Regulatory Compliance: A Necessary Evil or a Streamlined Process?

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Why Are You Here?

What specific challenge or question drew you to this session on regulatory compliance?

Objectives

Learning	Learning Relevant Regulations: Learning relevant CFR and GCP regulations will empower individuals to proactively address regulatory inquiries and ensure adherence to the requirements
Developing	Developing a Standardized Binder Template: Creating a consistent regulatory binder template improves efficiency and ensures all essential information is readily available.
Implementing	Implementing Comprehensive Checklists: Utilizing checklists helps minimize errors and ensures all regulatory activities are completed throughout the study lifecycle.
Establishing	Establishing Clear Naming Conventions: Consistent naming conventions improve file organization, facilitate efficient data retrieval, and enhance overall productivity.
Documenting	Documenting Training Effectively: Recognizing and documenting the training efforts of the Principal Investigator (PI) and study team not only ensures compliance but also documents the effort that is put forth for a study.

Regulations: The necessary evil

Code of Federal Regulations (CFR)

- Federal Register
- Codification
- Title 21: Food and drugs
  - Section 11 – electronic records and signatures
  - Section 50- Protection of human subjects in clinical trials
  - Section 54 – Financial disclosure
  - Section 56 – IRB
  - Section 58 – Good laboratory practices for nonclinical studies

Regulations: The necessary evil

International Council for Harmonization, Good Clinical Practices (ICH E6 GCP)

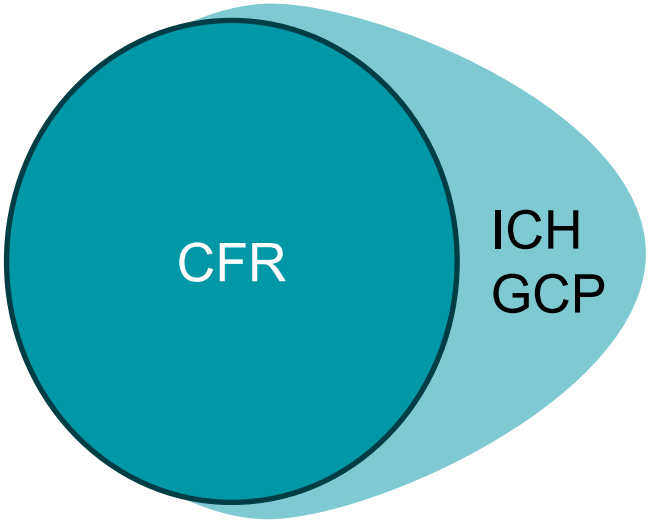
Goal

- Standardize technical guideline and requirements for drug marketing registrations
- Reduce redundancy

Regulations: The necessary evil

Organization of ICH E6 GCP

- Section 1 Glossary
- Section 2 Principles of ICH GCP
- Section 3 IRB/IEC
- Section 4 Investigation
- Section 5 Sponsor
- Section 6 Clinical Trial Protocol and Protocol Amendments
- Section 7 Investigator's Brochure
- Section 8 Essential Documents for the Conduct of a Clinical Trial



Developing a Standardized Binder Template

- Challenges of sponsor provided regulatory binders
  - Documents are grouped differently
  - Navigation can be difficult
  - Not easily accessible

Developing a Standardized Binder Template

Check the box if present; list dates/specifics as applicable

Contact information		**Date of Document**
✓	Version 1	13Oct2016
✓	Version 1	23Oct2015
Protocol and Protocol Signature Page		
	PSP	**Signature Date**
✓	Protocol Version 2.0	21Apr2016
✓	Protocol Version 1.0	10Sep2015
	Protocol	**Protocol Date**
✓	NTF: Protocol Location	
✓	Protocol Version 2.0	02Mar2016
✓	Protocol Version 1.0	22Jul2015
Logs		
	DoA	
✓	NTF: Training and Delegation Logs	20Jan2014
	Subject Enrollment Log	
	Monitoring Log	
	Subject Screening Log	
	Equipment Loanded Log	
	Site Training Log	
✓	NTF: Training and Delegation Logs	20Jan2014
	Temperature Log for Ambient Samples	
Investigational Product		
	Temperature Monitoring Form	
✓	NTF: Temperature Monitoring	30Nov2015
	Thermometer use and Disposal	
	Drug Storage Temperature Excursion Report and Assessment Form	
	Version 2.0	21Oct2015
	Elpro Libero Logger	
	Instructions	16Sep2015
	Logger Printouts	
	Almac_IXRS Manual	
	Blinded Site User	Version 1
	Investigator Site User	Version 1

SRA INTERNATIONAL

Benefits of a standardized (electronic!) binder

- Accessibility
- Version control
- Reduce Storage needs
- Improve data integrity (audit trails)
- Centralized Document Storage
- Cost Savings

Building Your Regulatory Binder Blueprint

BUILD IT

Existing Binder
Colleagues
Conferences

CHECK IT

ICH E6 GCP Section 8

Test it!

Don't be afraid to change it at first if something isn't working but once you move it to more studies really consider the 90%

Building Your Regulatory Binder Blueprint

TEMPLATES

- Box_template
- Advarra_template

ICH GCP

- ICH GCP_pdf
- ICH GCP_excel

Establishing Clear Naming Conventions

- Improves file organization
- Facilitates efficient data retrieval
- Enhances productivity.

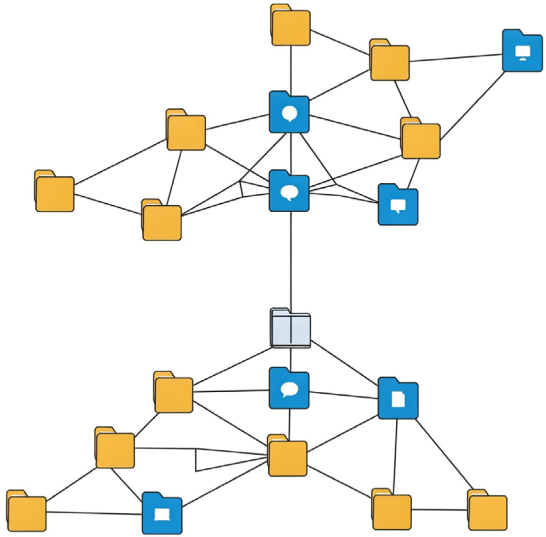
Establishing Clear Naming Conventions

Descriptive title	Date format	Version	Separators
• Short • Relevant	• If Date is the primary data method of sorting, use the YYYYMMDD format • Use leading '0'	• Working vs final • Communication	

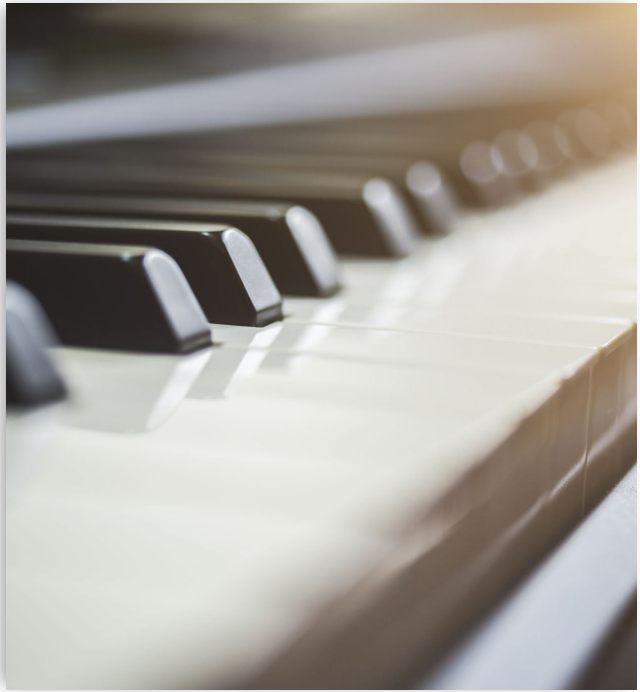
Establishing Clear Naming Conventions

Examples

- Correspondence
  - Sort by date: 2024-12-30_[subject]
  - Sort by subject: Monitoring Visit_2025-01-05
- Training logs
  - Training Log_Protocol v 4, IB 21
  - New Staff_JDoe
- IRB approvals
  - Folders:
    - 0. New Study Approval
    - 2024-02-14_New Study Approval
  - Documents
    - Approval Letter_[title of Amendment]
    - Approved ICF_[title of Amendment]



Checklists: Create the Streamline Process



- Minimize errors
- Ensure all regulatory activities are completed
- Accountability
- Collaboration and **delegation**
- Increased efficiency and **creativity**

Checklists in Action

- ICF Template
- IRB Application
- Reliance agreements
- After New Study IRB Approval Checklist
  - Document management
  - Sponsor Notification
  - Training Logs
  - Investigational Drug Servies
  - CTSI
  - REDcap
- Monitoring Visits
- Amendment Submissions
- Continuing Review
- Study Closeout
- Adding to staff or investigators

Tips for implementing Checklists

Easy to Use and Access	Simple language Speak to the 90% Use bullet points
Highlight what is in it for them	Feeling overwhelmed? Empowerment and ownership of a task
Foster a culture of checklists	Use them! Make it collaborative

Documenting Training Effectively

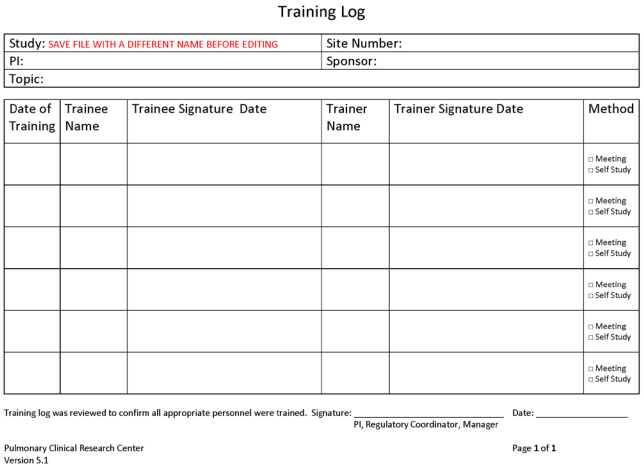
What is adequate training?

Familiar with the purpose of the study and the protocol	Adequate understanding of protocol details and attributes of the study drug to perform tasks	Aware of regulatory requirements and standards	Competent to perform and have been training to perform tasks they are delegated to	Informed of any pertinent change and receive training as appradditionalopriate

Give the PI and team credit for all they do to make the study be successful

Training: Initial or Formal Documentation

- Traditional training log
- Elements:
  - Topic
  - Site number
  - Protocol name
  - Signatures and dates
- Documents
- In person?



Training Log

Study: SAVE FILE WITH A DIFFERENT NAME BEFORE EDITING	Site Number:
PI:	Sponsor:
Topic:	

Date of Training	Trainee Name	Trainee Signature Date	Trainer Name	Trainer Signature Date	Method
					□ Meeting □ Self Study
					□ Meeting □ Self Study
					□ Meeting □ Self Study
					□ Meeting □ Self Study
					□ Meeting □ Self Study
					□ Meeting □ Self Study

Training log was reviewed to confirm all appropriate personnel were trained. Signature: _____ Date: _____
PI, Regulatory Coordinator, Manager

Pulmonary Clinical Research Center
Version 5.1

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Training: Follow-up or Informal Training

- Meeting Minutes
  - Include topics of discussion
- Emails
  - Confirmation of training
  - Include topics
  - Include email and attachments
- Naming conventions

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Learning	Regulations
Developing	Standardize Regulatory Binder Template
Establishing	Naming Conventions
Implementing	Checklists
Documenting	Training

Questions/Discussion

Thank you for joining this session.

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