Automating SOPs, FDA Compliance & Being Audit Ready is Easier than You Think

A Note On Today's Presenters

SLINGSHOT

Slingshot Software is an enterprise software provider with over 30 years of experience based in Massachusetts.

Today's Presenters:

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Presentation Overview

- ➢ **The Drug Approval Process**

- ➢ **The Long Road to Compliance**

- ➢ **FDA System Requirements**

- ➢ **Traditional Alternatives**

- ➢ **Next Generation Technology**

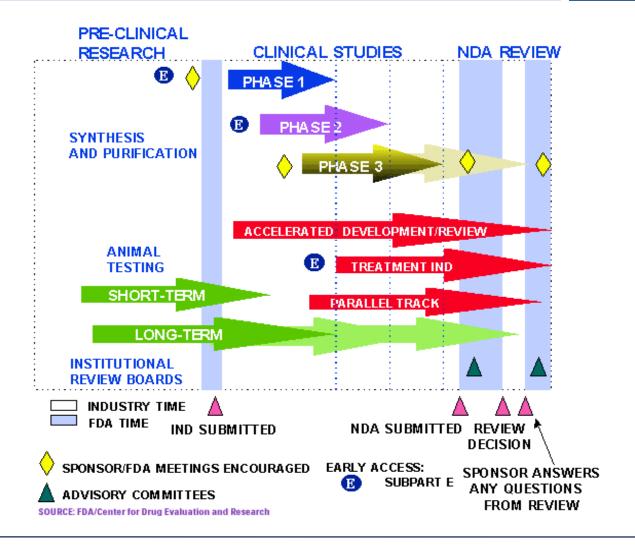- ➢ **Slingshot Solution Set**

The Drug Approval Process

➢ **Development of new medicines is costly, time consuming and rigorous:**

> ➢ Average 10-13 years + $350m to bring a drug to market
>
> ➢ Average of 3.5 years of testing
>
> ➢ 1 in 1000 drugs lab tested make it to market

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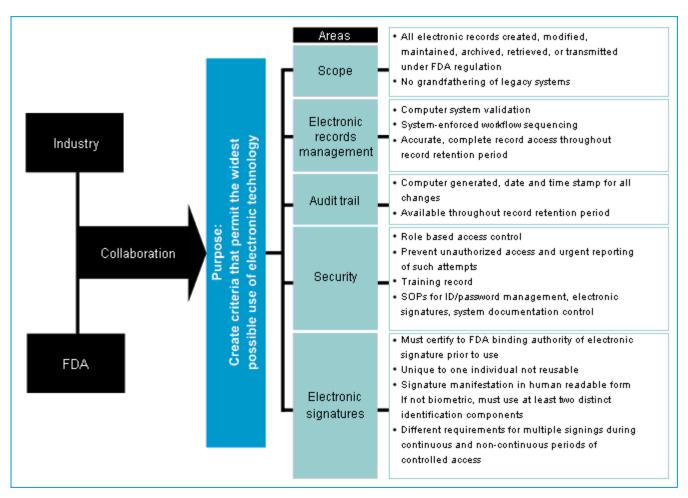## State of Control - Compliance From the Ground Up

➢ Tight, auditable Lot Control
  - ➢ Lot expiration controls
  - ➢ Lot genealogy

➢ Tight, auditable cGXP Control
  - ➢ Material movement control
  - ➢ Temperature and humidity

➢ Strong internal quality procedures
  - ➢ Enforced best practice operational procedures
  - ➢ Software quality validation
  - ➢ Controlled training and documentation procedures
  - ➢ Individual accountability (for action initiated under electronic signature)

➢ Record Retention
  - ➢ Digital data preservation
  - ➢ Data integrity preservation and protection through secure archive and audit controls

Audit Prerogative: "If it isn't written down, it didn't happen."

Source: Cap Gemini Ernst & Young (*CGE&Y*)

Traditional System Alternatives

Human Systems

➢ Shortcomings
  - ➢ Prone to Error
  - ➢ Expensive
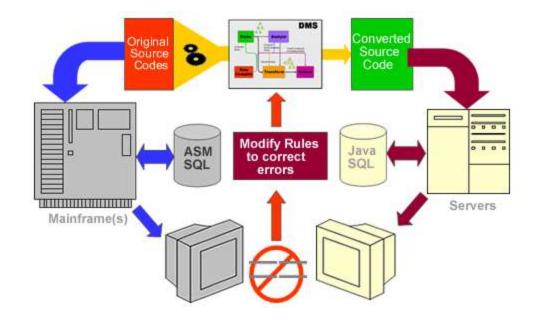 - ➢ Risky

Traditional System Alternatives

Legacy Applications

➢ Shortcomings

    ➢ Inflexible

    ➢ Difficult to Upgrade
       or Expand

    ➢ Expensive

Traditional System Alternatives

Custom ERP Packages

➢ Shortcomings

    ➢ Legions of Consultants

    ➢ Inflexible

    ➢ Deploy their SOPs, not yours

    ➢ Never Ending Money Pit

Next Generation Technology

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Control Your Changing Requirements

➤Modern Systems Use Tools That Allow You To Be:

- ➤ **Flexible:** Implement your SOPs your way

- ➤ **Configurable:** You're in control

- ➤ **Extensible:** Control all steps and
  approvals in your ever changing SOPs

- ➤ **Scalable:** Add additional workflows and
  other facilities.

Slingshot Software Solution Set

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Slingshot - A Next Generation Solution

➢ Broad Off-the-Shelf Functionality to Support your SOPs

➢ Flexible, Extensible and Configurable with Web-based 21 CFR Part 11 Tools -- *No Programming Required*

➢ Scalable from a Handful to Thousands of Users with the latest Web-based Architecture

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Slingshot - A Next Generation Solution

➢ Easy to Control

➢ Easy to Use

➢ Easy to Administer

Absolute Control with eTools

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What is eTools?

➢ 21 CFR Part 11 Compliance toolkit

➢ Allows You to:

    ➢ Map our Software to your existing SOPs without compromise and without programming

    ➢ Prototype and deploy web applications as requirements emerge

    ➢ Securely Audit and Archive all transactions with their Electronic Signatures

➢ This can be done:

    ➢ Quicker

    ➢ Faster

    ➢ Better

    ➢ With Less Risk, and

    ➢ With Less Cost

Control and Compliance with eTools

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eTools and 21 CFR Part 11 Compliance

➤ Authentication & Validation

➤ Record Replication

➤ Archiving

➤ Secure Sign On

➤ Control from the Ground Up

Business Case: "Easier Process Validation = Return on Investment"

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eTools and 21 CFR Part 11 Compliance

➢Roles and Span of Control

➢Single and Double Electronic Signature

➢"Double Blind" Entry

➢"Double Blind", "Double User" Entry

SOP Sponsorship : "With eTools, Slingshot applications enable compliance through control and enforced quality procedures."

eTools In Action – Screen Cast

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Delivering Compliant, Auditable Applications

➢Logging In and User Roles

➢Electronic Signature Controls

➢Blind Entry Controls

➢Automatic, Configurable Audit Trails
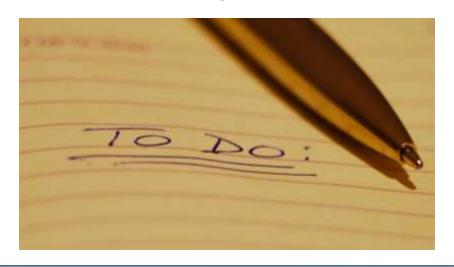
Register For Webinar to View Screen Cast

https://www2.gotomeeting.com/register/294994770

Presentation Review

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How Will You Approach Systems Differently?

➢ Compliance is necessary

➢ Slingshot can help you do it efficiently

➢ Slingshot's system will match your SOPs, not the other way round

➢ Slingshot's system will meet your unique requirements

➢ Remember to be Flexible, Configurable, Extensible & Scalable.

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