

ROLE-PLAY EXERCISE

QRS AsthmaCare Products, Inc.

PROCESS

1. Make copies of the role-play exercise pages (one copy of background page for each student in the class; one set of four roles for every four students in the class).
2. Develop teams of four students (there are seven unique roles in ABIG Company).
3. Have each student read the QRS AsthmaCare Products background page as an introduction to the exercise.
4. Assign each student a role to play and give him or her the specific role description to review.
5. Indicate the desired outcome of the process (for example, press conference, written and/or oral presentation, short-term plan, long-term plan, employee meeting, etc.).
6. Allow the teams to proceed without interruption for at least forty-five minutes, depending on the outcome specified above.
7. Create feedback mechanisms appropriate for the desired outcome.
8. Link exercise issues, processes, outcomes, and experiences to course training and learning objectives.

Key Issues

1. Product misrepresentation
2. Product safety

QRS AsthmaCare Products, Inc. Background

(Everyone reads.)

QRS AsthmaCare Products, Inc. is a medical manufacturer established in January 2013. It is dedicated to delivering low-cost, accurate medical products to the global homecare market. QRS is headquartered in Boulder, CO, and has research and development facilities in Hong Kong and leases manufacturing space in Southern China.

The first product line developed by QRS was the AsthmaPeak (AP) electronic peak flow meters. The AP's were designed as two models, the AshtmaPeak and the AsthmaPeak+, and were intended for over-the-counter sales. Peak flow meters measure the rate of flow of air blown through them. The user places the mouthpiece into his or her mouth and blows out as hard as he or she can. The meter then uses these measurements to derive maximum ventilator flow rate, typically expressed as either:

- peak expiratory flow (highest rate of flow attained during a blow), or
- one-second forced expiratory volume (volume of air exhaled within first second of blow)

Since the AsthmaPeaks are medical devices, submission for product release to the FDA for pre-market product approval is required. This entails the submission of an extensive file (called a 510K document, submitted by the director of quality assurance) that includes product description, materials used, and proof of product safety. If the product is intended to be placed in humans' mouths, then proof of human safety testing of the product material is necessary.

QRS identified a plastic developed by 5-M called RS171 to be used in the molding of the mouthpieces for the AsthmaPeak. This plastic was selected because it could be molded clear as well as in many different colors. 5-M provided a document certifying that RS171 was approved by the FDA as "safe for human use." However, once QRS submitted the 510K, the FDA notified QRS that the RS171 material was not approved for human use. Upon contacting 5-M, QRS was told that RS171 has an almost identical molecular structure to RS170, and that because the molecular structure was so close, RS171 should pass human safety testing just as RS170 had. However, when QRS pressed 5-M further, the company admitted that it had not run any human tests using the new material.

QRS was six months behind in product release. They had an agreement with the manufacturing facility in southern China to produce 10,000 units each month starting six months earlier. The Director of Sales and Marketing had three potential multi-million dollar orders waiting for FDA approval, and cash flow within the company was running low. The FDA approval was necessary to sell the AsthmaPeak in the United States, which is the largest market for peak flow meters. The management team made the decision to state to the FDA that it would switch the plastic to

the approved RS170 material and would mold the mouthpieces in this material. The FDA accepted the modification and gave pre-market approval for the AsthmaPeak products.

However, the RS170 material cannot be molded in different colors. Additionally, the director of manufacturing discovered that it would be much more expensive to make this product in China as there was not a readily available supply anywhere in the area. So he, the CEO, and the Director of Marketing made the decision to mold the mouthpiece in the originally identified RS171 material with the intention of running their own human safety testing, and retrospectively, provide the documentation to the FDA.

After being on the market for approximately two months, QRS was called at least 10 times with customers having allergic reactions and breaking out in blisters in and around their mouths. The CEO called an emergency meeting with the Director of Sales and Marketing, the Director of Manufacturing, and the Director of Quality Assurance to develop a comprehensive action plan.

Robert Matson, CEO

You are the founder and CEO of QRS. You are a 34-year-old entrepreneurial spirit who was extremely successful at raising venture capital for your start-up company. A long-time sufferer of asthma, you fervently believe that your product will be a valuable addition to combating this disorder. As such, you are highly passionate about the product and believe the different colors will appeal to a variety of people.

However, since inception, QRS has failed to meet revenue or earnings expectations. The investors' attitudes have shifted from excited to optimistic to skeptical to angry. You have an entire career ahead and the last thing you want to happen is to be a failure with your first business venture.

Pressure has been coming from the investors, asking when they will see a return on their investment. You know the current business plan does not project the profits for two more years and cash flow is tight. You know that RS171 could provide the financial injection QRS needs. You have tried the product yourself and had no reaction, so you assume that it is safe for the majority of people. You believe the FDA does not know what it is talking about. After all, it has approved plenty of drugs for the market that later turned out to be recalled due to side effects or health dangers. Conversely, there are no known side effects of RS170, and you have received assurances from the supplier that RS171 is practically the same thing with just a small change in the molecular structure.

Early sales reports of the RS171 AsthmaPeaks show great promise. Now with reports of allergic reactions, investors, the FDA, and the media want answers. You call an emergency meeting with your direct reports to determine a course of action. You wonder if there is anything you can do to protect yourself should the company get in trouble for misrepresenting a product to the FDA.

Della Antista, Director of Quality Assurance

You are the Director of Quality Assurance for QRS. You have a Bachelor's degree in mechanical engineering and a Master's degree in quality assurance. You have 15 years of experience in the medical manufacturing industry and have been involved in many successful pre-market product approval processes through the FDA. Your responsibilities at QRS include assurance that QRS is compliant with all national and international quality standards, maintaining quality control over all products, preparing and maintaining all FDA forms, product label documentation, and approval notification. You are also responsible for reviewing and preparing all Engineering Change Orders, planning and implementing internal quality audits, and creating all audit reports. Additionally, you initiate, supervise, and complete all corrective and preventative actions.

You were not aware until today of the decision made by the CEO, the Director of Sales and Marketing, and the Director of Manufacturing to continue molding the material with the RS171 material. The CEO just stopped by and told you the whole story. You are very concerned for many reasons, one of which is that you signed all the quality documents submitted to the FDA stating which material was being used. It also was your responsibility to initiate the human safety testing process, which you did, but could not get into a test lab for two months. The testing has been scheduled, but no action has been taken to complete the process.

Dylan Meade, Director of Sales and Marketing

You have been very anxious to release the AsthmaPeak medical devices. You had been hired to market and sell this particular product. Your team had sold three multimillion-dollar orders to asthma hospitals around the country and were anticipating very hefty commissions. In fact, you had already planned a trip to Hawaii for you and your team for a product launch party.

The management team had met several times, and you were always asking why the product was taking so long to release. Though told several times about the fact that the plastic that was needed for the devices needed FDA approval as well as human testing, you wanted to roll out the product. The plastic would probably pass testing because the supplier assured you that the molecular structure was so close they were almost identical. But you thought it was ridiculous to wait, which is what the Quality Assurance Manager would most certainly have done. You feel like the product only needs to be delivered to be a blockbuster. With much persuasion, you have managed to convince the company CEO to give approval to launch the product. You are aware that the FDA was told the plastic was changed to the approved RS170 material, but you figure this small deception won't hurt anyone once the newer RS171 material is proven safe for human use.

After two months of being on the market, there have been at least 10 complaints from customers that they have had allergic reactions in conjunction with their use of the AsthmaPeak medical devices. The CEO has called an emergency meeting—you are concerned because you were the one who had convinced the others to release the product. Maybe there should have been more testing done before its release.

Shams Siddiqui, Director of Manufacturing

You are the Director of Manufacturing of QRS. You are a 37-year-old industrious spirit who has had a broad range of experience in manufacturing over the past 18 years. You started out in the aerospace manufacturing industry. You are a numbers person looking at technical information specializing in custom-made products.

You are excited about the different color clear molds for the AsthmaPeak Meter and have spent weeks enhancing the manufacture of this product. A few months ago you were made aware that the plastic, RS171, that you thought would be used on this product was not approved by the FDA or human tested. You also found out that the plastic product RS170 that had been approved is not easily available in southern China where there is an agreement pending to produce 10,000 units. Though the plastic RS171 has not been approved for human use, it has the same basic molecular structure as RS170. There was a big push to get the product launched, so you agreed to launch the product without the final testing.

You knew that the development of the AsthmaPeak devices could put you on the map as a Director of Manufacturing in the medical manufacturing field. A meeting has been called by the CEO because there has been a series of complaints from consumers breaking out in blisters and having allergic reactions.