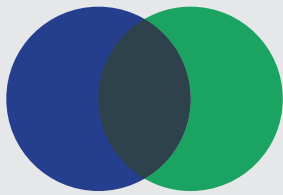




Microbiotic medicinal products



## MICROBIOTA & HUMAN HEALTH

The microbiota plays a central role in human health ; it therefore opens a door to a new type of medicine, one which is preventive and personalized.

**Microbiotic Medicinal Products represent an essential means in acting on the microbiota.**



## THE REGULATORY STRATEGY

 **IDENTIFY**  
Regulatory challenges

 **DISCUSS**

Proposals with the European pharmaceutical authorities as a **recognized\* representative organization**  
(\*EMA, European Commission, European Pharmacopoeia)

 **PROPOSE**

Solution with our unique **collaborative approach**

The pharmaceutical regulations in Europe were designed for chemical molecules, and are thus not adapted to the particular nature of Microbiotic Medicinal Products.

## NEW INDUSTRIES REQUIRE NEW INSIGHT

We strive to facilitate the development of Microbiotic Medicinal Products by enhancing the visibility of the new microbiota & human health industry, as well as build the necessary regulatory affairs intelligence which will help to make Microbiotic Medicinal Products a therapeutic reality.

- **Facilitate the development of the microbiome industry in Europe** (see Partnering Platform)
- **Develop the necessary regulatory affairs intelligence** (see Regulatory membership)



# TWO LEVELS OF MEMBERSHIP

We offer two levels of membership, each adapted to our members' needs.  
Your membership level depends on your activities within  
the Microbiota & Human Health industry.



## PARTNERING PLATFORM

- > Yearly event : Pharmabiotics Global
  - 20% discount to attend the event
  - BtoB networking event
- > Active assistance with the identification of potential partnerships
- > Complimentary webinar to help you find partners for your project
- > Continuous access to the PRI qualified contact database



## REGULATORY MEMBERS

### Regulatory Strategy

- > EMA Scientific Advice
  - Working groups
  - Previous scientific advice
  - PRI internal Guidelines
- > On-site training with our regulatory affairs expert on a case-by-case basis
- > Actively provide you with a better understanding of the authorities mindset
- > Anticipate new regulatory changes
- > 30% discount to attend the Pharmabiotics Global event

## ANNUAL MEMBERSHIP FEES

### PARTNERING PLATFORM

€1500 / year

### REGULATORY MEMBERSHIP

(indexed on member-company's annual turnover)

- €3 000 /year (annual turnover: €3M)
- €7 000 /year (annual turnover: €3M - €10M)
- €10 000 / year (annual turnover: > €10M)

## PHARMABIOTIC RESEARCH INSTITUTE (PRI)

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AUVERGNE - Rhône-Alpes