Regulatory Bootcamp

@ the Mayo Clinic Symposium 2023
April 5, 2023 | 1:30 pm – 5:30 pm

By the end of the 4 hr. course, participants will have a basic understanding of how the FDA reviews and regulates human medical products, including how to engage and navigate interactions with the FDA.

During the Bootcamp participants will learn:

- Learn the products that the FDA is responsible for regulating
- Understand how the product definitions help determine jurisdiction
- Understand how the FDA determines jurisdiction for human medical products
- Understand how to integrate a manufacturing strategy with overall product development
- Learn how to develop and utilize a TPP (Target Product Profile) as a tool to guide your product development activities
- Phase-appropriate implementation of GxP enabling quality systems
- Identify best practices for FDA interactions, including preparation, types of interactions, and analysis for follow-up steps (potentially at the end with remaining time)

Session Name	Start Time	End Time
Check-in Check-in at the ARMI | BioFabUSA table outside the meeting room. *Attendees to identify which products the FDA regulates upon arrival. Check out the screens!*	1:15 PM	1:30 PM
Opening Remarks from Richard McFarland, Ph.D., M.D. Chief Regulatory Officer ARMI | BioFabUSA	1:30 PM	1:35 PM
General FDA Overview of Structure & Authority	1:35 PM	1:55 PM
Review which Products Are Regulated by FDA	1:55 PM	2:00 PM
Overview of FDA Regulatory Pathways Tissue	2:00 PM	2:20 PM
Q&A	2:20 PM	2:25 PM
Overview of Regulatory Pathways	2:25 PM	2:50 PM
Break	2:50 PM	3:00 PM
Attendee Poll	3:00 PM	3:05 PM
TTP	3:05 PM	4:05 PM
Integrating Manufacturing Strategy	4:05 PM	4:30 PM
Break	4:30 PM	4:35 PM
Implementation of GxP Enabling Quality System	4:35 PM	5:00 PM
FDA Interaction Best Practices	5:00 PM	5:25 PM
Wrap Up	5:25 PM	5:30 PM

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Regulatory and Commercialization Resources

Getting a product out of the lab and into the hands of doctors who can transform and even save people's lives is a complex challenge. BioFabConsulting can help you get it all done.

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