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Fast dissolving drug delivery systems

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Fast-dissolving formulations represent excellent opportunities for life cycle management to the pharmaceutical companies. Fast dissolving technologies have many advantages like ease of swallowing, administration without water, quick onset of action for improving both patient convenience and compliance as benefits for patient; extended life cycle, product differentiation, patent protection as benefits for pharmaceutical companies and so on. But there are some challenges for formulation development studies like taste-masking, disintegration time, moisture sensitivity, friability, packaging and intellectual property issues especially for the generic companies. The technologies are under patent protection like Zydis[®], Flashtab[®], OraSolv[®] and DuraSolv[™], WOWTAB[®] and so on. One of major issues like taste-masking problem may overcome with using cyclodextrins, polymer coating, flavoring & sweetening agent, microencapsulation techniques. There are some modified excipients for providing both taste-masking and productability properties in the formulation like Ludiflash[®], Pharmaburst[®], etc. What about Quality by Design (QbD) development approach for fast dissolving drug delivery systems? From the analytical development point of view there are a number of different methods from conventional dosage forms which are determined in the Pharmacopoeias. And for comparison and assessment of taste masking, electronic tongue may be a good opportunity which was developed by Alpha M.O.S. In the sense of generic companies, developing a fast dissolving tablets version of an existing immediate-release product means that the two formulations must be bioequivalent and this can be challenging for *in vivo* studies especially if the method of taste masking retards the dissolution rate of the active ingredient after disintegration. What about the future of fast dissolving technologies? Orally disintegrating extended Release (ODT-ER) dosage forms are providing all of the benefits of these two drug delivery technologies in a single pharmaceutical product. And oral rapid films also may be a good alternative especially for the OTC market.

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Building a NBE pre-formulation screening funnel to accelerate biologics drug development in China

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Antibody-based therapeutics has become the driving force of the pharmaceutical industry. With 61 different antibody-based drugs on the market by 2015, antibody-based therapeutics has brought 90.6 billion USD to the industry in 2015 and keeps growing at a phenomenon speed. However, the biopharmaceutical industry is also facing issues such as patent expiration, new target identification, drug resistance etc. How to bring a biologics drug to the patients at a fast pace is one of the top priorities in the field? One of the major bottlenecks in biologics drug discovery and development is drug pre-formulation. This presentation will discuss how we build a world-class high throughput new biologics entity (NBE) pre-formulation screening funnel to accelerate biologics drug development in China.

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