



FDA/MEDICAL DEVICE INDUSTRY COALITION, Inc. (FMDIC)
Medical Devices 101 – August 26, 2019
MedtoMarket – Austin, TX

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|---------------|----------------------------|---------------------|
| 7:30 – 8:00 | Registration | |
| 8:00 – 10:00 | Welcome | Beckie Ellis |
| | Introduction to FDA | William Shackelford |
| | It's A Medical Device | John Criscione, PhD |
| | Device Classification | John Criscione, PhD |
| | Establishment Registration | John Criscione, PhD |
| | Device Listing | John Criscione, PhD |
| | Pre-Market Notification | John Criscione, PhD |
| | Questions | Panel |
| 10:00 – 10:15 | BREAK | |
| 10:15 – 11:45 | Premarket Approval | John Criscione, PhD |
| | IDE & HUD | John Criscione, PhD |
| | Labeling | Beckie Ellis |
| | Questions | Panel |
| 11:45 – 12:30 | LUNCH | |
| 12:30 – 1:45 | Quality System Regulations | Beckie Ellis |
| 1:45 – 2:00 | Break | |
| 2:00 – 2:55 | Post Market Surveillance | Beckie Ellis |
| | Device Recalls | Beckie Ellis |
| | Questions | Panel |
| 2:55 – 3:10 | Break | |
| 3:10 – 5:00 | Medical Device Reporting | Beckie Ellis |
| | Special Cases | Beckie Ellis |
| | FDA Inspections | William Shackelford |
| | Questions | Panel |