

Quality – Compliance

Your Objectives:

At the end of the lesson, you will come to know how vital it is to preclude noncompliance.

Just what is meant by ‘regulatory compliance’?

Meeting regulatory requirements is a prime requirement for all associated with all such regulated industries.

Healthcare compliance is the process of following rules, regulations and laws which relate to healthcare practices. Compliance in healthcare can cover a wide range of practices and rules observed both internally and externally.

These regulators lay down regulations to ensure that manufacturers produce quality products. So, it goes without saying, complying with regulators is important for businesses across all sectors. However, compliance is arguably even more crucial within the pharmaceutical, medical-devices and healthcare sectors. Here is why:

A chief benefit of strict compliance to regulatory requirements lies in the fact that organizations in healthcare-, pharmaceutical- and medical-device industries will want to identify, mitigate and ultimately eliminate risks at all stages. Risk elimination is at the core of regulatory compliance and must thereby be built into the core of all processes.

Regulatory agencies clearly spell out those guidelines, not least as a ready reference for organizations that manufacture any kind of product, but which serve to identify and mitigate all risk factors involved. And, in so doing, they also encourage risk elimination—this industry’s principal aim.

Equally important is that once a product meets regulatory compliance requirements, it is bound to win the trust of all concerned, namely its customers, stakeholders, investors, not to mention employees. Only once a pharmaceutical, medical device or healthcare company has won the trust of all abovementioned players can it be truly valued.

Furthermore, vigilant compliance with regulatory requirements also means assuring a product’s efficiency and efficacy at the highest, as well as being a safeguard against any possible infringements. Which brings us to the next, often overlooked, benefit of compliance. Vigilant compliance inevitably invites cost-saving. In the event a company fails to meet regulatory requirements, at any stage of the lifecycle of the product, high costs associated with ensuring compliance override, therefore, the cost of noncompliance (many times over). If an organization faces a breach of compliance at a given point, it is, basically, practically impossible to stop in one’s

tracks, as the costs of doing so would be astronomical. It is, therefore, not an option to drop everything and simply start afresh, because it renders void and useless all that is done up to a particular stage—a Catch-22 situation, generally speaking.

Simply put, products which **fail** regulatory tests will not pass regulatory approval. If they should have to fulfil the penalty requirements of the FDA or other regulatory agencies, the costs go through the roof. Meeting regulatory compliance requirements at every stage is the safest and most economical option within the pharmaceutical, healthcare and **medical**-devices industries.

These three industries obviously have much in common, but most importantly is that together they play a critical role in ensuring health and **wellbeing** of people. It is unthinkable how pharmaceutical, medical devices and healthcare can be seen to serve any purpose other than this.

It needs to be understood, within the three industries, that there is ultimately no other means of ensuring the wellbeing and health of people than through complete regulatory compliance. Regulatory compliance is essential and **indispensable** for making sure that the devices, **processes** and end-products in these industries meet top-quality standards, as that is the sole means by which human wellbeing is ensured.

In sum, meeting regulatory compliance requirements are to be followed without exception by pharmaceutical, medical-devices, and healthcare companies such as ours.

Adapted from:

<https://www.gcplearning.com/blog/why-regulatory-compliance-requirements-importance>