COMPANY PROFILE

The Company operates at a global level serving the Pharmaceutical Industry with analytical testing of biological samples and validation of bioanalytical methods.

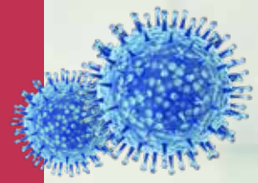
Established in 2009 in Siena (**Tuscany**) after the founders' academic experience in bioanalytical testing for influenza vaccines, VisMederi currently receives orders from all over the world, working in partnership with the **biggest Pharmaceutical Companies** in the world. VisMederi has a **qualified staff** of scientists and technical experts and its own **Scientific Committee** for a constant and objective evaluation of its research projects. All VisMederi activities comply with the **European System of Accreditation**:

- UNI EN ISO 9001:2008
- UNI CEI EN ISO/IEC 17025:2005
- UNI EN ISO 15189:2013
- Good Clinical Laboratory Practices (GCLP)

VACCINE ASSESSMENT

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

Ever since its foundation, VisMederi has mainly focused its attention 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 EMA, FDA and PMDA.



The assays performed at VisMederi constantly undergo validation processes in accordance with **international guidelines**, in order to demonstrate 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 works continually for the optimization and validation of **serological assays** with special attention towards innovative platforms.

ASSAY DEVELOPMENT

VisMederi offers its clients a large portfolio of qualified biochemical services including preclinical and clinical activities.

The tests carried out within VisMederi's facilities constantly 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**+ containment facilities.

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.

VaxArray® *is an immunoassay, imaging, and potency interpretation platform. When the Imaging system is paired with the Influenza Seasonal and Pandemic Hemagglutinin and Neuraminidase potency assay kits, it creates a semi-automated platform to rapidly perform singleplex and multiplex immunoassays for hemagglutinin and neuraminidase quantification. It can be used at any stage in the vaccine manufacturing process*

The VisMederi 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 assay for emerging pathogens (Yellow Fever, Dengue, West Nile, etc.).
- IgA ELISA-based Assay for anti-Flu, anti-Antrax PA and anti-RSV antibodies detection in human and animal nasal secretion.
- ELLA (Enzyme-Linked Lectin assay) assays for anti NA (FLU) antibodies detection.
- Pseudotypes particles production for FLU, LASSA VIRUS and NIPAH VIRUS.
- 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.

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

- Analyses of cellular response using cytofluorometry (FACS)
- ELISPOT assay
- ADCC antibody-dependent cellular cytoxicity

Other tests:

- LAL Test (Limulus Amebocyte Lysate) for the quantitative determination of endotoxins.
- Yield-reduction assays (TCID50 titration and immunoplaque).
- Influenza Haemagglutinin potency assays.
- **VAXARRAY** Influenza Seasonal and Pandemic Hemagglutinin and Neuraminidase Potency Assay.
- Single Radial Diffusion Assay (SRD) for the quantification of viral antigens.

VISMEDERI
ANALYSES FOR LIFE IMPROVEMENT

Strada del Petriccio e Belriguardo, 35
53100 Siena, Italia

tel +39 0577 381253
+39 0577 381255
fax: +39 0577 381258

info@vismederi.com
www.vismederi.com

PROJECT MANAGEMENT

VisMederi offers its clients full clinical trial and research project support from concept to completion with high quality standards.

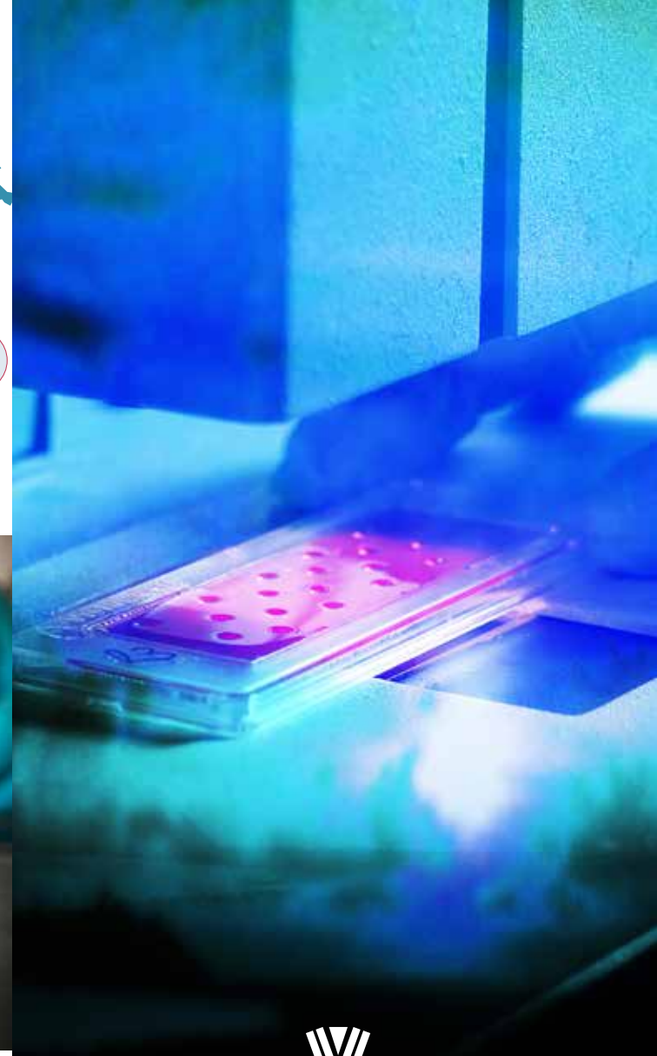
Services include scientific, technical and logistics assistance for protocol design and review for experiments, process monitoring, samples analysis, data elaboration, release of results and reporting. A team with relevant and complementary expertise allows us a full management of projects, in order to improve our understanding of our **clients' needs** and **business goals**.

VisMederi's **laboratories** and **research facilities** assist us in the full and successful implementation of all the procedures related to the development of **Phase I**, **II**, **III** and **IV** of clinical trials. We have also been able to create a perfect synergy among laboratories, research facilities and international research centers for the development of **pre-clinical protocols**.

Throughout the years, the Company has developed a **Diagnostic Testing Division**, focused on the evaluation of new drugs using in vitro tests and consulting **services and microbiological analyses** in the environmental field.

Why VisMederi?

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



VISMEDERI
ANALYSES FOR LIFE IMPROVEMENT

We prove. You improve