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New manufacturing technologies and excipients will change future drug production

Dieter Lubda

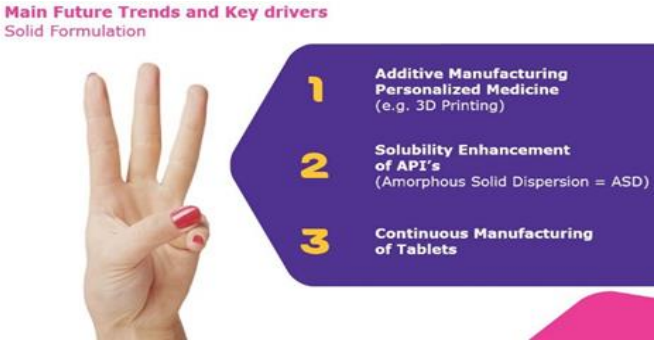
Merck KGaA, Frankfurter Str. 250, 64293 Darmstadt, Germany

Abstract

The requirements of customers with regard to convenience and range of application for oral and liquid administration of active pharmaceutical ingredients (APIs) have increased significantly in recent years. In addition, solubility and bioavailability of APIs for oral administration has become a main issue of pharmaceutical industry.

Nearly all new chemical entities (NCE's) under development are suffering in aqueous solubility during pharmaceutical drug product development therefore showing limited oral bioavailability. At least, in the preclinical stage every 3rd drug candidate offers poor bioavailability. Different strategies to enhance the drug's bioavailability are commonly used showing beneficial effect. Therefore, technologies to address these challenges have never been more important! But although there are a number of approaches to improving solubility, bioavailability and dissolution rates, they have, for the most part, remained unchanged for decades. The use of drug carriers (such as mesoporous silica), spray drying and hot melt extrusion (HME) are all effective technologies, but as we move into a new era of pharmaceutical development, the excipients used in formulation should be as advanced as the emerging techniques being seen in other areas of the pharma industry. For example, future trends and key drivers of the industry point towards continuous manufacturing, personalized medicine, 3D printing, and increased importance on amorphous solid dispersion, with the goal of dispersing or dissolving an API in a polymeric matrix in the amorphous state. These technologies have the potential to disrupt the market as we know it.

The presentation will give an overview about trends of products and technologies used nowadays to address delivery challenges of small and biomolecules focusing on excipients and technologies for oral administration. Technologies exemplary described increasing bioavailability through enhancement of solubility or trying to address user convenience.



Biography:

Dr. Dieter Lubda is director of R&D Operations of Actives and Formulation within Merck KGaA (Germany) Life Science business unit. He has contributed to 77 Peer-reviewed publications and as one of the inventors to more than 50 patents filed or granted. Dr. Dieter Lubda holds a Ph.D. degree in Chemistry from the University of Vienna, Austria and had got the degree "Diploma Engineer of Chemistry" after finalizing his thesis at the Technical University of West-Berlin, Germany

Speaker Publications:

1. Bernd Van Snick et al. (2018) A multivariate raw material property database to facilitate drug product development and enable in-silico design of pharmaceutical dry powder processes; International Journal of Pharmaceutics 549 (2018) 415–435.
2. Kasselkus A. et al., (2018) White paper Merck KGaA Germany, Improving solubility – a close look at available approaches

3. Palekar S., Nukala PK., Mishra SM., Kipping T., Patel K. (2019), Application of 3D printing technology and quality by design approach for development of age-appropriate pediatric formulation of baclofen; International Journal of Pharmaceutics, 2019. 556: p. 106-116.
4. Kun Liang et al. (2018) 3D printing of a wearable personalized oral delivery device: A first-in-human study; Sci. Adv. 2018;4
5. Dressman, J.B., et al. (2016) Mesoporous silica-based dosage forms improve release characteristics of poorly soluble drugs: case example fenofibrate; Journal of Pharmacy and Pharmacology, 2016. 68(5): p. 634-645.

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