ISAPP 2023: Discussion Group 5

How does the development pipeline differ between microbiome-based therapeutics and traditional probiotics for foods/supplements?

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Increased interest in the microbiome field has also boosted the interest in the clinical application of live micro-organisms to prevent or treat disease. According to the ISAPP consensus definition, these live micro-organisms meet the criteria for probiotics, but there are differences with traditional probiotics for foods and supplements, because the final products with these microorganisms will have to be registered as medicinal products to reach the market in the US and in Europe. The FDA has defined these products as "live biotherapeutic products" (LBP) and is one of the first authorities formulating important guidelines. (https://www.fda.gov/files/vaccines,%20blood%20%26%20biologics/published/Early-Clinical-Trials-With-Live-Biotherapeutic-Products--Chemistry--Manufacturing--and-Control-Information--Guidance-for-Industry.pdf). Since 2019, this category of drug products has also been included in the European Pharmacopoeia. In addition, in also other areas around the world, innovative microbiome-based drug products are explored and developed. For some background information, we refer to this publication of the Pharmabiotics Research Institute (PRI) (https://www.nature.com/articles/s12276-020-0437-6).

In this workshop, we will discuss
1) What is the difference between probiotics and microbiome-based or live biotherapeutic products (LBPs) from a product development point of view?
2) What are different target application areas for probiotics versus LBPs/microbiome therapeutics ?
3) How should clinical trials be designed differently with probiotics versus LBPs/microbiome therapeutics?
4) How can we bridge the current gaps between the probiotic and LBP/microbiome industry and scientists?

The aim of the discussion group is to explore, with other expert scientists (from academia and industry), the current state of the science and make recommendations on how to make progress in this area. We hope that the discussion will result in a focused review article, to be written by participants after the meeting.

We propose focusing a maximum of 1hr discussion on each of the 4 points. Expert scientists will have 10min (maximum) to introduce specific aspects of an assigned topic, which will then open for general discussion and debate.