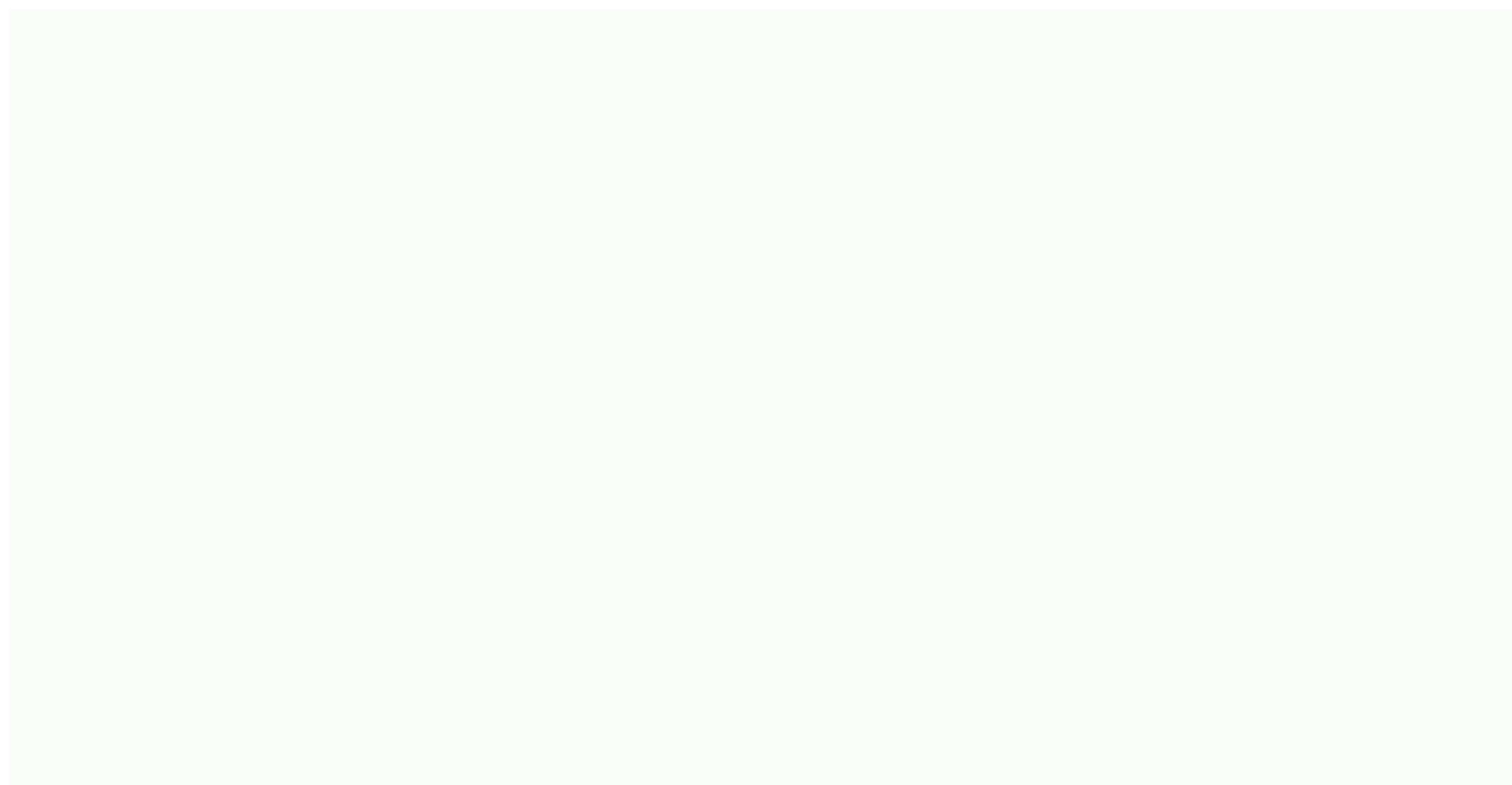


Manufacturing drugs is one thing but its effective usage is another. Howsoever, complex the treatment or its term be, it all boils down to the dosage to the patients reaches in its most-liked form. With all that is going around, while reconstructing the design and application pattern, one of the most important elements i.e. scalability is well taken into account. World Pharma Today, in its quest to gather information towards it and how they have become increasingly conscious about the soaring aspirations of the patients. Nasal dosage forms, wearable technology and injectables are witnessing express innovation and no pharmaceutical company is refraining from trying out options that could help them build a promising path. In this article, we also throw light on the extent of challenges faced by the drug development companies and how they have been coping up on the delivery front. To be customer-centric, one has to be very particular on how effective the dosage comes out and whether or not it has been received well by the patients. Through this piece, we have a crystal clear picture of the current processes that are becoming a norm in the drug development landscape. The motive of the task undertaken by the pharmaceutical companies today lays out a plan that talks of the innovations taking place in the drug form and also the effects that the dosing regimen is going to have because of it. Experts thereby do share their experience and how the manufacturers have involved themselves lately in continuously working out for a solution-driven, customized, and overall a liked-by-all alternative that is here to stay. Ramarketing roundtable feature on 'Oral Solid Dosage'. World Pharma Today recently spoke with Robert W. Lee, PhD, President at Lubrizol Life Science Health's (LLS Health) CDMO Division about trends and innovation in drug dosage forms. Rob Lee, President at Lubrizol Life Science Health A Decade of Revolution The demand for long acting injectables and implants has been rising over the last five to ten years in parallel with an increase in water insoluble compounds emerging from the drug development technologies have enabled enhanced formulation of water insoluble compounds and previously challenging compounds now have a greater chance of success and being used in breakthrough treatments. Less invasive implantable drug delivery systems tailored to different durations of action are advancing. selection. Bioresorbable implants that fully degrade within the body are extremely patient-centric, can potentially reduce the number of procedures a patient needs as they do not require removal. Bio durable implants also play a vital role, for instance for extended duration of action or when implant removal is needed to stop treatment. Such devices utilize non-resorbable polymers, including thermoplastic polyure thane and silicone, which remain intact in the body. Increasingly sophisticated technology and formulation products are rising. Such innovations are designed to be more user-friendly, e.g. wearable devices delivering a constant, subcutaneous infusion of drug or ophthalmic topical delivery devices that deliver microdose mists. There are many self-administration medicines currently on the market, including nasal-halers to treat epilepsy, administered by the patient by simply shooting a mist into the nose. Overlooked routes of drug administration, such as nasal dosage forms, hold great potential for innovation, specifically for central nervous system disorders. Nasal delivery can offer an ideal route and increased bioavailability for several drug types. While oral dosage forms remain extremely popular as they are non-invasive, the growth in biologics could reshape the status quo increasing the need for long acting injectables. Innovation Novel excipients and innovative technologies enable drug formulation scientists to develop better injectable dosage forms for water insoluble compounds. Other innovative technologies enable drug formulation scientists to develop better injectables. microparticles, biodegradable polymers, or other delivery systems, increasing overall product yield. The development of novel auto-injectors and wearable devices is propelled by a desire to give patients more control. Drug innovators are applying a patient-centric approach to early-stage development, considering unique genetic and biologic attributes of patient populations and disease states that may have an impact on dosage form selection. Outlook The Food and Drug Administration's (FDA) 505(b)(2) pathway is driving innovative drug dosage form work to improve existing drug products with new dosage forms, indications, dosing regimens, and routes of administration. Ultimately, the goal is to design and produce the most effective drug products for patients. The move to more specialized and personalized medicines will continue to positively impact the future of drug dosage forms by achieving more patient-centric medicines. Manuel Leal, business development director, Idifarma 1. Given the complexities and challenges of manufacturing safe, effective medications of all kinds, what recent innovations and processes are helping the industry formulate and finish complex drugs which often have solubility problems. Spray drying is one of the most suitable technologies to improve the solubility, and hence the bioavailability of low soluble compounds (BCS class II and IV). Solving this complex problem improves efficiencies and opens a wide range of potential applications. indications or new dosage forms and taking advantage of the hybrid regulatory pathways enabled by FDA – 505(b)(2) – and EMA – 10 (3) – have improved efficiency. Hybrid drugs often use innovative technologies to achieve the required dosage form and can be very beneficial to certain groups of patients (pediatric and geriatric) and can also help sustain healthcare systems. 2. With the pipeline dominated by potent small-molecule compounds intended for oral delivery, what is challenging drug developers most when it comes delivering these kinds of compounds to patients effectively? Drug developers face many challenges in the effective delivery of potent small-molecule compounds intended for oral delivery. An ideal dosage form would be one that achieves the intended action, does not require special storage conditions, has the precise strength, minimizes side effects and is easy to dose for the patient, increasing the compliance to the treatment. It should also be able to be manufactured affordably. Oral delivery meets most of those characteristics compared to other routes and by applying innovative technologies or excipients, the formulation scientists can overcome many of the challenges to bring drugs to the market in the most suitable dosage form. At Idifarma, we have successfully developed improved oral drugs, like fast-dissolving tablets with the right excipients and manufacturing process, and we have also used innovative technologies to achieve a faster reconstitution rate of injectable drugs, or dosing some of them as oral solid drugs. 3. Patients are front-in-center in drug development. What drug development. some of the specific challenges associated with manufacturing them? Patient centricity is one of the most relevant trends in the development of most drugs, which involves aligning the characteristics of the drug to the characteristics of the drug to the characteristics of the drug to the characteristics of the most relevant trends in the development of most drugs, which involves aligning the characteristics of the drug to the drug characteristic, but an essential one, for instance with the growing elderly population, specifically those affected by neurodegenerative diseases. Adherence or compliance problems are apparent within many chronic therapies, which might result in a lower therapeutic effect of the treatment. By improving the solubility with technologies such as spray drying, drugs with parenteral administration could be administered by oral route. This improves comfort for the patients, allowing them to take the drugs at home. Plus, the costs associated with the administration of a product at a hospital and manufacturing sterile products are avoided. The benefits of this technology are particularly compelling for orally administered drugs because more problems related with this route can be encapsulated and released in another part of the GI tract, avoiding the food effect, and simplifying the delivery of the drug for the patient. Enhancing a dosage form is even more relevant with IV pharmaceutical forms, because of the reduction of needle punctures the patient centricity through taste-masking, as bad tastes are common in a lot of active substances. Overcoming this using spray drying technologies can also directly impact the comfort of the patient taking the product, and therefore in therapeutic compliance. 4. Engaging strong external partners has become a common theme of successful drug development. What is your organization doing to support the drug strategies of clients and partners more effectively? Choosing the right external partner is essential for the development of many drugs because both technically and economically, it is the most sensible approach for many pharmaceutical companies that do not have the knowledge or capabilities in-house. Finding a CDMO that meets the technical requirements of the product to develop as well as being the right fit for the client is not easy. For many of our clients, working with a smaller, more specialized partner is the best and most effective support for their drug strategies because we manage projects closely with the client for quicker decision making and less delays. 5. Taking into consideration patients and the pipeline, what is on the horizon for drug delivery development and technology innovation? Personalized and more user-friendly dosage forms will become more and more important. In particular the possibility and challenge of achieving user-friendly formulations of drugs that are currently formulated in injectable dosage forms due to low soluble compounds. Lonnie Barish, VP business development and marketing Bora Pharmaceuticals 1. With the pipeline dominated by potent small-molecule compounds intended for oral delivery, what is challenging drug development pipeline is being filled with harder to formulate and manufacture compounds as well as manufacturers looking for ways to extend their patent life. The increasingly potent active pharmaceutical ingredients (APIs) reaching patients today are requiring more complex delivery strategies to ensure both safety and the desired therapeutic effects. Formulators are being challenged on three important fronts when it comes to developing their "difficult" compounds and APIs into effective medicines: 1. Low solubility 2. Low permeability 3. Short half-life Many of those issues can be overcome by precisely controlling the delivery of API payloads and carefully managing their release in-vivo. More and more commercial contract manufacturers like Bora Pharmaceuticals are being tasked with developing complex modified release dosage forms that require a high level of technical skill. Not only are today's modified release technologies effective for today's potent, challenging APIs, but they are also proving useful tools for improving existing formulations, thus paving the way for line extensions and other lifecycle management strategies. For example, the FDA's accelerated 505(B)(2) development pathways are allowing drug developers more economic routes to breathe new life into existing products. The FDA 505(B)(2) pathway allows drug developers a faster route to improve existing drugs. This development route is helping pharma develop new dosage forms that are longer acting, easier to swallow or combining two active ingredients in a new way to simplify treatment. 2. Given the complexities and challenges of manufacturing safe effective medications of all kinds, what recent innovations and processes are helping the industry formulate and finish complex or ally administered drugs more efficiently? Extrusion-spheronization is a formulating and processing technique for controlling API delivery. Suitable for a broad range of oral solid dose therapeutics, extrusion-spheronization offers an efficient route to more effective, patient friendly therapeutics and a reliable, effective way to manufacture today and tomorrow's complex oral solid dose drug products. Extrusionspheronization creates bead shapes that offer superb functional and manufacturing utility while supporting a wide range of release profiles, depending on the formulation. Although well understood, the process and its core technologies have seen significant improvement over the decades, with advances decreasing variation, increasing yield, and throughput among other benefits. Bora has kept pace and offers extensive capabilities and experience applying the process in an advanced CGMP environment. 3. Patients are front-and-center in drug development. What drug delivery technologies and dose forms are proving effective to meet patient friendly therapeutic goals? Designing and formulating dose forms to better suit a given patient population's specific needs to treat disease more effectively – in principle – is a patient friendly strategy. Orally administered drugs are by far the preferred dose form. Most patient groups respond well to taking oral medications that are easy to swallow, require fewer doses to be effective (for longer periods), and reduce or eliminate unpleasant side effects. For drug strategists looking to develop patient friendly oral solid doses (OSDs), there are two emerging finished dose forms that extend extrusion-spheronization's dose-controlling functionality and offer drug developers economic ways to explore and exploit complex patient friendly OSD drug strategies: I. Fixed-dose combinations (FDCs) combined, modified release single-capsule forms II. Multi-unit particulate system (MUPS) tablet designs Multi-particle, multi-sphere finished-dose forms, for example, are consistently demonstrating higher levels of desired reproducible PK and PD behaviors (including insoluble potent APIs) resulting in improved therapeutic effect in patients. 4. Engaging strong external partners more effectively? One of the biggest changes to the pharmaceutical manufacturing industry is the increasing reliance on external partners to develop and commercialize their products. Broadly the change has been extremely positive for the entire pharma supply chain by promoting quality, innovation, and cost-efficiency. Companies engage international manufacturing partners for several reasons. Access to lower-cost manufacturing and proximity to emerging markets are two prominent drivers. But considering recent development paths and other trends, securing strategic experience and expertise is playing an even bigger role in successful drug strategies. Although managing costs are a central theme, access to capacity, integrated technical capabilities, and leading-edge technology is prompting many of our recent partnerships, while sustaining our more mature relationships, especially those involving commoditized, high-volume products. Unlocking an API's therapeutic value requires focused science, technical expertise, and operational excellence to do it wellandmeet the industry's commercial, financial, and regulatory expectations. It is becoming increasingly recognized that, by the very nature of working on many compounds for numerous clients, CDMOs can offer these broad capabilities. 5. Given the drug pipeline what is on the horizon for drug delivery development and technology innovation? Demand for therapeutics of all kinds is increasing at an incredible pace now that much of the world has better access to healthcare and there is a demand to treat more diseases. It is also prompted the development of medications to treat or cure more "niche" diseases. It is also prompting further development and exploration of new modalities, genetic techniques, and chemistries to make better performing drugs for more people. The drive towards enhancing patient compliance and better outcomes will likely prompt the development of even more complex but functional drug forms, including combining APIs for related disease states and deploying them in bilayer/tri-layer tablets and more sophisticated combination products. Personalized/precision medicine continues to play an important trend in pharmaceutical development. Personalized medicine principles are being applied in new and innovative ways including diagnostics, genetic profiling, and the creation of advanced analytical techniques. pharmacokinetic and pharmacodynamic effects of drug substances. With this data, researchers will become even more successful in developing the effective patient friendly pharmaceuticals that societies are demanding now to meet the future of healthcare. Torkel Gren, Senior Director, Technology Officer & Strategic Investments at Recipharm AB 1. With the pipeline dominated by potent small-molecule compounds intended for oral delivery, what is challenging drug developers most when it comes delivering these kinds compounds to patients effectively? Many customers have very innovative projects but struggle to manage the complexity associated with development and scale-up of these products. A such, these developers look to third parties for support in simplifying their molecule's journey to market and are increasingly turning to partners that can offer more innovative approaches. To obtain an acceptable oral bioavailability for poorly soluble molecules is a common challenge. There are several advanced formulation technologies available such as different types of amorphous formulations. This means that the formulations. This means that the formulator has a larger toolbox than before. At the same time, it is important to remember not to increase the complexity more than needed so in order not to unnecessarily delay development or increase manufacturing cost. In many cases, conventional formulation technology will be sufficient to give a product with acceptable oral bioavailability. The cost and risk involved in developing new NCE's has resulted in a growing a growing interest in innovative drug products based on existing molecules. This is also driving the need for new strategies that can deliver these products more effectively to patients. Developers are facing challenges of repositioning old molecules for new indications and are increasingly looking to create modified release versions and fixed dose combinations. Specialist expertise is a key requirement in successfully repositioning these existing products. Finally, developers are also facing challenges in the pursuit to combine multiple Active Pharmaceutical Ingredients (APIs) into single formulations. Each compound may call for specific formulations. Each compound may call for specific formulations. Each compound may call for specific formulations for specific formulations. complexity of the analytical methods required, making the development of suitable analytical chemical methods even more complex. 2. Given the complexities and challenges of manufacturing safe effective medications of all kinds, what recent innovations and processes are helping the industry formulate and finish complex drugs more efficiently? Many recent innovations have come in the form of applying greater innovation to existing development approaches, making it easier to develop valuable dosage forms. Medical devices are an excellent example of this. Inhalation devices have been around for decades. However, new, and more innovative devices are now available and are much easier for patients to use, facilitating greater patient compliance. The same is true for injection devices. Many technologies for modified release, such as coated pellets, were also development. What drug delivery technologies and dose forms are proving effective to meet patient centric therapeutic goals and what are some of the specific challenges associated with manufacturing them? There are several technologies and dosage forms that are focused on 'patient-centricity' in new therapeutics. Oral formulations are generally user friendly as it is something patients are used to. With tablets developers can achieve many different things, including immediate release, modified release, orally disintegrating tablets, fixed dose combinations and many others. Consequently, there is a lot of opportunity to develop a product that is adapted to varying patient needs. One major challenge is to ensure that swallowing is not unpleasant due to the size, taste, or odour of the product. Inhalation is also proving to be an excellent administration to most patients. In addition, in order to get the right effect, it is important to use the device correctly. The major challenge here is to develop a device and a composition that limit the risk of an unskilled patient not getting the intended effect from their medication. Parenteral products that require this route of administration. In some cases, parenteral products are injected by the patient and in these cases patient-friendly devices can be very important but, in most cases, parenteral products are administered by nurse or physician. For these dosage forms it may be more relevant to talk about user friendliness rather than patient centricity. When used by health care professionals the user is very skilled. Still, valuable time can be saved by convenient products such as prefilled syringes. However, today parenteral administration is often performed by the patient and this is likely to increase. In these cases, a device that is easy to carry and simple to use is necessary. 4. Engaging strong external partners has become a common theme of successful drug development. What is your organization doing to support the drug strategies of clients and partners, including CDMOs, can provide access to more technology and competence for dosage form development locally as well as globally. In addition to accessing technical capabilities and a global manufacturing network, pharma companies can also access years of development expertise. Recipharm offers both development and commercial manufacturing services to help guide customers' molecules from concept to market. We focus on developing dosage forms with manufacturing services to help guide customers' molecules from concept to market. ensure smoother progress of a drug. Put simply, customers come to us because they see that we can help them get new products to the market quickly and efficiently. Many customers need a partner in innovation. They choose us because they trust our ability to solve different challenges and manage complexity when developing and scaling up an innovative product. Other customers need help with generic or other less innovative products. These customers choose us because we offer on time, reliable delivery of their development and manufacture. Ultimately, our end-to-end development and manufacture offer on time. market. 5. Given patients, the pipeline what is on the horizon for drug delivery development and technology innovation? While the growing number of biopharmaceuticals may be more affordable, in the future there will be a huge pressure on healthcare budgets and in many areas small molecules will give more value for money. Another reason why small molecule drugs will remain is that most biopharmaceutical products that are tailored for smaller groups of patients. Products for orphan diseases are one example of this. The trend toward precision medicine. However, several issues regarding quality assurance and cost may limit the use of 3-D printing in the next 10 years. Instead, adapting conventional manufacturing technology, making it more flexible and allowing smaller batches may be particularly useful. Pellet technology and minitablets are examples of conventional manufacturing technology that allows a high degree of flexibility as it is easy to combine different pellets and/or mini tablets to achieve combinations of different drugs in different drugs in different drugs and make it possible to track dosing and increase compliance may become common. Jeremy Drummond, SVP Business Development, MedPharm Ltd 1. Given the complexities and challenges of manufacturing safe, effective medications of all kinds, what recent innovations and processes are helping the industry formulate and finish complex drugs more efficiently? Traditionally, the topical drug delivery market has been dominated by North America, followed closely by Europe. Nevertheless, as a result of an increasingly ageing population, increasing healthcare expenditure and refocusing on these areas, the Asia- Pacific market is expected to see the most significant growth in the near future. Most of the pharmaceutical market is achieved through oral or intravenous dosage forms. For some drugs, conventional delivery is not possible due to drug instability, inability to get the drug to the target site, or systemic side effects. As patient expectations continue to rise, so too does the requirement for pharmaceutical companies to develop more 'userfriendly' dosage forms. Many patients prefer to use dosage forms that positively impact their health while integrating seamlessly into their lifestyles. This is especially important with topical formulations as the cosmetic and aesthetic properties are a critical aspect as patient compliance is often driven by the ease of use and the application experience. At MedPharm, the end users' opinion and preferences are crucial from the start and are incorporated into the product profile we establish with our clients from the outset. 2. With the pipeline dominated by potent small-molecule compounds intended for oral delivery, what is challenging drug developers most when it comes delivering these kinds of compounds to patients effectively? When development programmed must begin by considering the active pharmaceutical ingredients (API) as these are fundamental. A guide for the most appropriate dosage form can be formed through understanding the active(s) and its key physical and chemical properties. For example, formulators could be encouraged to focus on dosage (OSD) if the active exhibits issues with first pass metabolism. Another key aspect to consider is the packaging of the formulation. In combination with these factors the use of in vitro models, using fresh tissue such as whole eyes, cultured human nasal tissue or fresh skin, can de-risk the development of the optimal formulation for the patient for that particularly useful for products acting locally and now used not only to measure permeation but also monitor the activity of formulations and de-risk the decision to enter clinical trials with fresh human tissue. 3. Engaging strong external partners has become a common theme of successful drug development. What is your organization doing to support the drug strategies of clients and partners more effectively? One of the biggest trends that has impacted drug dosage forms is the rise in the use of biologics. These complex entities have brought their own challenges that has led to the need for new solutions in terms of in terms of packaging, analysis, delivery and stability, of which MedPharm is at the forefront. MedPharm is at the forefront. on topical deliver of these macromolecules and demonstrated that some aptamers can penetrate skin and still be active despite their large molecular weight (20k Daltons). This research offers hope for the discovery of new treatments of difficult-to-treat dermatological diseases. Another important trend in the future is certainly going to be the combination of dosage form delivery with technology, which will further support the goal of a more patient-centric approach. Partnering with an expert for specialist dosage forms such as topical products for skin, eye, airways or mucosal membranes has many benefits. To facilitate optimum formulation development unique knowledge and experience are required, something that most development companies lack in-house. The 20+ years of experience available by partnering with a specialised contract developer like MedPharm, provides the basis of an in depth understanding of what it takes to get a product to market whether it is a new chemical entity, a re-purposed drug for a new indication, an OTC product or a generic. Steve Rode, Manager Business Development, Capsules and Health Ingredients, Lonza Group AG 1. With the pipeline dominated by potent small-molecule compounds intended for oral delivery, what is challenging drug development development, Capsules and Health Ingredients, Lonza Group AG 1. With the pipeline dominated by potent small-molecule compounds intended for oral delivery, what is challenging drug development development. is moving away from blockbuster drugs with their one-size-fits-all approach for large patient groups and is moving towards more patient-centric dosage forms. With this in mind, oral solid dose small-molecule pharma development is continuing increasing in prominence. complexity in new ways. For example, many new active pharmaceutical ingredients (APIs) are highly potent and many have compliance. Sustainability is making inroads into pharma innovation as well. Manufacturers are now prioritising clean label ingredients for their products with the intent to provide vegetarian dosage forms where possible, meaning new polymer such as HPMC are being introduced. Lonza's Capsugel® business recognized this trend early introduced. Lonza's Capsugel® business recognized this trend early introducing a high-quality clean-label HPMC are being introduced. compatibility goals as well. The FDA's 505b2 pathway is another driver of drug innovation, and to a certain extent, drug complexity, depending on the formulations of existing drugs, it provides developers a less-risky economic path to improve the therapeutic performance and dose control of proven formulations. It also supports the efficient development of new fixed-dose combinations (FDCs), which according to our research, are also likely to administered in encapsulated forms. 2. Given the complexities and challenges of manufacturing safe effective medications of all kinds, what recent innovations and processes are helping the industry formulate and finish complex drugs more efficiently? Functional excipients have been made available to improve stability and solubility of Class II biopharmaceutic compounds and to allow for more targeted delivery – this has removed some potential barriers to oral bioavailability in these formulations. With capsules, a key consideration relates to the characteristics of the API. The size of a molecule may make it impossible to deliver a substance orally so drug candidates withlow solubility or bioavailability of ten require increased utilisation of techniques such as spray dried dispersions (SDD). Pelletized and particalized API formulations are also serving developers and helping to manage a broad range of delivery challenges presented by today's potent drugs. Inherently functional for capsulated dose forms. 3. Patients are front-in-center in drug development. What drug delivery technologies and dose forms are proving effective to meet patient centric therapeutic goals and what are some of the specific challenges associated with manufacturing them? With the focus on patient-centricity there has been greater exploration of nasal, pulmonary and transdermal routes as alternatives to parental or oral dose administration. Despite great innovation in those areas, OSDs are still the preferred administration route and drug developers are increasingly seeking ways to make taking these kinds of drugs more patient-oriented. Manufacturers should understand dose ranges, minimum intake per day, limitation of side-effects, swallowability, handling limitations, visual impairments and then develop dosage forms accordingly while also considering the market and patient access. 4. Engaging strong external partners has become a common theme of successful drug development. What is your organization doing to support the drug strategies of clients and partners more effectively? representative associations and discussion forums. Pharmaceutical developers are also collaborating with patients more effectively during trials, as well as after, with post-market studies becoming a critical element of the process. This dialogue is yielding big strides in the development of drugs but also driving the need for expert partners and suppliers to collaborate to generate high-fidelity data and view products in a more holistic manner so that they can design and develop the most effective, patient-centric dosage forms possible. At Lonza Capsules and Health Ingredients we work to deliver and shape the future. We monitor trends, and investign and develop the most effective, patient-centric dosage forms possible. in advanced technologies and skillsets that enable commercialisation. Our clients can define their own tailored service package from a complete set of development and trechnology innovation? Patient dose compliance is a critical aspect of drug design that impacts overall treatment efficacy. It also has a major impact on trial and patient outcomes and the eventual commercial success of most contemporary Rx drugs. Ultimately, there is a strong incentive for companies to develop well-adapted dose forms that support patient compliance — especially for children and aging patients. At Lonza Capsules and Health Ingredients we see the increasing prominence of higher-value, personalised medicines that will likely that the industry will continue to move away even more deliberately from aone-dosage-form-fits-all approach and towards a more patient-centric individualized approach.



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