VisMederi srl

Life Sciences

ANNUAL REPORT 2013

Our 2013? A year of change, with quality in mind!

Simona Piccirella
Chiara Gentile
VisMederi's Board of Directors

There are years that leave their mark in the history of a company. Years in which everything that has been patiently "seeded" with tenacity, professionalism and commitment finds its turning point, a new and more complete realization.
2013 has been a special year for VisMederi.
Twelve months in which we have consolidated our experience in our core business – creation, validation and optimization of bioanalytical testing of pathogens – and continued to push the boundaries of our collaborations, especially at an international level, with public and private organizations. The relations with Japan, started in 2012, have significantly strengthened, thus making our company a great success on the internationalization front, as well as in terms of leadership in the development of serological assays.
Competing in a global market, for a young, small-medium size company such as our, it was not a step taken for granted, especially in such an economically complex time. If we grew up, in terms of quality and quantity of collaborations, we owe it certainly to the high standards achieved in the provision of services in the field of immunology. And this goal would not have been possible without the group of scientists and researchers working alongside us with total dedication and professionalism.
The staff of VisMederi has grown year after year, with an increase of 80% (70% of which are women) from 2009 to present. This growth of human capital and know-how has enabled us to successfully deal with new challenges.
In 2013, in fact, we made our entry into the Food and Environmental Sciences sector, investing in new equipment and qualified personnel. This growth confirms quality. Our laboratory has been accredited according to UNI EN CEI ISO 17025:2005 for the microbiological analysis of food and surfaces at Accredia, the only accrediting agency in Italy.
A further factor that provides value to the services offered by VisMederi and that adds to certifications for the advice and analysis of biological matrices, ISO 9001:2008, obtained between 2010 and 2011.
One step after another, we continue to grow, convinced that our work, if done with care and passion, can generate new qualified services for research and further employment opportunities for young researchers.

Message of the Scientific Director

Emanuele Montomoli
Professor of Public Health,
University of Siena
VisMederi's Scientific Director

In VisMederi, we strongly believe that behind the development of excellent drugs and vaccines lies a fundamental process of high quality evaluation, both in terms of traditional clinical studies and for laboratory tests related to them. And it is exactly with this aim that we work every day, confident in the quality of our work and strong ethical principles that lie at the basis of our job.

In order to pursue these objectives and participate in global supply chains aimed at having the best pharmaceutical products, we offer high-quality biological laboratories, a biosafety PCL 3 laboratory where we work safely with highly pathogenic microorganisms and, above all, a staff of experts who are scientifically valid and very motivated to achieve the company's mission.

Inside of the University of Siena, our working group has gained nearly two decades of experience in the development and validation of serological methods for the control of pharmaceutical products, especially in the prevention of infectious diseases and Public Health. The transfer of the "modus operandi" in VisMederi made it possible to quickly reach a high level of quality in our work.

In 2013 we continued the consolidation of existing activities by placing them in new market niches and, simultaneously, we have gained knowledge and technologies in emerging areas. One example is the implementation of new technologies and laboratory tests for the control of immunogenicity of innovative influenza vaccines, such as those produced in cell cultures.

For our scientific growth in the next future we primarily look at international collaborations, taking inspiration from centres of excellence worldwide and continuously and collectively examining the outcomes of opinion leaders in the field of Life Sciences.

VisMederi srl
Life Sciences

• History and Core Business

VisMederi is a research and qualified services company operating in the field of Life Sciences and Public Health. It was born in 2009 from the experience on bioanalytical testing for influenza vaccines and from networks of contacts acquired by the founders of the Laboratory of Molecular Epidemiology at the University of Siena. Today the company has global contracts in the field of vaccines and performs analytical testing of biological samples and validation of bioanalytical methods for the pharmaceutical industry. VisMederi has a structure able to cover all the activities required for the conduct of clinical trials phase II, III and IV and takes advantage of synergies with international research centres and facilities for the performance of protocols for preclinical and phase I studies. Since its foundation, VisMederi has invested a lot of resources available to the optimization of laboratory testing for the assessment of the immune response. Recently, the company has also specialized in testing for cellular immune response and the development of specific methods targeted to the "efficacy studies". VisMederi has experience in the design and evaluation of animal models.

In 2013, the company has also developed a new line of business targeted to the analysis of quality control for food, water and environment. In this context, VisMederi works thanks to granting of public organizations, corporations and private individuals and to the collaboration of qualified companies for the conduct of its activities.

VisMederi has operational headquarters in Siena, within the bioincubator of Toscana Life Sciences Foundation.

Vision & Mission

Our Vision defines the universe of values from which VisMederi takes inspiration for its work in the present and the goals and objectives that will guide its business decisions in the future. VisMederi was created to contribute to the improvement of the Public Health System through the analysis and evaluation of the effectiveness of vaccines, drugs and molecules for therapeutic purposes – A goal that finds a solid foundation in the quality and professionalism of the services and researchers who make up the working group. **Quality and professionalism** are VisMederi's "North star": two values allowing us to act consistently with business objectives and their natural evolution.

The **Mission of VisMederi** is to contribute to the development of better and safer drugs and vaccines, ensuring maximum attention to the quality of the system and analytical data. In particular, VisMederi works to offer accurate and documented test results and a highly qualified service in the interpretation of provided data, to the overall customer satisfaction. In the field of vaccines, VisMederi aims to become a leader in providing quality services to pharmaceutical companies.

Simona Picciarella, Chiara Gentile, Emanuele Montomoli

Management

Simona Piccirella

After earning her degree in Biological Sciences at the Università Politecnica delle Marche, she obtained a PhD in Molecular Medicine and a post doctorate in Molecular Epidemiology at the University of Siena. She has significant experience in the validation of analytical methods and developed specific expertise in the management of clinical trials and in the execution of serological tests for the validation of analytical methods. Since 2009, the year of birth of the company, she is VisMederi's CEO.

Chiara Gentile

After earning her degree in Natural and Biological Sciences at the University of Siena, she obtained a PhD in Molecular Medicine, Department of Pathophysiology, Experimental Medicine and Public Health, University of Siena, and a post doctorate at the same Department. During the post-graduate training course she gained experience in the field of Quality Management System, as well as in purely scientific aspects. She is the author of publications on international scientific journals. Co-founder and Administrator of VisMederi, she plays the role of Financial Manager, Quality Manager and Human Resources Manager within the company.

• Scientific Committee

DIRECTOR

Emanuele Montomoli

Emanuele Montomoli is Professor of Hygiene and Preventive Medicine at the University of Siena. After graduating of the University of Siena with a thesis entitled "Optimizing the Use of MDCK Cell Cultures (Madin Darby Canine Kidney) for the Epidemiological Surveillance of Influenza" in 1997, he obtained a Bachelor's Degree in Clinical Biochemistry Specialized in Diagnostics at the University of Siena in 2001. His primary field of interest is focused on the research in the field of vaccination, particularly in the study of correlates of protection for influenza vaccination. He has conducted multiple clinical trials for the evaluation of the immunogenicity and efficacy of many vaccines in Europe and in the rest of the world. Since 2002, he is the Head of the Laboratory of Molecular Epidemiology at the University of Siena. In addition to the Scientific Advisory Board of VisMederi, he is a member of the Scientific Committee of international organizations such as WHO Regional Office and ECDC, and he is an active member of the Scientific Board of the International Society for Influenza and other Respiratory Virus Diseases. He is the author of over 50 scientific articles with a total Impact Factor of 200, abstracts and other publications on national and international journals.

COMPONENTS

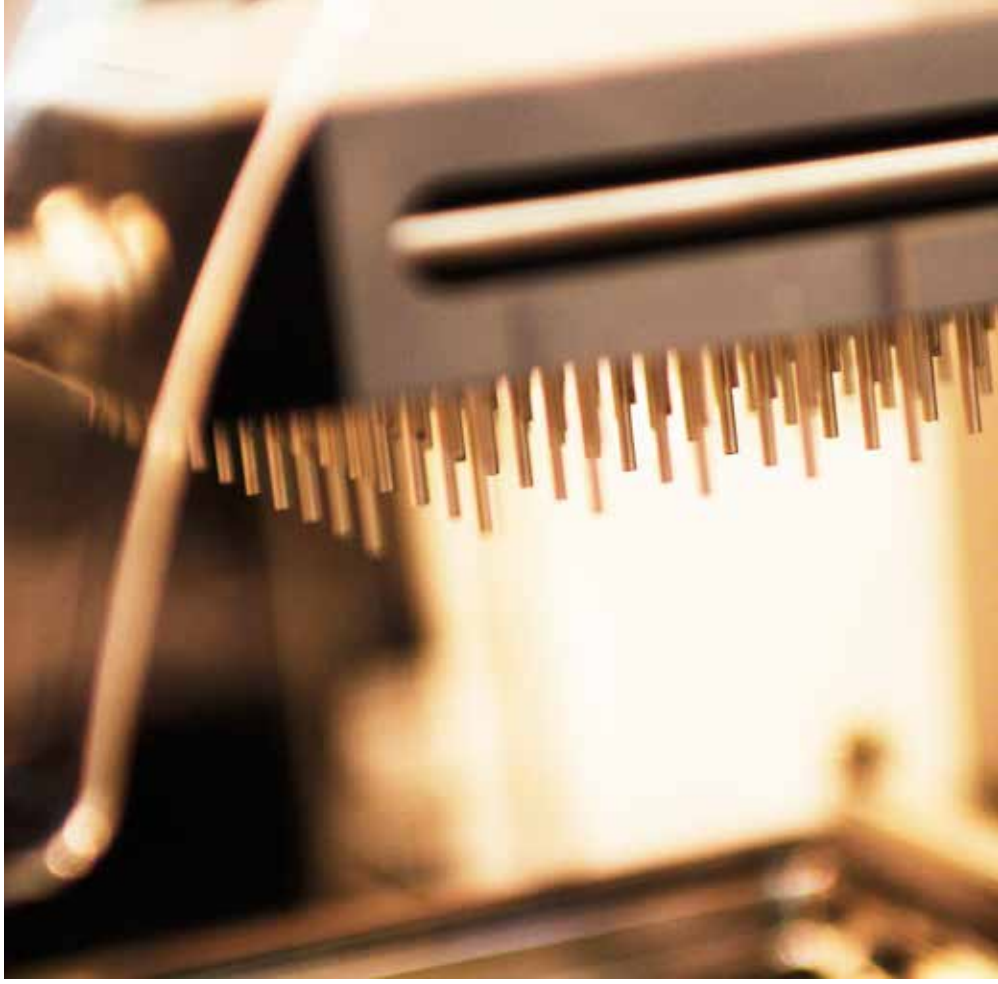
Roberto Gasparini

Director of the Interuniversity Research Centre on Influenza and Viral Infections, he is Professor of Hygiene and Preventive Medicine at the University of Genoa. From 1986 to 2000, he was lecturer at the University of Siena, where he conducted research on the epidemiology and prevention of dental diseases, epidemiology and prevention of influenza, innovative pertussis and influence vaccines. His research covers topics related to health promotion and prevention, with particular reference to innovative vaccines for influenza and meningitis. He is currently engaged in the development of the application of Health Technology Assessment in the field of immunization and in the development of mathematical models for assessing the best vaccination strategies and pharmacoeconomic models for the introduction of new vaccines in Italy. Author and co-author of about 500 publications on printed national and international journals of medical sciences, he is a member of the Order of Physicians, Surgeons and Dentists of the province of Genoa.

Silvano Focardi

Professor of Ecology at the University of Siena since 1990, he was Dean of the Faculty of Mathematical, Physical and Natural Sciences of the University of Siena from 1999 to 2005 . In 2005 he received the honorary degree in "Ciencias ambientales" at the Universidad de Concepcion (Chile). From the March 30th 2006 to October 31st 2010 he was Rector of the University of Siena. The main research lines in which he has been busy in recent years are concentrated in the following areas: the study of contamination in the Mediterranean Sea; the study of contamination in remote areas; studies on the ecology of Adélie Penguin (Antarctica); the study of the effects of persistent contaminants on organisms; the development of techniques for the detection of the quality of brackish and marine environments; the study of the impact of fisheries and aquaculture on the environment and the development of techniques for the detection of food quality.

COMPONENTS SCIENTIFIC COMMITTEE



Aldo Tagliabue

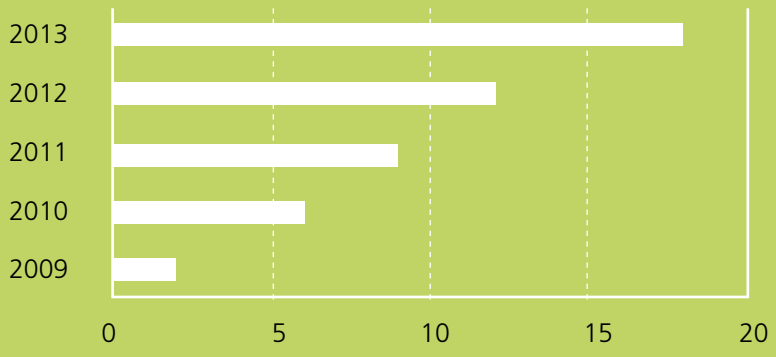
After graduating in Biology at the University of Milan in 1974, he later obtained a specialization in Experimental Pharmacology in 1976 at the Mario Negri Institute in Milan. From 1976 to 1979, he worked at the National Cancer Institute, NIH, Bethesda, Maryland being one of the first researchers in the world dealing with cytokines. In 1981 he moved to Siena as Head of the Laboratory of Immunology of the new Sclavo Research Centre. At that time, he developed independent research projects in the field of mucosal immunology, applying basic discoveries in the study of immune responses in vaccinated volunteers. In 1990, he became Research Director for Dompè SpA. In 1998, he founded Siena ALTA Ricerca & Sviluppo in Biotecnologie Srl, a service company in the field of research projects and technology transfer for Research & Development in Biotechnology. During his career, he has published more than 120 original scientific papers and has been editor of several books in the fields of mucosal and cytokine immunology. He is the inventor of 10 international patents and has been teaching since the beginning of his career. In 2006, he was appointed Project Leader for the creation and building of Novartis Vaccine Institute for Global Health, headquartered in Siena, whose mission is to develop vaccines for developing countries on a non-profit basis.

Costante Ceccarini

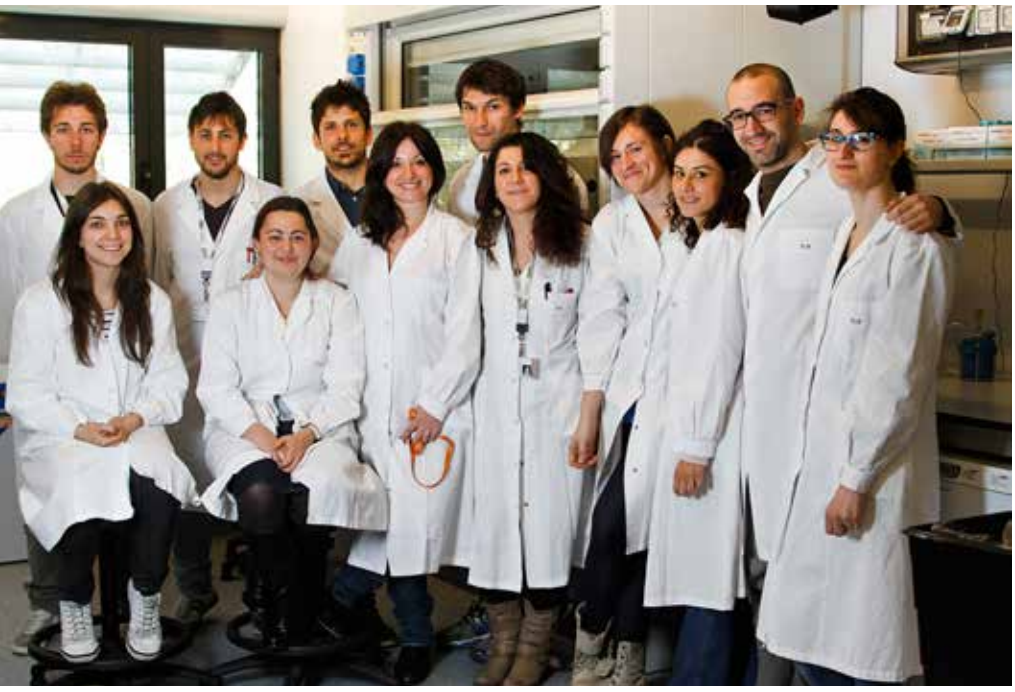
Constant Ceccarini has more than 35 years of academic and industrial experience behind him, in the area of Research and Development. He received his Bachelor of Science at Peters College and a Master's Degree in Biology at Oberlin College in Ohio. He received his Ph.D. in Biochemistry and Biology at Princeton University in New Jersey. Professor at the City University of New York from 1970 to 1980, he then held management positions within Sclavo Diagnostics International (1981-1989). In 1989, he became Head of the SIFI research group, leader in Italy in the Eye Care field. In 1991 he returned to Siena to direct the R&D area of Sclavo, then Chiron, a role he held until 1998. In 1998, he became a consultant of the World Health Organization (WHO), where he was called to identify companies potentially able to produce vaccines respecting the standards set by WHO, in the countries of the Third World. At this time, he has been entrusted to a technical report to reach the production of a safe and effective conjugate vaccine against type A Meningococcal bacteria. The project was supported by a grant of U.S. $ 70 million granted by the Bill and Melinda Gates Foundation in 2000. During his career, he has published more than 70 articles in peer-reviewed scientific journals. Today, he is a member of SAG (Scientific Advisory Group) of the International Vaccine Institute in Seoul.

• Human Resources, a growing capital that makes us grow

The people we employ. With their expertise and experience, they make VisMederi a young, dynamic and innovative company. We are talking about a human capital of competent and motivated women and men, which over the years has grown and strengthened thanks to new highly technically and scientifically specialized professionals. On their side, the two founders of the company: Simona Piccirella, CEO, and Chiara Gentile, Financial Manager, Quality Manager and Human Resources Manager. Since 2009, the Scientific Director is Prof. Emanuele Montomoli.
The two main business areas – vaccines and food industry, safety and environment – are supported by an administrative area for all research activities, consisting of two employees, both graduates. In 2013, the research area was composed of thirteen graduate employees, including four PhDs.
Our staff attends an on-the-job training program and takes part into seminars and specialized courses in collaboration with international centres and universities. The high profile of the working group is one of the strengths of VisMederi, which chose to bet on young people and to enhance their talent to grow and successfully enter



Progression of VisMederi's Staff from 2009 to 2013.



6 **Permanent Employees**

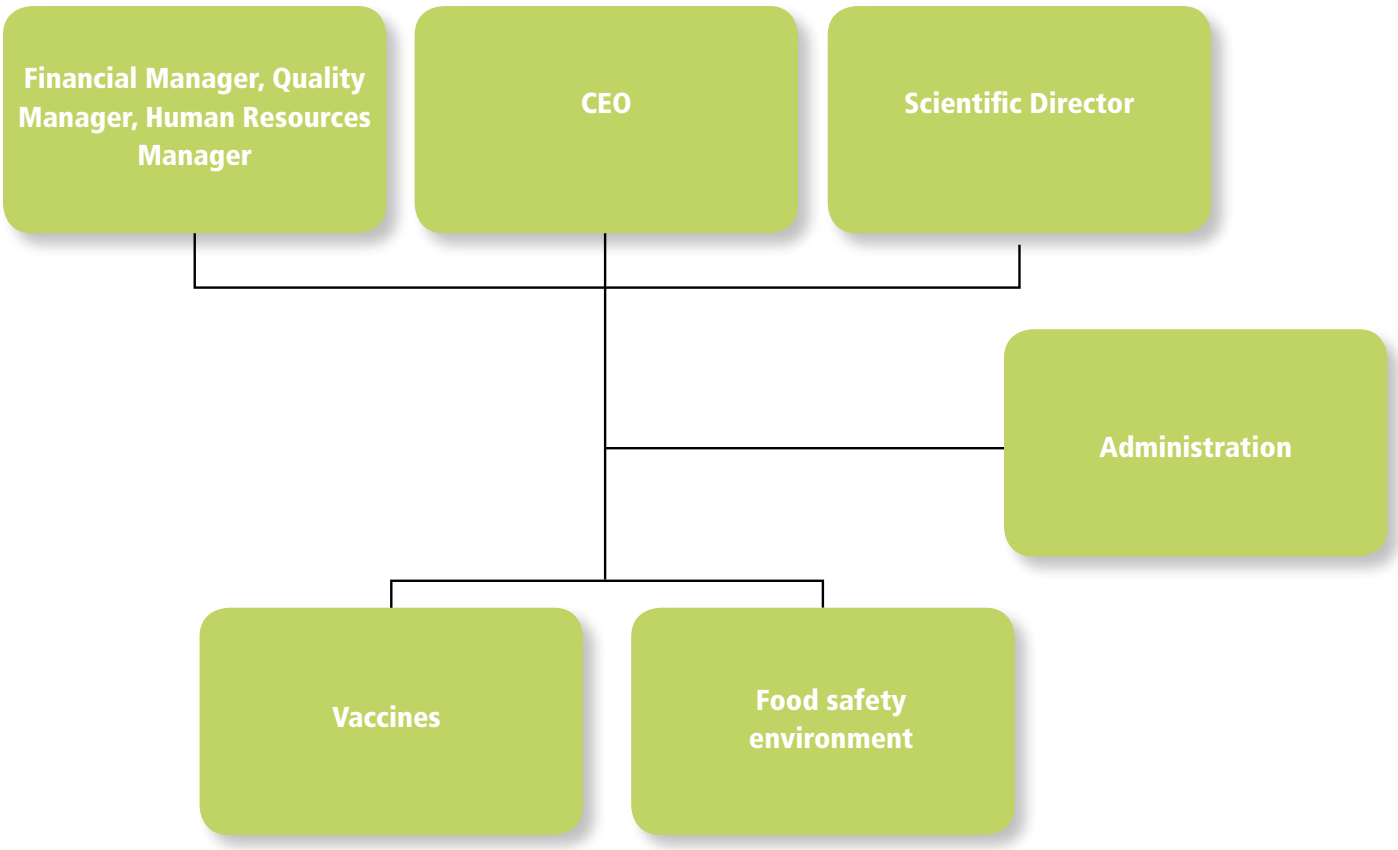
3 **Temporary Employees**

4 **Fixed-term contract Employees**

3 **University Researchers**

2 **Interns**

VisMederi's Organizational Chart for 2013.



VisMederi srl
Life Sciences

Business Area

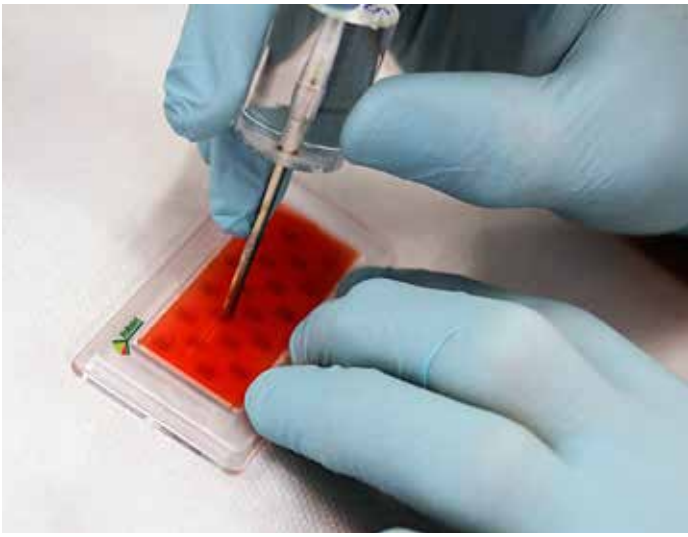
VACCINE DEPARTMENT (IMMUNOLOGICAL ASSESSMENT OF VACCINES)

Since its founding, VisMederi has turned his attention primarily to the **development of serological tests** required for registration of both seasonal and pandemic influenza vaccines by international regulatory bodies such as EMA (European Medicines Agency), FDA (Food and Drug Administration) and PMDA (Pharmaceuticals and Medical Devices Agency).
Assays performed at VisMederi are continually subject to validation processes in accordance with **international guidelines,** in order to demonstrate the solidity and reliability of the tests.

In particular, VisMederi operates in accordance with:

- "Guideline on bioanalytical method validation" – EMA;
- "Guidance for Industry: Q2B Validation on Analytical Procedures Methodology" – FDA;
- "Validation of analytical procedures: text and methodology; ICH Harmonised Tripartite Guideline, Q2(R1)" – ICH.

The **traditional immunological evaluation assays** of viral vaccines, such as Haemagglutinin Inhibition (HAI), single Radial Haemolysis (SRH) and Virus Neutralization (VN), are daily activities in VisMederi. In this context, the experience accumulated over the years makes it possible to ensure high quality results combined with very short lead times.
In the course of 2013, VisMederi devoted its work to the **continuous optimization** and **validation** of these **assays,** with eyes constantly turned to new platforms. In this context, important results have been achieved using pseudo viral particles for microneutralization testing and in the development of enzyme immunoassays for the assessment of response to neuraminidase of influenza vaccines, Enzyme-Linked Lectin Assay (ELLA test).
For the completion of activities in this sector, and in addition to the panel of tests available for the study of humoral immune response, we implemented **protocols for the study of cell-mediated immune response** through ELISPOT and FACS platforms.



VisMederi also carries out laboratory activities for the immune evaluation of bacterial vaccines, via "bactericidal" (SBA Assay) and "opsonisation" (OPA Assay) tests.
VisMederi has recently developed and validated numerous essays also usable for the performance of **"efficacy studies" on vaccines**. Of particular importance in this area, in addition to the isolation of micro-organisms in cell culture and molecular identification of bacterial and viral isolates from clinical specimens are the methods of quantization of microorganisms through "real-time PCR".

2013 also represented for VisMederi the beginning of the structuring of a new division devoted to the evaluation of the effectiveness of new drugs using in vitro tests, with the aim of providing a broader range of services in addition to those devoted to the studies on vaccines.

Business areas

FOOD, SAFETY AND ENVIRONMENT DEPARTMENT

Since 2013 VisMederi has been investigating on chemical and microbiological aspects of any type of food, water and work surfaces. A specialized laboratory, equipped with modern equipment and advanced technology, allows us to perform quality checks and audits in compliance with the provisions of the legislation.
VisMederi's laboratory is accredited by Accredia (Italian Accreditation Body) for certain microbiological tests in compliance with UNI CEI EN ISO / IEC 17025:2005. The laboratory is included in the official list of facilities that can perform analysis for the purposes of food self assessment and safety of the working surfaces in the Region of Tuscany.

FOOD AND WORK SURFACES

Analysis on food

- Research of pathogenic microorganisms, process indicators and shelf life, safety indicators
- Nutritional analysis and determinations of contaminants
- Shelf-life studies: quality consistency checks on product

HACCP Services

Our laboratory performs the analysis on food provided by the HACCP legislation on self assessment and works with companies in the development, drafting and revision of food self-assessment manuals. It also offers consulting services and training in the field of HACCP.

- **Consulting services**

VisMederi follows other companies in the process of voluntary certification through the preparation of quality manuals according to BRC and IFS standards and provides support in second and third party audits.

- **Microbiological analysis of work surfaces**

VisMederi performs assessment and sanitization of work surfaces, equipment and tools for food processing through the use of swab tests, sponges and slides.

WATER

VisMederi performs the sampling, the determination of the parameters laid down by the legislation in force and the check of process parameters for

- water for human consumption
- wastewater
- natural water
- technological water
- swimming pool water
- thermal water

For water intended for human consumption, VisMederi carries out the check of compliance with the Legislative Decree 31/01 and subsequent amendments as well as sanitary quality check of water used in food factories.

LEGIONELLA

The operators of tourist facilities and spas are required to perform an assessment of the risk associated with Legionella infection and to prepare a document for the purpose of self assessment. The laboratory of VisMederi searches for Legionella in water and biofilm, and carries out self-assessment procedures.

Water

Water from sanitary network (taps, showers, storage tanks and autoclaves), swimming pools, spas and fountains. Swab tests on condensed water from air conditioners and cooling towers

Biofilm

Swab tests on organic composition (biofilm) material outcropping from pipes and suspect materials

Procedura di autocontrollo

- Implementation and drafting of self-assessment manuals and records for Legionella
- Analytical monitoring plan established by law
- Advice and resolution of problems due to the presence of Legionella

Economic and Financial Data

From 2009 to today, the company recorded an exponential increase in turnover, with an annual growth rate (**CAGR**) of 538%. VisMederi is a dynamic company which, even in a difficult environment, is able to grow with significant increases in sales and earnings. If we take into consideration year 2010 as the true beginning of the activity, the increase from 2010 to 2011 was 71%, which was followed by an increase of 59% from 2011 to 2012. The real leap forward is recorded from 2012 to 2013, when the turnover more than tripled (343%).
Even the operating profit margin – which indicates the operating profit amount (EBIT) as a percentage of revenues – has followed a steady **upward trend** in the last three years, stating economy and efficiency of management. 2013 ended with a significant increase in profitability on invested capital, witnessed by the value of **ROI** (Return On Investments).

	2011	2012	2013
TURNOVER GROWTH	71%	59%	343%
OPERATING PROFIT MARGIN	8,18%	10,07%	59,55%
ROI	9,28%	19,88%	77,05%

VisMederi's Financial Indicators from 2011 to 2013.

In 2013, VisMederi consolidated and developed strategic partnerships in Europe and in the rest of the world, particularly in Japan, but also in Canada and the United States. A strong international qualification about the services offered by the Immunological Assessment of Vaccines Department confirming that VisMederi is a reliable partner for leading companies in the pharmaceutical sector.

Geographical distribution of partnerships developed by VisMederi in 2013.

Participation in European Research Projects

In 2013, VisMederi consolidated its expertise and leadership in the evaluation of the immunogenicity of vaccines using serological tests through participation in European Projects involving a number of partners such as Research Centres, Universities, SMEs and Big Pharma.

NASPANVAC (Intranasal Pandemic Influenza Vaccine). Since 2012, VisMederi has been involved in the "NASPANVAC" Project, which includes eight international partners (Research Centres, Universities and SMEs) with the aim of developing a new nasal vaccine for pandemic strains of influenza. The project has enabled the collection of important results, some of which have already been published in international journals (A study of Chitosan and c-di-GMP as mucosal adjuvants for intranasal influenza H5N1 vaccine. Svindland SC, Pedersen GK, Pathirana RD, Bredholt G, Nøstbakken JK, Jul-Larsen Å, Guzmán CA, Montomoli E, Lapini G, Piccirella S, Jabbal-Gill I, Hinchcliffe M, CoxRJ. Influenza OtherRespirViruses. 2013 Nov;7(6):1181-93). www.naspanvac.com

ADITEC (Advanced Immunization Technologies). The objective of ADITEC – which involves scientists from 43 research institutions in 13 different countries – is the development of innovative technologies for immunization to be used for the next generation of human vaccines. ADITEC, the largest project on vaccines financed by Europe with 30 million Euros, involves prestigious universities and research institutes together with leading U.S. groups in the field of system and adjuvant biology. The consortium also participates in numerous pharmaceutical and biotechnology companies in Europe, engaged in the study of innovative technologies for the development of more effective and safer vaccines. www.aditecproject.com

BIOVACSAFE This international project aims at developing cutting-edge tools to improve the analysis and monitoring of vaccine safety before and after marketing. The project, with a duration of 5 years, is funded by the Innovative Medicines Initiative (IMI), a public-private partnership between the European Union and the European Federation of Pharmaceutical Industries and Associations (EFPIA) for a total of over 30 million Euros of public and private investment. www.biovacsafe.eu

Synergies and Partnerships

The synergy with the University of Siena, where both the founders of the company were educated, continued in 2013, both within European Projects and for the research activities of the Laboratory of Molecular Epidemiology (EpidMol). Intense collaboration continued with the Bioincubator of Toscana Life Sciences – where VisMederi is based along with other companies active in the field of services – and with partners in the Opera Consortium. Below, in detail, the main synergies implemented during the year.

University of Siena. Alongside of the University of Siena in European Research Projects on vaccines, VisMederi has also found an important source of talented people in the University of Siena in the form of PhDs in firms. In 2013, three researchers worked in VisMederi. The Company has granted a loan to the PhD program in Life Sciences for the year 2014, helping to support the training of human capital on the local area.

Opera Consortium. The consortium involves four different companies – PHSE, Latis, JMB and VisMederi – that together allow us to offer all the services necessary for the execution of a clinical trial. The collaboration within the consortium continued in 2013 and was aimed at facilitating the implementation of clinical trials able to generate more opportunities for the involved companies.

Toscana Life Sciences. Since its establishment in the incubator, VisMederi works at scientific dissemination projects promoted by the TLS Foundation to young people. In 2013, in particular, VisMederi's management and researchers who participated in the "Science + Economics = Enterprise" Project, devoted to the promotion of an enterprise culture in the field of biotechnology. The students of two colleges of Siena, in the guise of young entrepreneurs, followed a path of classroom sessions, guided tours and workshops in businesses and entrepreneurial and scientific seminars and consultations, which led them to the creation of a virtual biotech company, "from A to Z".

Accurange. In 2013, VisMederi entered the capital of a new service company in the field of Life Sciences. Accurange srl strengthens the core business of VisMederi, as well as allowing the internal performance of some activities that had previously been outsourced. The core business of Accurange is the "Calibration, Maintenance and Adjustment" of laboratory equipment, with particular reference to micropipettes and dispensers of volume in general. Accurange ensures, by the adoption of the ISO 9001 quality system and validated procedures, the highest quality standards, providing all the documentation in compliance with GLP. In compliance with EN ISO 8655, Accurange uses the best equipment currently available on the market and employs highly qualified staff to carry out the operations.

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Quality Growth

VisMederi carries out all activities in accordance with the UNI EN ISO 9001:2008 European Certification System and is frequently inspected by its customers in order to ensure the highest quality in all its activities. In 2013, with the entry into a new business area, VisMederi has started the paperwork to be accredited as a laboratory operating in compliance with UNI CEI EN ISO / IEC 17025:2005. VisMederi is included in the list of regional laboratories performing analysis in the context of self-assessment procedures in the food industry at No. 065 and has obtained accreditation for microbiological analyzes on food and surfaces at Accredia (Italian Accreditation Body).

At the end of 2013, we began the process of accreditation of laboratories for UNI EN ISO 15189:2007.

Annual Performance

- **revenue growth:** 343% compared to 2012
- **staff increase:** three new employees
- **paperwork / services management times:** the size of the company, despite a growth, promotes rapid issue of paperwork, supported by efficient and standardized procedures. In terms of offered services, VisMederi ended in 2013 respecting the delivery times agreed with the customer, ensuring an excellent service and high professionalism
- **quality:** UNI CEI EN ISO / IEC 17025:2005 (Accredia) accreditation
- **working areas:** development of the "Food, Safety and Environment" Department
- **collaborations and partnerships:** further synergies and collaborations
- **research activities:** involvement in three European Research Projects

2014: Objectives for the New Year

In 2014, VisMederi wants to pursue its core business to consolidate the excellent performance that characterized 2013. Two strategic objectives: developing the new "Food, Safety and Environment" Department, expanding the customer portfolio from the territory of reference; structuring a pharma and diagnostic area for the evaluation of the efficacy of new drugs by *in vitro* tests. Both business objectives aim at expanding the current boundaries of business and the development of partnerships in new markets. The expansion of quality / quantity of supply of services for VisMederi is, at the same time, an opportunity for professional development for current and future employees. In terms of quality, the company expects to achieve the accreditation of laboratories for the UNI EN ISO 15189:200 as well by the end of year.

VisMederi srl
Via Fiorentina 1 53100 SIENA-ITALY
Tel: +39 0577231253 Fax: +39 057743444
E-mail: info@vismederi.com
Web-Site: www.vismederi.com