

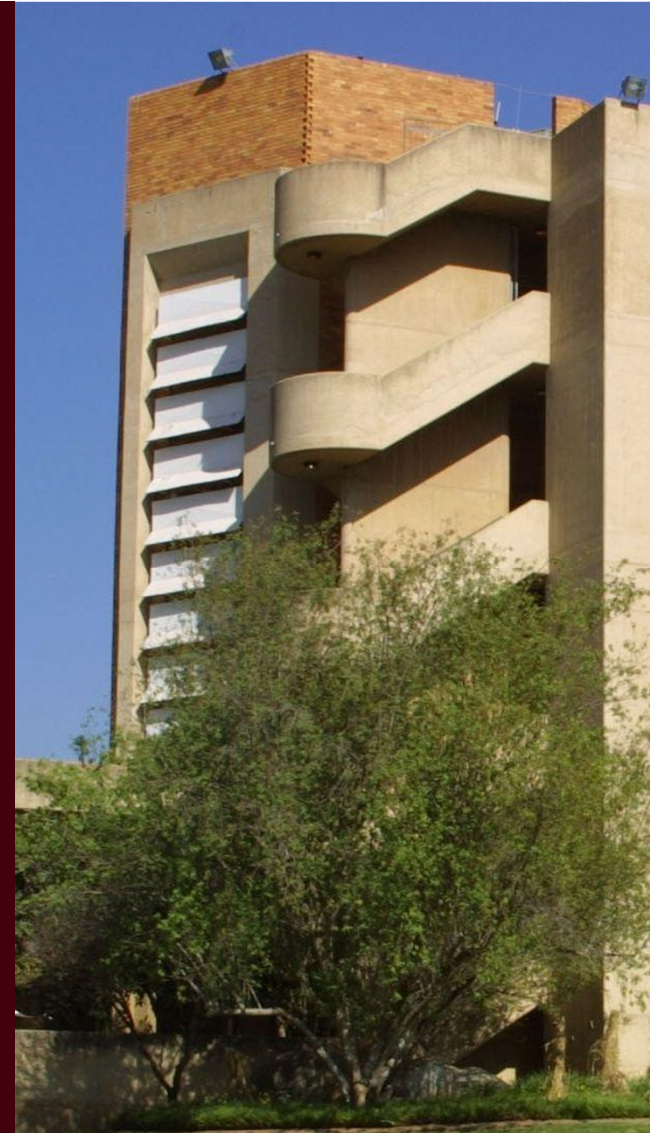


UNIVERSITEIT VAN PRETORIA
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Expectations from Academia

A South African Perspective

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Veterinary Training





South African Veterinary Landscape

- 2700 Veterinarians: Registered with South African Veterinary Council
- Declared Scarce Skill
- Veterinary Specialist
 - 180 Specialist veterinarians
 - 22 specialist disciplines
 - 4 Veterinary pharmacologists (none in full-time state regulatory employ)



Developmental Landscape

- Service Availability
 - Three GLP accredited lab: One for preclinical, one owned by Pharma, and third for parasites
 - Limited plasma analytical capacity: None GLP
 - Limited residue testing capacity
 - No accredited pathology services
- Regulatory Framework
 - Advanced policies in process
 - Proper standards in Animal Ethics
 - Standards in animal housing facilities

Regulatory Framework

- Veterinary Statutory Body
 - South African Veterinary Council
 - Separated from Ministry of Agriculture
- Accreditation Standards Body (SANAS)
- Environmental Protection Legislation
- Animal Disease Legislation



Regulatory Framework

Over the Counter (OTCs)

- Stock Remedies
- Fertilizers, farm foods, agricultural remedies and stock remedies Act
- Act 36/47

Prescription Only (POMs)

- All Human medicines
- Veterinary medicines
- Medicines and related substances control Act
- Act 101/65



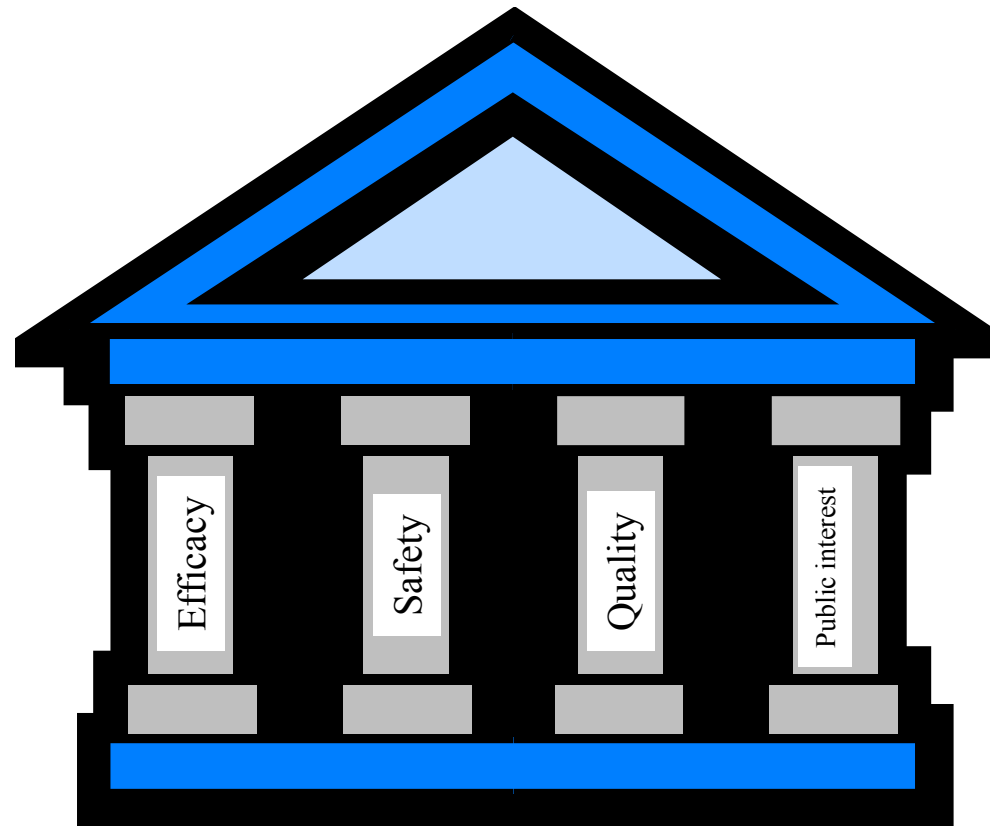
agriculture,
forestry & fisheries

Department:
Agriculture, Forestry and Fisheries
REPUBLIC OF SOUTH AFRICA

SAHPRA

South African Health Products
Regulatory Authority

Cornerstones of Medicines Registration





Evaluations

- Two Types of Dossiers
 - International and Local
- Different Quality
 - High quality dossiers to non compliant
 - International dossiers missing information: Costs of printing, poor collation, etc
- Applicants expect mutual recognition
- International applicants not open to discussion
- Reviewers need to be trained
 - Understand guidelines
 - Reject poor study designs



Training in South Africa

- Veterinary Training
 - Specialist Training
 - Clinical Medicine
 - Pharmacology, Toxicology and Laboratory Animal Science
 - Pathology
 - Advanced Knowledge
 - Course Work Masters in Industrial Pharmacology
 - Post-grad diploma in lab animal science
- Research Training
 - Masters in Science
 - Doctor of Philosophy



Training Concerns

- Difficulties in training
 - Old analytical laboratory at faculty
 - Pseudo-GLP only
 - No pharmacovigilance training
 - No access to complete dossier
 - Trainers not available
 - Poor understanding of regulatory pharmacology by researchers/applicants
- Theoretical versus Experiential



VICH Documentation

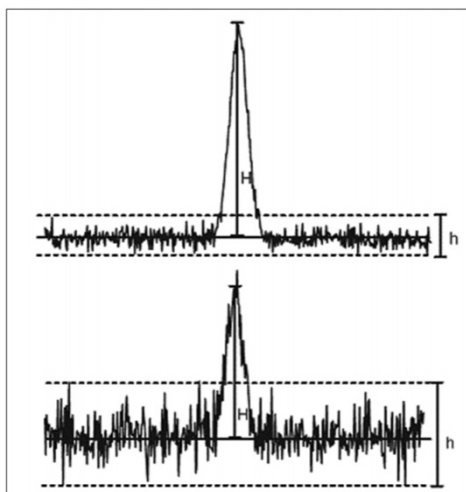
- Standardised Guidelines
 - Required Reading
 - Easier Training
- Can they be converted to trainee manuals
 - More complete examples
 - Helpful to have access to background thinking

Example: Validation of Analytical Methodology

7.2. Based on Signal-to-Noise Approach

This approach can only be applied to analytical procedures that exhibit baseline noise.

Determination of the signal-to-noise ratio is performed by comparing measured signals from samples with known low concentrations of analyte with those of blank samples and by establishing the minimum concentration at which the analyte can be reliably quantified. A typical signal-to-noise ratio is 10:1.



← Illustrated example:



Training needs

- Practical Exposure
 - Internships in accredited facilities
 - Analytical laboratories
 - Requirements for analytical reports
 - Pharmacovigilance Exposure
- Access to Mentors
 - Contact persons list
 - Virtual Class-rooms
- Access to a full dossier
 - And full evaluator report



Pharmaceutical Stats

- Very poor exposure in veterinary training
- Potential for guidance on applicable stats
 - Withdrawal Periods
 - Bioequivalence
 - Non-inferiority testing

Scarce Skills Field

- Environmental Toxicity
 - Training in application of the guidelines
 - Aquatotoxicity still a new field





Conclusion

- VICH process facilitate easier training
- Not always easy to train with limited facilities
- Training needs:
 - Guidelines to be linked with working examples
 - Access to mentors
 - Opportunities for experiential training