



**AUSTRALIAN AND NEW ZEALAND
COLLEGE OF VETERINARY SCIENTISTS**

FELLOWSHIP GUIDELINES

Veterinary Applied Pharmacology (Industrial Pharmacology option)

ELIGIBILITY

1. The candidate shall meet the eligibility prerequisites for Fellowship outlined in the *Fellowship Candidate Handbook*.
2. Membership of the College must be achieved prior to the Fellowship examination.
3. Membership may be in any discipline.

OBJECTIVES

To demonstrate that the candidate has sufficient training, experience, knowledge and accomplishment in Veterinary Industrial Pharmacology and that may lead to registration as a specialist in this field.

LEARNING OUTCOMES

The candidate is expected to have:

1. Extensive practical experience and accomplishment relevant to Australia or New Zealand and an understanding of Veterinary Industrial Pharmacology on a global basis.
2. Recognition as an authority in the field by veterinary colleagues and by other professional people working in the field.
3. Critically evaluated the current literature and concepts in the field of Veterinary Industrial Pharmacology.

At the completion of training, the candidate should have **detailed**¹ knowledge of:

¹ **Knowledge levels:**

Detailed knowledge — candidates must be able to demonstrate an in-depth knowledge of the topic including differing points of view and published literature. The highest level of knowledge.

Sound knowledge — candidate must know all of the principles of the topic including some of the finer detail, and be able to identify areas where opinions may diverge. A middle level of knowledge.

Basic knowledge — candidate must know the main points of the topic and the core literature.

1. Discovery and development of new drugs including research procedures for the testing of a wide variety of therapeutic candidates.
2. Various types of pharmaceutical preparations and their manufacture.
3. Quality control and quality assurance of drugs during manufacture including Good Manufacturing Practice (GMP) and pharmaceutical process validation.
4. Good Laboratory Practice (GLP) including specified pathogen free (SPF) flocks and animals.
5. Pharmaceutical principles involved in the formulation of veterinary dosage forms.
6. Modes of drug presentation including novel presentation and delivery systems.
7. Design, implementation, analysis and interpretation of clinical trials.
8. Design, implementation, analysis and interpretation of chemical residue trials.
9. Veterinary applied immunology, principles of vaccine production, adjuvants, clinical application of vaccines, and agents used in, and the principles of, immunodiagnostic tests.
10. Manufacture, testing and usage of the groups of chemotherapeutic agents currently in use in Australasia.
11. Product registration in Australia and/or New Zealand – legal, regulatory and professional (ethical) aspects.
12. Pharmacovigilance including complaint investigation procedures, decision analysis and product recall action.

At the completion of training, the candidate should have **sound** knowledge of:

1. The pathophysiology and mechanisms of disease in domestic animal species at a standard sufficient to rationalize drug action and effect.
2. The principles of pharmacokinetics and pharmacodynamics applicable to domestic animal species.

At the completion of training, the candidate should have **basic** knowledge of:

1. The general pharmacology involved in each of the following areas:
 - (a) drug application in ophthalmology
 - (b) general and local anaesthetics and fluid and electrolyte therapy
 - (c) drugs used topically for the treatment of skin disorders
 - (d) vitamin and mineral supplements
 - (e) drugs used in the treatment of reproductive disorders
 - (f) toxins
 - (g) disinfectants and antiseptics

- (h) drugs affecting central and peripheral nervous systems with particular reference to pain management and restraint
- (i) drugs used in the control and management of inflammation
- (j) hormone agonists and antagonists
- (k) antimicrobial drugs, antiparasitic drugs, antifungal drugs and antiviral drugs
- (l) drugs used in the treatment of diseases of each of the following systems -
 - (i) cardiovascular system
 - (ii) gastrointestinal system
 - (iii) urogenital system
 - (iv) respiratory system
- (m) drugs used in the treatment of neoplastic disease
- (n) adverse drug reactions and drug interactions in domestic animal species in health and disease
- (o) chemical residue implications and avoidance

EXAMINATIONS

Refer to the *Fellowship Candidate Handbook*, Section 7.

TRAINING PROGRAMS

Refer to the *Fellowship Candidate Handbook*, Section 3.3.

Candidates for Fellowship in Veterinary Applied Pharmacology (Industrial Pharmacology option) must complete at least two years of supervised training as stipulated by the *Fellowship Candidate Handbook*. Supervised training may be undertaken in the veterinary pharmaceutical industry **OR** in an institution that specialises in contract research for the veterinary pharmaceutical industry **OR** in a government agency that regulates the veterinary pharmaceutical industry.

EXTERNSHIPS

Refer to the *Fellowship Candidate Handbook*, Section 3.4.1.

Candidates for Fellowship in Veterinary Applied Pharmacology (Industrial Pharmacology option) must complete at least one Externship as stipulated by the *Fellowship Candidate Handbook*. For the purpose of this non-clinical subject, some externships can only be achieved by training under the supervision of a recognised expert who does not necessarily have specialist qualifications as per the Principal Supervisor. However, this ‘adjunct’ supervisor must be authorised by the FTCC based on his/her qualifications and experience.

During periods of training with ‘adjunct’ supervisors, the Principal Supervisor must:

1. Maintain prime responsibility for and regular contact with the candidate, and monitor the candidate’s progress.
2. Communicate by phone, electronically or in person with the candidate at least once weekly to discuss the training the candidate has been exposed to during periods of ‘adjunct’ training.
3. Sign the Activity Log entries that represent ‘adjunct’ training periods, indicating that they accurately document work completed by the candidate during periods of ‘adjunct’ training.

Externship(s) must be undertaken in one or more of the following areas:

1. Veterinary pharmaceutical R&D;

2. Veterinary vaccine R&D;
3. Government regulation of veterinary drugs and vaccines;
4. Contract research for the veterinary pharmaceutical industry.

TRAINING IN RELATED DISCIPLINES

Refer to the *Fellowship Candidate Handbook*, Section 3.4.2.

Candidates for Fellowship in Veterinary Applied Pharmacology (Industrial Pharmacology option) must spend time as stipulated by the *Fellowship Candidate Handbook*, in one or more of the following related disciplines: veterinary clinical pharmacology, pharmaceutical sciences, statistics, veterinary parasitology, veterinary microbiology, veterinary immunology, veterinary virology.

ACTIVITY LOG AND ACTIVITY LOG SUMMARY

The Activity Log (AL) should be recorded in accordance with the example given in Appendix 1).

The Activity Log Summary (ALS) should be kept in the format of Section 8.9 with the exception that the cells of the table show 'Number of Weeks' and not 'Number of Cases'.

Categories for Sections 8.6 and 8.9 are as follows:

- Veterinary pharmaceutical R&D
- Veterinary vaccine R&D
- Trial design, conduct & data analysis
- GMP audit of veterinary pharmaceuticals and vaccines
- Pharmaceutical formulation development
- Government regulation of veterinary drugs

PUBLICATIONS

Refer to the *Fellowship Candidate Handbook*, Section 3.11.

RECOMMENDED READING LIST:

The candidate is expected to research the depth and breadth of the knowledge of the discipline. This list is intended to guide the candidate to some core references (indicated by an *) and source material. The list is not comprehensive and is not intended as an indicator of the content of the examination.

General Pharmacology

Brunton, L., Lazo, J. and Parker, K. (eds.) Goodman and Gilman's The Pharmacological Basis of Therapeutics, 11th ed, McGraw-Hill, New York, 2006.

Katzung, B.G. (ed.) Basic and Clinical Pharmacology, 10th Edition, McGraw-Hill, New York, 2006.

Minneman, K.P. and Wecker, L. (eds.) Brody's Human Pharmacology: Molecular to Clinical, 4th Edition, Mosby, St Louis, 2005.

Carruthers, S.G., Hoffman, B.B., Melmon, K.L. and Nierenberg, D.F. Melmon and Morelli's Clinical Pharmacology: Basic Principles in Therapeutics, 4th Edition, New York, McGraw-Hill, 2000.

Industrial Pharmacology and Pharmacy

* Hardee, G.E. and Baggot, J.D. (eds.) Development and Formulation of Veterinary Dosage Forms, 2nd Edition, Marcel Dekker, Inc., New York, 1998.

* Lachman, L., Lieberman, H.A. and Kanig, J.L. The Theory and Practice of Industrial Pharmacy, 3rd Edition, Lea & Febiger, Philadelphia, 1986.

Veterinary Clinical Pharmacology and Pharmacotherapeutics

* Giguere, S., Prescott, J.F., Baggot, J.D., Walker, R.D. and Dowling, P.M. (eds.) Antimicrobial Therapy in Veterinary Medicine, 4th Edition, Blackwell Publishing, Ames, 2006.

Plumb, D.C. Plumb's Veterinary Drug Handbook, 5th Edition, Blackwell Publishing, Ames, Iowa, 2005.

Maddison, J., Page, S. and Church, D. (eds.) Small Animal Clinical Pharmacology. W.B. Saunders, London, 2002.

Boothe, D.M. Small Animal Clinical Pharmacology and Therapeutics, 1st Edition, W.B. Saunders, Philadelphia, 2001.

* Adams, H.R. Veterinary Pharmacology and Therapeutics, 8th Edition, Iowa State University Press, 2001.

Baggot, J.D. The Physiological Basis of Veterinary Clinical Pharmacology, 1st Edition, Blackwell Publishing, Ames, 2001.

Barragry, T.B. and Powers, T.E. Veterinary Drug Therapy, Lea & Febiger, Philadelphia, 1994.

Brander, G.C., Pugh, D.M., Bywater, R.J. and Jenkins, W.L. Veterinary Applied Pharmacology and Therapeutics, 5th Edition, Bailliere Tindall, London, 1991.

Pharmacokinetics

Gabrielsson, J. and Weiner, D. Pharmacokinetic-Pharmacodynamic Data Analysis: Concepts and Applications, 4th Edition, Swedish Pharmaceutical Press, Stockholm, 2006.

Birkett, D.J. Pharmacokinetics Made Easy, Revised, 2nd Edition, McGraw-Hill, Sydney, 2002.

Riviere, J.E. Comparative Pharmacokinetics: Principles, Techniques and Applications, Iowa State University Press, Ames, 1999.

Rowland, M. and Tozer, T.N. Clinical Pharmacokinetics: Concepts and Applications, 3rd Edition, Lippincott Williams and Wilkins, Philadelphia, 1995.

Gibaldi, M. Biopharmaceutics and Clinical Pharmacokinetics, 4th Edition, Lea & Febiger, Philadelphia, 1991.

* Gibaldi, M. and Perrier, D. Pharmacokinetics, 2nd Edition, Marcel Dekker, Inc., New York, 1982.

Biopharmaceutics

Florence, A.T. and Attwood, D. Physicochemical Principles of Pharmacy, 4th Edition, Pharmaceutical Press, London, 2006.

* Aulton, M.E. (ed.) Pharmaceutics: The Science of Dosage Form Design, 2nd Edition, Churchill Livingstone, London, 2002.

* Rathbone, M.J. and Gurney, R. (eds.) Controlled Release Veterinary Drug Delivery: Biological and Pharmaceutical Considerations, Elsevier, Amsterdam, 2000.

Various volumes from the Drug and Pharmaceutical Sciences Series published by Marcel Dekker.

Veterinary Vaccinology

* Tizard, I. Veterinary Immunology: An Introduction, 7th Edition, W.B. Saunders, Philadelphia, 2004.

* Pastoret, P.-P., Blancou, J., Vannier, P. and Verschuere, C. (eds.) Veterinary Vaccinology, Elsevier, Amsterdam, 1997.

Wood, P.R., Willadsen, P., Vercoe, J.E., Hoskinson, R.M. and Demeyer, D. (eds.) Vaccines in Agriculture: Immunological Applications to Animal Health and Production, CSIRO Australia, Melbourne, 1994.

Special issue of Immunology and Cell Biology titled 'Recent developments in veterinary vaccines', Vol 71, Part 5, October 1993.

* Burleson, F.G., Chambers, T.M. and Wiedbrauk, D.L. Virology: A Laboratory Manual, Academic Press, Inc., New York, 1992.

Veterinary Parasitology

* Holdsworth, P.A. (ed.) Ectoparasiticide use in contemporary Australian livestock production, Avcare Limited, Canberra, 2005.

Boray, J., Martin, P. & Rousch (eds.) Resistance of parasites to antiparasitic drugs, VIIth International Congress of Parasitology, Paris (MSD Agvet), 1990.

Charleston, W.A.G. (ed.) Ectoparasiticides of sheep in New Zealand and their control, N.Z.V.A. Sheep and Beef Cattle Society, 1985.

Clinical Trials

Spilker, B. Guide to Clinical Trials, 1st Edition, Lippincott Williams & Wilkins, Philadelphia, 1991.

Friedman, L.M., Furberg, C.D., DeMets, D.L. Fundamentals of Clinical Trials, 3rd Edition, Springer-Verlag, New York, 1998.

Biostatistics

Bolton, S. and Bon, C. Pharmaceutical Statistics. Practical and Clinical Applications, 4th Edition, Marcel Dekker, Inc., New York, 2004.

Redmond, C.K. and Colton, T. (eds.) Biostatistics in Clinical Trials, John Wiley & Sons, Inc., Chichester, 2001.

Pharmacoepidemiology

Strom, B.L. (ed.) Pharmacoepidemiology, 4th Edition, Wiley, Hoeoken, New Jersey, 2005.

Pathophysiology

Slauson, D.O. and Cooper, B.J. Mechanisms of Disease: A Textbook of Comparative General Pathology, 3rd Edition, Mosby, St Louis, 2002.

Veterinary Medicine

Ettinger, S.J. and Feldman, E.C. (eds.) Textbook of Veterinary Internal Medicine: Diseases of the Dog and Cat, Volumes I and II, 6th Edition. W.B. Saunders, Philadelphia, 2005.

Smith, B.P. Large Animal Internal Medicine, 3rd Edition, Mosby, St. Louis, 2002.

Current Veterinary Therapy

Kirk – Small Animal Practice

Robinson – Equine Practice

Howard – Food Animal Practice

Morrow - Theriogenology

Government Regulation

The following documents and guidelines are accessible from <http://www.apvma.gov.au>

Registration

Fact Sheets and Information Sheets on a range of registration topics

Stock Feeds/Vitamin and Mineral Supplements/Feed Enzymes/Direct Fed Microbials/Therapeutic Pet Food Diets

Policy on stock feeds and stock feed additives

Guideline for stockfeed supplement products containing vitamins, minerals or amino acids and containing only 'nutritional messages'

Guidelines for the registration of direct fed microbial products used in stock feeds

Guidelines for the registration of enzyme based products

Therapeutic pet food diets

Bioequivalence/Bioavailability Guidelines

Policy on the requirement to demonstrate bioequivalence and bioavailability

Companion Animal Ectoparasiticide Guidelines

Guidelines for acceptable claims based on currently approved constituents for ectoparasiticides used on cats, dogs or ornamental caged birds

Guidelines for small animal ectoparasiticide efficacy submission

Food Producing Animal Ectoparasiticide Guidelines

Guidelines for the registration of agents for the control and treatment of non-benign ovine footrot

Guidelines for the establishment of efficacy and management data in support of applications for the registration of products to be used in control of the buffalo fly (*Haematobia irritans exigua*)

Guideline for the establishment of efficacy and management data in support of applications for the registration of products to be used in control of the cattle tick (*Boophilus microplus*)

Guideline for blowfly specific (flystrike preventatives and treatments) efficacy submissions

Guidelines for ovine miticides efficacy submissions

Guidelines for ovine lousicides efficacy submissions

Intramammaries

Guidelines for registration of intramammary preparations for treatment of bovine mastitis

Anthelmintics

Guidelines for the registration of combination anthelmintics

WAAVP guidelines for evaluating the efficacy of anthelmintics in dogs and cats

WAAVP guidelines for evaluating the efficacy of anthelmintics in equine

WAAVP guidelines for evaluating the efficacy of anthelmintics in ruminants

WAAVP guidelines for evaluating the efficacy of anthelmintics in swine

Immunobiologicals

Data requirements and guidelines for applications to register new veterinary immunobiological products

Guidelines for variations to immunobiological products

General Guidelines

Guidelines for the efficacy and safety of coccidiostats

Registration requirements for allergenic substances

Policy on Limulus Amebocyte Lysate (LAL) Test

Policy document on calcium, magnesium, glucose and phosphorus solutions for the treatment of metabolic diseases in sheep and cattle

Policy for the registration of sheep branding substances

Guidelines for data to support efficacy and safety of teat sanitisers

Chemistry

Guidelines for the generation of storage stability data for veterinary chemical products

Guidelines for the validation of analytical methods

APVMA requirements for the application/assessment/approval of extension of shelf-life for a particular batch of a registered veterinary chemical product

Residues

Animal transfer studies

External treatment of cattle with ectoparasiticides

Maximum residue limit proposals 'at or about the limit of analytical quantitation'

Definition of residues for the purpose of setting an MRL

Processing studies

Stability of residues during storage

Veterinary combination products

Withholding periods

Reporting of residue trials

Pro-pesticides or drugs

Animal housing

Injectable veterinary products

Formulation changes - animal health

Residue analytical method

Extrapolation of data - isomers

Residues in milk - non-antimicrobials

Data requirements for animal tissues residue trials

Residues in milk - antimicrobials

Veterinary drug residue analytical methods

Ectoparasiticide residues in sheep tissue

Residues in honey

Residues in abalone

Assessment of the effect of antimicrobial substances on activity of dairy starter cultures

Residues in poultry tissues and eggs

VICH (International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Products)

VICH guidelines for efficacy of anthelmintics - general requirements

VICH guidelines for efficacy of anthelmintics - specific recommendations for bovines

VICH guidelines for efficacy of anthelmintics - specific recommendations for ovines

VICH guidelines for efficacy of anthelmintics - specific recommendations for caprines

VICH guidelines for impurities in new veterinary drug substances

VICH guidelines for impurities in new veterinary chemical products

VICH guidelines for environment impact assessment for veterinary medicinal products (GL6 and GL38)

VICH guidelines for Good Clinical Practices

VICH guidelines for stability testing of biotechnological/biological veterinary medicinal products

VICH guidelines for impurities - residual solvents

VICH efficacy of anthelmintics: specific recommendations for equine

VICH efficacy of anthelmintics: specific recommendations for porcines

VICH efficacy of anthelmintics: specific recommendations for canines

VICH efficacy of anthelmintics: specific recommendations for felines

VICH efficacy of anthelmintics: specific recommendations for poultry

VICH studies to evaluate the safety of residues of veterinary drugs in human food:
reproduction testing

VICH studies to evaluate the safety of residues of veterinary drugs in human food:
genotoxicity testing

VICH safety of residues of veterinary drugs in human food - carcinogenicity studies

VICH safety of residues of veterinary drugs in human food - repeat-dose (90 days) toxicity
testing

VICH safety of residues of veterinary drugs in human food - developmental toxicity testing

VICH safety of residues of veterinary drugs in human food - general approach to testing

Other Sources

Proceedings No. 103, Post-Graduate Committee in Veterinary Science, University of Sydney,
“Veterinary Clinical Toxicology”, August 1987.

Proceedings No. 198, Post-Graduate Committee in Veterinary Science, University of Sydney,
“Pharmacological Bases of Veterinary Therapeutics”, June/July 1992.

Publication No. 7/92 Murdoch University Foundation for Continuing Veterinary Education,
“Pharmacology”, October 1992.

Journals

Journal of Veterinary Pharmacology and Therapeutics

Vaccine

Veterinary Record

Australian Veterinary Journal

New Zealand Veterinary Journal

Journal of the American Veterinary Medical Association

American Journal of Veterinary Research

Journal of Parasitology

FURTHER INFORMATION

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Appendix 1: Subject-specific Activity Log Template.

(Provide key for all abbreviations used eg PS = Principal Supervisor; BUS = Back-up Supervisor; PSE = Primary Supervisor for Externship; ASE = Adjunct Supervisor for Externship; PS TRD = Primary Supervisor for Training in a Related Discipline etc).

Category	Training facility	Training period	Supervisor	Activity Outcome*	Initials of Supervisor
Government regulation of veterinary drugs	APVMA	Start / finish dates	PSE	Trained in pre-market approval assessments of veterinary drugs and pharmacovigilance	
Veterinary vaccine R&D	Company ABC	Start / finish dates	ASE	Trained in veterinary bacterial vaccine R&D	
Trial design, conduct & data analysis	Company XYZ	Start / finish dates	BUS	Trained in residue depletion trial and proposing Withholding Period	
GMP audit of veterinary drugs/ vaccines	APVMA	Start / finish dates	PSE	Attended GMP audit of solid dosage forms with GMP Inspectors	
Pharmaceutical formulation development	Institution ABC	Start / finish dates	PS TRD	Trained in pharmaceutical formulation development of controlled release ruminal bolus	
Veterinary pharmaceutical R&D	Primary training facility	Start / finish dates	PS	Trained in R&D of intramammary infusions	

*A comprehensive report has been prepared on each of the training outcomes listed and is available for assessment on request.