



*BIOTrain*

# Introduction to Drug Development

## *Overview of the clinical trials process*

Designed with Biotechnology Industry Guidance

- The only two criteria: safe and effective
- The development of drugs, vaccines, devices and diagnostics under FDA review
- Documentation and regulation
- The roles of the sponsor, the clinical trials Manager, the clinical sites, and the regulatory agencies involved

Understand the central process in the Biotechnology business so you can move up in your job or find a place that suits your abilities

### Course Details

**Course Number:** BIT058 CRN 27096  
**Cost:** No Charge  
**Course length:** 12 hrs.  
**Dates:** November 18 and December 2, 2017  
10 am-4 pm  
**Location:** Room BE158 Bioscience Education  
Center, Montgomery College  
20200 Observation Dr  
Germantown, MD 20876

BIOTrain's ***Introduction to Drug Development*** continuing education course delivers instruction on the steps in bringing a drug, vaccine, device or diagnostic to market by proving that they are safe and effective

Upon completion of the course, students will be able to understand:

- Why drug development depends mainly on clinical trials
- The players in clinical trials and what they do
- What clinical trials are designed to prove
- How clinical trials prove safety and efficacy



Course Instructor:

Brad Gillespie, Pharm.D., Strategic Medical Counter Measures Drug and Vaccine Portfolio Leader, Washington & Old Dominion Biologics. Brad has held senior drug development positions at Leidos, Amgen and Pfizer

### To register:

Register on site the day of the first class (space is available)

**or**

Register by emailing a registration form available from [www.biotrain.org](http://www.biotrain.org)

Register in person at Montgomery College WD & CE

51 Mannakee Street, Rockville, MD 20850 or at Germantown, Takoma Park, or Westfield locations. Phone: 240-567-5188

For more information on the BIOTrain Program and other continuing education courses visit [www.biotrain.org](http://www.biotrain.org) or contact Michael Smith, Montgomery College Biotechnology Program Manager: (240) 567-7785 [michael.smith@montgomerycollege.edu](mailto:michael.smith@montgomerycollege.edu)



BIOTrain in partnership with Montgomery College is supported by an EARN grant from the state of Maryland