

Voisin Consulting and BioRun Announce the Completion of a Strategic Alliance to assist biotechnology companies with their Monoclonal Antibodies Development Programs

Paris, February 8, 2005: Through this alliance Voisin Consulting and BioRun are at the forefront of monoclonal antibodies development programs and make this field a core area of expertise.

Voisin Consulting and BioRun deliver:

- Assistance in the design and implementation of the optimal regulatory strategy for the development of MAbs pipeline, covering the EU, USA and Australasia
- Acceleration of monoclonal antibody development programs from concept to approval
- Design and validation of nonclinical development programs
- Project management of nonclinical and clinical development programs
- Clinical protocols design
- Review and revision of nonclinical and clinical documentation, drafting regulatory submissions (Investigator's Brochure, Clinical Study Protocols, Clinical Trial Applications...)
- Agency "Road Shows" to fully validate the development plan

With a project management-based approach, Voisin Consulting and BioRun provide a broad panel of competences including their external network of recognized Experts, and aim to create a focused multi-disciplinary team functioning as an extension to their client' staff.

Together Voisin Consulting and BioRun now offer a comprehensive range of advisory services that span the entire MAbs research and clinical development lifecycle.

About Voisin Consulting

Voisin Consulting advises start-up biotechnology and pharmaceutical companies in the design and implementation of their global regulatory strategy, and emphasises harmonization between Europe and the USA. Voisin Consulting assists its clients in the development of their products: drugs, biologics, cell and gene therapy products, human tissue engineered products (hTEPs), combination products (drug/device), and medical devices including *in vitro* diagnostics.

About BioRun

BioRun offers innovative services in the development of MAbs and related molecules intended for diagnostic and therapeutic applications. Based on 30 years of experience in Research & Development in the pharmaceutical industry, together with a strong scientific and technical background in antibodies and transfusion medicine, Dr. Dominique Blanchard, founder of BioRun, brings a significant assistance to antibody developers.

For further information:

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