

# WHO WE ARE ...



Assist organizations and partners to develop and implement practices to secure IT systems and comply with regulations



## DIY TOOLKIT

DIY assessment, training, customized policies & procedures and much more ...



## CONSULTING

Professional services to help you with your Compliance needs



## MANAGED SERVICES

Managed compliance and security services to focus on your key business outcome.

# DISCLAIMER

Consult your attorney

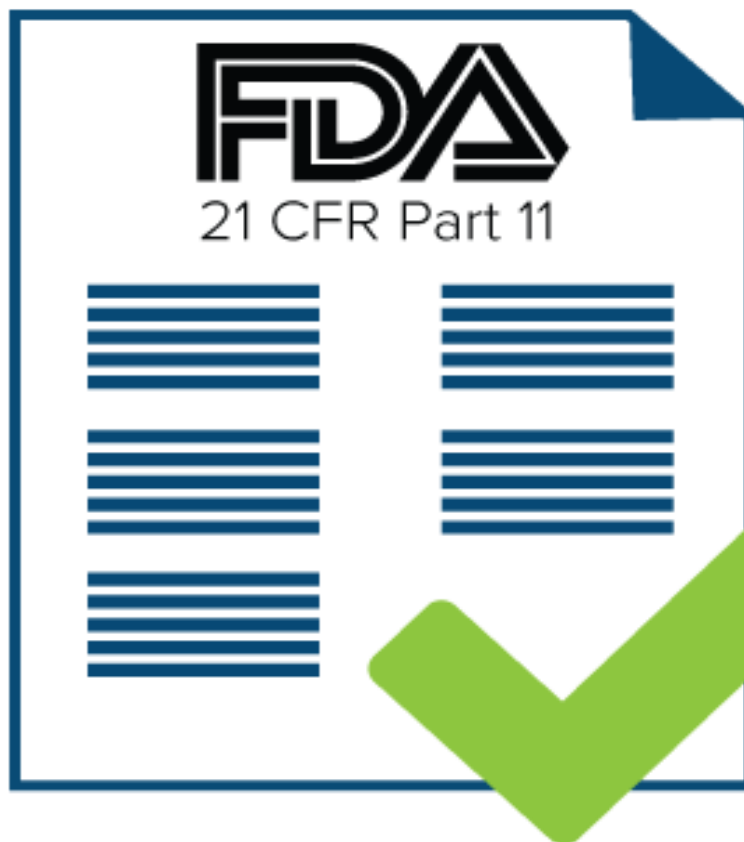
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This webinar has been provided for educational and informational purposes only and is not intended and should not be construed to constitute legal advice.

Please consult your attorneys in connection with any fact-specific situation under federal law and the applicable state or local laws that may impose additional obligations on you and your company.



ALL WEBINARS ARE RECORDED AND AVAILABLE AS AN "ON DEMAND" SUBSCRIPTION



*Presented by:*  
**R. Greg Manson**

# About Greg



## Greg Manson CISA, MBA

- 18 years of experience as an IT Director for organizations in compliant environments
- Healthcare, medical device, and pharmaceuticals
- MBA from UNC-Wilmington
- Learn more at

<https://www.carolinasit.com/about-us/leadership>





# Predicate Rules

- Any other FDA Regulation for maintenance of records and reporting... e.g. GxP
- Part 11 applies



# Part 11 Compliance

- SOPs

- Data Security
- Data Backup

- Audit Trails
- Electronic Signature
- Versioning
- User Authentication
- Login Controls
- Data Security

- Audit Trails to ensure Integrity and Nonrepudiation

- Infrastructure Qualification

- SOC 2 Attestation, TSP S,A
- Change Management and Assurance of Migration

- Computer System Validation

# Validation

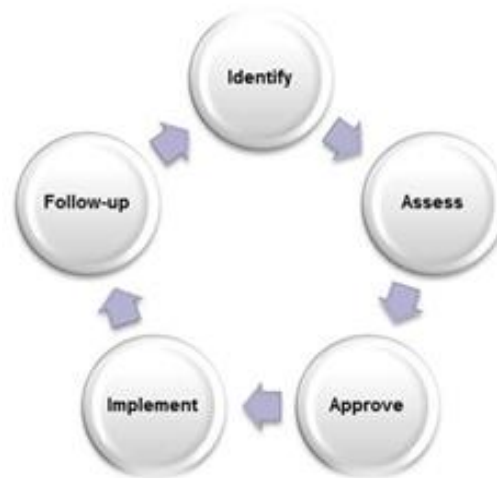
- Validation Master Plan (VMP) SOP
- Validation Plan
  - Risk Assessment compared to User and Functional Requirements
  - Traceability Matrix: cross reference between requirements and test cases
- IQ/OQ/PQ Test Cases and Results
- Validation Report
- Change Control





# Change Control

- Request
- Risk Assessment
- Re-Testing
  - If required by Risk Assessment
  - If change impacts an explicit test in IQ/OQ/PQ
- Implementation



***Thank You!***

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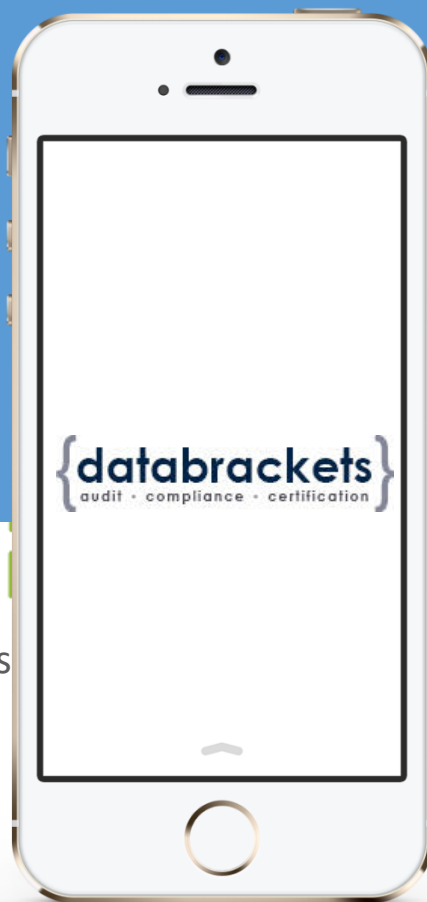
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# Upcoming Events

- GDPR 101 – 7/25
- How to Comply with California Consumer Privacy Act - 8/15
- Register at [databrackets.com/webinars](https://databrackets.com/webinars)

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# Questions

*Please don't hesitate to ask*