

Chapter Scenario, Part I:

Roberta Matthews, the 33-year-old project manager for the pacemakers produced by her global biotech firm, had spent the last three weeks painstakingly checking every step in the manufacturing process in the South Florida plant after receiving the disturbing news that the pacemakers were estimated to fail 2% of the time. “This is completely unacceptable,” she thought. “Pacemakers failing 2% of the time may not sound like much—especially when many of them function more as heartbeat monitors rather than regulators—but anything more than zero defect is unacceptable. Especially if the pacemaker is monitoring and ensuring the proper function of your loved one’s heart!”

She presented her findings to upper management, and explained how there was no evidence suggesting that the defect was being caused in the South Florida plant. Instead, she explained that the problem

must be coming from the partially assembled pacemakers they received from the Dutch firm with whom her firm contracted. (Assembly was completed and the product tested in the South Florida plant.) She requested and was given approval to visit the Dutch plant to help find and fix whatever was causing the pacemakers to fail.

When Roberta arrived, sharply dressed in a well-fitting suit and standing beside Carlos, the lead engineer who reported to her, Dennis van der Reis, VP of Operations in the Netherlands, looked her up and down and said, “OK, so you’re the secretary. Is he (looking at Carlos) the project manager?” Roberta, with a master’s degree in biomedical engineering, two patents to her credit, and a successful track record as both engineer and manager, was floored. She could barely speak. . . .