

15

Practical Rules for Cost-Effective FDA Quality Systems

SOPs

- Flowchart a process before you wordsmith its SOP
- Target a reading level of 11th - 14th grade; people skim
- Have 3 or less approval signatures for any SOP or form

Training

- PowerPoint® slides do not training make
- Test for comprehension—not attendance
- Train everyone on your overall quality policy

CAPAs

- More training is rarely the solution
- Write action plans as checklists to simplify verification
- Verify any resolution(s) within 90 days or less

Audits

- Everyone makes a mistake or two; three opens a CAPA
- Ask 10 “why” questions on a subject to find the reason
- Get an independent audit every two years

Risk

- Three risk categories are good enough for the FDA
- Risk control ≠ risk elimination
- The longer you wait to control the risk, the more it costs

for more lean compliance advice that works

Cerulean Associates LLC • www.CeruleanLLC.com