

# Medical Device Development

57-MINUTE ONLINE COURSE | LEVEL 2

SUGGESTED PREREQUISITES: DIAGNOSTICS' ROLE IN MEDICINE TODAY,  
MEDICAL DEVICE OVERVIEW AND REGULATION

## OVERVIEW

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**Medical Device Development** provides a detailed look at the five stages of medical device development including market opportunity evaluation, concept evaluation, engineering design, verification/validation and manufacturing transfer. If you are an engineer, manufacturer, information technologist, investor or someone who finds themselves in development, Medical Device Development will broaden your knowledge of the entire development process.

### Five Takeaways:

1. Understand the importance of the five phases of medical device development.
2. How to evaluate market opportunity.
3. Determine the manufacturing feasibility based on a medical device's design.
4. Learn the required prototype specifications needed in device design, documentation and testing.
5. Appreciate the process of device scale-up production.

## AGENDA

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- **Market Opportunity Evaluation** explains how to evaluate the value and opportunity of the product, the user and the market.
- **Concept Evaluation** determines the feasibility of the medical device's conceptual design and how that blueprint is used to map out the key steps in product design.
- **Engineering Design** discusses how required medical device prototype specifications are designed, documented and tested.
- **Verification and Validation** advocates for a process of verification and validation in engineering builds, packaging, labeling, human factors testing and manufacturing.
- **Manufacturing Transfer** shows the arduous process of how to move from small scale to large scale production.