Andrea Castiglioni, Regional Manager South Europe – CAI



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CAI is an engineering service company. Its regional manager for South Europe, Andrea Castiglioni, comments on the pharma industry's need for commissioning and qualification services when looking to reduce time to market or set up new production facilities. He also outlines the role of CAI in helping companies who produce medicines in Italy, and analyses industry trends, including a surge of investment during the pandemic across many European markets.

Andrea, can you begin by introducing CAI as a service provider for the pharmaceutical industry and your responsibilities as regional manager for the South Europe cluster?

CAI was founded in 1996 to provide the highest quality of commissioning service to our clients. Over the last 26 years, we have maintained this high standard to meet the specific needs and requirements of each project. Our philosophy is based on five main pillars: project, people, process, facility and quality. Why CAI? The company exists to offer a trusted solution for companies, striving to build better workflows and improve the human experience. We are a company that looks for trusted partnerships where we can provide our long experience in the sector.

I am the Regional Manager for South Europe and one of my responsibilities is the coordination of activities in my area of control. Our mission is focused on providing support to the pharmaceutical and biomedical industries from the beginning of a project to its completion, in reducing the timeline for a product to reach patients and in decreasing project complexity by delivering a high quality

standard while maintaining a predefined budget. Everything we do is based on this premise.

The range of the services we offer is designed to embrace the process from the beginning to the end of the project by guiding our client to operational readiness. In fact, we follow and support our client from the engineering design, to the site start-up and product commercialisation.

CAI has eight main business areas: commissioning and qualification; building commissioning; quality, compliance and regulatory; process and manufacturing technology; asset management and reliability; automation and information technology; project and program management, and human ferformance.

How does it all work? Can you take us through the process that CAI would use with a client that might be interested in building a plant, adding a product line or optimising existing production?

We first do a comprehensive assessment, during the project kick-off, by looking both at the partner's needs and how the project can benefit from CAI's services as our team has good expertise to support them in projecting the activity from scratch.

Due to our extensive experience, we are able to provide the knowledge that corresponds to the level of a project's complexity, from the simple activities relating to commissioning and qualification up to the more challenging ones relating to process optimisation in order to ramp up efficiency and productivity. We deliver teams with an appropriate mix of knowledge based on project complexity.

What kind of companies make up CAI's client portfolio in Italy? What is the split between multinational and local companies considering that the country is one of the two main manufacturing hubs of pharma products in Europe?

Almost 80% of CAI's clients in Italy are multinational companies, but we also serve mid-size Italian companies that are well established across the territory.

As far as the local market in concerned, I see the high level of bureaucracy to be the biggest issue we have at the moment. Fortunately, the Italian Government has passed new laws to reduce it and to accelerate the process for new investments. The COVID pandemic, so far, has resulted in a high number of new projects being carried out by the pharmaceutical companies, for which they have

needed the expertise of companies like CAI. We are growing by following the industry's needs.

The biopharmaceutical market is also growing in Italy both in terms of processes and investments. There are plenty of on-going projects, not only for refurbishing and revamping existing plants but also for the construction of new sites, production lines and equipment installation, particularly following the vaccines market.

With respect to other countries, at the moment, we are seeing a big uptake in investment in the Swiss market, possibly due to much simpler regulations.

Can Switzerland compete with Italy on price?

That is a good point. Italy is perhaps able to compete with Switzerland today, mainly due to the reduced costs of operation, but as mentioned previously a bureaucracy reduction would be the main target to be attractive for big pharma company investments. Although more countries are making new efforts to have a larger piece of the pharma production market in their territory such as Germany and the Netherlands.

How did the pandemic change the Italian authorities' persective on the pharma industry?

The message when the pandemic stuck was clear, Italian infrastructures were not ready to face the effort needed. The action taken was to try to simplify procedures to access credit financing in order to allow pharmaceutical companies to invest and transfer processes and products to rapidly cover the gap. In my opinion, the lesson learned from this critical event is to work on operational excellence as the answer to a possible new emergency. In such a context, CAI has acted as a key support to pharmaceutical and biotech companies, due to its long and proven track record.

What can you tell us about the market, the competitive landscape for CAI, and the elements that separate you from your competitors?

CAI has about 850 agents around the globe. There are several competitors on the market but maybe only a few of them can match our consolidated knowledge and the level of investments CAI focuses on the improvement of its personnel's expertise through different levels of training and

networking. Our philosophy, as a company, is to be a well trusted long-term solution for our customer rather than a one-off consultant for a single project. Therefore, CAI aims to become a long-term trusted partner for all of its customer. To illustrate this, I can say that several of our clients have been in a business relationship with us since 1996.

Our main advantage is our extensive experience in the various processes of the pharmaceutical market and the wide interaction CAI has with professional organisations such as ISPE, PDA and ASTM, for example. Our company is able to deliver the most modern approaches to new projects within the life sciences industry by being an active member of those organisations. Recently, the most requested service has been to provide support on the design of new buildings and technology. It is not a secret, in this industry expertise and reliability are what matters the most and CAI offers a high standard of consulting to its customers.

The aseptic market is also growing in Italy both in terms of numbers and complexity. Our role as an organization is to support our clients to reduce the time they need to reach patients by maintaining the standard of quality requested and by keeping the project costs under control. CAI's services allows pharmaceutical companies to grow.

In Italy CAI has over 40 agents. What is the general background of your team?

The South European team includes people with more than two decades of field experience in the industry. The core of our business is mainly in commissioning, qualification and validation projects, but we have also experts, who are former senior managers of high-profile companies, in the quality, compliance and regulatory area. Our company understands that hiring talent and senior resources is important, but transferring knowledge is also fundamental and a key to success. As a result we have an internal training program based on five tiers that is capable of providing high quality content to junior people.

CAI also supports the industry with GMP inspections. What can you share about that part of your job?

We have a strong department composed by certified senior auditors who are involved in overseeing FDA renewals and other global processes. It is a very interesting part of CAI's business as the complementary steps to equipment commissioning and qualification lead clients to be able to reach the compliance of their processes. All of these investments need design, qualification and

quality, and regulatory solutions. Clients need skilled people that are up to date with regulations applicable to each market. As a worldwide company, we are in a great position to deliver these services with a high standard of quality.

A recurring question from partners and potential clients might be about quantifying the return on the services CAI provides. How do you typically address that?

Due to our approach, we are able to reduce the time to patient of our client's processes by more than 20 percent. There are many solutions that CAI can provide depending on a client's QMS and other organisational circumstances. CAI is a leader in delivering a novel risk-based approach for commissioning and qualification. If this is well-managed, it allows clients to drastically reduce the time to operational readiness. It is not just a matter of money, but also of the time dedicated to process optimisation, allowing for a vertical process start-up.

Is there anything else you would like to share with PharmaBoardroom's readers?

I want to briefly discuss operational excellence. It is the process through which clients are able to reach the best level of process readiness, from both quality and quantity perspectives. If a project has been properly set up and executed, time to patient can be greatly reduced. CAI can deliver clients a dedicated solution that supports process optimisation, resulting in time saving.

Our company has managed to partner with one of the top companies in the world that produces solutions around paperless validation. This has given CAI the chance to redefine our approach to validation. Reducing the time spent on paperwork and the related risks will play a key role in the future of the industry.

Pharma 4.0 should concern both the industry and the providers of engineering services, especially now that data protection and integrity have become dominant. Digitalisation is a priority for most industries, and especially the pharma and biopharma industry. Companies need safe data to rely on, even in that space CAI can provide a higher standard and proven experience to support our current and future customers.

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