Rapamycin-coated Stents for Johnson & Johnson
(recommended by Scott L. Diamond, U. Penn)

In the treatment of heart disease, a common procedure involves balloon angioplasty to expand a narrowed coronary artery followed by placement of a metal support called a stent to keep the vessel open. Stenting helps reduce vessel closure, a process called restenosis. However, even stented vessels can undergo restenosis. There were 926,000 angioplasties in the U.S. in 1998 and 800,000 angioplasties outside the U.S. in 1999. Johnson & Johnson recently finished a clinical trial with polymer-coated stents that slowly release the drug rapamycin. In 238 patients in Europe, not a single patient had restenosis after 6 months with the rapamycin-coated stents. Johnson & Johnson is positioned to obtain over 50% market share in the highly competitive stent market.
Production Criteria

1) Produce and purify medical grade Sirolimus (rapamycin) via batch bioprocessing using streptomyces fermentation. Determine how much rapamycin you must produce annually and how many batches will be necessary.

2) You will be provided with the metal stents from the Stent Manufacturing Group. You will carry out the drug-polymer coating of the stents and deliver the drug-polymer coated stents to the Catheter Manufacturing Group on a monthly basis.

3) You will buy pure medical-grade speciality chemical components for the polymer coating, but must develop the coating technology to achieve the correct drug loading and release characteristics needed in the clinical application. You will have to design a spray-coating process using ultrasonic nozzles as well as a drying process to remove the solvent. Solvent recovery is also required. Degradable polymers will include \( \text{-caprolactone-co-glycolic acid.} \)

4) Manufacture: 500,000 drug-polymer coated stents in year 1

1,500,000 drug-polymer coated stents in year 2 and after.

5) Estimate the capital cost and annual operating cost of the drug manufacture and coating systems.

References:

www.uspto.gov patent 6,153,252
patent 6,273,913


