

SERVICES

PARTIAL OR COMPLETE MANAGEMENT OF R&D PROGRAMS FOR APPLICATIONS IN RESEARCH, DIAGNOSTICS, OR THERAPEUTICS

From the concept to the product

FUNDAMENTAL OR APPLIED RESEARCH

From the concept to the proofs of concept

➤ **Validation of the concept**

- ✓ Scientific survey,
- ✓ Identification of research data and programs already performed in the domain;
- ✓ Identification of potential applications;
- ✓ Validation of the concept : critical analysis.

☞ Preparation, validation and/or help for the preparation of the program (steps, cost, necessary resources).

➤ **Financing : public or private funding**

- ✓ Public funding
 - Survey of possible financing,
 - Preparation of application,
 - Follow-up of the application: presentation, completion of the application, preparation of intermediate and final reports ;
- ✓ Private funding
 - Review of potential investors,
 - Preparation and diffusion of the application,
 - Follow-up : presentation of the company, project and goals,
 - Follow-up with investors.

➤ **Conception**

- ✓ Bibliographic analysis: state of the art,
- ✓ Preparation of the research program (steps, dead lines, detailed planning, responsibility of actors, ...),
- ✓ Follow-up of the program
 - Follow-up of investigators (internal and outside services),
 - Preparation of intermediate and final reports.

➤ **Exploitation of data**

- ✓ Scientific publication of investigations, assistance to writing;
- ✓ Preparation of posters for congresses and meetings;
- ✓ Industrial property: preparation and registration of patents;
- ✓ Industrial applications : contacts with the industry.

DEVELOPMENT OF DIAGNOSTIC PRODUCTS: *Diagnostic applications* *From the concept to the commercial product*

- **Market study (*Diagnostic applications in diagnostics, and therapeutics*)**
 - ✓ Identification of concurrent products,
 - ✓ Identification of targets,
 - ✓ Validation of marketing surveys: analysis of report, contact with customers.
 - ☞ Validation and/or assistance for preparation of business plan of a project;
- **Financing : public or private funding**
 - ✓ Public funding
 - Survey of possible financing,
 - Preparation of application, follow-up: presentation, completion of the application, preparation of intermediate and final reports ;
 - ✓ Private funding
 - Review of potential investors,
 - Preparation and diffusion of the application, follow-up : presentation of the company, project and goals,
 - Follow-up with investors.
- **Conception**
 - ✓ Bibliographic analysis: state of the art,
 - ✓ Preparation of the research program (steps, dead lines, detailed planning, responsibility of actors, ...),
 - ✓ Follow-up of the program
 - Follow-up of investigators (internal and outside services),
 - Preparation of intermediate and final reports.
- **Validation of R&D data**
 - ✓ Proofs of concept : suitability of the technology with the industrial application;
- **Pilot production**
 - ✓ Production,
 - ✓ Purification,
 - ✓ Quality control;
- **Conditioning and validation of the reagent/diagnostic kit.**
 - ✓ Formulation and conditioning,
 - ✓ Stability study,
 - ✓ Evaluation of the final product, according to the regulation (program set in collaboration with selected testers),
 - ✓ Preparation of the evaluation report;
- **IVD registration (collaboration with an expert consultant cabinet)**
 - ✓ Quality requirements,
 - ✓ Risk analysis,
 - ✓ Preparation of the IVD application;
- **Quality assurance**
 - ✓ R&D step (work and reporting according to GLP), and production (GMP) ;
 - ✓ Applicable regulation for IVD labeling and FDA.

DEVELOPMENT OF THERAPEUTIC PRODUCTS: • Therapeutic applications *From the concept to the clinical investigation.*

- **Market study (• applications in diagnostics, and therapeutics)**
 - ✓ Identification of concurrent products,
 - ✓ Identification of targets,
 - ✓ Validation of marketing surveys: analysis of report, contact with customers.
 - ☞ Validation and/or assistance for preparation of business plan of a project;
- **Financing : public or private funding**
 - ✓ Public funding
 - Survey of possible financing,
 - Preparation of application, follow-up: presentation, completion of the application, preparation of intermediate and final reports ;
 - ✓ Private funding
 - Review of potential investors,
 - Preparation and diffusion of the application, follow-up : presentation of the company, project and goals,
 - Follow-up with investors.
- **Conception**
 - ✓ Bibliographic analysis: state of the art,
 - ✓ Preparation of the research program (steps, dead lines, detailed planning, responsibility of actors, ...),
 - ✓ Follow-up of the program: follow-up of investigators
 - ✓ Preparation of intermediate and final reports.
- **Development step**
 - ✓ Feasibility study: validation of data obtained in the research step, proof of the biological activity of the potential therapeutic product,
 - ✓ GMP pilot production: (outsourcing)
 - Identification and audit of the partner,
 - Preparation of requirements, preparation of the service contract,
 - Follow-up of the partner work, reporting,
 - ✓ Production of the final product with the selected partner(s): production, purification, controls, conditioning, ...
 - ✓ Complete characterization of the product,
 - ✓ Stability study;
- **Pharmacokinetic analysis and toxicology tests on animals: outsourcing**
 - ✓ Identification and audit of partner(s),
 - ✓ Preparation of requirements, preparation/validation of service contract,
 - ✓ Follow-up of investigations,
 - ✓ Critical analysis of the study reports.
- **Preparation of the AFSSaPS application for clinical investigation in humans**
- **Quality assurance : R&D (GLP), and production (GMP); regulation: AFSSaPS ; FDA.**
- **Regulation aspects (collaboration with an expert cabinet)**

MARKETING ASSISTANCE, SALES (☛ diagnostic products)

From the product to the customer

OFFERING MARKETING

Analysis and validation of the marketing offer: suitability of the offer with the customer need.

OPERATIONAL MARKETING

Assistance to customers: description of applications, preparation of application notes, training.

SALES

Identification of resellers worldwide.

Direct promotion and sales of selected products

COMMUNICATION: ORGANISATION OF SCIENTIFIC MEETINGS (SYMPOSIUMS, CONGRESSES, ...) ; ORGANISATION OF TRAINING

ORGANIZATION OF SCIENTIFIC MEETINGS AND CONGRESSES

- ✓ Preparation of the program with speakers ;
- ✓ Announcement: mailing web, www.biorun.com website or dedicated website ;
- ✓ Registration and convocation of participants ;
- ✓ Logistics: meeting rooms, material, coffee breaks, lunches, ... ;
- ✓ Publication of data: (web mail, www.biorun.com website or dedicated website).

COMPLETE MANAGEMENT OF CONGRESSES WITH MANAGEMENT OF DEDICATED WEBSITE

- ✓ Preparation of the program with speakers ;
- ✓ Announcement: mailing web, dedicated website, press ;
- ✓ Registration and convocation of participants ;
- ✓ Logistics: meeting rooms, material, coffee breaks, lunches, lodging... ;
- ✓ Publication of data: abstracts, reports, presentations; publication on the dedicated web site, proceedings, specialized press.

TRAINING

- ✓ Preparation of the training program with trainers;
- ✓ Announcement: company website or dedicated site;
- ✓ Registration and convocation of participants ;
- ✓ Logistics: meeting rooms, material, coffee breaks, lunches, ... ;
- ✓ Preparation and diffusion of the documentation: photocopies, CD-ROM,...;
- ✓ Follow-up: communication to participants of evaluation results.

MAIN APPLICATION DOMAINS

- **Immunology** : Monoclonal and polyclonal antibodies, diagnostic reagents, therapeutic agents, vaccines, cellular receptors, fusion proteins, ...
- **Hematology** : diagnostic reagents, flow cytometry, ...
- **Transfusion Medicine**
- **Bacteriology, virology, other specialized domains**
- **Cellular therapy : progenitor cells and blood cells**
- **Technical domains of expertise**
 - ✓ Automatic storage and management of biological samples (bio libraries, repositories) ; applications in cancerology, genomics, gene therapy, ...
 - ✓ Automation of processes,
 - ✓ Bioinformatics.