Medical Device Approval and Commercialization

55-MINUTE ONLINE COURSE | LEVEL 3 | SUGGESTED PREREQUISITES: MEDICAL DEVICE OVERVIEW AND REGULATION, MEDICAL DEVICE DEVELOPMENT

OVERVIEW

Medical Device Approval and Commercialization explains the medical device approval process from initial regulatory submission through commercialization. Learn the diverse best practices accompanying a successful regulatory outcome, including manufacture scale-up, reimbursement strategy, product launch and post-launch assessment. If you are working in the diagnostics industry, this course gives you a game plan to undertake a successful launch.

Five Takeaways:

1. Choose the appropriate level of clinical trial based on risk assessment to the patient.
2. Explain the process of obtaining approval to initiate human clinical trials to test a new medical device.
3. List the challenges of launching a new medical device in terms of marketing, sales, reimbursement and manufacturing scale-up.
4. Outline a reimbursement strategy for coverage, coding and payment of a medical device.
5. Write a post-launch assessment and surveillance protocol.

AGENDA

- **Clinical Trials for Medical Device** discusses how to choose the appropriate level of clinical trial for a medical device based on that device's risk assessment to the patient.
- **Investigative Device Exemption** explains the process of obtaining approval to initiate human clinical trials, including how to identify a reference device and the importance of testing a new device against the reference device when seeking FDA approval.
- **Regulatory Submission for Medical Device** reviews the time cycle for submission approvals.
- **Business Decisions for Medical Device Launch** helps you think through the challenges of a product launch in terms of marketing, sales, reimbursement, and manufacturing.
- **Manufacturing Scale-Up for Medical Device** highlights the challenges involved in scaling up manufacturing in preparation for product launch and lists the time cycle for manufacturing scale-up.
- **Reimbursement for Medical Device** demonstrates how to outline a reimbursement strategy for coverage, coding and payment.
- **Medical Device Product Launch** lists the various pre-launch preparations and shows how to write a post-launch assessment and surveillance protocol. It concludes with a look at the mandatory medical device reports required by the FDA.