COMPANY PROFILE

The company operates at a global level serving the pharmaceutical industry with analytical testing of biological samples and validation of bioanalytical methods

Established in 2009 in Siena (Tuscany) from the founders' university experience in bioanalytical testing for influenza vaccines, VisMederi currently receives orders from all over the world, collaborating with major pharmaceutical companies worldwide. VisMederi has a qualified staff of scientists and technical experts as well as its own Scientific Committee which constantly and objectively evaluates its research projects. All of VisMederi activities are carried out in compliance with the European system of certification

- **UNI EN ISO 9001:2008**
- **UNI CEI EN ISO/IEC 17025:2005**
- **UNI EN ISO 15189:2013**
- **GCLP**
- **ISO/IEC 27001:2012**

VACCINE ASSESSMENT

VisMederi researches and develops methods of analysis and evaluation of vaccines, drugs and molecule efficacy for preventive and therapeutic purposes

Ever since its foundation, VisMederi has focused its attention mainly on the **development of serological tests** requested for the registration of both seasonal and pandemic **influenza vaccines**. Vismederi constantly undergoes a validation process in accordance with EMA, FDA and PMDA **international guidelines**, in order to demonstrate the validity, the trustworthiness and robustness of its tests.
Traditional assays for the evaluation of **virus vaccine immunogenicity** characterize VisMederi's daily research, but in order to respond effectively to the needs of current and potential partners, the company constantly works for the optimization and validation of **serological assays**, with particular focus towards innovative platforms.

ASSAY DEVELOPMENT

VisMederi offers its clients a large portfolio of qualified and IVD serological assays for pre-clinical and clinical activities

The tests carried out within VisMederi's facilities regularly undergo validation and standardization procedures in order to ensure **high-quality protocols** applicable both in clinical trial settings and in research contexts. All laboratory tests are performed in **BSL2**, **BSL3** and **BSL3+** VisMederi's **Assays Development division** deals with the creation, optimization and standardization of bioanalytical microbiological, serological and virological assays and tests associated with vaccine immunogenicity assessment and epidemiological screening.

Serological and cellular assays for COVID-19:

- Enzyme-Linked Immunosorbent Assay (ELISA) for IgG, IgM and IgA in serum/ plasma samples
- ELISA - Avidity
- Elecsys Cobas (ROCHE) for S and N quantitation
- S-IgA quantitation in mucosal samples
- Neutralization CPE
- Neutralization RNT
- Pseudotypes MN Lentiviral
- Pseudotypes MN VSV
- Analyses of cellular response using cytofluorometry (Intracellular staining – FACS)
- ELISpot

VisMederi's team guarantees proven experience in conducting a wide range of serological assays, including:

- Assays for Influenza vaccines licensing: HAI (Haemagglutinin Inhibition), SRH (Single Radial Haemolysis) and MN (Microneutralization)
- Neutralization assays for emerging pathogens (Yellow Fever, Dengue, West Nile, etc.)
- Antigenic Drift of influenza vaccine stocks
- Pseudoparticle Neutralization assays (PPN)
- Complement fixation assays
- ELISA assays for antigen and antibody detection
- Immunofluorescence tests for detection of specific antibodies

In vitro Immunological assays and bioanalytical services are offered at VisMederi to understand Cell Mediated Immunity:

- Cellular response analyses using cytofluorometry (FACS)
- ELISPOT assay
- ADCC antibody-dependent cellular cytotoxicity

Other tests:

- LAL Test (Limulus Amoebocyte Lysate) for the quantitative determination of endotoxins
- Yield-reduction assays (TCID50 titration and immunoplaque)
- Influenza Haemagglutinin potency assays
- Single Radial Diffusion Assay (SRD) for the quantification of viral antigens
- Real Time RT-PCR
- Serum Bactericidal assay (SBA)
- OPA-Assay (Opsonophagocytic assay)

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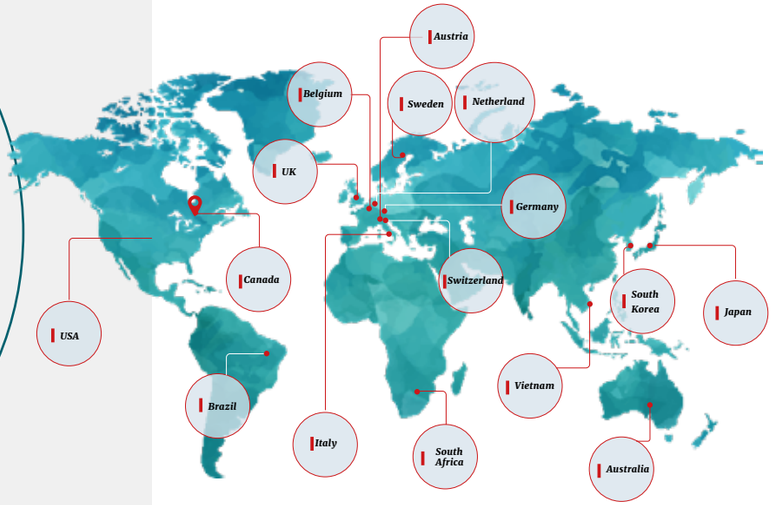
PROJECT MANAGEMENT



VisMederi offers its clients full clinical trial and research project support from concept through completion based on high quality standards.

Our Services include scientific, technical and logistic assistance for protocol design and review for experiments, process monitoring, samples' analysis, data elaboration, release of results and reporting. A team of diverse and complementary expertise allows us to fully administer projects, in order to better interpret **clients' needs** and **business goals.**
VisMederi's **laboratories** and **research facilities** enable to completely cover all the procedures related to the development of p**hase I, II, III,** and **IV** of clinical trials.
It also works in synergy with laboratories, research facilities and international research centres for the development of **pre-clinical protocols.**

Why VisMederi?

1. Competence, skills and professionalism
2. Quality
3. Reliability
4. Flexibility, dynamism and speed

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