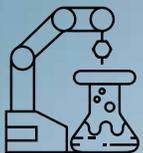


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EUROPE SPECIAL



TECH OUTLOOK



LABORATORY
AUTOMATION
EDITION

LifeBee

LIFE SCIENCE
CONSULTING
FOR GxP
REGULATED
AREAS



RAFFAELLA VAIANI,
PARTNER & LAB BUSINESS
UNIT DIRECTOR

\$15



LifeBee

LIFE SCIENCE CONSULTING FOR GxP REGULATED AREAS

“Anything you are good at, contributes to happiness”—Bertrand Russell, philosopher 1930.

Although this might be just another quote for many, it is a mantra that LifeBee relentlessly follows. “This is what drives us in our everyday activity: we strive to deliver the best possible services to our customers while maintaining a fulfilling experience throughout,” says Raffaella Vaiani, LifeBee’s Partner and Lab Business Unit Director.

Founded in 2004 in Milan, LifeBee focuses on consulting and digitalization services for the Life Sciences. “We have consistently supported our customers in their path towards digital transformation, proactive compliance and operational excellence, by providing tailored services to address business

challenges and opportunities for each client,” says Raffaella. Today, LifeBee is serving more than 70 customers across Europe and the U.S. and Extra UE, with a critical focus on GxP regulated areas. The company provides services for QC and R&D Laboratories in addition to production, logistics, quality assurance, regulatory, and pharmacovigilance.

LifeBee: “A Company that was Missing”

LifeBee’s uniqueness lies in the principle that the continuous improvement of operational processes, digitalization, and compliance are only different sides of the same coin. Over the years, the company has defined a proprietary methodology and multiple best practices

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suitable to its customers, who are always different in focus, type, and dimension. “We have realized that looking for a specific solution for a specific topic is too restrictive and not effective, sometimes even worse if seen from a different perspective,” mentions Raffaella.

For example, a data integrity remediation plan focused only on instrument compliance, introducing more paper logbooks and strict procedures, or a lean project delivered without adding new digital solutions to support it at the same time. In the end, the only approach that leads to the best results is the outcome of a broader vision and a holistic view among improving together operational processes, the use of technology, and compliance.

LifeBee was defined as “a company that was missing” by its very first customer. “This originated from our unique selling point within the Life Sciences. Our team effectively redesigns material flows, personnel and information flow, procedures, and digital solutions, extensively combining the lean and compliance approaches simultaneously with the customers. We define ourselves as a consulting boutique,” Raffaella continues. “We are like tailors because we create dress models when we deliver strategy; we sow when we deliver digital solutions using the best fabrics, meaning the software market leaders.”

Delivering Innovative Digital Solutions Using 4.0

With increasing international presence LifeBee recently opened a new office in Switzerland (just before the pandemic). In the last few years, the company has already provided up to 20 per cent of services outside its borders. The benefits have been very well received by the international customers, demonstrating the importance of being a niche consulting company with a profound understanding of sector needs regarding process improvements, digitalization, and compliance. “Not to forget that our rates are more sustainable if compared to consulting companies from other countries,” says Raffaella. This is due to LifeBee’s focus, and their proprietary methodologies and accelerators developed during the sector experience.

On the other hand, 4.0 enables technologies to drive innovation to support Life Science professionals in their daily work and support big and small decisions from operators, analysts, supervisors, middle managers, top managers, and regulators. LifeBee believes that to adequately sustain all of the players within Lab Life Science ecosystem, a collaboration must be created among humans and computers, consistently delivering the correct information in the right place and at the right time to our Users. “That’s why we are focusing more and more on delivering innovative digital solutions using

4.0 enabling technologies like Gxp SaaS, Virtual Reality, IIoT, predictive and on demand analytics,” informs Raffaella. Further, LifeBee is also identifying the best promising software vendors at the international level thanks to the collaboration with lead analysts like Gartner, while also very active within different Pharma associations, as ISPE.

Delivering Holistically Operational Excellence, Digitalization and Compliance

LifeBee kicked-off the “Lean Lab” initiative in 2009 as an interest group that meets annually to share ideas and experiences among Life Science Labs, QA, and IT, reaching about 250 professionals today. Annual surveys have been performed to identify Lab trends, and they clearly show:

- A continuous increase in digital projects, involving more Electronic Lab Notebooks (ELN), integration with instrumentation and with other systems (from 2017 to 2019: + 15 per cent ELN and – 8 per cent xls)
- Remarkable developments in the culture of measurement (measured-based projects from 27 per cent in 2019 to 46 per cent in 2020)



LifeBee targets all these trends thanks to its holistic approach, designed explicitly for regulated Labs. More than 40 Lab Consulting Studies have been provided, including Digital Plans, Lean (on processes and layouts), and Data Integrity Studies. To meet the growing need of “high quality, on-time, on budget” digitalization, over 30 successful projects have been completed with LIMS/ELN and relevant integrations. “Our uniqueness lies in acting on operational

processes, digitalization and compliance, as a whole and at the same time, targeting long-term goals with quick wins,” states Raffaella. Customers recognize its value by grasping actual results, such as:

- Reducing non-value adding activities to increase Lab productivity by 20 per cent
- Increasing QC Lab adherence to the Supply Chain release plan, up to 80 per cent
- The decreasing workload for analytical reviews by 70 per cent

One recent case study worth mentioning is a two-month definition of a 4.0 roadmap for QC and R&D Labs for a U.S.-based company. LifeBee’s strongpoint is the view of 4.0 as a feasible and productive transformation with specific customer constraints and targets rather than an industry-wide blueprint towards one standard model. The two-year digital journey achieved: a reduction of 25 - 40 per cent in response time of manual processes and an efficiency increase that has reached 50 per cent. “Another case study we are proud to share is a lean and compliance study, aiming to revise processes, personnel, and material flows, for a new QC and R&D Lab,” Raffaella adds.

The target was Labs’ operational empowerment to deal with the planned increase in activity, ensuring high reliability, an adequate service level, and complete control in investments efficiently. The three-month study resulted in the revision of layout and physical flows, the introduction of shared metrics, improved use of systems and instruments. “FTE expected growth was estimated from 45 to 85: we demonstrated that with all the identified actions, the required FTE totaled only 60,” says Raffaella.

The Lab of the Future in LifeBee’s view

According to LifeBee, the Lab of the future is not a lonely place void of human beings, full of autonomous robots and equipped with the most advanced technologies. Innovative technologies must be present for sure, but their primary role is to empower Lab personnel (who will always be part of the Lab, even if, in some cases, connected remotely). It needs to support them and their stakeholders to decrease innovation deployment timelines, improve quality, efficiency, and data integrity for Labs in R&D and Manufacturing. Further, the Lab should also sew close collaboration among professionals from diverse locations and multidiscipline backgrounds.

On the other hand, the current technology landscape presents multiple promising opportunities that are sometimes difficult to prioritize in their introduction to the Labs. “At LifeBee, we are convinced that the first step is to build a sound roadmap with a pragmatic yet foresighted approach,



We have realized that looking for a specific solution for a specific topic is too restrictive and not effective, sometimes even worse if seen from a different perspective

before starting the journey towards the ‘Lab of the future.’ This requires a combination of long-term strategy (the ‘why’), step-by-step execution with quick-wins, process improvement, proactive compliance (not ‘reactive’ as a mere fulfillment of rules, but compliance by design) and sustainability in terms of investment and resources,” mentions Raffaella. These elements are tailored to specific customer needs, combined and composed to obtain incremental results during the program continuously, but starting from the very beginning.

The Lab of the Future is then created by a new generation of empowered Lab personnel who take full advantage of interaction with innovative equipment and digital solutions. These professionals can easily access a trusted and secure Lab knowledge base, allowing them to make the right decision in the right moment and place, using predictive analysis when advantageous. Such professionals would be strolling through more lean and collaborative layouts, applying more effective operational processes and methodologies in a compliant and traceable manner. “As in any boutique: the quality is high, everything is tailored to specific need taking sustainability into account. Passion for customer success and ingenuity are essential, and that’s where LifeBee excels,” concludes Raffaella. [Ph](#)

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*The annual listing of 10 companies that are at the forefront of providing
Laboratory Automation solutions and transforming businesses*