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VisMederi

# Company Profile

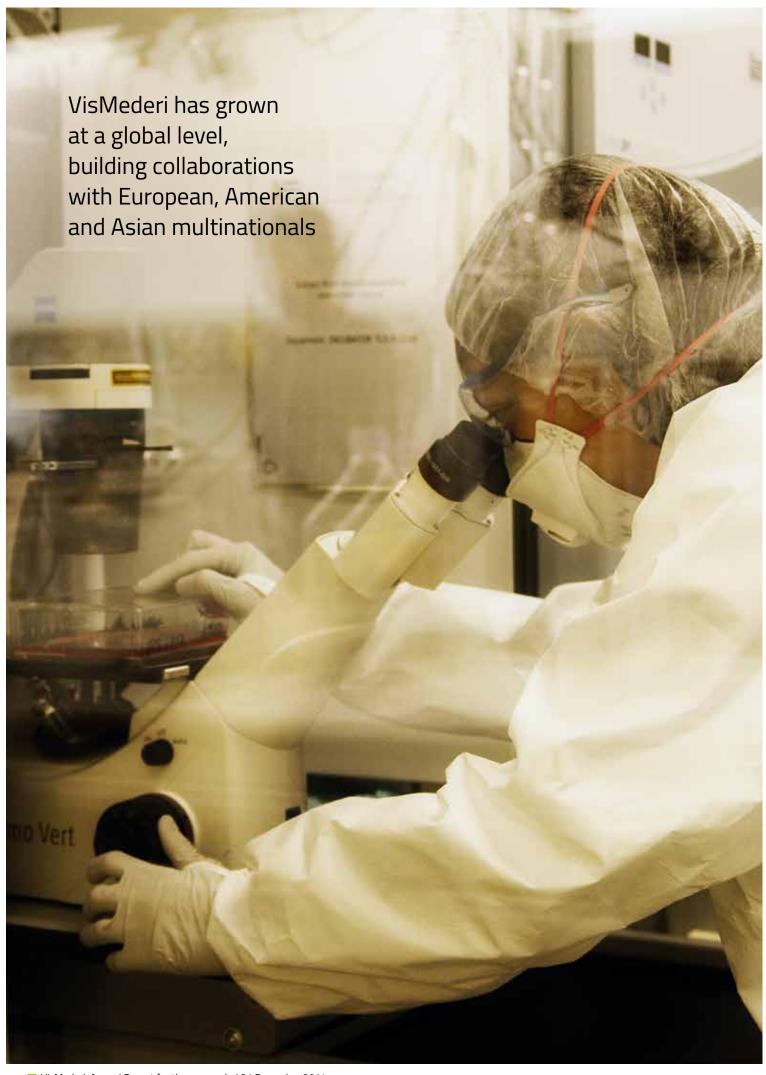
VisMederi is an esteemed partner for the pharmaceutical and biopharmaceutical industries

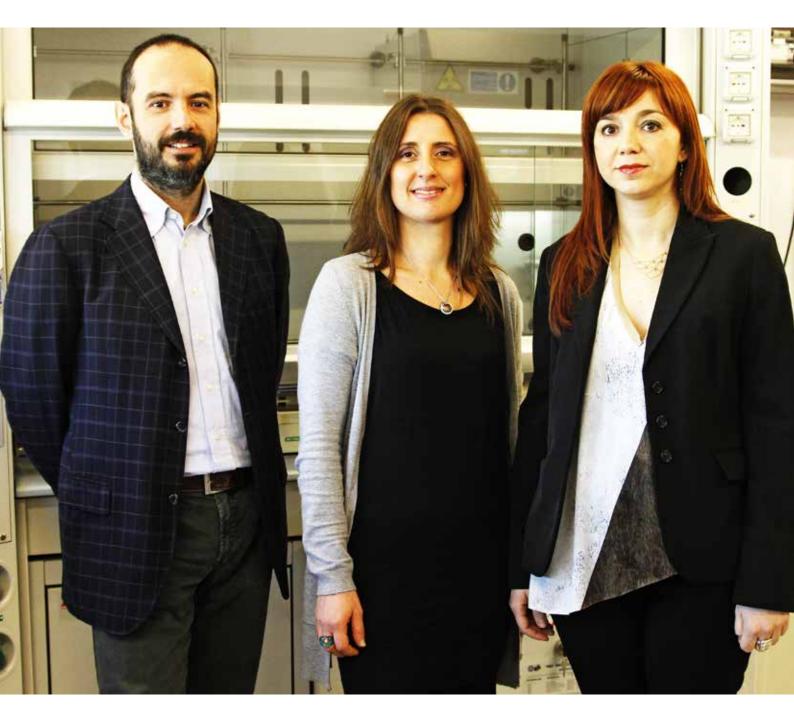
VisMederi is specialized in evaluation of the efficacy of influenza vaccines

Born in 2009, VisMederi is a company that operates in the field of Life Sciences and Public Health, and an esteemed partner for the pharmaceutical and biopharmaceutical industries. The company carries out analytical testing of biological samples and validation of bioanalytical methods, with a comprehensive preclinical testing program that well serves the needs of the drug development industry. In particular, VisMederi evaluates the efficacy of influenza vaccines. In five years, the company has grown at a global level, building collaborations with European, Asian and American

multinationals, with important assignments on the Japanese market. The company boasts a qualified staff of scientists and technical experts as well as its own Scientific Committee for a comprehensive and thorough evaluation of its research projects. All of VisMederi activities are carried out in compliance with the European system of certification UNI EN ISO 9001:2008.







Emanuele Montomoli, Chiara Gentile, Simona Piccirella

### **OUR 2014**

Our story goes on and VisMederi keeps on growing, showing to be up to international competition in the offer of highly qualified services in the field of Life Sciences

# The year 2014 has been a strengthening year for our company.

The entry to the Japanese market – one among the most open to international collaborations – took off in 2013 and then settled down in the year just ended. From our Siena's laboratories, we collaborate with almost all the Japanese influenza vaccines producers, ensuring a quick evaluation process, with high quality and competitive prices. This is a global sector and if three years ago we had not had the courage to look for new markets, maybe now we would tell you another story.

Since its founding in 2009, VisMederi has not stopped growing in services, quality, work places, keeping on expanding its business and facing with international dynamics. Our company is also present in America and in Europe, where we receive orders for the evaluation of safety and immunogenicity of vaccines and where we have established partnerships in the development of projects alongside research centers, universities and big pharma.

In 2014, VisMederi has performed as one of the 10 Italian start-ups that have invoiced more than 2 million euros. We are proud of this result because we are the proof that it is possible to create innovative business successfully in our country.

Now, that we are no more a start-up, we continue in our business, bearing the experience of the first years of activity and even more certain that our future is related to the high quality of our services, always under a customer-focused validation process.

With this mission, we started a new line of activity dedicated to food, water and

environment analysis, investing on our scientific background in order to contribute to the improvement of Public Health System even on our territory. We did it to grow, to face a new challenge, but also because in VisMederi we are all sure that our expertise can be useful to improve the life and health of people, giving reliable information about what we eat and drink.

VisMederi's is a small story, but it is our story and a new year of success is source of pride and fulfillment for us – for the results achieved, but above all for our staff of young researchers – the main driving force behind VisMederi.

Chiara Gentile, Emanuele Montomoli, Simona Piccirella

Founders of VisMederi

# Professionalism and accuracy, working for better and safer vaccines

We strongly believe in what we do, working for better and safer vaccines and drugs, confident in our expertise

ooking back on the road travelled since we created VisMederi in 2009, I feel very proud of what we accomplished in these five years in the field of Life Sciences and Public Health. We strongly believe in what we do, working for better and safer vaccines and drugs, confident in our expertise achieved in nearly two decades of experience in the University of Siena and conscious that the quality must be the basis of all our activities.

Our modus operandi, characterized by professionalism and accuracy, is the key of our success and the reason why so many international big pharma rely on us for the

control of pharmaceutical products. To be competitive at global level, we have modern facilities and a biosafety PCL 3 laboratory to work safely with highly pathogenic microorganisms.

Nevertheless, nothing would have been possible without our team of scientists. Our staff is strongly scientifically competent and they all work for a shared objective, putting forth the good of the company rather than personal success. It is certainly thanks to them that we are growing so fast and we want to achieve even higher goals in the next years. In 2014, we strengthened our activities reaching new international markets, Japan

in particular, with which we started to collaborate intensively. Moreover, we found the subsidiary VisMederi Research to implement our R&D sector in order to satisfy all our clients' needs with specific solutions. The aim is not to stop here, but to keep on developing new activities and finding new collaborations worldwide in order to become a market leader.

Emanuele Montomoli Professor of Public Health, University of Siena

VisMederi's Scientific Director

Bio

Emanuele Montomoli is Professor of Hygiene and Preventive Medicine at the University of Siena. After graduating at 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 con-

ducted 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 250, abstracts and other publications on national and international journals.



# «Listening to customers is at the heart of our activity»

In 2014, VisMederi developed a stronger strategic awareness about new businesses and new markets, improving its sensitivity in respect of the clients' needs

imona Piccirella is the operating chief of all VisMederi's activities. Graduated in Biological Sciences, she takes each order in charge, managing the relations with the clients, choosing how to structure the work and organizing the teams. Thanks to her experience in the laboratories of the University of Siena and in other pharmaceutical companies, Simona Piccirella founded VisMederi in 2009, with Chiara Gentile and Emanuele Montomoli. She is responsible for each order, both in the vaccine area and in diagnostics and food analysis.

#### Let's look back at this year just ended and try to take stock of it. Which growth elements have been the most important ones for VisMederi?

«In 2014, VisMederi developed a stronger strategic awareness about new businesses and new markets, improving its sensitivity in respect of the clients' needs, giving importance to the listening to build a lasting relationship of trust. In order to respond more effectively, we changed the work management, through the creation of little teams. This allows us to ensure specialized staff for each assignment».

#### Is it worth to invest in clients' loyalty?

«Loyalty does not rely only on high quality service, but on the listening skill, trying to find unexpressed needs and supporting the client alongside the entire project. This kind of approach made our clients feel that their goals are our own goals, with mutual

fulfillment».

# We often talk about one market, but we should talk about more markets on an international scale. Which markets do you work the most with?

«At the moment our main market is Japan, but we consolidated the relationships with European clients and we started a process to achieve American big pharma loyalty. We have optimized the validation processes following FDA's guidelines, in order to support and respond at the best to this new market, with totally different logics and modus operandi».

#### VisMederi ensures a long experience in the implementation of a large portfolio of clinical trials. Which ones are the most requested?

«Serological tests for the registration of influenza vaccines are still our gold standard, but in the last year we have been more involved in the consulting activity in order to understand the results and in the selection of the procedures to use to evaluate immunogenicity of the vaccines. VisMederi has become a point of reference for the clients who have to approach the regulatory framework. In the last year, the company continued to invest in the diagnostics area, implementing the tests. Another important target we reached is the execution of tests for molecule and nutraceuticals for therapeutic purposes for Tuscan clients. Finally we are starting dealing with biopharmaceutical companies on the territory».

#### In 2014, the choice to found another company, VisMederi Research, to separate the research activity from activities aimed at providing services. Why?

«VisMederi Research wants to satisfy all those clients who are developing molecules, both natural and synthetic, or who have to study biological processes through ad hoc experimental protocols. VisMederi Research aims at searching, studying and developing new experimental protocols where the ones in use cannot fully investigate the object of the study».

#### VisMederi's success in brief: a well-known SME at a national and international level.

«The winning intuition has been to invest in certified biological tests in niche sectors that only few laboratories in the world did and that did not need commercial kits or special facilities, but expert researchers, as biologists and biotechnologists for the proper execution. We started from our competences, from our expertise acquired in years of activity in the University laboratory. We can certainly say that now our main strength is our staff, competent researchers who love what they do».

Simona Piccirella

VisMederi's CEO

## Bio

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.



# Our strengths? Competence and motivation

Our success is the result of different factors, but our young, competent and motivated team has been a great strength

er education is scientific, but in VisMederi she is responsible for the financial area, quality and human resources. Versatile and resourceful, since 2009 she has been at the helm of the company, for which she has created and implemented a Quality Management System that allows VisMederi to map, organize and redefine all corporate processes. She supports a quality ideal involving the whole organization and not only the services offered. Chiara Gentile is also responsible for the coordination and supervision of the administrative work, financial situation control and staff management.

How much does working in Siena – a city strictly linked to vaccine research – and in Toscana Life Sciences (TLS) has influenced and encouraged collaborations and inspirations?

«Siena has a solid culture and a strong tradition in the biotechnological field. Here, Achille Sclavo founded the Istituto Sieroterapico in 1904, realizing the importance of scientific research; still here, Albert Sabin developed the first vaccine against polio in the late 50's; finally here, Novartis Vaccines developed the first vaccine against Meningococcal B bacteria».

Human Resources as a key of the company's success. This seems true in your case. Let's try to briefly describe the profile of your collaborators.

«Our success is the result of different factors, but I firmly believe that our young, competent and motivated team has been a great strength. Only graduated people, almost all of them with a Research Doctorate, compose our staff. For us it is a source of pride to be able to bring together the university group in the company, giving them the opportunity to invest in themselves as we did».

Human capital, but not only. How much are facilities important for your activity?

«In Toscana Life Sciences, we have at our disposal equipped laboratories with different risk classes, including a biosafety PCL 3 laboratory for highly pathogenic microorganisms. This allowed us to become partner of multinationals producers of vaccines and drugs, being competitive at an international level»

Quality is a very important part of the corporate culture. Accreditations and certifications testify this.

«We chose to invest in quality, certain that this could make the difference in the competitive market. VisMederi carries out all of its activities in compliance with the European system of certification UNI EN ISO 9001:2008 and obtained accreditation as an operating laboratory in compliance with the UN CEI EN ISO/IEC 175025:2005 standards for the food sector. Furthermore we started the process to obtain the UNI EN ISO 15189:2013 certification: we would be the first private company in Italy to receive it».

In the last two years, you started a process of diversification of your business, first with food area and then with diagnostics. Why?

«The strengthening of vaccine area is still a strategic objective. We made decisions in order to reduce business risk, protecting VisMederi from critical situations linked to possible decreases in market opportunities in our core business. Taking up new paths, both in the food analysis sector and in the diagnostic field, also allows us to exploit all the opportunities arising from our scientific competences applied in other sectors».

Chiara Gentile

VisMederi's Financial, Quality Assurance & HR Manager

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.





The company started its business based on the expertise of its founders and on their experience gained in the Molecular Epidemiology Laboratory of the University of Siena

# The History and core business

VisMederi is a research and qualified services company founded in 2009 that operates at an international level in the Life Sciences and Public Health fields

isMederi is a research and qualified services company founded in 2009 that operates at an international level in the Life Sciences and Public Health fields. The company started its business based on the expertise of its founders and on their experience gained in the Molecular Epidemiology Laboratory of the University of Siena. In the first five years of activity, the company received orders from worldwide in the field of vaccines, building collaborations with the major players of the pharmaceutical industry, carrying out analytical testing of biological samples and validation of bioanalytical methods.

VisMederi offers a wide portfolio of services and it is able to completely cover procedures required for phase II, III, and IV of clinical trials and avails of the synergy it has with laboratories, research facilities and international research centers for the development of pre-clinical protocols and phase I studies. Since its foundation, the company has invested much of its resources in the optimization of laboratory assays for the evaluation of immune responses and the development of serological tests for

influenza vaccines. VisMederi has specialized in cell immune response testing, paying particular attention to innovative platforms and in compliance with international guidelines. In addition, VisMederi has developed expertise in the design and evaluation of animal models.

In order to consolidate its roots within the territory, the company developed a new research line in 2013 aimed at implementing quality control analysis for food, water and various types of environment, ensuring consulting services about safety and evaluation of HACCP systems and Hygiene Packages. This allows VisMederi to contribute to the improvement of people's life and health at a territorial level, giving them information about the environment where they live as well as about what they eat and drink.

In 2014, VisMederi Research has been established in order to enhance the research activity, separating it from services management. This company has met the need to investigate new experimental protocols to better respond to clients' needs, whose fulfillment is always VisMederi's main objective.





# Vision & Mission

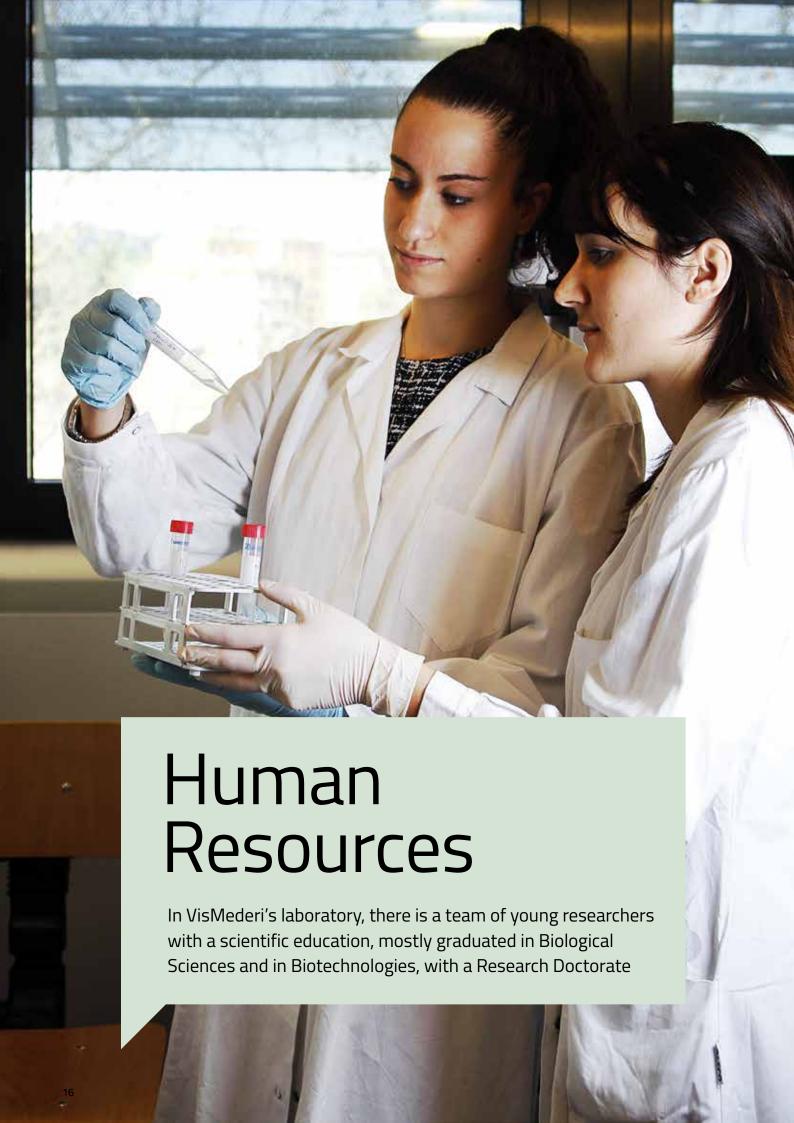
VisMederi operates with moral conscience, doing its best to improve and enhance Public Health through the analysis and evaluation of vaccines and drug efficacy. To this end, the company relies on a team of young and competent researchers who ensure high quality in each project. With their professionalism, they are the cornerstone of VisMederi. Teamwork is at the basis of the corporate culture – an opportunity to grow professionally and personally for each collaborator. The Mission of VisMederi is to work in order to develop better and safer vaccines and drugs, paying attention to quality systems and analytical data. The

importance of quality gives priority to the development of high qualitative analysis and to the continuous improvement of procedures, technological facilities and equipment, looking for the full participation of the staff and for the complete satisfaction of the clients. VisMederi receives orders from worldwide, but the goal is to become a leader in the field of qualified services for the pharmaceutical industry. The company aims at supporting economic growth and the creation of workplaces, giving birth to new companies, as Envepi and Accurange, and creating spin-offs such as VisMederi Research.

The corporate Vision is a summary of all the values and objectives leading VisMederi towards future goals since its foundation

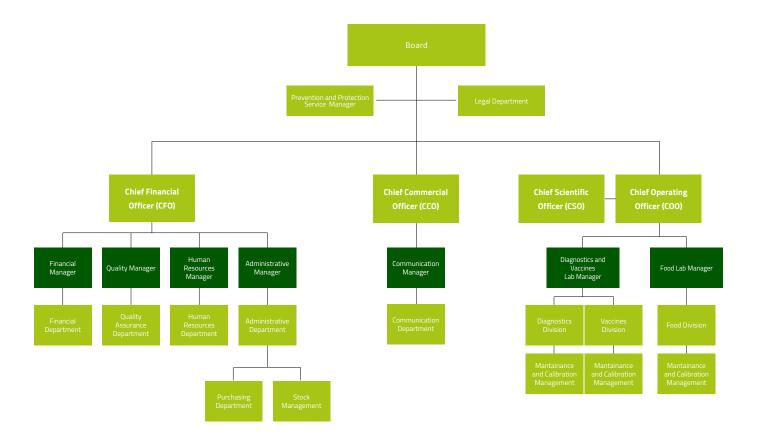


Toscana Life Sciences incubator





# 2014 Organizational Chart





#### VISMEDERI SCIENTIFIC COMMITTEE

VisMederi has its own Scientific Scientific Advisory Board, whose purpose is to evaluate VisMederi's scientific research continually and objectively.

Emanuele Montomoli Otfried Kistner

Simone Blayer Roberto Gasparini

Costante Ceccarini Aldo Tagliabue

Silvano Focardi Simonetta Viviani



VisMederi's staff, working in team to achieve the excellence

### Human resources

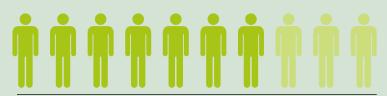
VisMederi places an enormous value on its own human capital

isMederi places an enormous value on its own human capital, working on professional growth and on staff fulfillment, certain that the company's success is strictly linked to the quality of the working team. The entry-level selection, thanks to the University of Siena, is oriented towards the choice of appropriate profiles

for the company and clients' needs. In VisMederi's laboratory, there is a team of young researchers with a scientific education, mostly graduated in Biological Sciences and in Biotechnologies, with a Research Doctorate.

They work in team to achieve the excellence, sharing the company objectives with the

board: Simona Piccirella, CEO, Chiara Gentile, Financial, Quality and Human Resources Manager, Prof. Emanuele Montomoli, Scientific Director. This allows a continuous professional growth, oriented to clients satisfaction and improvement of the services offered. It is the reason why our clients keep addressing to VisMederi. +13



2014

The growth of the staff from 2013

The staff is divided into different working groups corresponding to the three areas of activity:

#### VACCINES

The team is responsible for the development of clinical trials for vaccines, daily performing validation and standardization of the procedures requested in compliance with international guidelines. This is a strengthened team with a lot of experience, which has been working in this field for years and is capable of managing analysis and procedures independently. The staff also offers a consulting service about the best approach to the procedure to make it specific for the vaccine under study. They carry out most of their activity in the laboratory, getting orders from worldwide.

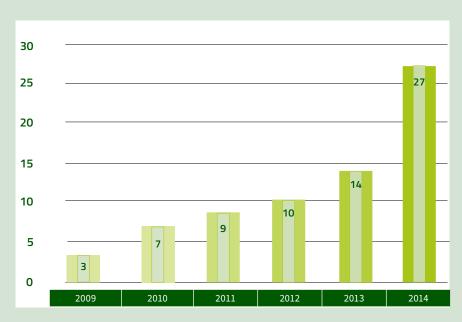
#### DIAGNOSTICS

It is a working team recently formed in order to develop procedures, following specific requests of the client, for the release of molecules or systems for diagnostic purposes.

To this end, the staff guarantees a deep knowledge and a constant updating of the international guidelines, ensuring a technical expertise concerning the regulatory aspects.

#### FOOD ANALYSIS

The team, born in 2013, is extremely focused on food and environment microbiology, working closely with territorial companies. The involved roles have a long and consolidated experience in this field, both in company and in laboratory analysis, realizing samples and chemicalphysical and microbiological investigations. The staff ensures support for the companies to improve the food production in order to eliminate risks for human health, as well as analytical work and support for the drafting of documents requested for normative compliance.



The growth of the staff from 2009 to 2014



### Staff



---- EMILIA ACETO

Scientist

After carrying out several years of research at the University of Siena, in 2011, I had the opportunity to work for VisMederi. I was especially encouraged by the idea of dealing with international companies, working in the safety sector and giving importance to quality. VisMederi has developed a real work "culture" in which everyone has a strong interest and responsibility to the company's success. It is impossible to get bored at VisMederi!



#### GIULIA ADDOLORATI

Administrative Office Specialist

My experience in the Administrative unit of VisMederi started in 2010. Many interesting aspects make my activity extremely interesting - work with Heads and colleagues, growth in tackling issues that may arise, personal fulfillment, contribution to business development, acquisition of new knowledge. This is a precious job opportunity for my professional career and I'm very proud to be here



#### **IRENE BARNESCHI**

Intern

Now that I am writing my final dissertation, working in VisMederi is important because it gives me the opportunity to increase my knowledge and competences in a young and dynamic environment.



#### FABRIZIO BIUSO

PhD student, Researcher

My goal has been to join a private company since the beginning of my studies. Luckily, VisMederi is a challenging company where I can both express my passion in biotechnology and enlarge my knowledge thanks to the high profiled people working within it, and I am happy that they have chosen me. The key of this company's success -together with its wise management - is represented by the synergy between colleagues. I am sure that working within VisMederi is the best chance I can have to improve my personal and technical skills.



#### CHIARA CENTI

Junior Scientist

I have learned many new things since the day I joined VisMederi almost 4 years ago: my colleagues taught me about life sciences and vaccines and shared their knowledge with me. I will always be thankful to the people who have believed in me and I feel a strong sense of pride in being part of a team that is able to grow in a period of economic downturn, developing a business that puts us in touch with the whole world.



#### **ELENA GIANCHECCHI**

the possibility to work for Vismederi because I truly love what I do. I have the opportunity to work in a team with my colleagues but also to grow individually without losing ber and we must continuously improve our working skills.



Cell Culture Responsible

In VisMederi I have found the possibility to work with such a diverse group of people, where everyone is helpful and where I can learn a lot thanks to them and to their experience. Working for VisMederi is a unique opportunity for me to grow, not only within the company



Junior Scientist

I feel lucky that I am having sight of my personal career objectives: we are not just a num-



#### **ELISA Llorente PASTOR**

but also as a person.



Working in Vismederi, an internationally exposed company, is a rare opportunity for a scientist to get in touch with the scientific world. The collaborations continuously built by VisMederi with other companies and renowned research centers, always allow me to grow both professionally and personally in a strong scientific atmosphere. The state-of-the-art techniques developed here are innovative while always keeping an eye on the practical aspects of our delivery commitments.



#### ··· ALESSANDRO MANENTI

PhD Student, Researcher

Working for Vismederi is a great opportunity for growth in science, business and human aspects. I am very proud to be part of a young, dynamic and experienced group, always in evolution, always evolving.



GIULIA LAPINI

Scientist

I started to collaborate with Prof. Montomoli at my university department, where I found a familiar team who has allowed me to learn and enhance my scientific knowledge in a nice environment. I am very grateful for the experience that introduced me to VisMederi's activities with a good background. I do not fully know what "working for an enterprise" means, but working for VisMederi is often feeling like at university for its friendly approach aiming at the improvement of each member of the staff. VisMederi is a young enterprise made of young people: in such conditions, it is easier to be motivated and give maximum of our capabilities to improve our knowledge.



MARZIA TRICARICO

External Communications

For a newly graduated like me, this is a very important opportunity. Nowadays, it is not easy to find a job in the field that you love the most and in a growing company like VisMederi. Here, I have found helpful colleagues and a supportive work environment.



GIULIA PICCINI

Research Technician

I joined Vismederi as an intern student 2 years ago, and since then I have had the opportunity to grow not only from a professional point of view but also as a person. Working with such a highly specialized and diverse team allowed me to better understand the value of collaboration, focus and perseverance in achieving objectives. I will always be thankful for this experience.



--- ELISA MENNITTO

Scientist

I started working with Prof.
Montomoli in 2007 and I joined
the staff of VisMederi in 2010. Here
I found a very positive environment, with young and competent
colleagues, with whom I am
currently sharing my professional
and personal growth. VisMederi's
success and growth motivate me
in always giving my best.



**VALERIO STANZANI** 

Senior Technician

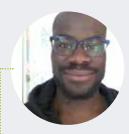
I started working for Vismederi almost 3 years ago and now I am responsible for VisMederi's equipment calibration and maintenance. I have learned so many new things: colleagues taught me about life sciences and vaccines and shared their knowledge with me. I will always be thankful to the people who believed in me and gave me this opportunity to grow, not only within the company but also as a person.



··· SARA SBRAGI

PhD Student, Researcher

I am attending the last year of my PhD in VisMederi: I had never worked for a private company before and I believe that this is a special opportunity for my career. In this experience, I am learning a lot about life sciences: my work environment is full of many capable scientists with whom it is possible to exchange thoughts and ideas and grow professionally.



#### ERIC OFORI

Intern

I can only say thank you to VisMederi for this chance. I am putting into practice all the subjects of my studies, effectively learning the job I want to do in the future.



LICIA VITALE

Lab Manager

I started my experience in VisMederi 5 years ago as a PhD student. I have grown so much in these years, I have done many different experiences and now I feel more competent and confident about my capabilities. I cannot express how grateful I am to the people who believed in me and who gave me the possibility to work in VisMederi, hoping I will repay them keeping growing together.



SARA PUGLIESE

Administrative Office Junior Specialist

Working in VisMederi is a very important and precious opportunity for me to grow and improve both work-wise and personally. VisMederi is a company made up of young and motivated people and being part of it not only means being part of a work team, but of a kind of family where everyone is busy in helping each other so that the activities can take place in the best possible way.



--- SIMONE PALETTI

Corporate Finance & Management Accounting

«I am so proud of having had the opportunity to join the Vis-Mederi's staff. Every day we try to build something new, to improve ourselves and to compete with the world market. Working in the Finance and Management Control means to translate every professional aspect into a challenge and an incentive to personal improvement, to be pursued in an always positive climate full of confidence in the future».



···· ALESSANDRO TORELLI

Scientist

My will to work in the life sciences industry brought me to VisMederi in 2012. My previous experience taught me how to survive in big and structured companies and how to set molecular biology experiments, so the idea to work in a small company working in the vaccine landscape was something new to me. Now VisMederi has grown but its roots remain in the people working in it and as part of them I hope to re-pay the trust VisMederi had in me with a different approach to clinical and vaccine research.



- CLAUDIA MODENESE

Food Area Responsible

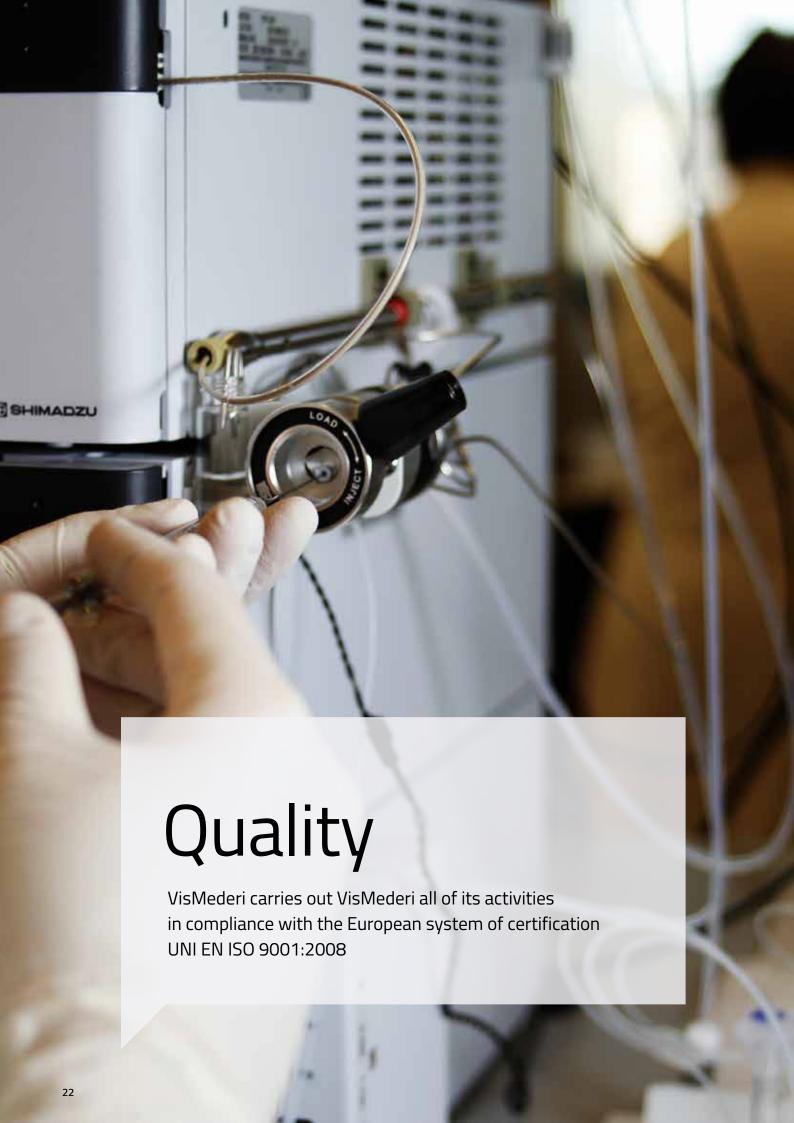
In VisMederi I found the chance to put in practice my competences and to develop new ones, feeling that I'm contributing to the company growth thanks to the stimulating environment and the positive people I work with.



- DANIELE PERINI

Scientist

Working in VisMederi is a big opportunity for a scientist like me. Competent colleagues, positive and stimulating environment, international collaborations... – all these things help me to grow and to gain experience in fields that I did not know before.



The certifications testify the professional competence of VisMederi

# Quality as a value

The quality for VisMederi is the basic value for all the company's processes, integral part of the corporate culture

isMederi carries out all of its activities in compliance with the European system of certification UNI EN ISO 9001:2008, receiving frequent inspections to ensure the highest quality possible. In 2013, with the birth of Food Safety Environment area, VisMederi obtained the certification for UNI CEI EN ISO/IEC 17025:2005 for the food sector and is registered in Tuscany under the regional list of laboratories

who perform analyses in the area of self-checking procedures of the food industry at number 068. In 2015, the company aims at getting the certification UNI CEI EN ISO/ IEC 15189:2013, which outlines the requirements that must be respected by medical/clinical laboratories. These certifications testify the professional competence of VisMederi, stimulus for a continuous improvement of the company.





#### **UNI EN ISO 9001:2008**

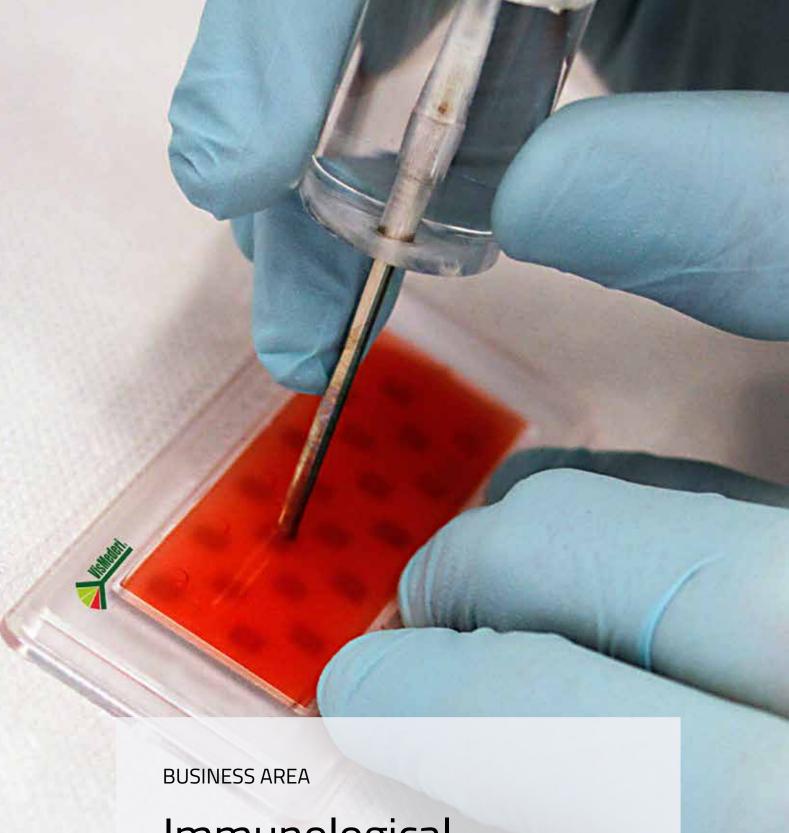
Certification body. TUV Austria Release Date: March 2010

In 2010, VisMederi obtained certification for the UNI EN ISO 9001:2008 standard. The Quality Management System ensures the requisites of management systems for quality that a company must meet in order to show its capability to provide products and services that meet the requisites of the client in regulated areas. Quality is defined by the ISO 9001:2008 as the level in which a series of intrinsic characteristics meet the requisites in a process of continual improvement.

#### **UNI CEI EN ISO/IEC 17025:2005**

Accreditation Body: Accredia Release Date: December 2013

In 2013, the company obtained accreditation as an operating laboratory in compliance with the UN CEI EN ISO/IEC 175025:2005 standards for the food sector through Accredia (Italian governmental body of accreditation). Accreditation verifies and guarantees the competence and expertise of a test laboratory, according to objective parameters. Obtaining accreditation signifies for the company that its respectability and professional competence are officially recognized at an international level.



Immunological Assessment of Vaccines

# Vaccines division, our core business

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 (European Medicines Agency), FDA (Food and Drug Administration) and the PMDA (Pharmaceuticals and Medical Devices Agency).

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. In particular, VisMederi operates in compliance 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

Traditional assays for the evaluation of virus vaccine immunogenicity, for example Hemoagglutination Inhibition (HAI), Single Radial Hemolysis (SRH) and Virus Neutralization (VN), characterize VisMederi daily research, as well as the classic procedures ELISA and immunofluorescence (IF).

n order to respond effectively to the needs of current and potential partners, VisMederi works continually for the optimization and validation of serological assays, with particular focus towards innovative platforms. In this area of research, important results have been reached with the use of innovative pseudoviral particles for Microneutralization tests and with the development of immunoenzymatic doses used for the evaluation of

the response toward the neuramidase in influenza vaccines (ELLA test).
Finalizing this area of research and in addition to the test panels available for humoral immune responses, cell-mediated immune response study protocols have been implemented through EliSpot and FACS platforms. VisMederi conducts laboratory research for the evaluation of immune responses to vaccines against bacterial strains as well, through bacteri-

cide tests (SBA-Assay) and opsonization (OPA-Assay).

Recently, VisMederi has developed and validated numerous assays that can be used for vaccine efficacy studies. In addition to the isolation of microorganisms in cell cultures and the molecular identification of viral and bacterial isolates from clinical samples, quantization of microorganisms through real-time PCR are of particular importance in this area of research.



Since 2013, VisMederi developed a new line of activity Food Safety Environment, performing microbiological and chemical-physical analysis on any type of food, water and work surfaces.

A specialized and well-equipped laboratory ensures reliable quality controls, for this reason the laboratory has requested and obtained to be registered in Tuscany under the regional list of laboratories who perform analyses in the area of self-checking procedures of the food industry. The laboratory has also obtained the Accredia certification (Italian Accreditation Body), in compliance with UNI CEI EN ISO / IEC 17025:2005.

#### What we do:

- •Chemical and microbiological food analysis
- •Research on pathogenic microorganisms, process and conceivability indicators, safety indicators
- •simple and extensive analyses and determinations of contaminants and
- •Analysis using FSIS methods Shelf-life studies: verification of qualitative duration of products
- •Mycotoxins research allergen research
- •Analysis of materials in contact with food
- •Analysis of pet food
- •GMO research
- •Detection of DNA of animal origin and the identification of species

According to (EU) 1169/2011 regulations concerning the provision of food information to consumers, VisMederi laboratory performs analytical determinations for the energetic tag and the technical and legal validation of the tags and the technical sheets of food products.

#### **Work Surfaces Analysis**

- Examination and sanitization of work surfaces, equipment and instruments for working with food through the use of swabs, sponges and slides
- Research of microorganisms which are indicators of contamination
- · Research of pathogenic microorganisms

#### **HACCP Services**

The laboratory carries out analysis on food and validation for self-checking procedures according to current regulations, offering specific consulting services to write a HACCP manual and for the application of HACCP Hygiene Packet and System.

#### Water

VisMederi performs sampling, determination of parameters according to the laws currently in effect and the examination of procedure parameters for:

- Water for human consumption and process waters
- Swimming pool water
- Thermal water
- Waste water
- Natural mineral water and spring water

For water for human consumption, VisMederi performs controls in compliance with Decree Law 31/01, ensuring quality of the water aimed at food industries.

#### Legionella

Tourist accommodation and thermal facilities managers are required to make an evaluation of the risks linked to infection by Legionella and create a document for self-checking. VisMederi Laboratories offer support to businesses through:

- Analysis of water
- Biofilm analysis
- Self-checking procedures

#### Research

VisMederi is engaged in research and development of nanotechnologies, which make possible the manipulation of food ingredients at a molecular level. VisMederi operates to develop applications in the field of treatment of mechanical-sensorial properties of food, in order to change the

flavor or the texture and the alteration of nutritional values. Nanotechnology can be applied even on food packaging with the aim of ensuring a better protection or measuring the level of freshness of the food. The company conducts research paying attention to the health and con-

sidering possible risks about it. VisMederi also carries out research aimed at studying the phenomenon of food adulteration, analyzing foreign substances that alter the essence of food, changing or spoiling the natural composition in order to improve the appearance or cover up the flaws.

### **Economic and Financial Data**

In 2014, VisMederi pursued with tenacity its consolidation plan in the field of Vaccines Assessment, increasing its client portfolio worldwide

The financial year just ended has been characterized by important investments in order to expand the spaces and the structures, as deducible from the value of the index of material immobilization, increased from 2% to 13%. The 2014 has also seen considerable investments in R&D, from the foundation of the subsidiary VisMederi Research to the realization of numerous innovation projects,

which cannot be capitalized according to existing accounting rules, thus producing an underestimation of the real economic result of the period because of costs of multi-annual strategic significance. VisMederi made advertising and marketing investments, whose effect on the income statement must be considered in the light of the economic benefit expected for future years. Great

attention was paid also to the expansion of the Food Safety Environment division, constantly growing.

Simone Paletti

Corporate Finance & Management Accounting

#### Financial indicators

2014* 0.79
****
21.070/
21.07%
1.2669
0.2669
0.23%
8.18%
0.00%
20.25%
4.98
4.862
21.35%
16.71%
20.15%

Fig. 2: The main financial indicators of the last three years

Provisional data referred to fourth quarter of 2014

#### Capitalization

### 2012 → 0,41 2013 → 0,60 2014 → 0,79 0,00 0,10 0,20 0,30 0,40 0,50 0,60 0,70 0,80 0,90

Fig. 3

#### Leverage

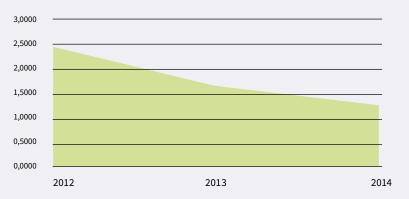
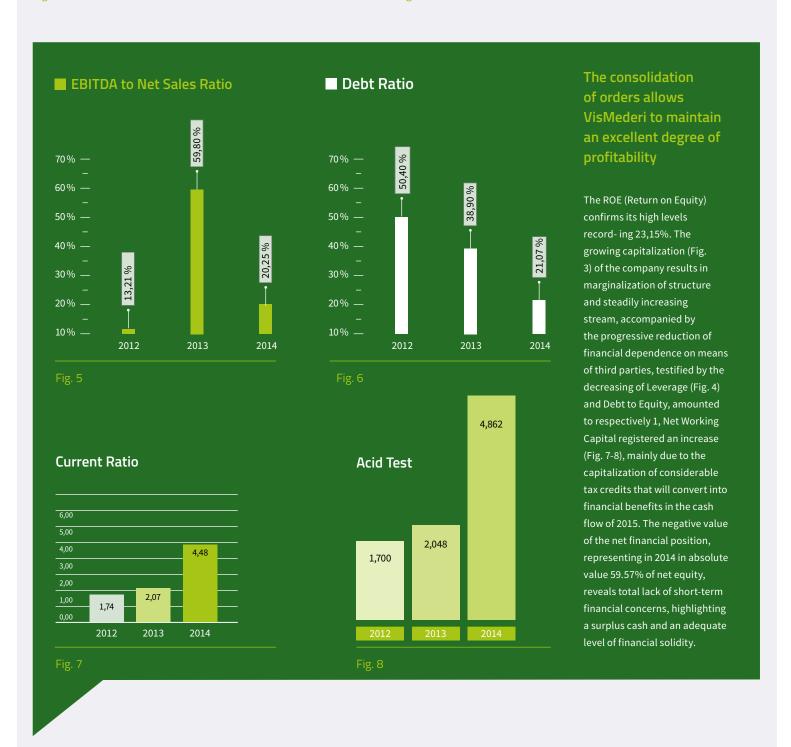


Fig. 4



# Participation in international research projects

In 2014, VisMederi confirmed its effort supporting relevant research projects of significant impact on the innovation in the field of Public Health, collaborating with a vast network of partners composed by research centers, universities, SMEs and Big Pharma throughout Europe. Compared with the previous year, the company increased the number of projects, being currently committed in three European projects concerning the Seventh Framework Programme (FP7/2007-2013) and in seven national announcement of FESR-2014-2020

#### 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



Geographic locations of the partnerships developed by VisMederi until 2014

## Shareholdings 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

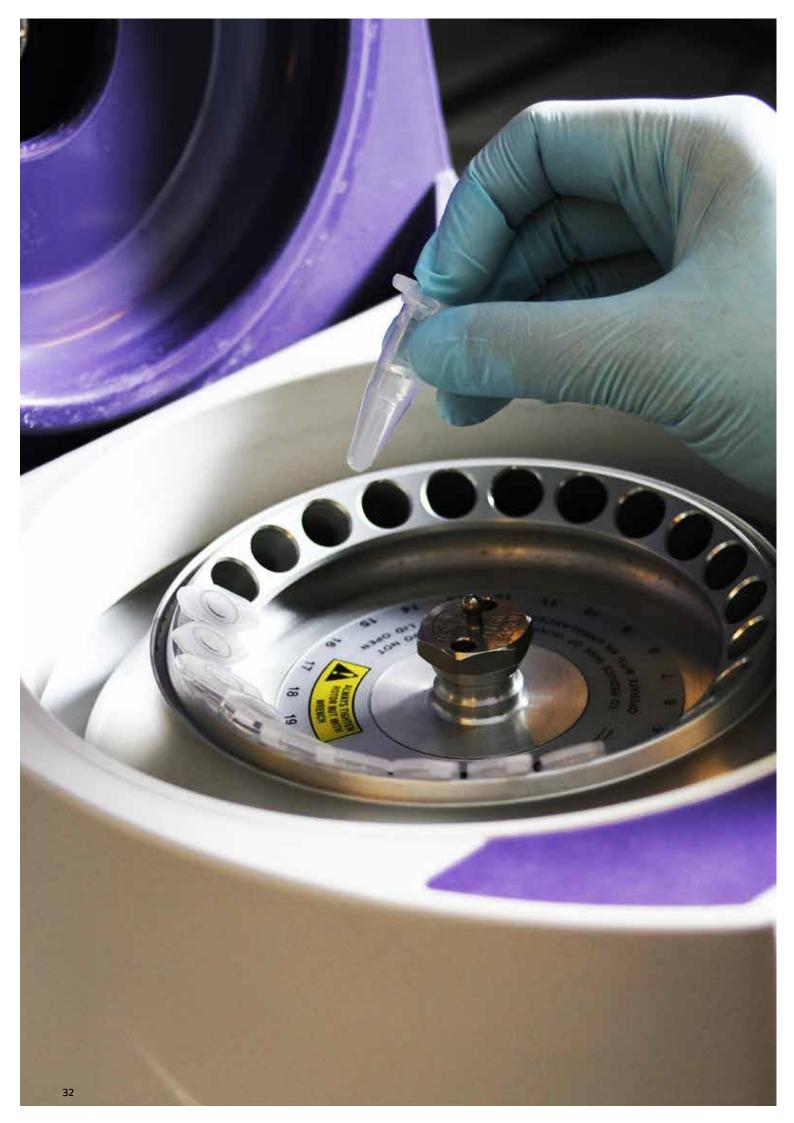
VisMederi. The Company has granted a loan to the PhD program in Life Sciences for the year 2014, helping to support the training of human capital on the local area.

roscana Life Sciences. Since its establishment in the incubator, VisMederi has been working at scientific dissemination projects promoted by the TLS Foundation to young people. In 2014, in particular, VisMederi's management and researchers participated in "Thousands Faces of Biotech" Project, devoted to the promotion of an enterprise culture in the field of biotechnology.

**ACCURANGE.** VisMederi holds 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.

**ENVEPI.** In 2014, VisMederi entered the capital of a start-up in the field of Life Sciences. Envepi offers services concerning genetics, epigenetics and environment. The strong scientific background that characterizes the company makes Envepi a good partner for the exploitation of complementarity that can enforce VisMederi's business model and expand the reachable markets.



## Objectives for the new year

In 2014, VisMederi enhanced the activities in the vaccine field and developed new projects in diagnostics and food analysis area, laying the foundations for a profitable diversification of the business

2013 was a turning point, VisMederi achieved many goals and great successes, even in terms of exponential growth of turnover; in 2014, VisMederi capitalized that result, making the most of the excellent performances reached

The objective is to continue towards this direction in 2015, with the will to strengthen the company core business in the target market and expand the collaborations in new countries, developing in parallel the Food Safety Environment area in terms of services and client portfolio, enforced by the good results of the year just ended. 2015 will be the year of the diagnostics area, with the aim of increasing the development of new procedures for molecules release or systems with diagnostic purpose, and

the first year of activity of VisMederi Research, the subsidiary founded in order to enhance R&D, at the basis of the corporate business since the very beginning.

VisMederi has a strong international vision that pushes it towards new markets and partnerships worldwide. The company will continue to improve the services offer in terms of both quality and quantity, working on the optimization of processes and procedures to achieve the complete satisfaction of the clients.





Prof Emanuele Montomoli at EVI Rendez-Vous 2014, the annual review of EVI portfolio at Institut Pasteur Paris, France



Simona Piccirella, VisMederi CEO, at the BIO Convention USA, San Diego



Chiara Gentile receives the "Ambassadors of Europe Award" for VisMederi at Smau Florence by the regional council member of Tuscan Government



Alessandro Torelli, Scientist, at the 14th Annual World Vaccine Congress 2014 in Washington

# Annual Highlights

#### What happened in our 2014



Prof. Emanuele Montomoli giving lecture at the first annual EDUFLUVAC in Carcavelos, Portugal



Simona Piccirella, VisMederi CEO, introducing herself in front of the audience of the Leopolda meeting 2014, the annual event founded by Italian Prime Minister Matteo Renzi in Florence



#### CONTACT





