Non-Living Biotherapeutic ProductsTask Group

A task group dedicated to supporting the development of microbiome-based drug products by addressing the key challenges regarding the development and registration of medicinal products containing dead/inactivated/stabilized/lysed microorganisms.

As mechanisms of action start to be better understood when it comes to microbiome-based drug products, it would appear that **microorganisms which are not alive may still present efficacy** in the prevention or treatment of human pathologies.

If the regulatory path has indeed been clarified for living cells (due in part to the new Eur. Ph. monograph on LBPs and the FDA guideline on LBPs), the fate of products which contain inactivated/dead/stabilized/lysed cells has not yet been clearly defined.

If the stabilization of sensitive cells could present a significant advantage for developers as it could help to maintain a product's stability over time for cells which can be efficacious even if not living, it is important to highlight that this category of products is still not commonly addressed from a regulatory standpoint in the EU - and that regulatory challenges not foreseen by the developers may arise in the near future.

In order for such developers to build upon their common expertise to 1) identify the regulatory challenges, and 2) assess the state of the art of science when it comes to addressing the corresponding questions, the PRI proposes to engage its regulatory support through the coordination of a dedicated Task Group by applying the foot print of its work on LBPs for this new type of products.

Any organisation interested in this initiative is more than welcome to contact the PRI and learn how to get involved.

For more information about this or any other project coordinated by the PRI, please contact:

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