

Drug use in Calves

Food Armor®- The Proactive, Non-regulatory Approach

VFD- The Regulatory Approach

DAVID A. RHODA, DVM

Starting STRONG

Ask the Expert: How Will the New VFD Rules Affect Me? - Dr. Al Schultz, Vita Plus

Back to Issue: [Vita Plus Starts Strong: Calf Care E-news - February 2016](#)

Posted: February 2016

By Dr. Al Schultz, Vita Plus vice president of technical services

Question: How will the new VFD rules affect my calf program?

Answer: We hear considerable argument about the factors contributing to the loss of antibiotic efficacy and the role animal agriculture plays in it. In general, the public has been led to the conclusion that antibiotics are overused in agriculture and contribute to the resistance problem. Critics of our current regulatory framework have called for the removal of all antibiotics from livestock production. Meanwhile, many food retailers and restaurants are offering products produced from animals that are "antibiotic-free," hoping to appeal to a market segment attracted to these claims.

In response, the **Food and Drug Administration (FDA)** is changing the manner in which feed-grade and water-soluble antibiotics can be used in animal production. FDA has the support of all drug manufacturers in this new approach. These changes are referenced by the term "**Veterinary Feed Directive**" or VFD. All changes take effect on January 1, 2017.

Antibiotics are now classified as medically important or not medically important. If a drug is not used in human medicine, its status and regulations affecting its use are unchanged. However, if a drug is shared-use (used in both animals and humans), it's deemed medically important and subject to new regulations. A full explanation of the changes is beyond the scope of this short article, but discussion of the key issues affecting calf raisers follows.

There is no change in the use of tetracyclines (**Chlortetracycline**® **Scourin**® or **Cantrac**®) or oxclozoxate (**Calox**® or **Doxox**®), however, the use of chlorotetracycline and oxytetracycline, and the combination use of neomycin/oxytetracycline, are affected by the new rules.

New antibiotic use rules
Any use of these medically important antibiotics in feed will be under the direction of a veterinarian as stipulated in a VFD form the veterinarian completes. The veterinarian can authorize the use of these products, but only under the exact label directions. There is no extra-label use of any feed grade antibiotics, even with a VFD. Your feed provider cannot sell you the antibiotics without a VFD.

Regulatory vs. Non-Regulatory

Drug residues are not a drug problem.
They are a people problem.
Be the solution.

VVMA FOOD ARMOR® HACCP FOR PROPER DRUG USE

- Our Story
- What is Food Armor®
- Why Food Armor®
- What Matters®
- Getting Started
- Veterinary Accreditation
- Farm Certification
- Third Party Verified
- Sponsors

Both require a valid VCPR

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VCPR is the common thread

Veterinarian Client Patient Relationship

- VFD- Valid VCPR Team
 - Veterinarian of Record (VOR)/Owner/Feed distributor
 - Stake holders
- Food Armor®- Valid VCPR
 - Veterinarian of Record/Client (Owner)/Patient (cow-side people)
 - Stake holders

The FDA expects justifiable drug use
(Where does science stop and sales begin?)
For the dairy we do economic justification

©
RI

A Lawful VFD Has to Be Complete

What do I have to include in a VFD?

Must

You must include the following information on the VFD for it to be lawful:

- veterinarian's name, address, and telephone number;
- client's name, business or home address, and telephone number;
- premises at which the animals specified in the VFD are located;
- date of VFD issuance;
- expiration date of the VFD;
- name of the VFD drug(s);
- species and production class of animals to be fed the VFD feed;
- approximate number of animals to be fed the VFD feed by the expiration date of the VFD;
- indication for which the VFD is issued;
- level of VFD drug in the feed and duration of use;
- withdrawal time, special instructions, and cautionary statements necessary for use of the drug in conformance with the approval;
- number of reorders (refills) authorized, if permitted by the drug approval, conditional approval, or index listing;
- statement: "Use of feed containing this veterinary feed directive (VFD) drug in a manner other than as directed on the labeling (extralabel use), is not permitted";
- an affirmation of intent for combination VFD drugs as described in 21 CFR 558.6(b)(8); and
- veterinarian's electronic or written signature.

May

You may also include the following optional information on the VFD:

- a more specific description of the location of the animals (for example, by site, pen, barn, stall, tank, or other descriptor the veterinarian deems appropriate);
- the approximate age range of the animals;
- the approximate weight range of the animals; and
- any other information the veterinarian deems appropriate to identify the animals at issue.

The veterinarian must keep the original VFD for two years.

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We have a similar list of must be included for prescription writing

Should versus must
May or Can
Choosing Semantics

We must listen to semantics of our opponents

Veterinarians' Responsibilities

- must be licensed to practice veterinary medicine;
- must be operating in the course of the veterinarian's professional practice and in compliance with all applicable veterinary licensing and practice requirements;
- ➔ • must write VFD orders in the context of a valid client-patient relationship (VCPR); **Write VFD**
- ➔ • must issue a VFD that is in compliance with the conditions for use approved, conditionally approved, or indexed for the VFD drug or combination VFD drug; **Only according to Label**
- must prepare and sign a written VFD providing all required information;
- may enter additional discretionary information to more specifically identify the animals to be treated/fed the VFD feed;
- must include required information when a VFD drug is authorized for use in a drug combination that includes more than one VFD drug;
- must restrict or allow the use of the VFD drug in combination with one or more OTC drug(s);
- ➔ • must provide the feed distributor with a copy of the VFD;
- ➔ • must provide the client with a copy of the VFD order;
- ➔ • must retain the original VFD for 2 years, and
- must provide VFD orders for inspection and copying by FDA upon request.

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To Do – VFD compliance by 12/31/16



Choose a Veterinarian of Record

- He/she has new set of regulations and labels to learn
- Set up an efficient way to communicate with VCPR team (Owner, Veterinarian, feed distributor)
- Establish a drug plan for your dairy

Choose a Feed Distributor

- Secure signed VFD

You manage this team

Don't procrastinate, 12/31 will come soon

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WHAT MATTERS®

Food Armor® for Proper Drug Use



VETERINARIANS AND DAIRY FARMERS WORKING TOGETHER TO ENSURE SAFE MEAT AND MILK

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The Fact Was ...

- Wisconsin had the most dairy beef drug residues in the nation
- Drug screening in the slaughter plant had changed
- Failed EU (European Union) milk audit (passed meat)
- FDA (Food and Drug Administration) turned its attention to milk residues
 - 31 drugs are included in this plan
 - Blind testing
 - 900+ repeat violator farms
 - 900+ farms with no meat violations

August 2010

Industry called to meeting at Wisconsin Department of Ag (DATCP)

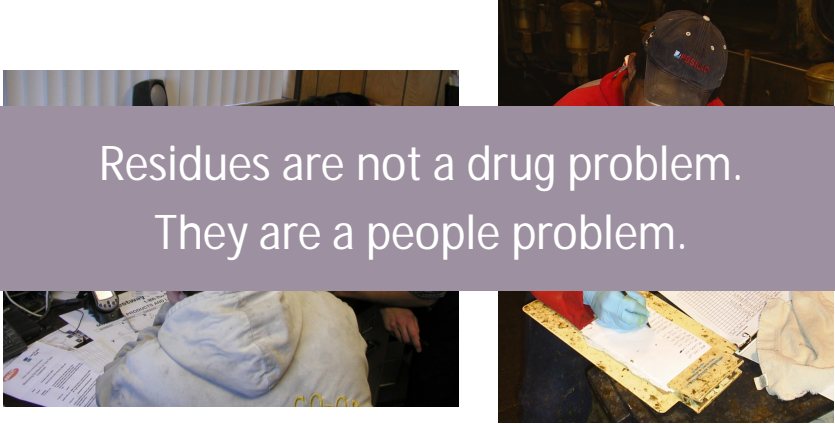
- Regulators
- Beef and dairy cattle producers
- Markets
- Meat processors
- Other stakeholders

Call to action

- More regulation for dairy producers
- Producers and veterinarians were singled out

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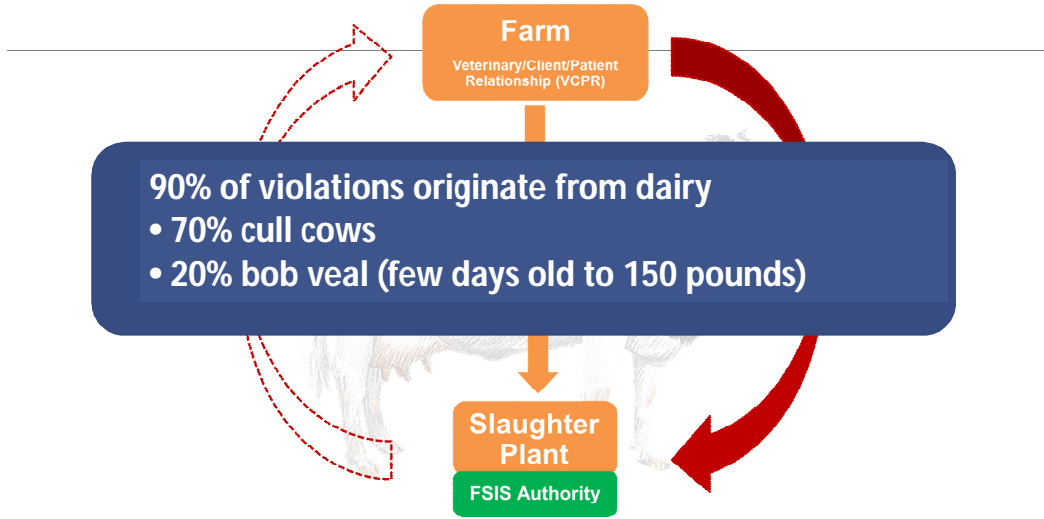
Mindset Shift



Residues are not a drug problem.
They are a people problem.

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Dairy Beef Regulatory Authority System

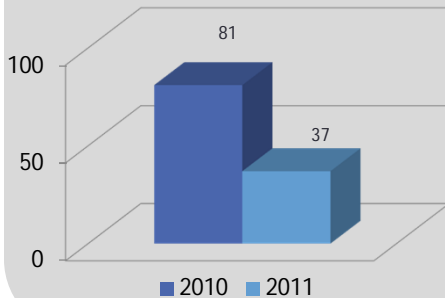


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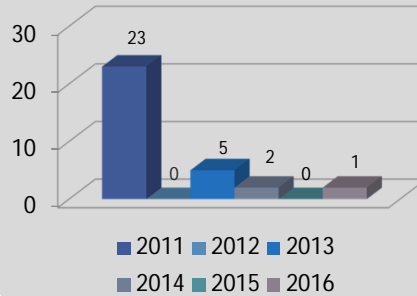
Wisconsin's Proven Progress

Tissue Residue Violators

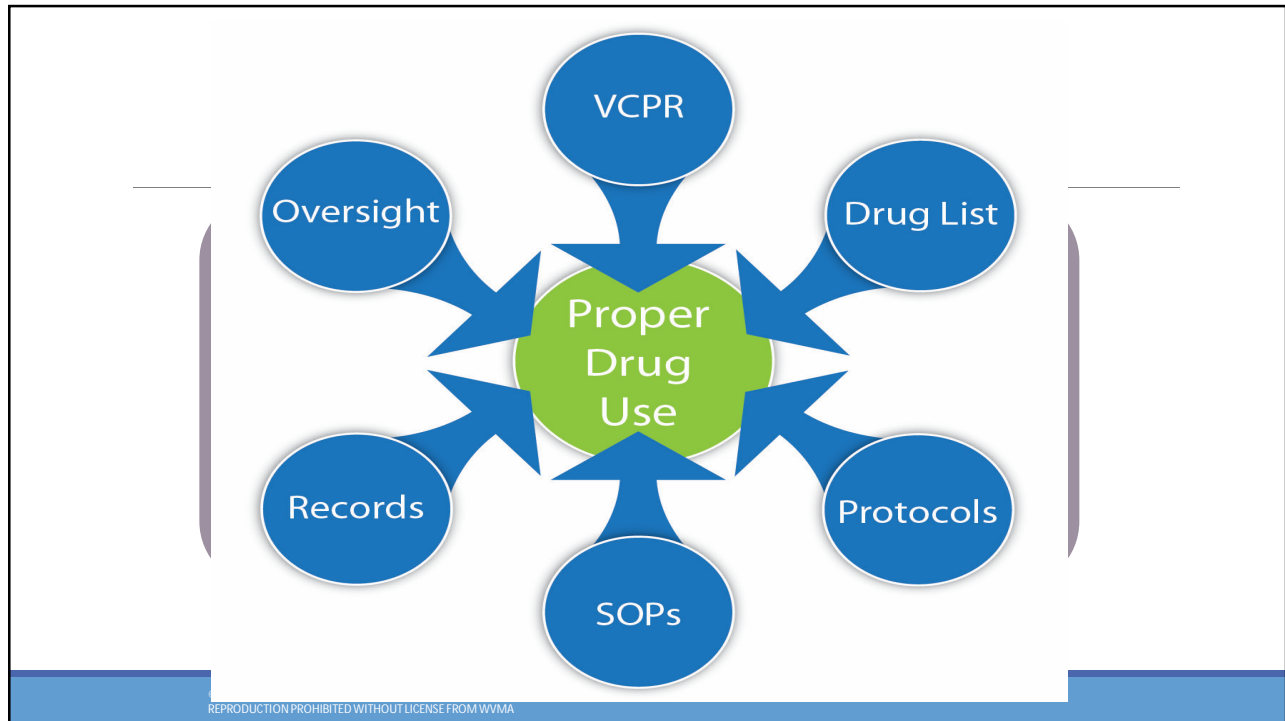
- Cull Cow Processor - Green Bay, WI
- Harvests 800-1000 dairy cull cows daily
 - Tested 70 percent more head than 2010



FSIS Repeat Violator List



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Food Armor[®]

HACCP For Proper Drug Use
(Hazard Analysis & Critical Control Points)

PROACTIVE APPROACH TO DRUG RESIDUE PREVENTION

What is a HACCP plan?

(Hazard Analysis and Critical Control Points)

A management system that ensures food safety from harvest to consumption

- A **proactive approach**: preventing problems by identifying risks
- **Science-based and systematic**: (science not semantics; actions and accountability)
- The concept of HACCP plans is applicable to all segments of the food industry:
 - Growing, producing, processing, manufacturing, distributing, and merchandising

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Food Armor[®] WVMA HACCP For Proper Drug Use

HACCP: Hazard Analysis & Critical Control Points

Traditional HACCP

Identify hazards
Establish critical control points
Monitors
Breakpoints
Action at breakpoint
Mandatory records
Verify the system

WVMA HACCP



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Meeting HACCP Principles

Identify Hazards:

- Identify the VCPR team and farm drug list

Establish Critical Control Points:

- VCPR responsibilities, protocols, SOPs

Breakpoints:

- Regulatory tolerances in milk and tissues
- Proper drug use (FDA guidelines)

Monitors:

- Records and Oversight
- Change Control

Action at breakpoint:

- On-the-job training (teachable moment)

Mandatory Records

- VCPR agreement, drug list, treatment logs, permanent records

Verification

- Milk processor oversight
- Veterinarian and producer oversight and records analysis



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Two Areas of Focus

1. Milk and Meat residues

- Food safety

2. Proper drug use

- Label and extra label drug use
- Accountability to treatability
- Maintain freedoms to operate

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Start with the End in Mind

What is Oversight?

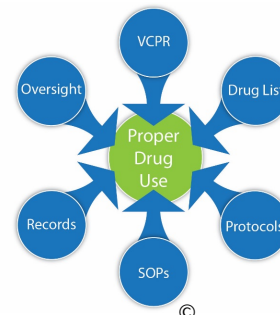
Timely monitoring of proper drug use

Timely monitoring of effective drug use

Problem cow identification

Identifying economic opportunities for producers

Veterinarians and producers working together to ensure safe meat and milk



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Veterinarian client patient relationship

VCPR

How does VCPR fit into a HACCP plan?

The VCPR section, and therefore identifying the roles and responsibilities of people, is used to identify “hazards” on the farm.

Drug residues are not a drug problem.
They are a people problem.

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VCPR Objectives

Regulatory accountability

- Meet law requirements
- Prescription drugs and ELDU require a valid VCPR

Non-regulatory approach

- Accomplish intent of law
 - Customized by farm and the accompanying skill sets of management/employees
 - Define each role within the VCPR team

Veterinarians and producers working together to ensure safe meat and milk



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More Than a Signature

A valid VCPR provides producers the flexibility to use drugs without a veterinarian present for every treatment

FDA expects a valid VCPR in the utilization of drugs

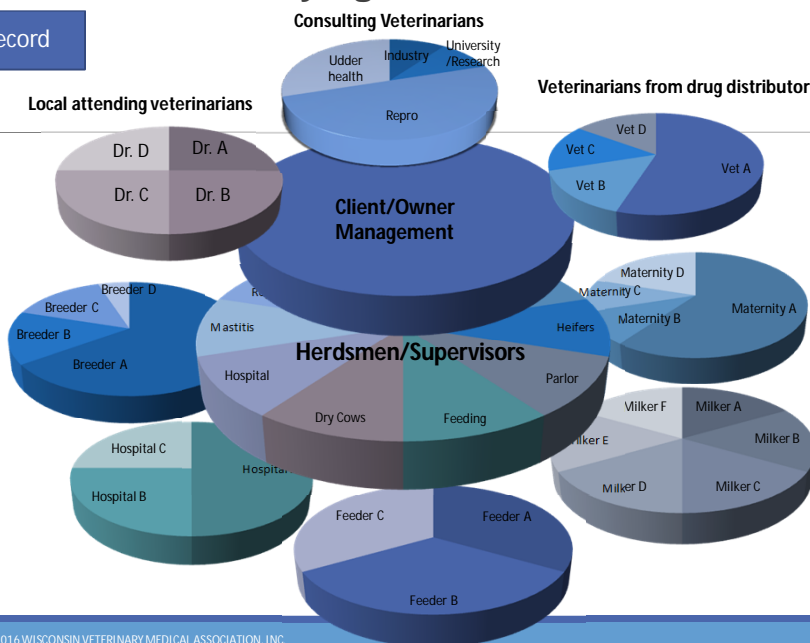
Boundaries give us freedom

FDA has same level tolerance and sense of humor as the IRS

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Identifying the VCPR Team

Veterinarian of Record



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First step for on-farm implementation

Determine Veterinarian of Record

- Ultimately decided by you, the Farm Owner
- Consensus among all veterinarians that service your farm



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Drug list



How does Drug List fit into a HACCP plan?

The Drug List is used to identify “hazards” on the farm, specifically identifying all drugs that are used on your particular farm.

Target drugs that are a risk
(ELDU, Unapproved for category of animal)

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Drug List Objectives

- Definitions
 - Over the counter (OTC) vs Prescription (R)
 - Label drug use (LDU) vs Extra label drug uses (ELDU)
 - Tolerance levels
- Purpose of the Drug List:
 - Identify all drugs specific to your individual farm
(Added Feed Grade Antibiotics Requiring VFD)
 - Identify extra label drug use
 - Identify high risk drug use



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Extra-label drug use

OTC and Rx

Intended use differs from label by:

- Species
- Production class
- Indication
- Dose
- Route
- Frequency
- Duration
- Withdrawal times

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Confirmed Violative Residue Detected

Veterinary Drug	Confirmed Residue in Targeted Group	Confirmed Residue in Non-Targeted Group	Approved for use in lactating/dry cow	Approved for use in dairy cattle <20 months and/or beef cattle	Extra label drug use allowed
Ciprofloxacin*	1	0	No	Yes	No
Sulfamethazine	1	0	No	Yes	No
Tilmicosin	1	0	No	Yes	Yes
Tulathromycin	2	0	No	Yes	Yes
Florfenicol	6	4	No	Yes	Yes
Gentamicin	1	0	No	No	Yes
Total	12 (1.15%)	4 (.42%)	No significant difference between target/non-target groups		

*Ciprofloxacin is a metabolite of Enrofloxacin, which the FDA test detects, therefore the test cannot distinguish which drug was given to the animal.

Courtesy of National Milk Producers Federation



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First step for on-farm implementation

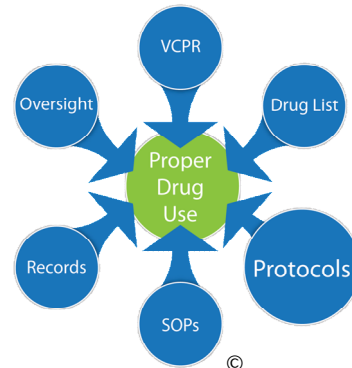
Make a drug list specific to your farm

- The drug list for your farm should only include the drugs and medications specifically used on your farm in your written treatment protocols



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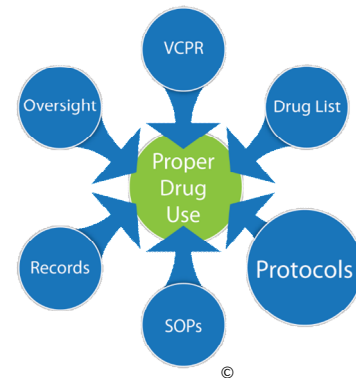
Protocols



How do protocols fit into a HACCP plan?

Protocols are used to establish control points on your farm relative to how drugs are used

- Identify farm-specific definitions of disease conditions and farm-specific treatment plans for each of these conditions



Protocol Objectives

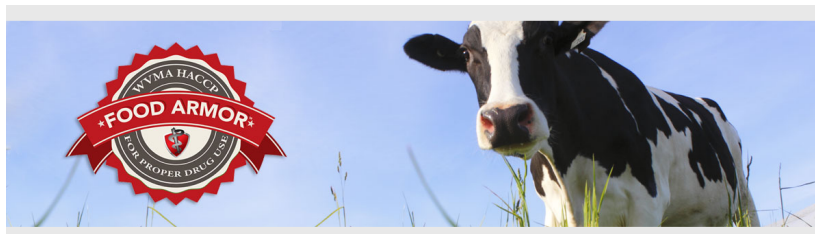
Treatments given in our name; in our absence

- **1. Define condition 2. Drug protocol 3. Records 4. Withdrawal times**
- **Identify label drug use opportunities first**
- Plan food safety if ELDU (Extra Label Drug Use) is appropriate
 - Work with your Veterinarian of Record
- Plan how to change an individual cow recommendation without confusion that it is a change of protocol
- Develop a training plan

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First step for on-farm implementation

Working with your Veterinarian of Record to create customized written treatment protocols for pneumonia, mastitis, and metritis on your farm



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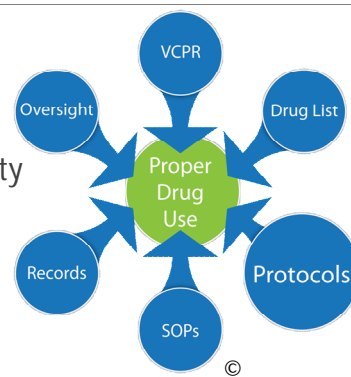
Protocols vs. SOPs

Protocol - What to do

- Defined condition (situation)
- Drug treatment - dose, route, duration
- Records to keep for verification of food safety and accountability for proper drug use
- Withdrawal for meat and milk

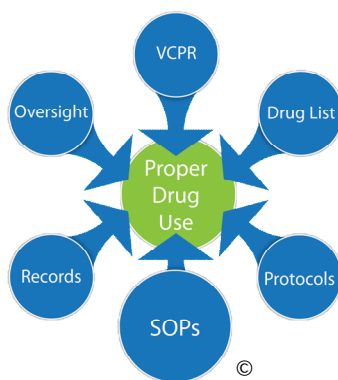
SOP – How to do it

- Steps to a process and procedure
- People responsibilities



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SOPs



How do SOPs fit into a HACCP plan?

SOP – The “How to Do”

- Steps to a process and procedure
- People responsibilities

Consistency, compliance, competency

Identifying people skills through the records

Allows on-going, on-the-job training at oversight

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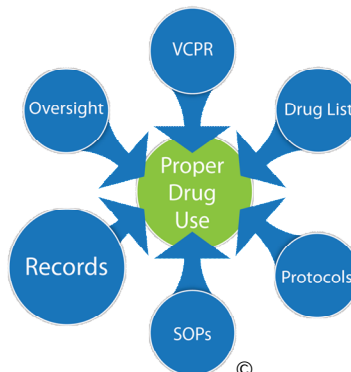
First step for on-farm implementation

Working with your Veterinarian of Record to create customized written SOPs on your farm for returning treated animals back into the food supply

- Who's responsible?

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Records



How do records fit into a HACCP plan?

Records establish a way to monitor critical control points and are a vital component of the verification process

ID	Date	Severity/quarter/drug	Culture	CMT	Relapse, interval, times mast
Day/treatment	Day/treatment	Day/treatment	Day/treatment	Day/treatment	Day/treatment
Day/treatment	Day/treatment	Day/treatment	Day/treatment	Day/treatment	Day/treatment
Day/treatment	Day/treatment	Day/treatment	Day/treatment	Day/treatment	Day/treatment
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Day/treatment	Day/treatment	Day/treatment	Day/treatment	Day/treatment	Day/treatment

ID	2078	LACT	9	DIM	205	PEN	1
BRED1	74	TBRD	3	DUE	-	MASTX	122
DRYLG	2.0	MILK	55	RPRO	NO BRED	PM305	23650
LOG1	4.2	SCC	1307	PRMLG	3.0	MP	21
4/24/11	FRESH	B		8/18/11	BRED	14H5411	0 5G
4/26/11	MOVE	F029T027		8/24/11	MAST	MIALL	S3
5/ 6/11	WATCH	PNEU		8/24/11	CULTURE	STAPH	
5/14/11	HRDWARE	MNGNT		8/30/11	MOVE	F012T021	
5/20/11	PNEU	XCD13		8/30/11	WELL	55135	
5/31/11	FOOTRMK	1		9/16/11	OPEN		
6/ 1/11	WATCH	PNEU		9/29/11	BRED	7H7615	5G
7/ 7/11	BRED	1H2848	0 5R	10/ 3/11	MOVE	F021T004	
7/22/11	MOVE	F027T026		10/19/11	DNB	AGE	
8/ 3/11	MOVE	F026T023		10/21/11	MOVE	F004T002	
8/ 5/11	OPEN			10/31/11	MOVE	F002T001	
8/15/11	MOVE	F023T021		11/ 2/11	TRIM	AK3LR	

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Three Record Categories

No records for the herd or a management group

Treatment logs = logs/minimum records

- Manage the case and food safety
- Treatment logs ≠ WVMA Food Armor® HACCP Plan
- ID, date, condition, drug, dose, route, duration, withdrawal times, name of individual administering

Permanent records = permanent medical history of each animal

- Manage case, food safety, herd epidemiology, proper drug use, oversight and outcomes

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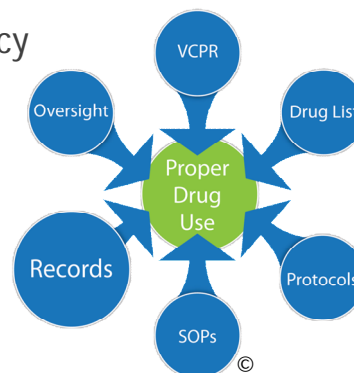
Plan What to Record So You Can...

Recognize SOP compliance and competency

Recognize protocol drift

Review epidemiology

Ensure food safety and proper drug use



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Daily Treatment Log

619	1/3/12	LDA	Polyflex 500mg/ml	10ml IM	96hr	12d
842	1/3	Crash	Probios L7	oral/IM	—	—
686	1/4	Crash/TRIP	Pump/Probios/X/UBIS	X IM	—	4
619	1/4	#	Flex			
842	1/4		L7			
686	1/5		X pump L7	20 IM	—	4d
619	1/5	#	Flex	10 IM	96hr	12d
842	1/5		L7 B95	20 IM	—	—
686	1/6		X	20 IM	—	4d
619			Flex	10 IM	96	10d
842	↓		UBISD	20 IM	—	—
842	1/7	LDA	Polyflex Pump	10 IM	96	10d
619			-11	70 IM	96	10d

How many times is 619 listed?
842?

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Herd Category – Permanent Records

The next level of record keeping is individual cow permanent records

The permanent record sets the stage for science-based appropriate drug use with consideration of medical history (Management Record)

Organizing individual permanent records is the basis for identifying epidemiology (disease patterns) and therefore prevention

Protect food supply and ensure proper drug use

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First step for on-farm implementation

Review current treatment logs - ensure all sections are included

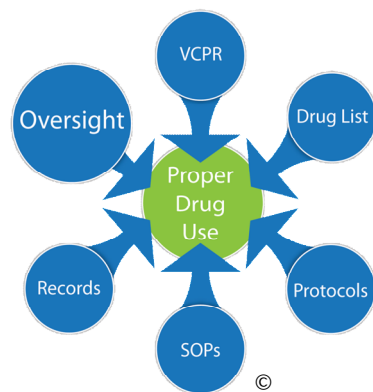
- Animal ID, date, condition, drug, dose, route, duration, withdrawal times (meat and milk) and person administering

619	1/12	LDA	Polyflex 500mg/ml	10ml IM	96hr	12d
842	1/13	Crash	Probios L7	oral/sm	—	—
886	1/14	Crash/RIP	Pump Probios/x/obis	X IM	—	4
619	1/14	#	Flex			
842	1/14		L7			
886	1/15		X pump L7	20 IM	—	4d
619	1/15	#	Flex	10 IM	96hr	12d
842	1/15		L7 B9F	20 IM	—	—
886	1/16		X	20 IM	—	4d
619	1		Flex	10 IM	96	10d
886	1		LB150	20 IM	—	—
842	1/17	LDA	Polyflex Pump	10 IM	96	10d
619	1		-11	20 IM	96	10d

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Regulatory record

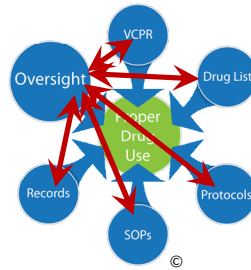
Oversight



How does Oversight fit into a HACCP plan?

Veterinary oversight provides for continual monitoring of the entire HACCP plan

- Routine veterinarian involvement satisfies the verification principle that validates all other sections of the plan



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Oversight – Is the “Key” Because...

It validates VCPR

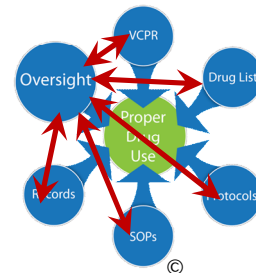
It allows your veterinarian to monitor and refine protocols and SOP's

- Are people doing what we agreed? (drift)
- Are patients responding? (effectiveness)
- Did the pattern change? (epidemiology shift)

It allows your veterinarian to watch the drug list

It reinforces the value of keeping records

It reinforces the value of veterinary involvement in treatment decisions and drug use



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Why Food Armor®?

Proactive

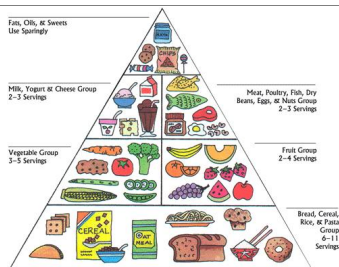
Non-regulatory approach

Raising the dairy industry's standard

Accountability and transparency

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Retailers and activists, not science,
will dictate future care policy



Opinion
Market Access

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Food Armor® - Progression

Food Armor® Certified Farm – requires involvement of a Food Armor® Accredited Veterinarian

Launched nationally

- AABP 2015 in New Orleans
- Public release to dairy industry in Fall 2015
- www.foodarmor.org

