Center for Veterinary Biologics Modified for CVB personnel from outside of IC
Inspection and Compliance Training Plan

Position: CVB-PEL Employee
This overview provides the trainee with the basic knowledge of IC activities and interactions between CVB's functional areas. Average time for completion is 24-30 hours. The training can be performed over a period of time and encouraged to be completed prior to participation on an on-site inspection.
Training is conducted with a Biologics Specialist experienced in the area assigned.

Trainee's Name: I acknowledge receipt of this plan _____
Trainee's Signature/Date

Training Coordinator: _____

Date Training Began: _____
Date Training Ended: _____

	Date	Mentor	Empl. Initials	Mentor Initials	Suggested Time
I. Introduction					
A. IC Roles/Authorities (can be removed if employee attended IICAB)		Karli			30 minutes
II. Overview					
A. Program Regulations/Procedures (VSTA, 9CFR, VS Memos, CVB Notices) (can be removed if employee attended IICAB)		IC Section Leader			30-60 minutes
B. Program Information Management and Security (File Room, AIMS, AdHoc Databases, Access, FOIA)		B. Coyle			60 minutes
C. Quality Management System (QMS/Quality Manual/Document Control)		Hyde			60 minutes

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The following activities (Sections III., IV., and V.) are meant to be a hands on experience if possible
Why these processes are in place and how outputs from PEL impact will also be a part of the training process

III. CVB-IC Support Activities		**Date**	**Mentor**	**Empl. Initials**	**Mentor Initials**	**Suggested Time**
A. Serial Release - Entry Process			Schiltz/Santi			2-3 hours either right before or right after lunch
B. Serial Release - Release Process			Ennis			1-2 hours first thing in the morning
C. Reviewing Firm Test Reports			Santi			Associated with III.A
D. Processing Prelicensing Material			Rasmussen			1 hour
	Establishment					
	Product					
E. Exports	APHIS 2017		BCA			30 minutes
	Certificate of Lic/Insp		Flickinger			30 minutes

IV. CVB-IC Program and Firm Request Activities			Specialist will also describe Support Staff process for (*) activities			
A. Program Coordinator (at least 6 weeks)			PC for the week			2 hours in the morning
*B. Specialist Review of Firm Request			Firm Request can be trained by any Specialist with a current request open			
	Reprocessing					
	EOD					
*C. Review of Facility Documents			Huls			1 hour
D. Enter Special Test Request			Osorio			10-20 minutes
*E. APHIS Form 2007 Review - Samplers			Schnurr			10-20 minutes
*F. Compliance Issues	Regulatory Letters		D. Coyle			2 hours
	Infractions, Warnings, Letter of Advice, Hold Release					
*G. Investigations	VBI's		Murtle			2 hours
	Interactions - Firm/PEL					
*H. Pharmacovigilance	AER Process		Taylor/Snavely			1-2 hours
I. Exports	APHIS 2017		Couture			2 hours
	CLI					

V. Inspections

A. In-depth — Usually as an Observer

	Start Date	Mentor	Empl. Initials	Mentor Initials	Suggested Time
1. Pre-inspection Review		Team Leader (TL) for Inspection			2-4 hours
2. Note Taking Expectations		Schnurr/TL for Insp			30 minutes
3. On-site Inspection		TL for Inspection			1-2 weeks
4. Inspection Report		Schnurr			4-8 hours

A special inspection does not need to be part of the training plan.

B. Special — Usually as a Requested Member of Team

1. Pre-inspection Review		TL for Inspection			2-4 hours
2. Note Taking Expectations		TL for Inspection			30 minutes
3. On-site Inspection		TL for Inspection			1-5 days
4. Inspection Report		TL for Inspection			4-8 hours

I certify that the individual listed above has completed the training as outlined in a satisfactory manner and has demonstrated his or her ability to effectively perform the duties:

Training Coordinator _____ _____
Date

Trainee's Supervisor _____ _____
Date

IC Director _____ _____
Date

Photocopy should be made at time of plan initiation and filed in the PEL employee files (with PSA).
Original should be maintained by employee with original signatures at each stage of the training.
Completed plan should be signed and dated by Training Coordinator, Training Supervisor, and IC Director and then filed in the PEL employee's file (with PSA).