

FDA/MEDICAL DEVICE INDUSTRY COALITION, Inc. (FMDIC)
Medical Devices 101 – August 13, 2018
Norris Center – San Antonio, TX

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