

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

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