

5 things a realistic and functional quality system should have

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No matter what purposes or what line of business your Quality is universal and we all have it for the same reason, to accomplish a better profit. We need to keep in mind 5 basic but in some business complex things in mind while we build the quality system that fulfill our needs. The five points I think are basic for any business, I will discuss 2 cases per every point, I'll cover one for drugs (including large and small molecules) and one for medical device. Study cases of how the institution fails to deliver that particular basic step from my professional perspective.

- I. The identity and functions of this particular product.
- II. The Consumer/Costumer/Patient needs with the product in perspective
- III. Identify the parameters acceptable and unacceptable of this product and the reasons for them.
- IV. Research to adopt realistic manufacturing agreements.
- V. Keeping a healthy a robust CAPA system.

I think is also very important that we learn how to communicate with the management level of our organization in order for them to start seeing Regulatory/Compliance and Quality as a tool and not as an imposition of the Regulatory agencies. We are regulated by the agreements we made with our regulatory agency, so at the end of the day we deviate from our own manufacturing routes and specifications. We must be very careful with what we agree to do and how.

Biography

Rosario Quintero-Vives has completed his BS in Biology with a minor in Chemistry has 8 years of experience in different areas of the pharmaceutical, biopharmaceuticals and medical devices industries. Including but not limited to Quality and Regulatory areas of manufacturing, he also is the author of the Interphex presentation: *7 things you should do before you face an inspection*

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