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Quality's Increasingly Pivotal Role In Sustainable, Profitable Businesses: Are You Choosing The Right CMO Partner?

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Quality and compliance might be associated with bottlenecks and the creation of complexity, but it does not have to be like this. When a CMO has the right quality culture, knowledgeable quality personnel are involved in the earliest phases of customer projects and everyone upholds a customer-centric vision; a reliable, flexible, and transparent quality system is the norm.

Global CMOs with a harmonized quality management system (QMS) and continuous talent exchange between continents assure desired levels of quality and fit-for-purpose products in any part of the world. Furthermore, by promoting an operational excellence mindset, flexible organizational structure, and empowered teams, such organizations can quickly identify and creatively overcome unexpected challenges during product project implementation or novel issues — saving their customers millions and upholding their reputation.

Moreover, only a strong and robust quality system can easily adapt to support new, exciting business expansion opportunities, as evidenced by ESTEVE's recent acquisition of a new site — fully transformed and adapted to our demanding standards in a record time of 5 months.

The CMO customer experience starts behind the curtain with quality assurance (QA). A well-developed quality system is fundamental to every step of the pharmaceutical manufacturing process. It not only is conducive to consistent, high-value products and services, it also fosters practices and documentation that withstand regulatory scrutiny, promotes continuous improvement, and empowers an organization to be confidently transparent and agile in its operations.

A CMO should operate as an extension of its partner. Thus, pharmaceutical and biopharmaceutical sponsors face a critical decision in choosing a CMO to produce their drugs. Understanding what to look for when vetting a CMO's quality system eases the decision-making process.

Quality Partnership From Day 0

At ESTEVE Química, quality engagement starts even before the prequalification audit, when potential customers talk to our senior leaders and gain insight into their experience, self-confidence, and motivation. Early initiation of the quality discussion also ensures our procedures will support the project scope and our vision is aligned with the customer's. Once a project begins, we build a core team, led by a project manager, that includes experts in R&D, production, procurement, EHS (environment, health, and safety), and, of course, QUALITY. ESTEVE shares best practices and learnings among all its sites, ensuring we are cognizant even of the newest regulations and well-prepared to overcome any challenge.

We continuously collaborate with the customer to exchange process knowledge and expertise, to improve together, and to familiarize them with our facilities and our people. In general, all GMP documents and necessary actions throughout the project life cycle are created and managed in this early phase. This way, quality topics and QMS activities are seamlessly integrated and executed leveraging our customers' timelines. ESTEVE's customers also enjoy unmatched visibility into quality operations and documentation. Staying true to our philosophy, all GMP data is transparent for our customer, without any exceptions — an openness customers have repeatedly lauded.

Throughout the partnership, our core team meets regularly with the customer to discuss trends, training, observations, or upcoming regulatory concerns. The customer's preference usually dictates meeting frequency. Clarity of understanding is assured since our experts are trained in customer experience and can communicate in the same wording, at the same level as our customers. In short, every ESTEVE team member is empowered with appropriate knowledge and decision-making capability to accommodate each customer's unique pathway to success.

A customer-centric mindset is an integral part of ESTEVE's way of work, and it can take many forms. Typically, it means viewing things through the lens of, "What if the customer organization was my company?" As an example of the latter, we may start a project that requires a test we previously have not conducted. We may need to act immediately to invest in the appropriate equipment to serve that customer, which requires fast intra-organizational decision-making to appropriate funding and act in the customer's best interest.

Such flexibility is essential to effective CMO quality; our QA leaders recognize that the needs and processes required to propel each new project are not the same as the previous one. This principle enabled us to navigate the COVID-19 pandemic without disruption. It speeds deployment by combining clinical-phase manufacturing and commercial products at the same site, and it fosters QMS adaptation that minimizes lead times for both standard products and fast-track projects (e.g., urgently needed medicines).

We have successfully executed timing adjustments on numerous projects, adapting to specific requests and redefining strategy without compromising our commitment to quality. This preparedness, and the fact that regulatory authorities recognize us as a reference, allows ESTEVE to partner with customers to advance creative and compliant solutions, whether they are necessary to complete a validation or to save a batch. Informed by comprehensive quality risk assessments, we can make the right decisions together with our partners.

A Quality Mindset Drives Business Performance

Compliance-driven metrics — guided by regulatory agencies and indicative of quality related to operations — show compliance maturity and organizational agility. They can be used as a compass to guide an organization's process improvements (e.g., percentage of deviations, right first time [RFT], batch release time, and timely closure of deviations) throughout manufacturing and the entire supply chain.

ESTEVE Quality Management tools are used to implement standardized processes that result in reproducible production outcomes (desired levels of quality and fit-for-purpose products) in any part of the world, allowing us to manage six plants across three continents, operating in Mexico, Spain, and China. As a global organization, ESTEVE shares best practices and learnings among all its sites, ensuring we are cognizant even of the newest regulations and well-prepared to overcome any challenge.

To achieve a truly cross-functional, quality-minded view and to promote visibility of the data that drives improve-

ment, processes and systems must be fully integrated. In addition to investing in suitable systems and tracking key performance indicators (KPIs), ESTEVE Química sets annual objectives relevant to process improvements (e.g., reducing the wasted time associated with specific actions within an operational workflow).

ESTEVE is proud to foster a quality culture where individuals report deviations without delay. When an issue arises, it is not "someone's fault." Our quality team undertakes root-cause investigations alongside engineering and production — whoever is affected — devising solutions together and applying lessons learned at all our sites.

Quality is naturally integrated in our actions and creates a deeper connection with our customers, who indicate quality metrics important to them at the start of a project. Typically, compliance-related metrics are applicable to all ESTEVE projects, while customer metrics tend to focus more pointedly on our relations with each customer and how we manage their product. We strive to treat each customer as an active member of our team, communicating events in real time throughout the project lifecycle.

Moreover, ESTEVE's quality team are engaged members of several pharma associations, including the Active Pharmaceutical Ingredients Committee (APIC). We prioritize training not only when a product concept or a regulatory guideline is novel to us, but as a means of staying at the forefront of industry standards and regulations. We also supplement our in-house training by attending conferences, as well as welcoming consultants and experts to conduct walkthrough audits while educating our personnel. Our training plan is reevaluated annually to decide and describe training needs common across the business.

Quality also has a seat at our senior leadership table — not the case at all organizations. From the top down, we discuss quality metrics and scorecards, identifying and exploring potential issues by being physically present in the boardroom, QC labs, and production floor.

Quality is in the walls of every site (literally and figuratively, thanks to quality reminder posters featuring actual images of people who work in each plant). At the start of a project, we welcome the customer to speak to our teams in person, explaining the product and how it will improve patients' lives. This helps to build the sense of purpose inherent in everything we do.

In this way, our quality members are not police; we are a consultancy working as part of our customer, enmeshed in their network, and invested in their successes.

To learn more, contact the authors and visit us at esteve.com.

About ESTEVE Química

Innovating to improve people's lives has been our mission since our establishment in 1929. We are a global company headquartered in Barcelona, with pharmaceutical affiliates in Spain, Germany, France, the U.K., and Portugal, as well as state-of-the-art industrial sites in Spain, Mexico, and China to serve our CMO customers.

We take pride in our values and espouse them in everything we do: people, transparency, and accountability matter. This is the only way we know how to do business because, as a healthcare company, we have a huge responsibility to both people and the environment.

Our CMO platform, ESTEVE Química, was founded in 1966. From the beginning, we have implemented an API manufacturing concept that combines the best of the chemical and pharmaceutical worlds by using advanced technologies and installations, such as cleanroom areas for the last steps of manufacturing.

We develop and manufacture small molecules, advanced intermediates, and active ingredients for our customers, always focusing on long-term partnerships. We are committed to excellence across a complete range of services from the initial stages of API development to the manufacture of on-market commercial products. We have manufactured APIs for the most highly regulated markets for more than 50 years.

ESTEVE Química's development capabilities, deep knowledge, fast adaptation to customers' requirements and shifting regulations, technical capabilities, strategic geographical locations and, particularly, commitment to excellence, drive premium service and reliable response, whatever the scale of the project — allowing us to continue to serve the medical needs of patients with passion and commitment.

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About the Authors

Sandra Lopes Guerreiro is the Global Quality, Health, Safety & Environment Director for ESTEVE Group. She graduated with a degree in Pharmaceutical Sciences and has concluded several specialization studies in Product Management, Leadership and Pharmaceutical Management. Sandra has more than 20 years of pharmaceutical industry experience, in several big pharma companies.

In her current position, she is responsible for the organizations of Quality, Compliance & Regulatory and Health, Safety & Environment at both 1) the chemical business at ESTEVE Quimica (CDMO), which includes six state-of-the-art, fully compliant industrial sites on three different continents as well as 2) the pharma business at ESTEVE Pharmaceuticals (including commercial and industrial affiliates).

Sandra joined ESTEVE in 2021, bringing her diverse background, enriched by the management of different teams throughout her career: Quality, Compliance, Customer Service, External Suppliers and Operational Excellence.

Dolors Rafart Pujadas is the Global Quality API Director for ESTEVE Group. She graduated with a degree in Chemical Sciences from University UAB Barcelona. She joined Esteve in 1997, accumulating more than 25 years of quality operational experience, and has held a variety of senior positions including Quality Control and Quality Assurance at several sites. This encompasses overseeing the quality of all API sites as well as a full complement of CDMO services provided on a worldwide basis.

In her current position, Dolors is responsible for the organization of quality across six ESTEVE Química (CDMO) manufacturing sites. At ESTEVE, her primary focus is improving quality operations for key healthcare clients.