The benefits & opportunities of inhalation

Orest Lastow (Head of organizing committee and president of Medicon Valley Inhalation Consortium [MVIC]) introduced the symposium theme “Explore the Inhalation Opportunity”, the program and the sponsors.

Kerstin Jakobsson (Medicon Village, Lund, Sweden) gave a presentation of Medicon Village (MV). MV is a nonprofit organization that has taken over the AstraZeneca site in Lund. It offers world class facilities to life science companies, both start-up and established. Today, MV houses over 60 companies, University departments and research organizations.

Lastow gave an introduction as to why inhalation is the preferred route of drug delivery compared with, for example, orals and parenterals. The greatest advantage is the local delivery to the site of action. There is no first-pass metabolism and no risk of degradation in the GI tract. The use of an inhalation device also offers additional functionality and intellectual property protection. The great challenges with poor compliance were discussed together with different ways devices could lead to better compliance.

Per Wollmer (Lund University, Lund, Sweden) discussed new opportunities of inhaled drug delivery. The lung has a large surface area and is suitable for systemic drug delivery. Inhaled insulin is an example of a drug that can be inhaled instead of subcutaneous injection. The absorption profile of inhaled insulin is closer to endogenous than subcutaneous injection, which can provide better flexibility for diabetics. However, a challenge with inhaled insulin is the lower absorption.

Lastow then explained the advantages of dry powders compared with liquid formulations. The key advantages are simplicity, better chemical and physical stability and higher drug load. Another advantage is that the dry powder inhaler is smaller, more portable and cheaper than a liquid delivery system.

Stefan Ulvenlund (CR Competence, Lund, Sweden) addressed the many misconceptions regarding liquid formulations. Views that liquids require bulky delivery systems and long delivery times are not correct since smaller and more efficient devices are available. The many excipients used in liquid formulations are to be seen as a strength and an opportunity.

Ola Nerbrink (Respiron Consulting, Lund, Sweden) gave an overview of available nebulizers.

A panel discussion was held by Lastow and Ulvenlund where the audience, together with moderator Ola Nerbrink, asked questions to the speakers. Many projects use nebulization in early clinical trials and then shift over to dry powders. One question was regarding the risks with such transition and the speakers agreed that this is a very established approach with low
manufacturing challenges of formulations for particle deaggregation. A device in terms of powder emptying and can be used to optimize the performance of inhalation device, inhalation resistance/pres can be used to predict flow distribution in an established. Computational fluid dynamics methodological methodologies such as, computational fluid dynamics are not often discussed at inhalation meetings. The computational methodologies such as, computational fluid dynamics are not often discussed at inhalation meetings. The computational methodologies such as, computational fluid dynamics are not often discussed at inhalation meetings. The computational methodologies such as, computational fluid dynamics are not often discussed at inhalation meetings. The computational methodologies such as, computational fluid dynamics are not often discussed at inhalation meetings.

Karin von Wachenfeldt (Truly Translational, Lund, Sweden) discussed the metabolism of an inhaled drug in terms of both local and systemic delivery. The benefit of inhaled drug delivery was explained from a pharmacology perspective showing what type of drugs are most suited for inhalation.

Thomas Brimert (Red Glead Discovery, Lund, Sweden) questioned how should a compound be designed to work well with inhalation? This was clarified together with the concepts of prodrug and soft drug. Drugs for inhalation can be designed to utilize the specific transporters in the lung through a prodrug. Examples of soft drug long-acting β2-agonists and p38 kinase inhibitors were described.

Björn Ullbrand (Validus Engineering, Staf-fanstorp, Sweden) shared an observation that the physics of inhalation devices are not often discussed at inhalation meetings. The computational methodologies such as, computational fluid dynamics are not often discussed at inhalation meetings. The computational methodologies such as, computational fluid dynamics are not often discussed at inhalation meetings. The computational methodologies such as, computational fluid dynamics are not often discussed at inhalation meetings. The computational methodologies such as, computational fluid dynamics are not often discussed at inhalation meetings.

Nils Ove Gustafsson (Galenica, Malmö, Sweden) shared his experience regarding manufacturing challenges of formulations for inhalation. The interaction of the formulation with the device adds an additional level of complexity to manufacturing. A useful tool is the quality by design approach. Quality by design promotes more science and understanding in the development, which should make manufacturing less challenging. Good planning based on understanding of the manufacturing processes and a clear definition of the product during the whole lifestyle is a prerequisite for successful manufacturing.

Morten Nielsen (B&O Medicom, Struer, Denmark), described how the inhalation market is saturated with products. An elaborate device strategy can be an effective weapon in the struggle for success. The total cost of asthma in the EU is staggering €18 billion. Successful management of the disease can reduce the cost significantly. Better designed devices offering better industrial design, ease of use, connectivity and accompanying services can be a competitive advantage. A more advanced device can reduce the treatment cost by better compliance and more efficient delivery.

Lars Borgström (Lars Borgström Consulting, Lund, Sweden) explained how lung deposition is the result of the device, the formulation and the patient behavior. Typical lung deposition values are; pressurized metered-dose inhalers 10–20%, dry powder inhaler 10–30% and small volume nebulizers 30–40%. The pharmacokinetics of inhaled drugs include both the drug deposited in the lung and the systemic uptake of the drug swallowed. By administering a slurry of charcoal that is swallowed prior to the inhalation, the systemic effect is eliminated. The clinical effect is, in most cases, local whereas the side effects are often systemic but can also be local. The bioequivalence requirement on generic drugs was discussed. Drugs that have a significantly different area under the curve in a pharmacokinetic study can still be considered bioequivalent.

Mårten Svensson (Emmace, Södra Sandby, Sweden) talked about the evaluation of inhalation devices, which is typically done using impactors. The tests can be significantly improved by using human-like inlet geometries. Using different anatomical throat geometries in combination with different inhalation profiles can provide very accurate lung deposition predictions. The method provides a good in vitro–in vivo correlation and can be used to predict the lung dose when designing clinical trials. It is also a valuable tool in the development and optimization of inhaled products.
Helene Sonesson and Gun Persson (NordicBiocube, Lund, Sweden) explained that when conducting clinical trials, a great deal of biological material is collected. Well-planned and well-organized handling and management of the biological material are of great value to the project and, subsequently, to the launched product. There are also legal and regulatory requirements dictating how biological material should be handled. The generation of the biological material is an investment and can be used for extended research into, for example, new indications or biomarkers.

Financial & competing interests disclosure
O Lastow is the Head of the organizing committee and the President of Medicon Valley Inhalation Consortium, and a director at Zenit Design. The Medicon Valley Inhalation Consortium is an organization comprising of 18 member companies. Zenit Design is a consultancy firm. The author has no other relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript apart from those disclosed.

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