Luigi Bellone

Head of Quality Assurance
Paullo, Milan, Italy

HIGHLIGHTS

Chemistry degree from the University of Pavia; secondary degree from Liceo Omodeo in Mortara.

20+ years of quality assurance (QA), quality control (QC), regulations and compliance experience.

Shares his QA expertise across Cambrex and with clients.

Develops new QA processes and systems to adapt to new molecules and changing client needs.

SUMMARY

Luigi has more than 20 years of experience in QA, QC, regulations, and compliance in the pharmaceutical industry. While he's based in Milan, Luigi's expertise is in high demand, giving him an opportunity to work across Cambrex sites, and with many of its clients.

AREAS OF EXPERTISE

- QA for Generic APIs
- Quality Control
- Regulatory compliance (including cGMP)
- Registration and audits

LINKEDIN

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What keeps you passionate about the work you do, and your career?

I wanted a career that was grounded in science, given my education and previous roles, but I'm also very social and personable. I didn't want to be in a lab on my own all day.

There is so much more to creating APIs for generics than simply following a recipe. Having the best tools and facilities is important, and Cambrex rises to the top given its investments, but the experts and the services we provide are critical.

"Our work impacts millions of patients who are counting on treatments to improve their lives. That's a huge responsibility and a big reason clients turn to Cambrex, knowing we have the expertise and extremely high standards for quality assurance and maintaining compliance."

Customers rely on our passion and expertise to make generics accessible and affordable to patients all over the world. In my experience, customers take notice when we go the extra mile and always put safety first. It's rewarding to work on something really important while being surrounded with experts, and having customers who appreciate our collaborative approach.

What is your biggest challenge with managing a diverse catalog of generic APIs?

The challenges that come with creating generics vary across risk, regulatory, and compliance issues, which is why a comprehensive approach to developing APIs is so important. Being able to manufacture some of our own materials provides a safe and sustainable supply chain, which helps to mitigate risks.

We embrace the unique scientific and process-oriented challenges associated with generic APIs. We're confident in our people, capabilities and the incredible facilities. But we also know that we can never feel too comfortable – and that's the challenge. Not feeling paranoid, but always on our toes. We investigate the smallest deviation and question everything. We treat every batch as if the entire business is depending on it.

Like anything else, you get better with repetition and by learning and adjusting. Cambrex manufactures over 70 generic APIs, which are produced to cGMP standards at the Milan site. We have seven production departments supported by a pilot plant, kilo scale plant and development and analytical laboratories. The combination of our leading experts, facilities and a culture built on quality gives Cambrex an advantage over other CDMOs—and our customers recognize that.

How do other Cambrex sites tap into your expertise?

While I'm flattered that I'm considered an expert, this is much bigger than any individual. It's a big reason why I love working for Cambrex. We don't just talk about QA and the processes we've put in place. It isn't simply a box we check. Quality assurance is part of our core beliefs and woven into our culture. Because in this industry, even the smallest setback can have an enormous impact.

There's a very open, collaborative mentality at Cambrex. Whether it's formal QA training, mentoring, or being pulled into a project to help address issues, I spend a lot of time working with other Cambrex teams. Our reputation is on the line as a company, so I'm happy when people reach out with questions or need assistance. That's how we work at Cambrex.

How is quality documentation managed across the Cambrex sites?

Over the past few years, and accelerated by the COVID-19 pandemic, we increased a lot of the digitalization of our quality processes. Now we have a single system for managing quality documentation across all Cambrex sites. We need to find ways to work smarter and more efficiently, especially when working with such sensitive data and reporting needs. Making these moves now puts us in a position to maintain our track record and strong QA reputation into the future.

How does Quality Control come into play during tech transfer?

Drug substance tech transfer is a complex activity carrying several technical, regulatory and quality risks. Although we draw upon our vast experience with tech transfer, we also recognize that every situation is potentially different and requires a distinct approach—or at least a tailored one.

With generic APIs, the tech transfer is typically from our R&D laboratories to the plants. We ensure that all the validation protocols are well established, critical points have been identified during the R&D studies, then tracked from the validation activities to the scale up, to commercial batches. Our QA specialists work closely with the other Cambrex sites to ensure a smooth transfer—from start to finish.

Do you take a different approach to QA with generic APIs?

Among our 70 generic APIs, we have controlled substances, intermediates, nitrophthalic acids and derivatives, pyridine derivatives, chiral compounds and several miscellaneous APIs. A wide range of APIs comes with a range of requirements. Given our focus on generic markets, we have experience with compliance requirements from Pharmacopeia, USP, JP, and more. While we have an established set of processes, tools and best practices, we know that every API is unique, and we treat it as such. That's the challenge, and excitement, of the work we do every day.

Creating generics isn't as simple as copying the existing branded drug. Making generics requires the mastery of a whole host of different skills, including the legalities of acquiring new products, regulatory support, research, and manufacturing, along with a strong distribution network. There is no room for inefficiency when developing generics, as products need to be delivered at the right time and at the right price, while being 100% safe and effective.