



Company Overview

Biostimulants and Nutritional Specialities

Research and development



Selection of targets

Microbial Strains

Natural extracts

Innovative formulations

Experimental protocols

Regulatory strategy



Product denomination within EU Regulations and National legislations
Reg. EU. 1009/2019
D. Lgs. 75/2010
Reg. EU. 1584/2018

Dossier preparation



Data collection

Tailored writing depending on product focus

File definition

Discussion with Authorities

Regulatory Complexity



Data gap analysis
Regulations analysis
Materials identification



Timelines
National restrictions
Fees

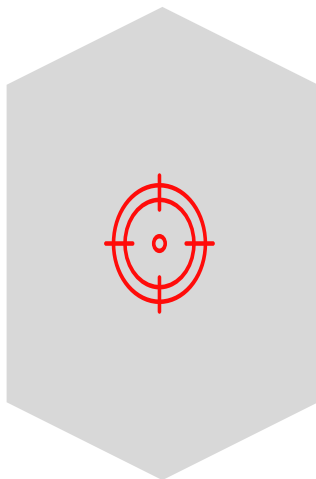


Investment evaluation
Risk analysis
Legal support



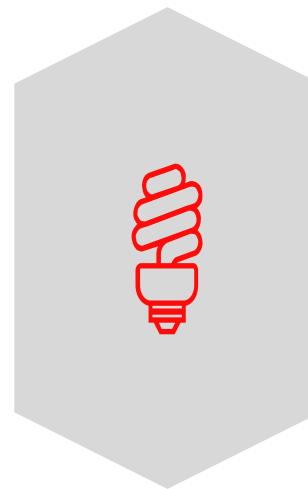
Classification and Labelling
Claims
MSDS
UFI code

Formulation development



Problem definition

- Efficacy
- Stability
- Classification
- Active ingredients
- Coformulants



Alternatives search

- "Green" coformulants
- Formulation changes
- Low toxicity
- Low environmental impact

Formulation development



Screening

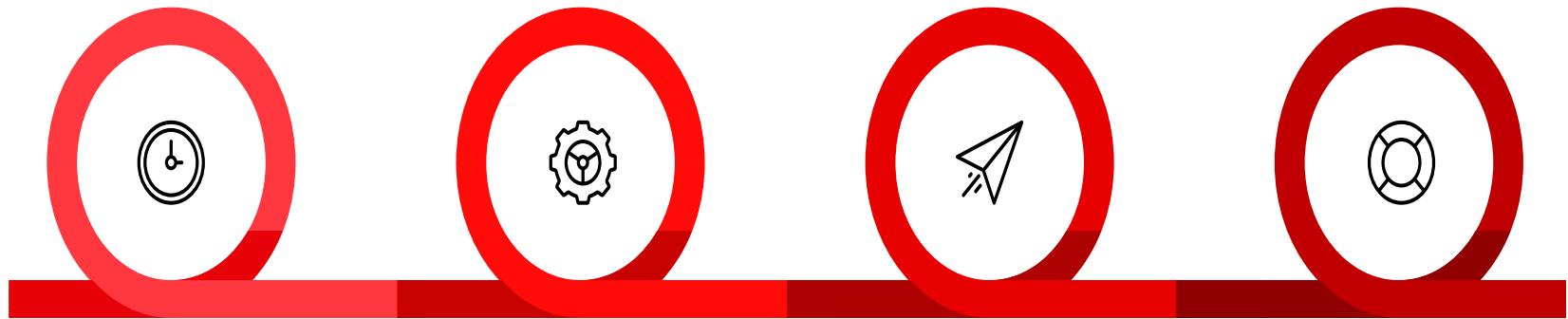
- Preliminary trials
- Immediate feedback
- Product improvement



Network and Mediation

- Patent verification
- Supplier / manufacturer liason
- Supply chain assessment
- Value chain promotion
- Legal support

Vitalia's approach



**Regulatory
strategy**

**Business Plan
Legal advisory**

**Formulation
development**

**(GxP) Study Plan
Dossier production**

