

Tacitus

**“Reason and judgment are the qualities of a leader. ”**

Charlie Gragg

CEO

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# Compliance to the Letter or to the Intent?

# Agenda

- What Compliance is
- Is Compliance working
- How does your organization view Compliance
- Compliance degree examples
- Moving from “Letter” to “Intent”
- Thoughts and Questions

# What is Compliance?

# Compliance Definition (Wikipedia)

- Conforming to a specification or policy, standard or law that has been clearly defined.
- Describing the goal that corporations aspire to in their efforts to ensure that personnel are aware of and take steps to comply with relevant laws and regulations.

# Compliance Definition (Layman)

- Having policies in place to meet regulatory requirements
- Having documented procedures describing how to work within those policies
- Following the documented procedures that are in place
- Documenting that we followed the procedures

# Compliance is the

- Basic (Minimum) level of activity
- Starting point for Customer Satisfaction
- Basic Framework for Business Success

**Is Compliance Working?**



# Total Product Life Cycle: Infusion Pumps— Premarket Notification

- 56,000 reports of adverse events related to infusion pumps between January 1, 2005, and December 31, 2009
- Many of the pump problems appeared to be linked to faulty design such as:
  - Software error messages
  - Human factors
  - Broken components
  - Battery failure

# Is Compliance Enough?

- If you follow all traffic laws you will never have an accident
- If you meet all college graduation requirements you will be successful
- If code passes Unit Testing, it will work
- If you successfully complete V&V, you will never have a product complaint

# Your Organization and Compliance

# Compliance

## Does Your Organization?

- Follow it
- Utilize it for improvement
- Embrace or Minimize it
- Rationalize Doing or Not Doing it
- Advocate it is needed or too time consuming
- Take the Quickest Path to Satisfy or Gain Value

# Degree of Compliance

## Examples

# Compliance Experience With

- 21 CFR §820.20 Management Responsibility
  - Management Review
- 21 CFR §820 .25 Personnel
  - Training

# Management Review

## 21 CFR §820.20(3(c))

- Management with executive responsibility shall review the suitability and effectiveness of the quality system at defined intervals and with sufficient frequency according to established procedures to ensure that the quality system satisfies the requirements of this part and the manufacturer's established quality policy and objectives. The dates and results of the quality reviews shall be documented.

# Management Review

Activity	Letter	Intent
Review of effectiveness at defined intervals	Yes	Yes
Satisfies requirements of Compliance	Yes	Yes
Results documented and dated	Yes	Yes
Follow-up of action items documented	Unknown	Yes
Defined relevant agenda	Unknown	Yes
Agenda pre-distributed	Unknown	Yes
Defined and appropriate attendees	Unknown	Yes
Documented feedback and follow-up	Unknown	Yes



# Training

## 21 CFR §820.25(b)

- Each manufacture shall establish procedures for identifying training needs and ensure that all personnel are trained to adequately perform their assigned responsibilities.
- Training shall be documented.
- Personnel shall be made aware of device defects which may occur from the improper performance of their specific jobs.
- Personnel who perform verification and validation activities shall be made aware of defects and errors that may be encountered as part of their job functions.

# Training

Activity	Letter	Intent
Aligned to job function	Yes	Yes
Documented	Yes	Yes
Knowledge of process risks & defects	Yes	Yes
Level of employee understanding	Unknown	High
Updated as necessary	Unknown	Yes
Employees tested for comprehension	Unknown	Yes
Duties restricted if non-compliant	Unknown	Yes
Certification required upon compliance	Unknown	Yes

Letter or Intent?

# Your Organization's Audit Preparation

# Your Examples - Good and not so Good

- To the Letter
- To the Intent

# Letter or Intent?

Activity	Letter	Intent
Reserve audit room	Yes	Yes
Setup back office	Yes	Yes
Verify and circulate SME list	Yes	Yes
Update audit procedure as necessary	Unknown	No
Complete outstanding M/R action items	Unknown	No
Review and update CAPA's as necessary	Unknown	No
Review and update training as necessary	Unknown	No
Check and update procedure references	Unknown	No
Review and update DHF documents	Unknown	No
Facility readiness walk through	Unknown	No

# Moving from the Letter to the Intent

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- Culture Change from “Me to We”
- Shared Quality Goals
- Ownership and Support
  - Senior Management
  - Cross-Functional
  - Local
- Available Resources
- Effective Training
- Realistic Development Cycles
- Procedures are Living and Progress Focused

Thoughts or Questions?