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You're the CEO: Can You Justify the Costs of These QbD Projects?

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There are many of us who would like to see manufacturing technologies advance so that we can produce quality product. We no longer want to have to "fix" product quality based on after-the-fact analysis. Many of us may be frustrated by what we perceive to be lack of management support for these efforts.
So, let's turn the tables. Pretend that you are the CEO, or senior executive of a pharma company.
Here are two hypothetical cases where someone like us (an advocate for PAT and QbD) wants to use modern science-based approaches for development and manufacturing.

Given the facts and assumptions required (detailed below), what would you tell them? What would be your justification to spend the money, and why? Or why wouldn't you go ahead with funding for the project? Please share your reasons.

Below are the details of the case.

There are two "blockbuster" drugs, A and B, each with annual sales of about $1 billion. These sales figures are based on average wholesale price, but not on factory costs of API and formulated tablets. There are still about seven years left in each of the patents involved.

Assume that it would be possible to have a process that will eliminate all of the intermediate sampling requirements, and produce a quality product all the time (i.e. it would be called a "quality by design" process).

Assume that this process will also lower the cost of API and formulation cost, at before tax levels, or by 10 to 35 % (i.e. profits will improve.)

The installed cost of the equipment required to achieve this gain will range between $100,000.00 to $200,000.00 for each API and formulation.

Engineering costs associated for improvements would be included in the factory costs. Also assume that it will take usual amount of time to go through the necessary regulatory approval for the process change, and that the costs are unknown.

Drug A

The annual API requirement for Drug A is about 500 pounds.
The selling price of the API includes 50% profit for the API manufacturer and is about $25.00 per pound. The bulk selling price of the formulated API in tablets, after provision for 50% profit, is about $250.00 per pound. The average wholesale price is much higher than the bulk tablet price.

Drug B

The annual API requirement for Drug B is about 50,000 pounds. The selling price of the API includes 50% profit for the API producer and is about $15.00 per pound. The bulk selling price of the formulated API in tablets after the 50% profit is about $150.00 per pound. The average wholesale price is much higher than the bulk tablet price.

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