

The author, Dr. Ludwig Huber, is an international expert on laboratory validation and compliance. Responsible for compliance programs at Hewlett Packard and Agilent Technologies, he has served as a consultant for the industry and regulatory agencies for more than fifteen years.

You will find that he answers tough questions like:

- What is an inspection and when will the FDA inspect what?
- How do I get prepared for an FDA inspection?
- What areas does the FDA target during an inspection?
- How do I prepare my staff for the inspection?
- When the inspector arrives, what should/must we answer and at what level of detail?
- What can we do during an inspection if the inspector identifies non-compliance?
- What are the most frequently cited deviations?
- What mistakes have others made and how can I avoid them?
- What is the meaning and difference between laws, regulations, and FDA guidance documents?
- Which actions and programs should be part of the routine operations for FDA compliance?
- What is FDA's approach for risk-based inspections?
- What are FDA's actions in case of non-compliance: 483s, EIRs, Warning Letters, import alerts, product recalls, seizures, consent decrees, and debarment?

Dr. Huber has been a member of the U.S. PDA Task Force on 21 CFR Part 11 and on the GAMP Special Interest Group for Laboratory Equipment. He is also on the advisory board for the European Compliance Academy and is a member of the IVT Task Force on network qualifications.

He is the author of several best-selling industry books and numerous times has been ranked as the featured presenter at various international conferences on validation and 21 CFR Part 11.