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