**1.** A patient comes to see a physician (YOU) for recent onset mid epigastric pain that is burning and very severe. The pain was first noticed when the patient was at the gym exercising on the treadmill. The patient became queasy and started vomiting. The patient shows up in your office and seeks relief. Describe the PROCESS that you would go through in evaluating the patient as well as what would you would do to determine what was wrong with this patient. Go through the process telling me what you would do from start to finish. Tell me all the results as you proceed as well as well as your thought processes on how you would proceed after each step. Be as DETAILED as possible describing your theoretical patient. Give me the patient’s history, a list of all possible things that could be wrong with this patient (the differential diagnosis) and how you would distinguish which of the possible diseases the patient had? Give specific test results as you proceed and how you would proceed based on the result.

Option 2. Instead of epigastric pain, you have the option of having your patient have severe shortness of breath as his symptom that was sudden in onset and feels like someone is sitting on his/her chest. Suggested length 3-4 pages. (20 points)

**2.** Watch one orthopedic surgery procedure and one cardiac surgery procedure video on <https://www.broadcastmed.com/orlive> and for each one, write a two – three page description of the disease being treated, the surgical procedure performed and any unique biomedical devices utilized during the procedure. (2-3 pages for each video) (20 pts.)

**3**. Write a 3-4page paper on everything you learned about the FDA by watching the videos on the FDA website on the FDA’s responsibilities. You can tailor your report to any aspect of FDA responsibility that interests you. See links to FDA webinars and presentations below. Find your own if you prefer. (20 pts)

**4.** Watch the video on Medical Imaging posted on the website and write a summary of the different technologies mentioned. (2–3 pages) (20 pts.)

**5.** Find a recently recalled medical device that has been pulled from the market and report on why the device was recalled, what adverse events were caused, the root cause for the adverse event and how the company responded when they found about the defect. Report on whether you think the company and the FDA handled this event appropriately. Include in your report significant documents that the FDA sent the company and the company’s responses. Suggested length 2-3 pages. (20 pts.)

Links to various FDA presentations for Question 3 from FDA website. You don’t have to use these and you may pick your own since there are many on the FDA website:

<https://collaboration.fda.gov/p6gw0o22gf4/?launcher=false&fcsContent=true&pbMode=normal>

<http://www.fda.gov/AboutFDA/WhatWeDo/ucm407684.htm#organization>

**Past Webinars**

[**https://www.youtube.com/watch?v=9jxM9980bSc**](https://www.youtube.com/watch?v=9jxM9980bSc)

**http://login.icohere.com/connect/d\_connect\_itemframer.cfm?vsDTTitle=FDA%20101%20%26%20How%20to%20Obtain%20Agency%20Resources&dseq=21289&dtseq=97734&emdisc=2&mkey=public1172&vbDTA=0&viNA=0&vsDTA=&PAN=2&bDTC=0&topictype=standard%20default%20linear&vsSH=A**

* [FDA Webinar: Draft Guidance: Use of an Electronic Informed Consent in Clinical Investigations Questions and Answers – April 20, 2015](http://www.fda.gov/Training/GuidanceWebinars/ucm440720.htm)
* [FDA Webinar: Draft Guidance for Industry (GFI) Uncomplicated Gonorrhea: Developing Drugs for Treatment - September 11, 2014](http://www.fda.gov/Training/GuidanceWebinars/ucm412324.htm)
* [FDA Webinar: Guidance for Industry Chronic Fatigue Syndrome/ Myalgic Encephalomyelitis: Developing Drug Products for Treatment - April 23, 2014](http://www.fda.gov/Training/GuidanceWebinars/ucm392577.htm)
* [FDA Webinar: Final GFI: Electronic Source Data In Clinical Investigations (Procedural) - January 29, 2014](http://www.fda.gov/Training/GuidanceWebinars/ucm382198.htm)
* [CDER Small Business Webinar on Stability Guidance for ANDAs, and draft Questions and Answers guidance – considerations – November 4, 2013](http://www.fda.gov/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/ucm372462.htm)
* [FDA Webinar: 60-Day Draft GFI On Antibacterial Therapies For Patients With Unmet Medical Need For The Treatment Of Serious Bacterial Diseases – September 27, 2013](http://www.fda.gov/Training/GuidanceWebinars/ucm369019.htm)
* [FDA Webinar: Draft GFI On Expedited Programs For Serious Conditions Drugs And Biologics - August 5, 2013](http://www.fda.gov/Drugs/ucm362706.htm)
* [FDA Webinar: Webinar Draft GFI on Human Immunodeficiency Virus-1 Infection: Developing Antiretroviral Drugs for Treatment; Availability - July 25, 2013](http://www.fda.gov/Drugs/ucm360922.htm)
* [FDA Webinar: Webinar Draft GFI On Rheumatoid Arthritis - Developing Drug Products For Treatment; Availability – July 25, 2013](http://www.fda.gov/Drugs/ucm360743.htm)
* [FDA Webinar: Draft Guidance For Industry On Alzheimer’s Disease: Developing Drugs For The Treatment Of Early Stage Disease; Availability - March 28, 2013](http://www.fda.gov/Training/GuidanceWebinars/ucm345077.htm)
* [FDA Webinar: Webinar Draft GFI On Enrichment Strategies For Clinical Trials To Support Approval Of Human Drugs And Biological Products – March 25, 2013](http://www.fda.gov/Drugs/ucm343578.htm)
* [FDA Webinar: New Draft Guidance on "FDA Guidance for Industry Webinar on Draft Guidance Vaginal Microbicides: Development for the Prevention of HIV Infection" - January 22, 2013](http://www.fda.gov/Drugs/ucm335030.htm)
* [FDA Webinar: 60-Day Draft Guidance on Using an Endpoint to Support Accelerated Approval of Drugs to Treat Early-Stage Breast Cancer - June 28, 2012](http://www.fda.gov/Drugs/ucm309182.htm)
* [FDA Webinar: New Draft Guidance on Safety Data Collection - March 27, 2012](http://www.fda.gov/Drugs/ucm296761.htm)
* [Guidance Webinar: Oversight of Clinical Investigations--A Risk-Based Approach to Monitoring - October 24, 2011](http://www.fda.gov/Training/GuidanceWebinars/ucm277044.htm)
* [DDI Webinar- “Introduction to FDA’s MedWatch Adverse Reporting Program”- February 9, 2016](http://www.fda.gov/AboutFDA/WorkingatFDA/FellowshipInternshipGraduateFacultyPrograms/PharmacyStudentExperientialProgramCDER/ucm468661.htm)
Sponsored by Division of Drug Information (DDI)
* [CDER Small Business and Industry Assistance (CDER SBIA) Webinar - New Requirement for Electronic Submission of Drug Master Files (DMFs): What You Need to Know - February 4, 2016](http://www.fda.gov/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/ucm481089.htm)
Sponsored by Small Business and Industry Assistance (SBIA)
* [FDA Webinar - FDA’s Overview of the Regulatory Guidance for the Development and Approval of Biosimilar Products in the US](http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/ucm428730.htm)
Sponsored by Office of New Drugs (OND)
* [DDI Webinar- “Regulation of Nonprescription Drug Products”- December 2, 2014](http://www.fda.gov/AboutFDA/WorkingatFDA/FellowshipInternshipGraduateFacultyPrograms/PharmacyStudentExperientialProgramCDER/ucm421157.htm)
Sponsored by Division of Drug Information (DDI)
* [FDA Basics Webinar - November 24, 2014: Drug Shortages](http://www.fda.gov/AboutFDA/Transparency/Basics/ucm422040.htm)
Sponsored by FDA Basics
* [DDI Webinar - FDA Online Drug Information Resources for Students and Clinicians – October 7, 2014](http://www.fda.gov/AboutFDA/WorkingatFDA/FellowshipInternshipGraduateFacultyPrograms/PharmacyStudentExperientialProgramCDER/ucm411865.htm)
Sponsored by Division of Drug Information (DDI)
* [CDER Small Business and Industry Assistance (CDER SBIA) Webinar on “How to use CDER Direct to submit Registration and Listing Structured Product Labeling (SPL) files” – September 16, 2014](http://www.fda.gov/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/ucm413379.htm)
Sponsored by Small Business and Industry Assistance (SBIA)
* [CDER SBIA Webinar - “Guidance for Industry: ANDA Submissions-Refuse-to-Receive Standards” and “Draft Guidance for Industry: ANDA Submissions-Refuse-to-Receive for Lack of Proper Justification of Impurity Limits.” – September 16, 2014](http://www.fda.gov/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/ucm414458.htm)
Sponsored by Small Business and Industry Assistance (SBIA)
* [FDA Webinar: Draft Guidance for Industry (GFI) Uncomplicated Gonorrhea: Developing Drugs for Treatment - September 11, 2014](http://www.fda.gov/Training/GuidanceWebinars/ucm412324.htm)
Sponsored by Office of Medical Policy
* [CDER Small Business and Industry Assistance (CDER SBIA) Webinar “Draft Guidance for Industry on Controlled Correspondence Related to Generic Drug Development” – August 26, 2014](http://www.fda.gov/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/ucm411456.htm)
Sponsored by Small Business and Industry Assistance (SBIA)
* [CDER Small Business and Industry Assistance (CDER SBIA) Webinar on “Form 356h - Update on Field 29” – July 16, 2014](http://www.fda.gov/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/ucm404339.htm)
Sponsored by Small Business and Industry Assistance (SBIA)
* [CDER Small Business and Industry Assistance (CDER SBIA) Webinar on “Overview of FDA’s Proprietary Name Review Process” - July 15, 2014](http://www.fda.gov/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/ucm403376.htm)
Sponsored by Small Business and Industry Assistance (SBIA)
* [Social Media Guidance Webinar – July 10, 2014](http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm403810.htm)
Sponsored by OPDP
* [CDER Small Business and Industry Assistance (CDER SBIA) Webinar on “An Overview of FDA’s Draft Guidance - Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification.” - July 1, 2014](http://www.fda.gov/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/ucm402366.htm)
Sponsored by Small Business and Industry Assistance (SBIA)
* [FDA Basics Webinar June 30, 2014: Over-The-Counter Medicines and Driving](http://www.fda.gov/AboutFDA/Transparency/Basics/ucm402791.htm)
Sponsored by FDA Basics
* [CDER Small Business and Industry Assistance (CDER SBIA) Webinar on Guidance for Industry: ANDA Submissions – Content and Format of Abbreviated New Drug Applications – June 12, 2014](http://www.fda.gov/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/ucm400805.htm)
Sponsored by Small Business and Industry Assistance (SBIA)
* [CDER Small Business and Industry Assistance (CDER SBIA) Webinar on Postapproval Changes Related to Drug Product Quality, Manufacturing and Controls that may be Documented in Annual Reports, May 12, 2014](http://www.fda.gov/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/ucm396083.htm)
Sponsored by Small Business and Industry Assistance (SBIA)
* [DDI Webinar - Overview of U.S. Drug Shortages - April 29, 2014](http://www.fda.gov/AboutFDA/WorkingatFDA/FellowshipInternshipGraduateFacultyPrograms/PharmacyStudentExperientialProgramCDER/ucm388748.htm)
Sponsored by Division of Drug Information (DDI)
* [CDER Small Business and Industry Assistance (CDER SBIA) Webinar on Fees Associated with Human Drug Compounding By Registered Outsourcing Facilities, April 24, 2014](http://www.fda.gov/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/ucm393786.htm)
Sponsored by Small Business and Industry Assistance (SBIA)
* [DDI Webinar - Safe Use Initiative, Collaborating to Reduce Preventable Harm.– March 24, 2014](http://www.fda.gov/AboutFDA/WorkingatFDA/FellowshipInternshipGraduateFacultyPrograms/PharmacyStudentExperientialProgramCDER/ucm387827.htm)
Sponsored by Division of Drug Information (DDI)
* [CDER Small Business and Industry Assistance (CDER SBIA) Webinar on The Drug Supply Chain Security Act (Title II of the Drug Quality and Security Act): Overview & Implementation - March 12, 2014](http://www.fda.gov/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/ucm388150.htm)
Sponsored by Small Business and Industry Assistance (SBIA)
* [DDI Webinar - Introduction to Post-Marketing Drug Safety Surveillance: Pharmacovigilance in FDA/CDER - February 11, 2014](http://www.fda.gov/AboutFDA/WorkingatFDA/FellowshipInternshipGraduateFacultyPrograms/PharmacyStudentExperientialProgramCDER/ucm368115.htm)
Sponsored by Division of Drug Information (DDI)
* [OPDP Enforcement Actions Webinar – January 30, 2014](http://www.fda.gov/Drugs/ucm364052.htm)
Sponsored by OPDP
* [FDA Webinar: Final GFI: Electronic Source Data In Clinical Investigations (Procedural) - January 29, 2014](http://www.fda.gov/Training/GuidanceWebinars/ucm382198.htm)
Sponsored by Office of Medical Policy
* [DDI Webinar - Introduction to FDA’s MedWatch Adverse Reporting Program - January 14, 2014](http://www.fda.gov/AboutFDA/WorkingatFDA/FellowshipInternshipGraduateFacultyPrograms/PharmacyStudentExperientialProgramCDER/ucm368114.htm)
Sponsored by Division of Drug Information (DDI)
* [CDER Small Business and Industry Assistance (CDER SBIA) Webinar - Draft Guidance for Industry on Safety Assessment for IND Safety Reporting - February 1, 2016](http://www.fda.gov/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/ucm482029.htm)
Sponsored by Small Business and Industry Assistance (SBIA)
* [Color Additives for Medical Devices - February 12, 2016](http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm484421.htm)
[Printable Slides](http://www.fda.gov/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM486081.pdf)
* [Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile Final Guidance - February 11, 2016](http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm482598.htm)
Presentation   [Printable Slides](http://www.fda.gov/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM485832.pdf)   Transcript
* [CDRH Industry Basics Workshop - Unique Device Identification (UDI), January 27, 2016](http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm480237.htm)
   [Full Presentation](http://fda.yorkcast.com/webcast/Play/06c7017ec9bd4ef3973cc7872339633b1d)
   UDI Overview: [Slides](http://www.fda.gov/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM483360.pdf) - [Transcript](http://www.fda.gov/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM484127.pdf)
   GUDID Account: [Slides](http://www.fda.gov/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM483361.pdf) - [Transcript](http://www.fda.gov/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM484128.pdf)
* [Premarket Notification Requirements Concerning Gowns Intended for Use in Health Care Settings - January 21, 2016](http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm481587.htm)
[Presentation](http://www.fda.gov/downloads/Training/CDRHLearn/UCM483805.wmv)   [Printable Slides](http://www.fda.gov/downloads/Training/CDRHLearn/UCM482416.pdf)   [Transcript](http://www.fda.gov/downloads/Training/CDRHLearn/UCM483806.pdf)