



**LDT Industry Education:
Record Keeping and Adverse Event Reporting:
Medical Device Reporting, Corrections and Removals,
and Quality System Complaint Requirements**

Webinar
October 28, 2024
2-3pm (*eastern*)

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| 2pm | Welcome & Introduction
Susan C. Winckler, RPh, Esq., Reagan-Udall Foundation for the FDA |
| 2:03pm | Background
Alberto Gutierrez, PhD, NDA Partners |
| 2:07pm | Medical Device Reporting, Corrections and Removals, and Quality System Complaint Requirements
Donna Hartzfeld, PhD, NDA Partners
Bobbi Druyor-Sanchez, MS, NDA Partners |
| 2:24pm | Case Studies
Julie Ballard, NDA Partners |
| 2:40pm | Question and Answer |