BACWA
TNI Training Workshop

Presented by
Kathryn and John Gumpper
ChemVal Consulting, Inc.

Who Are we?

- Both Started in Environmental Chemistry in 1985
- Kathryn did bench chemistry, quality assurance and project management before moving to clinical chemistry and DNA-sequencing bench chemistry and operations management

Who are we?

- John did bench chemistry and moved into operations management in Environmental and OTC Pharmaceutical laboratories
- Broad range of experience and “ways of doing things”

ChemVal Consulting, Inc

- Formed in 1997 as part-time venture
- John Full-time in 1998
- Kathryn Full-time in 2006

ChemVal, continued

- NELAC started in earnest in 2000
  - Need for people who understood self-inspection quality systems
  - Took on quality consulting and quality manager roles
  - Training
  - Data Validation projects
  - Third-party Internal Auditing

ChemVal, Continued

- Began performing assessments for Internationally-Recognized Accreditation Body
  - Environmental Laboratories
  - Industrial Laboratories
  - Food and Pharmaceutical Laboratories
  - Proficiency Testing Providers
  - Reference Material Producers

ChemVal, Continued

- Kathryn also assesses Medical Laboratories
- John also assesses Product Certification Bodies and Inspection Bodies

Environmental Lab Projects

- Quality Manager roles
  - One-person labs
  - Multi-person labs
  - Large labs
- Quality Consulting-Internal Auditing
- “Laboratory Salvage”
- Training

Standards Writing

- Both have contributed to the NELAC/TNI Standards
- Both have worked on related writing projects.

Two Keys to Success

- Know the Standard
- Know the Methods

Reading the Standard

- You will need to read the standard many more times than once!
- Think about why someone put that requirement into a laboratory Standard

Reading the Standard

- Highlight all words that say
  - Policy
  - Procedure
  - Program
- Policies must be described in your Quality Manual
- Procedures and programs will require written instruction in controlled documents

Reading the Standard

- Highlight in a different color
  - All places that require records
  - Use “Document” as a verb
  - Implied action
    - Example: V1M2, 4.11.2: Cause Analysis - The procedure for corrective action shall start with an investigation to determine the root cause(s) of the problem.

Reading the Standard

- Required Actions will require a system for keeping records of those actions
- Work to design records as consistently as possible
  - Have blanks for all ticky details
- Records may be paper or electronic

Reading the Standard

- Keep track of things you don't think apply to you
  - In your written management system (quality manual), say why they don't apply
  - Example: V1M2, 4.6: Subcontracting
  - NOTE: V1M2, 4.4 "Review of Requests, Tenders and Contracts" ALWAYS applies

Reading the Standard

- As you're reading, note things you already have in place
- Tweak, when possible, rather than rewrite
- Note: Under current CA Accreditation Requirements, Labs should have a Quality Manual and SOPs already, though not necessarily TNI compliant

Reading the Standard

- As you build your system, keep track of where each clause is addressed in your system.
  - Your Assessors will care about this!
  - This will help you in explaining and defending your system to outside assessors
  - This will help you during Internal Audits

Reading the Standard

- How to tell if you're doing enough reading:
- In 1-2 years, at least one person in the organization should know the standard well enough to say, "Oh, Corrective Action? That's in V1M2 4.11."

Running the Methods

- As Assessors, we often hear “We don’t need all this quality stuff! We just run the methods!”
  - Most of the laboratories who say that don’t actually run the methods as written and they don’t know it.
  - Why?

Running the Methods

- First, know which method you're running
  - Is it approved in regulation? (Method Update Rules for drinking water, wastewater)
  - Is it on the CA FOTs?
  - Will it meet your customer's needs?

Running the Methods

- Second, check your SOP against the Standard
  - Standard format for technical SOPs to include all points required by the Standard (V1M2 4.2.8.5)
  - There are many options for formatting

Running the Methods

- Third, check your SOP against the published method
  - All steps must be included
  - Modifications, if allowed, must be validated
  - Don’t assume the requirement doesn’t apply to your lab
  - “Method-Defined Parameters”
  - Where are the QC Requirements?

Running the Methods

- Fourth, Check you SOP against the analyst's practice
  - Watch the performance
  - Verify the record-keeping
  - Verify the traceability

Summation

- It’s Worth It!!

Thank You!!

- ChemVal Consulting, Inc.
- Kathryn and John Gumpper
- kgumpper@chemval.com
- jgumpper@chemval.com
- www.chemval.com
- Phone: 231-723-4043