and provides the drug company with lifecycle management enhancement through the status of the formulation. The ability to build or have access to technologies that can achieve these unique profiles, should be central to any oral dose strategy."

"Presently most companies are cautious about presenting their pre-marketed products into an unknown drug delivery system. But we are seeing interest from people very early in the post-marketing phase, much earlier than I would ever had anticipated, wanting to have a product that may be marginally more complicated but most importantly, more effective than the product they may have originally developed."

In the generics sector the drivers are different according to Paul Tredwell of Accord Healthcare who said off-patent drug firms are increasingly using delivery technologies to differentiate products from rivals.

"I think we are seeing a revolution in terms of added value products and generics companies are now looking at differentiating" he said, explaining they are using technologies to optimize dissolution rate, delivery times and administration methods.

MANUFACTURABILITY

Innovation in production methods like continuous manufacturing is a significant, if less immediately obvious, driver of interest in drug delivery technologies and novel formulations according to the panel.

For example, Ali Rajabi-Siahboomi said Colorcon's Opadry® QX coating technology has been adopted by pharmaceutical firms that have switched from batch-based production.

"Some of the trends that we see are that customers are going more and more for continuous manufacturing of solid dosage forms" he said, adding "For some of those high throughput products this coating system has become very important."

DELIVERING TECHNOLOGIES

New drug delivery systems come from a variety of sources, academic institutions, technology specialists and contract development and manufacturing organizations. This disparate range of sources can make finding the most appropriate technology to apply to a particular product can also be a challenge according to the panel.

Paul Tredwell from Accord Healthcare spoke about the organization's

approach to identifying technology partners and suppliers. They have a large business development team, which, after identifying an opportunity for "added product potential," actively searchers for partners.

"From the perspective of considering a larger or a smaller provider, I guess it's a big ship, small ship scenario. For example, one of the larger providers might be able to provide high quality and robust procedures but sometimes are unable to offer the same flexibility we might receive from a smaller provider.

"So, we are always looking for a combination of the two, high quality, good process, but nimble and attentive in the design of what we bring to market."

Thekla Kurz from Stada agreed, explaining "we have a similar approach in that we have agreement around certain deliverables and then review whether the deliverables were provided on time."

However, for complex products, the approach is more nuanced she said, adding "Stada is going more and more into specialties, and these are much more complicated to develop, so there is much higher risk associated with it.

"So, what we start to do now is work much closer with the senior scientists. We believe a discussion throughout the whole development really ensures that things are going in the right direction."

FUTURE NEEDS

Technology suppliers also take an active approach according to Howard Stevens, who said that BDD approaches potential customers based on research on their products and likely future delivery technology needs.

"We go on the basis on some knowledge of what this company is about and we spend a fair amount of time looking at their products. What are they doing? What's their pipeline? What does it look like? Is there any way in which we can add value?"

"We open doors and go and say to people, "We've got a really unique product (OralogiK™) backed with high quality science and we think there's a fit between what you're doing and what we can add, and then we'll have a discussion about the opportunities" he said.

INTERACTING WITH PAYERS

The competitive advantage of applying a technology to a solid dosage form can only be fully realized if the cost of investment is reflected in the product's pricing and reimbursement status.

As a result, companies use a range of approaches to convince payers of the benefits their product according to Paul Tredwell of Accord Healthcare, who said emphasizing the patient centricity of the product is a common strategy.

"During the process of innovation, we need to make sure that we are adding value that is perceived not only by the patients but also by the clinician who will prescribe the product."

"If there is a health economic value to this [novel delivery technology], whether it could be less infusion time for example, or other aspects, then you are able to make the case for the patient benefit.

"Such evidence means that you stand a chance of making a health economic model and securing an incremental price point. So, the pay back of development, the payback of time invested, then begins to look more worthwhile throughout the process."

CONVINCING CLINICIANS

Cláudia Silva, Chief Scientific Officer at Portuguese drug company, Bluepharma, emphasized the importance of demonstrating the benefits of delivery technologies to physicians as well as patients and payers.

"During the process of innovation, we need to make sure that we are adding value that is perceived not only by the patients but also by the clinician who will prescribe the product.

"The needs and concerns of patients, physicians and payers must be addressed in the target product profile, before even starting product development" she added.

Thekla Kurz from Stada shared a similar opinion. She said convincing clinicians of the product's quality is a key consideration when applying a delivery technology "and that's what you are relying on first.

"That's really the basic aim of product development and the rest is a nice to have," she continued, adding "then you have to see how much additional development cost you would be willing to spend on that."

DATA DRIVEN

One sure way of convincing patients, physicians and payers is to use hard data according to Howard Stevens from BDD.

"Using gamma scintigraphic imaging, we can often demonstrate these factors, whether it's easier swallowability or a clinical claim relating to enhanced performance of the product that we've been selling, we can demonstrate those things" he said, adding "we can do good science and persuade the payers that our science is good."

"If we just say, it is better because it smells better, no, that sort of claim is not sufficient in today's market. But if we've got good science to back up our product that delivers faster onset or a solid dose form that delivers once a day dosing – we can then use this data to build a solid commercial argument."

With the onset of novel therapeutic technologies and an increasingly competitive market place, consumers are less willing to settle for anything less than excellence in terms of prescription medication.

The ability to market an optimal formulation not only adds immediate differentiation but also provides originators with the opportunity to extend the commercial potential of their branded medication.

However, some 60% of researchers report project delay or even cancellation due to formulation failure. With over 40% of new IND's remaining oral solid dose delivery, there remains a clear and necessary role for novel solid dose formulations in the development of new or Value-Added Medicines

BDD Pharma is a specialist pharmaceutical development company providing expertise across all areas of drug delivery.

Our patented, time release technology - OralogiK™ provides unrivalled control of drug release in vivo – delivery at the right place, at the right time.

OralogiK™ enables the delivery of single, multi-dose or drug combinations at predetermined times post dose, thus enabling benefits such as

- Effective Drug Delivery during the night
- Pre-wake up delivery of therapeutic agents
- Conversion of twice a day to once a day product
- Combination Products
- Pre-treatment to prevent side effects
- Ability to delivery complex multiphasic delivery profiles

For researchers and commercial innovators, OralogiK™ provides a strong platform upon which a novel approach to the development of true value in oral solid dose technology can be built

For further information please call: **+44 773 425 7211**
or email: **enquiries@bddpharma.com**

Visit us online at www.bddpharma.com

bdd

POWERED BY:

Generics Bulletin

Pharma intelligence | informa

IN PARTNERSHIP WITH:

bddi