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### Key regulatory issues in the development of pharmabiotics in Europe

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**M**icroorganisms as drugs are not regulated consistently among EU Member States, which makes investment in R&D too risky for companies. Both the industry and regulators are interested in working on legislation together in order to enable developments in this area. Pharmabiotics/Live Biotherapeutic Products are a novel regulatory category in the European pharmaceutical landscape. Challenges in terms of the scope of the regulation, safety and efficacy standards are amongst the most important to be dealt with in these early discussions.

#### Biography

Luis Gosalbez is the Manager of Strategic Projects at Biopolis S.L. in Valencia, Spain. Previously, he was a Research Associate in Universidad Complutense de Madrid and in Centro de Biología Molecular Severo Ochoa-CSIC (both in Spain) and in the Korea Advanced Institute of Science and Technology (KAIST, South Korea). His research was always focused on microbiology, development of antimicrobials and antivirals. He also served as Senior Analyst for a leading Life Sciences and MedTech strategy and operations consulting firm in Munich (Germany). He received his BSc and MSc in Biotechnology from Universidad Complutense de Madrid and a Master's in Bioscience Enterprise from the University of Cambridge in the UK.

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