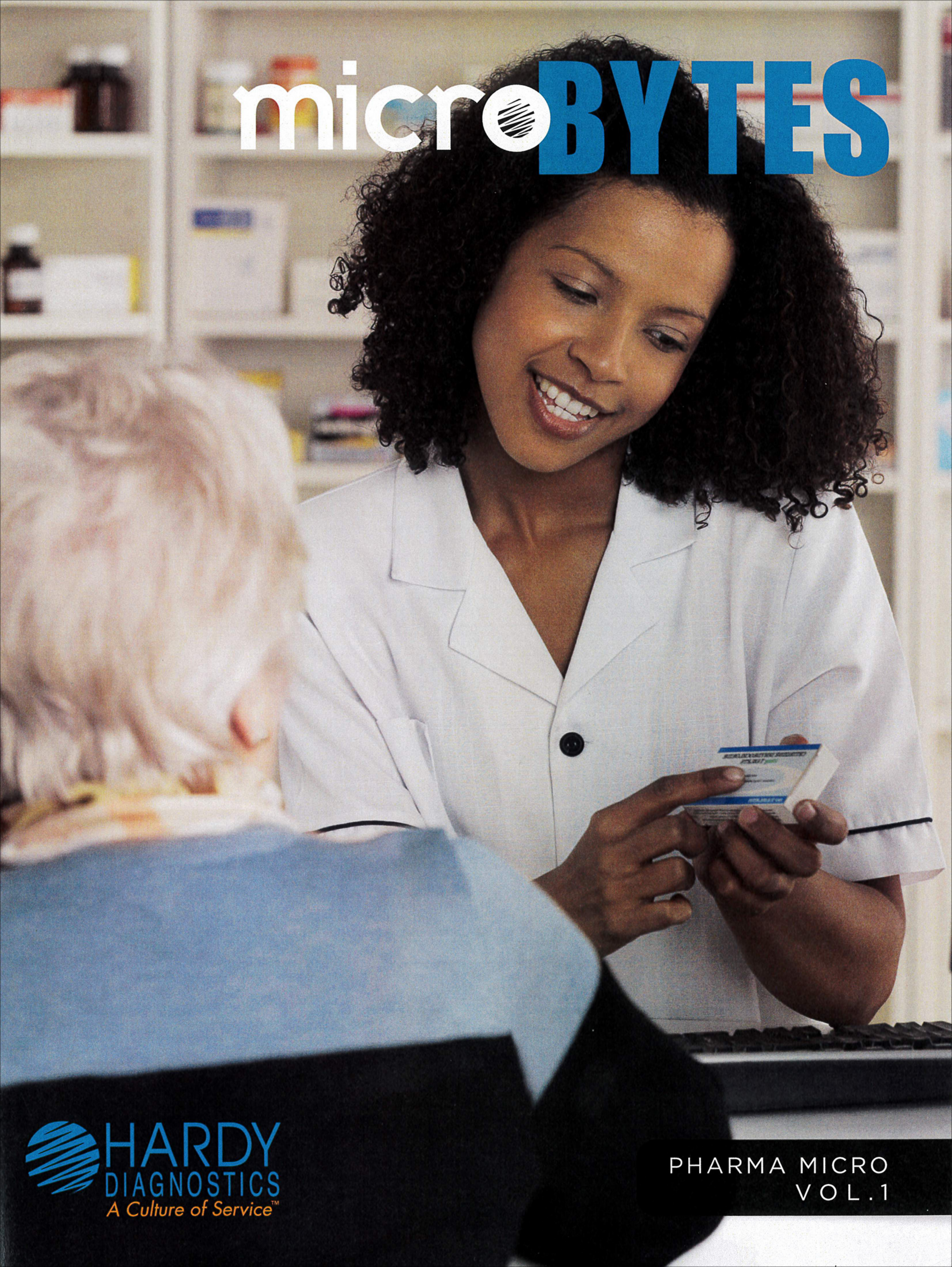


microBYTES



THE EVOLUTION OF ENVIRONMENTAL MICROBIAL AIR SAMPLING

A conversation with Roberto and Sandro Ligugnana

The evolution of environmental monitoring traces back to Italian scientists Francesco Redi and Lazzaro Spallanzani, and Frenchman Louis Pasteur, who demonstrated, through experimentation with a swan-necked flask, that life does not arise spontaneously as originally postulated with the medieval idea of "spontaneous generation." Thanks in part to Roberto and Sandro Ligugnana, the principle of the swan-necked flask can be repeated today in just minutes with active impact air sampling instrumentation.

Along with their father, Elio, Engineer Rino Tressoldi, and Microbiologist Lawrence Whittard, the Ligugnana brothers set out to find a more reliable and consistent solution to the more random environmental method of sampling air quality using "settling plates." The United States Pharmacopeia (USP) states the use of settling plates alone is not adequate to assess the quality of air in a controlled environment.

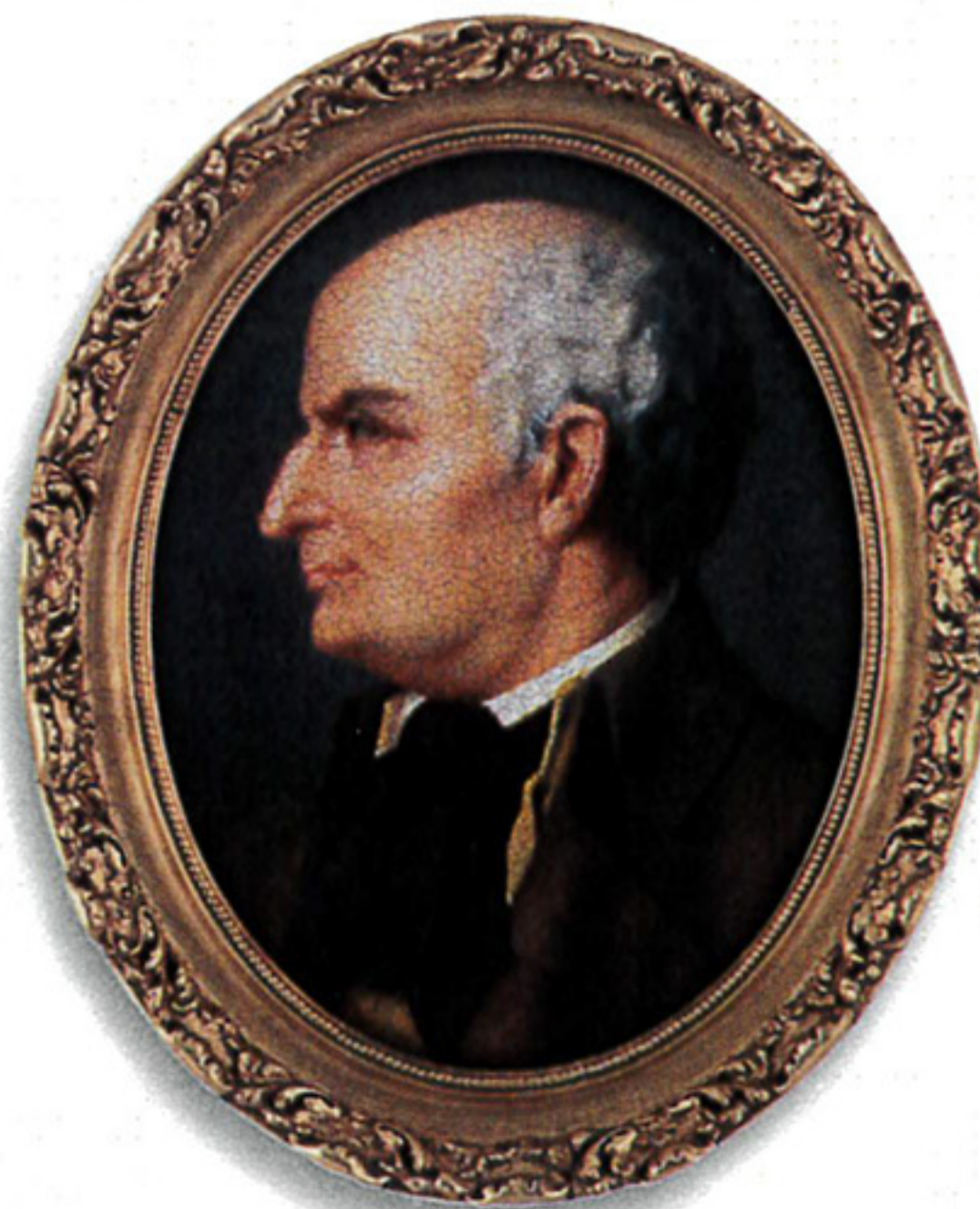
We visited with Roberto and Sandro Ligugnana, brothers and founders of Orum International, at their villa in Milan, Italy to hear about their journey in the production of active air sampling equipment.

Q: Roberto, what is your background and why were you motivated to discover a better way to conduct air sampling?

My background is in dairy microbiology. My first position was in Quality Control at a yogurt and Parmesan cheese production facility. The operation included every aspect of production; from the farm to the dairy and cheese factory. During that time, I spent my life with microorganisms and their positive and negative effects. The microbial air contamination of dairy products was important to learn about during the 1950's and '60's. Finding molds inside yogurt, butter, and cheese at that time was a frequent occurrence. At that time, the methods to discover and mitigate against molds involved using Petri dishes, open and exposed to the environment for 4 hours, and the use of stationary six-stage Anderson air samplers. The first method, using "settling plates", was quite non-consistent. The second method, using the Anderson method, was complex, and the equipment was not portable. We decided to develop, and patent, a portable and easy-to-handle instrument applying the Anderson principle.



Francesco Redi

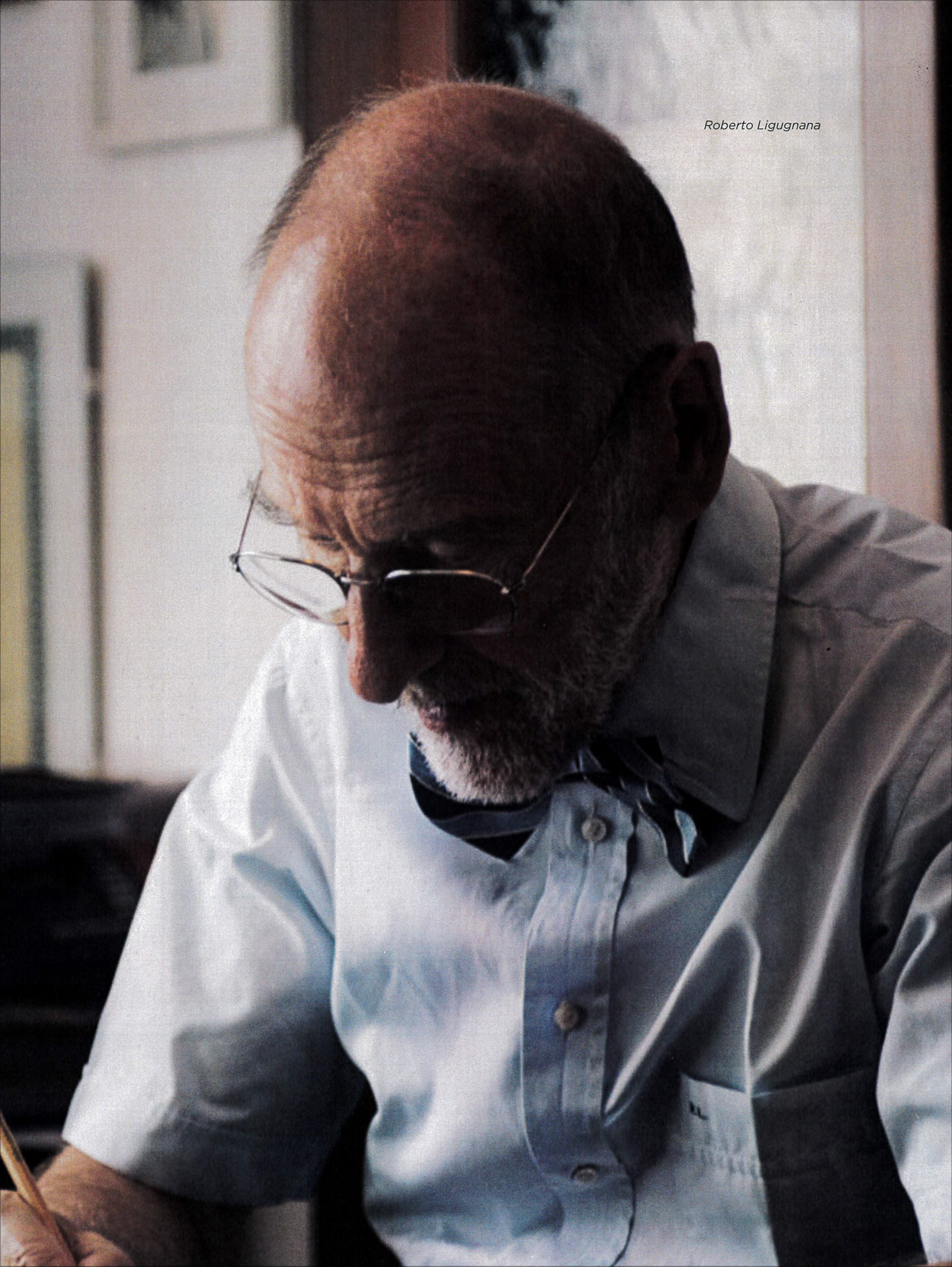


Lazzaro Spallanzani



Louis Pasteur

Roberto Ligugnana



Q. Sandro, there have been many versions since your original design 40 years ago. Your original patented invention has taken on many forms over the past 45 years. Would you please take us through history?

It is a long story spanning over 45 years. We started out by engineering a sampler with a separated battery pack that was quite heavy. We eventually produced a "gun-like" sampler which was much smaller and easier to handle for remote activities inside the MIR station. The years passed with around twenty other models and formats, bringing us to present day. We now have the most ergonomic, light, and technologically advanced version. TRIO.BAS represents the most complete line of active microbial air sampling instruments available. TRIO.BAS air samplers are sold in every continent, from Arctic regions to the desert, from Europe to the Far East, and from the North to the South.

Q. Sandro, how have you observed the industry changing over the years you've been in business?

In the 1960s, industrial microbiology was almost unknown. The Pharmaceutical industry was made up of small businesses mainly born in families' drugstores.

Companies were mainly artisanal, with solutions produced in smaller environments. There were no short shelf life concerns due to small scale production and rapid consumption of the products.

As years passed, the growth of the market required quality improvements to extend product shelf life.

During these years, analysis laboratories for quality control were created to support the increased demand for production.

Due to these historic evolutions, and thanks to our constant presence and our close contacts with customers and the university academic world, we gained great experience and knowledge in the field.

Our greatest satisfaction is that for over 45 years we still remain a reference point for the market, and are always among the first to offer innovative instruments to the international markets.

Q. Roberto, you found great success with your original concept. Why were you and Sandro motivated, in your golden years, to make improvements upon your original design, sparking a new company? Will you please explain the main implementations you've made?

We are passionate about the subject of Environmental Monitoring and decided to develop a new generation of instruments with several technological improvements. The most important advancements can be summarized as: (a) the creation of instruments with two and three aspirating heads, in addition to the best known classic "MONO" format; (b) Bluetooth capability for data transfer to a printer or PC; (c) an induction battery charger to eliminate an outer plug on the instrument, thereby making it more resistant to liquid cleaning agents penetration, as well as possible contamination; (d) IP65 certified protection from dust and water; (e) shockproof construction (f) cascade passwords; (g) quick bayonet manipulation of the much lighter stainless steel aspirating head to aid in loading and unloading culture media easily and aseptically; (h) Explosion proof certified instruments (in ATEX models); (i) 50% reduction of sampling time; (j) antibacterial treatment of the surface finish; (k) the option of certified sterile aspirating heads to save time in

the Cleanroom; (l) the option of "remote" satellite units in several different formats for varied applications and sampling flexibility.

Q. When it comes to compliance, why is it important to have a robust sampling plan, possibly exceeding minimum requirements?

A sampling plan should be risk-based, with well-mapped sampling of the most critical areas of the cleanroom. More frequent sampling produces more reliable trends. If something in the environment changes, appropriate action can quickly be taken.

Continuous microbial monitoring with multi-aspirating head samplers can capture sample data "at rest", "in operation", and "at the end" of the filling process to verify and apply the necessary "alert" and "action" interventions. Continuous monitoring activity is requested by the FDA in sterile drug manufacturing, but is a robust method for any cleanroom activity.

Q. This question is for each of you. In your long and illustrious careers, what is the most valuable lesson you have learned?

ROBERTO:

Our father, Elio, always told us we should come alongside the customer as valuable consultants. This is the reason we have produced a large amount of technical papers, application notes, bulletins, and have organized thousands of seminars and congresses around Italy and the world.

SANDRO:

Physical and mental discipline are very important ingredients to achieving goals.

I have always believed in technology and science as indispensable engines for growth. This is why, in our professional experience, we never fixed a final goal. We have always worked tirelessly, through knowledge, experience, and culture, to go further.

In the past 45 years, we've continued to create and update our instruments, adapting them to emerging industry needs. We're always looking for opportunities to adopt new technologies of mechanics, physics and electronics.

"Continuous growth" is the spirit that has driven my decisions; decisions always shared with my brother, Roberto.



