The inhalation & respiratory drug delivery market is experiencing a continuous growth and 2016 is forecasted to be a very exciting period for the industry. What would you attribute this growth to?

The anticipated growth of the inhalation & respiratory drug delivery market seems to be attributed mainly to the development of related supporting technologies, such as competitive new devices, powder technology, and the accumulation of R&D experience of these technologies in the pharmaceutical industry. In contrast to this, supporting technologies for oral small drugs for lifestyle related diseases are relatively mature. In addition to this, there seems to be a trend towards the increasing use of inhalation which is becoming recognised as a convenient route of administration. Furthermore, as the development of NCEs is getting difficult, there is an increasing opportunity for new drug products created by the idea of drug repositioning/supergenerics where existing API(s) (or candidates) are included in the drug product. In drug repositioning/supergenerics, there is a strong need for a competitive drug delivery technology in order to increase efficacy/safety and convenient use. This includes a switch in the route of administration. Combined with the above-mentioned trend of technology development, new drug products containing existing API(s) with competitive inhalation device/formulation technology are anticipated to appear on the market.

What do you think are the most inspiring new developments in the inhalation and respiratory drug delivery industry that will likely have an impact on the future?

It is difficult to predict technology innovation in the inhalation and respiratory drug delivery field, so I would rather focus on pointing out the importance of creating inhalation R&D projects in the pharmaceutical industry. These projects undoubtedly improve R&D in the inhalation and respiratory drug delivery industry as well, resulting in further technology innovation.

To improve R&D in inhalation, the definition of the early/exploratory research stage should be altered. This will lead to the exploration of a new drug delivery technology in addition to the lead discovery of NCE. The combination of an existing drug with a competitive inhalation drug delivery technology has a potential to outweigh NCE inhalations in terms of efficacy/safety, convenient use, and patent protection.

New inhalation device/formulation technologies are included into validated enabling technologies once tested in clinical use. In the late phase of lead discovery and NCE optimization, such technologies may survive the research project followed by the preclinical investigation, with reduction of fruitless (excess) lead optimization. I would like to call this ‘Drug Delivery Discovery & Optimisation’ as it involves the precise application of a validated delivery technology together with the exploration of a new drug delivery technology. On the contrary, there is the possibility that precise lead optimisation overcomes any difficulties including CMC issues indeed. To find out the right NCE candidate for inhalation, it is necessary to examine the interaction between medicinal chemistry and formulation science. As the usefulness and limitation of inhalation & respiratory drug delivery are revealed by the accumulation of R&D experiences in the pharmaceutical industry, a complex mode of research needs to be used.

In summary, by the creation of inhalation R&D projects activated by the Drug Delivery Discovery & Optimisation in the pharmaceutical industry, the activation and further technology innovations in the industry are anticipated accordingly.
What are the key challenges you are facing in your own research currently and how are you trying to overcome them?

I think that one of the key elements for successful inhalation R&D is accurate evaluation of toxicity (physical irritation) of the API to the mucosa. To achieve clinical investigation and commercialisation of inhalation products, accurate preclinical evaluation and predictive clinical evaluation of the toxicity is necessary in the translational research phase. Because the tolerability of toxicity is judged based on the safety margin, accurate evaluation of the efficacy is important as well. Our past inhalation projects seemed to be affected by indistinct acceptance criteria. Even if completely objective criteria cannot be set, improved predictive toxicity evaluation will help set reasonable acceptance criteria. Without facing the issue in an active R&D project, we will not be able to overcome the challenge on this matter. I think we need to be more careful with this when the team is involved in the next inhalation R&D project.

Career & Experience:

Since 1994, Dr Kasuya has focused his research activity on the exploration of new drug delivery technology (categorised into polymer complex/conjugates, nanomedicine, and various type of drug delivery formulations) and the application of validated drug delivery technology to NCE candidates in early/exploratory research stages. Also, he has been involved in translational research of several drug delivery R&D projects (mainly inhalation) including Inavil®, an anti-Flu inhalation with disposable inhaler, in which preparation for preclinical and early clinical investigations are conducted in consideration of commercialization. Dr Kasuya has worked in various research laboratories and has experience with the following: formulation technology (10 years+), DMPK (2 years+), medicinal chemistry (2 years), and biologics & new modality (2 years). He is currently enjoying working in the Vaccine Research Laboratories, Kitasato Daiichi Sankyo Vaccine, a group company of Daiichi Sankyo. Dr. Kasuya has a PhD in Materials Science (Keio University, Polymer Chemistry, 1994). He also studied biocompatible/biorecognizable polymers and polymer-drug conjugates at the University of Utah as a visiting postdoc for 2 years (Prof. J. Kopeček, 1999-2001).