



**COMPANY  
PROFILE**

VisMederi's **laboratories** and **research facilities** enable it to completely cover all the procedures related to development of **phase II, III, and IV** of clinical trials. It also has a synergy with laboratories and research facilities and international research centers for the development of **pre-clinical protocols** and **phase I studies**.

Throughout the years, the company has developed a **diagnostic testing division**, focused on the evaluation of new drugs using in vitro tests and a consulting **services and microbiological analysis area** in environmental, food and agricultural fields. In 2013, VisMederi became shareholders of Accurance Ltd. and in 2014 founded the subsidiary **VisMederi Research** with the aim to separate the R&D activities by the management of services.

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

Established in 2009 in Siena (**Tuscany**) from the founders' university experiences in bioanalytical testing for influenza vaccines, VisMederi currently receives orders worldwide, collaborating with the **major pharmaceutical companies** in the world. VisMederi has a **qualified staff** of scientists and technical experts and its own **Scientific Committee** for continually and objectively evaluate its research projects. All of VisMederi activities are in compliance with the **European system of certification UNI EN ISO 9001:2008**.



## VACCINES ASSESSMENT

VisMederi researches and develops methods of analysis and evaluation of vaccines, drug and molecule efficacy for therapeutic purposes.



Ever since its foundation, VisMederi has focused its attention for the most part on the **development of serological tests** requested for the registration of both seasonal and pandemic **influenza vaccines** on behalf of international regulatory bodies such as the EMA, FDA and the PMDA. The assays performed at VisMederi continually undergo validation processes in accordance with **international guidelines**, so as to demonstrate the trustworthiness and robustness of its tests.

Traditional assays for the evaluation of **virus vaccine immunogenicity** characterize VisMederi daily research, but in order to respond effectively to the needs of current and potential partners, the company works continually for the optimization and validation of **serological assays**, with particular focus towards innovative platforms.

## ASSAY DEVELOPMENT

VisMederi offers its clients a vast portfolio of services that includes serological and virological assays development and diagnostic testing for the assessment of the efficacy of new drugs and vaccines

The tests carried out within VisMederi facilities continuously undergo validation and standardization procedures in order to ensure **high-quality protocols** applicable in both in clinical trial settings and in research contexts. All laboratory testing is performed in **BSL2** and **BSL3** containment facilities according to an **ISO 9001:2008** certified quality system, integrated with GLP and GCP.

VisMederi's **Assays Development division** deals with the creation, optimization and standardization of bioanalytical microbiological, serological and virological assays and tests associated with vaccines' immunogenicity assessment and epidemiological screening.

### The VisMederi team guarantees proven experience in conducting a wide range of assays, including:

- Serological assays for Influenza vaccines licensing in particular: HAI (Haemagglutinin Inhibition), SRH (Single Radial Haemolysis) and MN (Microneutralization)
- Neutralization assay for emerging pathogens (Yellow Fever, Dengue, West Nile, etc. )
- Antigenic Drift of influenza vaccine stocks
- Pseudoparticle Neutralization assays (PPN)
- Complement fixation assay
- ELISA (Enzyme-Linked Immunosorbent Assay) assays for antigen and antibody detection
- Immunofluorescence tests for detection of specific antibodies
- Analysis of cell-mediated immune response using cytofluorometry (FACS) and ELISpot assay
- LAL Test (Limulus Amebocyte Lysate) for the quantitative determination of endotoxins
- Single Radial Diffusion Assay (SRD) for the quantification of viral antigens
- Real Time RT-PCR



## CELL CULTURE

VisMederi performs **cell culture-based assays** in order to fulfil the needs of different ongoing projects. VisMederi's staff experience ranging from the use and handling of cell cultures for testing to the optimization of cell growth and cell culture conditions, propagation and isolation of viral strains in cell cultures and the storage of adherent and suspension cell lines. The company owns master cell banks for several kinds of human and animal cell lines (such as MDCK, MDCK-SIAT, VERO, HEK293, Hep-2C, HL-60 or RD).



## PROJECT MANAGEMENT

VisMederi can offer its clients full **clinical trial** and **research project** support from concept through to the completion based on a high quality standard. 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**.