Perspektywa realizacji projektów B+R w obszarze biotechnologii

Na przykładzie projektu zrealizowanego przez firmę Biovico

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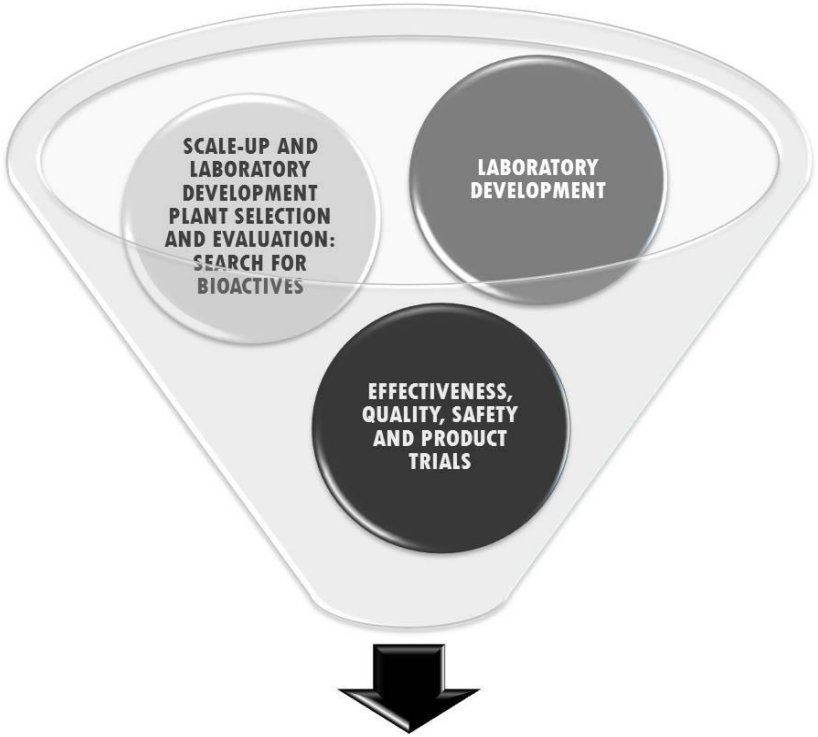
Development of novel Biovico's product under POIG 1.4 project imNutra

The main goal of the project is the study of a selection of plant species with **potential anti-inflammatory bioactivity** for the development of new anti-inflammatory nutraceutical products, assuring effectiveness, quality and safety of the whole process (from discovery of the bioactivity to the final product).



Development of novel Biovico's product under POIG 1.4 project imNutra

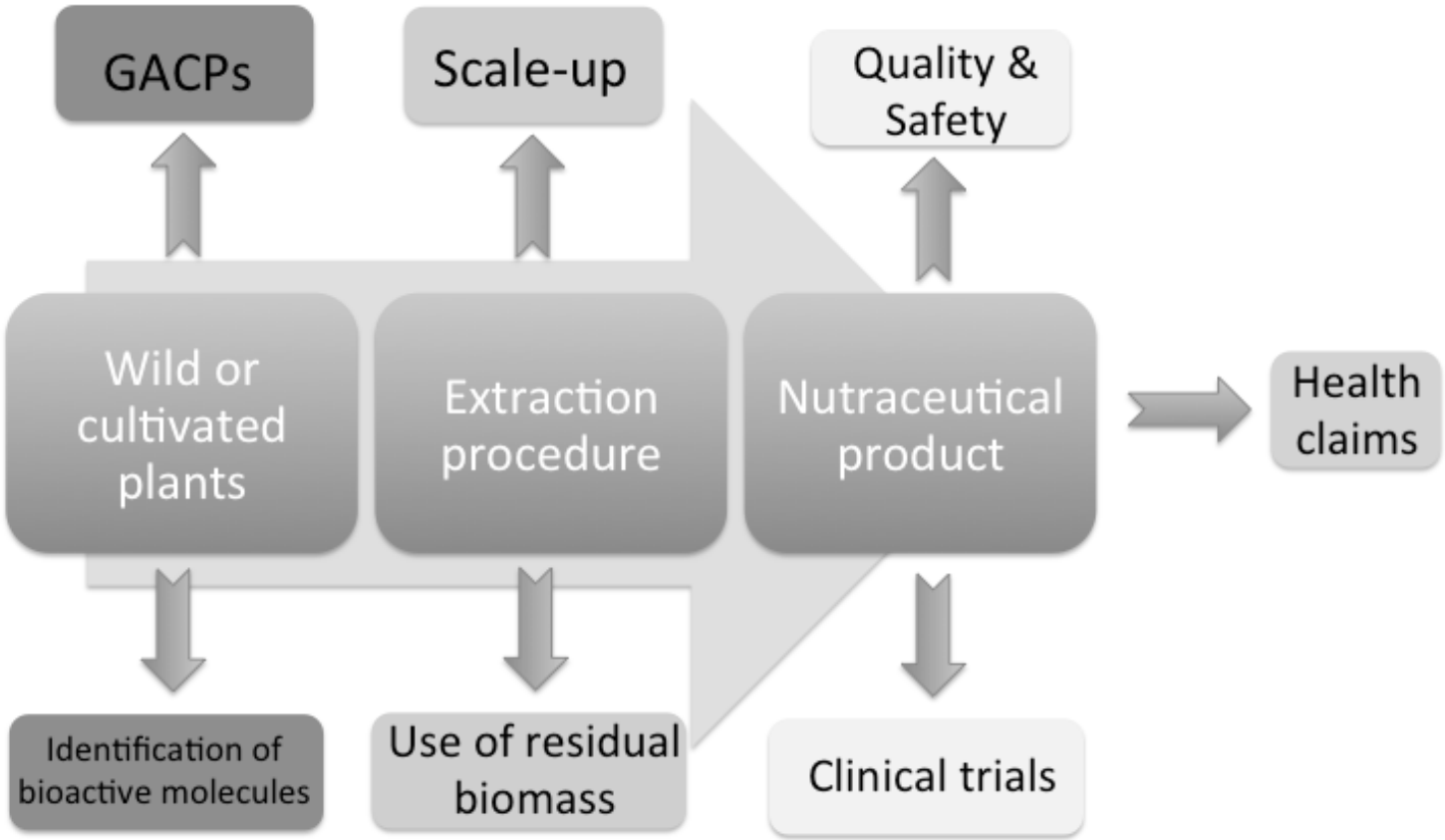
biovico

■ **Scientific objectives:**
- Selection of plants with immunomodulating activity and anti-inflammatory effects.
- Characterization of the plants in terms of bioactive compounds.
- Analytical standardization for state-of-the-art quality insurance of raw materials and extracts.
- Optimization of the extraction process towards commercial production using validated analytical quality control methods.
- Comprehensive evaluation of nutraceutical safety, based on the determination of pesticides, mycotoxins, Polycyclic aromatic hydrocarbons (PAHs) and heavy metals in raw material, plant extract and final product.
- Evaluation of *in vivo* efficacy, safety and quality of the developed products as a European Added Value and following future trends and consumer demands.
- Evaluation and demonstration of health benefits on humans by the performance of a clinical trial.

■ **Technological objectives:**
- Plant sourcing according to GACPs of the selected plants.
- Sustainable exploitation of residual plant biomass generated during the extraction process
- Scale-up of the production of extracts and/or bioactive compounds for commercial use.
- Suitable galenical formulation and validated manufacturing process.

■ **Societal objectives:**
- Provide suitable information to the consumer through a label for commercial use, containing health claims.
- Performance of a clinical study to support health benefits of the studies species, which should be evaluated by European Food Safety Authority (EFSA). EU and non-EU economic and regulatory issues will be taken into account.

Workflow of the preparation of the final product



Overall strategy of the work plan

Plant

Selection of potential raw plant materials

- Definition of plants for planned investigations
- Evaluation of preclinical properties (*in vitro* pharmacology)
- Phytochemical characterization of bioactive compounds

Plant sourcing, optimization of extraction process

- Establish analytical specifications for herbal material and plant extracts
- Optimization of the extraction process towards commercial production
- Scale-up of the production of extracts and/or bioactive compounds for commercial use

Galenic formulation

Galenical formulation development

- Development of optimized galenical formulations
- Development of specifications for analytical quality control of formulation

Scale-up of formulation

- Validation of production process of final formulation, including scale-up production
- Optimization of formulation process towards commercial production (scale-up).

Nutraceutical Finished product

Evaluation of quality

- Quantification of lead bioactive compounds
- Stability studies concerning bioactive concentration for shelf-life determination
- Evaluation and characterization of degradation products
- Monitoring of the occurrence of pesticides, organic contaminants

Finish product trials

- Preparation of batches of the developed nutraceuticals
- Preparation of a standard label for commercial use containing claims

Clinical Trials for health claims

- Design investigation on efficacy of finished products in healthy humans, according EFSA requirements
- undertake a double-blind placebo-controlled randomized cross-over, dose-response trial in human volunteers
- investigate dose-response relationships

Registration (GIS)

Estimated costs and duration for nutraceutical development

	Acute Oral Toxicity Study	Pilot Human Study (Dose Determination Exploratory)	Genotoxicity	Chemistry, Manufacturing & Controls (CMC) Studies	Sub Acute 28 Days Oral Toxicity Study	Mechanism Of Action Studies	Proof of Concept Human Study (Phase II b) with Bioavailability
Study Duration	**6 weeks**	**6-8 months**	**3-4 months**	**8 months**	**4-6 months**	**?**	**9-12 months**
		Documentation EC Approvals Patient Recruitment Data Management Report Writing		Formulation Development Analytical Development Purity Analysis Packaging Development Impurity Analysis Accelerated Stability			Documentation Site Selection, EC Approvals, Trial Supply Management Patient Recruitment, Monitoring Data Management & Final Report Writing
Guideline	OECD 423, Non-GLP	ICH-GCP	OECD 471, Non-GLP	EU, FDA, TGA	OECD 407, Non-GLP	Published models	ICH-GCP
Approximate cost	USD 1,500	USD 20,000-40,000 (+ Lab Charges)	USD 8,000 - 9,000	USD 80,000-120,000	USD 16,000-20,000	Variable	USD 120,000-240,000 (+ Lab Charges)

Summary

The market expectations for dietary supplements with anti-inflammatory properties are:

- *New formulation, which will increase bioavailability, and thereby increase efficiency.*
- *Final formulations, which cause a reduction in the size of the intake and recommended dosage.*
- *The use of well-tolerated excipients.*
- *Preparation of the formulation that will contain appropriate amount of „API" (active pharmaceutical ingredient) in the dosage, compliant with conducted clinical studies.*
- *New products with added value regarding quality and safety of the final product.*
- *Products with clinically proven bioactivity*

INTELIGENTNE SPECJALIZACJE POMORZA

DZIĘKUJĘ ZA UWAGĘ

Pomorskie

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