



NDA Whitepaper

Ensuring Quality and Compliance: Foundational Principles for Drug Development

Written by:

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About the author

Helen Kargaryani

Helen was the Head of Quality & Regulatory Affairs (QRA) for North and South America at The Linde Group (2010-2015). Prior to that, as the Head of Global Quality Assurance at the Linde Healthcare from 2015-2018, she led the Quality strategy for four different segments: Hospital Care, Gas Therapy, Homecare, and Respiratory Services (including pharmaceuticals & medical devices).

She was also a member of the US Compressed Gas Association (CGA) and The European Industrial Gases Association (EIGA), representing the Linde group and Linde Healthcare in various working groups. Furthermore, she has been working as Vice President of Operational Excellence at Pharmadule and Senior Regional Manager / Quality, Regulatory, & Audit within Contract Manufacturing Organizations at Pfizer Pharmaceuticals.

As the Global Head of Quality at NDA, Helen ensures that NDA's Quality Management System meets the requirements of our clients and conforms to relevant international standards and regulations. She has successfully developed the NDA Quality Management System and processes and helped numerous clients with Quality and Compliance projects throughout the different stages of the product life cycle.





Ensuring drug quality and regulatory compliance is no small task in today's complex pharmaceutical landscape. As industries worldwide race to develop new treatments, the importance of maintaining the highest possible standards has never been clearer. When lives are at stake with every new medication, researchers and manufacturers must navigate countless requirements across regulatory jurisdictions to guarantee patient safety from discovery to distribution.

Framework to Maintain Highest Standards

Regulatory quality and compliance refer to adhering to established rules, standards, and regulations within a particular industry or sector. The quality part involves maintaining high standards of safety, efficacy, and integrity throughout product development and processes. Compliance entails following legal and regulatory frameworks set by authorities to ensure operations meet specified criteria. Achieving regulatory quality and compliance requires understanding regulations and their relevance to your business, meticulous documentation, monitoring, and proactive issue resolution. These practices ensure the delivery of safe, effective, and trustworthy products or services while building trust among stakeholders.

According to Helen Kargaryani, Global Head of Quality Assurance at NDA, the key is having systems and documented processes in place to continuously meet the defined standards.

She adds that Quality Management Systems (QMS) must be built to comply with applicable regulations to ensure products and operations are aligned with both regulatory and client expectations. Overall, maintaining quality and compliance is about having the right infrastructure to

satisfy all requirements on an ongoing basis. Regulatory bodies define quality and compliance in much the same way, and they have numerous rules and guidelines to adhere to. This can be overwhelming for companies working on drug development, so it's a good idea to begin with the basics.

Conforming to FDA Regulations

The Center for Drug Evaluation and Research (CDER) has created the Office of Pharmaceutical Quality (OPQ). This initiative aims to establish a standardized drug quality program that spans all the manufacturing sites, whether local or international and encompasses a diverse array of human drug products. From groundbreaking innovations to generics, biosimilars, over-the-counter remedies, and carefully curated compounded drugs, OPQ's purview extends across the entire spectrum. The FDA offers many resources called "Quality Information for Applicants" related to Chemistry, Manufacturing, and Controls (CMC). These resources cover various types of applications (NDA, ANDA, BLA, and IND) and are meant to help both companies developing new drugs and manufacturers who are seeking marketing or clinical trial approvals.

The U.S. Food and Drug Administration (FDA) compliance involves the adherence to a set of regulations aimed at safeguarding public health. These regulations, established by the FDA, play a pivotal role

in guaranteeing the safety, effectiveness, and integrity of pharmaceuticals, medical devices, and biological products. Companies operating in the medical device and biotechnology sectors are required to conform to their own set of regulations as well as other quality system requirements (QSR), to gain authorization for selling their products within the United States. This compliance framework ensures that products reaching the market meet stringent standards for quality and safety.

Quality According to EMA Standards

The scientific guidelines on the quality of human medicines by the European Medicines Agency (EMA) are designed to assist applicants in preparing their applications for marketing authorization. These guidelines are based on a unified approach embraced by EU Member States and the Agency. They outline how the requirements for proving quality, safety, and effectiveness, should be understood, and implemented. It is strongly recommended that applicants and those with marketing authorizations adhere to these guidelines. If there are deviations from the guidelines, the applicants must provide a full justification and are also encouraged to seek scientific advice to discuss any planned deviations during the development of the medicine prior submission.

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Every entity engaged in the process of developing, marketing, manufacturing, and distributing medicines holds the obligation to ensure their alignment with the pertinent standards defined in European Union (EU) legislation and pharmaceutical guidelines. The task of aligning these standards across the EU falls under the jurisdiction of the EMA, which oversees the harmonization of these norms at the EU level. Additionally, the EMA takes on the role of coordinating inspections (EMA requests that the inspection be carried out by authorities in the EU Member States) aimed at validating compliance with these standards.

Navigating the differences

Both the FDA and the EMA play an important role in promoting high quality standards and adherence to regulations in the pharmaceutical industry. They are committed to scientific methods and consistent rules which protect patient health and encourage new drug development. As companies endeavor to develop new pharmaceuticals and expand into fresh markets, it is important to gain a



comprehensive understanding of the functioning of the FDA and EMA systems. By adhering to these regulatory processes, they can guarantee that quality principles and compliance serve as the fundamental pillars for advancing medical research.

For drug development companies eyeing new markets, comprehending regulatory differences regarding Quality and Compliance is of outmost importance. The journey entails not only understanding the requirements and differences on paper but also grasping the practical aspects and experiences in the field. The NDA team of experts offers valuable insights into this critical endeavour.

“The main distinctions lie between the terminologies used in the US versus Europe, as well as some varying requirements that companies need to be aware of. One notable difference is the presence of a key role in European drug manufacturing sites known as the “Qualified Person,” a position that has no equivalent in the US. In Europe, every manufacturing site is obliged to appoint a Qualified Person, responsible for upholding the quality of medicines and serving as the primary point of contact for regulatory bodies concerning compliance inquiries,” Helen Kargaryani explains.

Helen, who has experience in both markets, adds that in the US it is the Head of Quality who sometimes acts as the Qualified Person, depending on the product. Therefore, the company needs to have profound knowledge of the requirements and standards to be able to

make the right decisions. "Overall, the basic Quality principles and requirement are the same", Helen says. "There is a GMP [Good Manufacturing Practices, authors remark] in the US that covers everything; QMS, validation, manufacturing, warehousing, calibration and so on, but the main difference between the US and the European GMP guidelines is how it's interpreted. By that, I mean how strict the guidelines are implemented" she continues.

For example, regarding validation requirements, Annex 15 of the European regulations specifies that companies must conduct validation with a minimum of 3 batches. In contrast, U.S. regulations do not mandate a set number of batches for validation. US regulations, on the other hand, mandate that companies add all key performance indicators (KPIs) measurements to a designated portal. This portal then determines whether a regulatory inspection is necessary. Meanwhile, European regulations specify that firms should follow KPI measurements to ensure monitoring and oversight of quality management systems, manufacturing processes, and quality control procedures.

Experts to Elevate Quality

Quality is not just a set of standards; it's a system that must be woven into a company's identity from drug development to market readiness. Navigating complex regulations and distinctions can be daunting. In those situations, a reliable third party like the NDA Quality team becomes invaluable.

Our experts bring years of experience to the table. We observe, describe, and implement customized QMS and quality practices effectively. We can train your team, introduce new practices, and ensure compliance. Our senior quality experts can even lead projects or your entire quality function. Contact us today to discover how we can be your trusted partner in navigating the complex requirements and procedures in different markets, meeting the quality and compliance standards.



We bring men, women and children, all over the world, the best possible medicines without unnecessary delay

Contact us to learn how our experts can support you and your approval