STATUS OF VICH GUIDELINES & VICH WORKPLAN

1/ Draft and Adopted VICH Guidelines

Re	Topic	TITLE OF GUIDELINES	Expert Working Group in charge	Step Status	**Step 2** (EWG consensus) Signed on:	**Step 3** (SC approval of release for consultation) Signed on:	**Step 5** (EWG consensus) signed on:	**Step 6** (SC approval) signed on:	Implementation date
GL1	Validation definitions	Validation of analytical procedures: definition and terminology	Quality	Step 7	Mar. 1997	Aug.1997	Oct. 1998	Oct. 98	Oct. 1999
GL2	Validation methodology	Validation of analytical procedures : methodology	Quality	Step 7	Mar. 1997	Aug.1997	Oct. 1998	Oct. 98	Oct. 1999
GL3	Stability 1	Stability testing of new drug substances and products	Quality	Step 9	Sep. 1997	Feb. 1998	Mar. 1999	May 1999	May 2000
GL4	Stability 2	Stability testing for new dosage forms	Quality	Step 7	Sep. 1997	Feb. 1998	Mar. 1999	May 1999	May 2000
GL5	Stability 3	Stability testing : photostability testing of new drug substances and products	Quality	Step 7	Sep. 1997	Feb. 1998	Mar. 1999	May 1999	May 2000
GL6	Ecotox Phase I	Environmental impact assessments (EIAs) for veterinary medicinal product (VMPs) Phase 1	Ecotoxicity	Step 7	Sep. 1998	Oct. 1998	Nov. 1999	June 2000	Jul. 2001 (to be implemented in Japan upon completion of phase 2)
GL7	Anthelmintics General	Efficacy of anthelmintics: general requirements	Anthelmintics	Step 9	Aug. 1998	Oct. 1998	Nov. 1999	Nov. 1999	Dec.2000 – June 2001
GL8	Stability premixes		Quality	Step 9	Jul. 1998	Oct. 1998	Nov. 1999	Nov. 1999	Dec.2000 – June 2001
GL9	GCP	Good Clinical Practices	GCP	Step 7	Sep. 1998	Oct. 1998	Nov. 1999	June 2000	Jul. 2001
GL10	Impurities substances	Impurities in new veterinary drug substances	Quality	Step 9	Oct. 1998	Oct. 1998	Nov. 1999	Nov. 1999	Dec.2000 – June 2001

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GL11	Impurities products	Impurities in new veterinary medicinal products	Quality	Step 9	Oct. 1998	Oct. 1998	Nov. 1999	Nov. 1999	Dec.2000 – June 2001
GL 12	Anthelmintics bovine	Efficacy of anthelmintics: specific recommendations for bovines	Anthelmintics	Step 9	Nov. 1998	Feb. 1999	Nov. 1999	Nov. 1999	Dec.2000 – June 2001
GL13	Anthelmintics ovine	Efficacy of anthelmintics: specific recommendations for ovines	Anthelmintics	Step 9	Nov. 1998	Feb. 1999	Nov. 1999	Nov. 1999	Dec.2000 – June 2001
GL14	Anthelmintics caprine	Efficacy of anthelmintics: specific recommendations for caprines	Anthelmintics	Step 9	Nov. 1998	Feb. 1999	Nov. 1999	Nov. 1999	Dec.2000 – June 2001
GL15	Anthelmintics equine	Efficacy of anthelmintics: specific recommendations for equines	Anthelmintics	Step 9	Mar. 1999	Nov. 1999	Feb. 2001	Jun. 2001	Jul. 2002
GL16	Anthelmintics porcine	Efficacy of anthelmintics: specific recommendations for porcines	Anthelmintics	Step 9	Mar. 1999	Nov. 1999	Feb. 2001	Jun. 2001	Jul. 2002
GL17	Stability: Biotechnologicals/ biologicals	Stability testing of new biotechnological/biological products	Quality	Step 7	Apr. 1999	July 1999	Mar. 2000	Jun. 2000	Jul. 2001
GL18	Impurities: Residual Solvents	Impurities: residual solvents in new veterinary medicinal products, active substances and excipients	Quality	Step 9	Apr. 1999	July 1999	Mar. 2000	Jun. 2000	Jul. 2001
GL19	Anthelmintics canine	Efficacy of anthelmintics: specific recommendations for canine	Anthelmintics	Step 9	Nov. 1999	Nov. 1999	Feb. 2001	Jun. 2001	Jul. 2002
GL20	Anthelmintics feline	Efficacy of anthelmintics: specific recommendations for feline	Anthelmintics	Step 9	Feb. 2000	Jun. 2000	Feb. 2001	Jun. 2001	Jul. 2002
GL21	Anthelmintics poultry	Efficacy of anthelmintics: specific recommendations for poultry	Anthelmintics	Step 9	Feb. 2000	Jun. 2000	Feb. 2001	Jun. 2001	Jul. 2002
GL22	Safety reproduction	Studies to evaluate the safety of residues of veterinary drugs in human food: reproduction studies	Safety	Step 9	Apr. 2000	Jun. 2000	May 2001	Jun. 2001	Aug. 2002

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GL23	Safety genotoxicity	Studies to evaluate the safety of residues of veterinary drugs in human food: genotoxicity testing	Safety	Step 9	Apr. 2000	Jun. 2000	May 2001	Jun. 2001	Aug. 2002 2001 (to be implemented in Japan upon completion of phase 2)
GL24	Pharmacovigilance	Pharmacovigilance of veterinary medicinal products: management of Adverse Event Reports (AERs)	Pharmacovigilance	Step 7	Apr. 2000	(Jun. 2000) **Re-signed Nov 2005**	(May 2001) Sept. 2007	Oct 2007	December 2015
GL25	Biologicals	Testing of residual formaldehyde	Biologicals	Step 7	Jul. 2000	Nov. 2000	Feb. 2002	Apr. 2002	May 2003
GL26	Biologicals	Testing of residual moisture	Biologicals	Step 7	Jul. 2000	Nov. 2000	Feb. 2002	Apr. 2002	May 2003
GL27	Antimicrobial Resistance	Guidance on pre-approval information for registration of new veterinary medicinal products for food producing animals with respect to antimicrobial resistance	Antimicrobial Resistance	Step 7	May 2001	Jun. 2001	Aug. 2003	Oct. 2003	15 December 2004
GL28	Safety carcinogenicity	Studies to evaluate the safety of residues of veterinary drug in human food: carcinogenicity testing	Safety	Step 9	May 2001	Jun. 2001	Aug. 2002	Oct. 2002	Oct. 2003
GL29	Pharmacovigilance : PSU	Pharmacovigilance of Veterinary Medicinal Products: Management of Periodic Summary Update Reports (PSUs)	Pharmacovigilance	Step 7	May 2001	Jun. 2001	May 2006	June 2006	June 2007
GL30	Pharmacovigilance : list of terms	Pharmacovigilance of Veterinary Medicinal Products: Controlled List of Terms	Pharmacovigilance	Step 7	May 2006	June 2006	(Sept. 2007) **Re-signed** June 2010	June 2010	December 2015
GL31	Safety: Repeat-dose toxicity test	Studies to evaluate the safety of residues of veterinary drugs in human food: Repeat-dose toxicity testing	Safety	Step 7	Dec. 2001	Apr. 2002	Oct. 2002	Oct. 2002	Oct. 2003
GL32	Safety: Developmental toxicity test	Studies to evaluate the safety of residues of veterinary drugs in human food: Developmental toxicity testing	Safety	Step 7	Dec. 2001	Apr. 2002	Oct. 2002	Oct. 2002	Oct. 2003 (Exc. EU)
GL33	Safety: General approach to testing	Studies to evaluate the safety of residues of veterinary drugs in human food: General approach to testing	Safety	Step 9	Dec. 2001	Apr. 2002	Oct. 2002	Oct. 2002	Oct. 2003

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GL34	Biologicals: Mycoplasma	Test for the detection of Mycoplasma contamination	Biologicals	Step 7	Dec. 2001	(Sept. 2007) **Re-signed** Nov. 2011	Jan. 2013	Feb. 2013	Feb. 2014
GL35	Pharmacovigilance: ESTD	Pharmacovigilance: Electronic Standards for Transfer of Data	Pharmacovigilance	Step 9	(May 2002) **Re-signed** June 2010	(Sept. 2007) **Re-signed** June 2010	Feb. 2013	Feb. 2013	December 2015
GL36	Safety: microbiological ADI	Studies to evaluate the safety of residues of veterinary drugs in human food: General Approach to establish a microbiological ADI	Safety	Step 9	May 2002 by Task Force	May 2003	March 2004	May 2004	May 2005
GL37	Safety: repeat dose chronic toxicity	Studies to evaluate the safety of residues of veterinary drugs in human food: Repeat-dose Chronic Toxicity Testing	Safety	Step 7	May 2002 by Task Force	May 2003	March 2004	May 2004	May 2005
GL38	Ecotoxicity Phase II	Environmental Impact Assessment (EIAs) for Veterinary Medicinal Products (VMPs) – Phase II	Ecotoxicity	Step 7	July 2003	Oct. 2003	Sept. 2004	Oct. 2004	Oct. 2005
GL39	Quality: specifications	Test Procedures and Acceptance Criteria for new Veterinary Drug Substances and New medicinal Products: Chemical Substances	Quality	Step 7	July 2004	August 2004	Sept. 2005	Nov. 2005	Nov. 2006
GL40	Quality: specifications	Test Procedures and Acceptance Criteria for new Biotechnological/Biological Veterinary Medicinal Products	Quality	Step 7	July 2004	August 2004	Sept. 2005	Nov. 2005	Nov. 2006
GL41	TAS: reversion to virulence	Examination of live Veterinary Vaccines in Target Animals for Absence of Reversion to Virulence	TAS	Step 7	Sept. 2004	Oct. 2004	June 2007	July 2007	July 2008
GL42	Pharmacovigilance: Data elements	Pharmacovigilance: Data Elements for Submission of Adverse Events Reports	Pharmacovigilance	Step 9	Oct. 2005	Nov. 2005	Sept. 2007 **Re-signed** June 2010	Oct 2007 **Re-signed** June 2010	December 2015
GL43	TAS: Pharmaceuticals	Target Animal Safety for Pharmaceuticals	TAS	Step 7	Sept. 2006	Dec. 2006	June 2009	July 2009	July 2010
GL44	TAS: Biologicals	Target Animal Safety for Veterinary live and inactivated Vaccines	TAS	Step 7	June 2007	August 2007	June 2009	July 2009	July 2010

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GL45	Quality: Bracketing and Matrixing	Bracketing and Matrixing Designs for Stability Testing of new Veterinary Drug Substances and Medicinal Products	Quality	Step 7	Nov. 2007	Feb. 2008	Feb. 2010	April 2010	April 2011
GL 46	MRK: Nature of Residues	Studies to evaluate the Metabolism and Residue Kinetics of Veterinary Drugs in Food-producing Animals: Metabolism Study to determine the Quantity and Identify the Nature of Residues	MRK	Step 7	July 2009	Nov. 2009	Dec 2010	Feb. 2011	Feb. 2012
GL 47	MRK: Comparative Metabolism Studies	Studies to evaluate the Metabolism and Residue Kinetics of Veterinary Drugs in Food-producing Animals: Comparative Metabolism Studies in Laboratory Animals	MRK	Step 9	July 2009	Nov. 2009	Dec 2010	Feb. 2011	Feb. 2012
GL 48	MRK: Marker Residue Depletion Studies	Studies to evaluate the Metabolism and Residue Kinetics of Veterinary Drugs in Food-producing Animals: Marker Residue Depletion Studies to establish Product Withdrawal Periods	MRK	Step 9	July 2009	Nov. 2009	Dec 2010	Feb. 2011	Feb. 2012
GL 49	MRK: Method used in Residue Depletion Studies	Guidelines for the Validation of Analytical Methods used in Residue Depletion Studies	MRK	Step 9	July 2009	Nov. 2009	Dec 2010	Feb. 2011	Feb. 2012
GL 50	Biologicals: TABST	Harmonisation of criteria to waive target animal batch safety testing (TABST) for inactivated vaccines for veterinary use	Biologicals	Step 9	Sept. 2011	Nov. 2011	Feb. 2013	Feb. 2013	Feb. 2014
GL51	Quality: Stability data	Statistical evaluation of stability data	Quality	Step 7	Nov. 2011	Nov. 2011	Feb. 2013	Feb. 2013	Feb. 2014
GL52	Bioequivalence: Blood level	Blood Level Bioequivalence Study	Bioequivalence	Step 7	Oct. 2013	Nov. 2013	June 2015	Aug. 2015	Aug. 2016
GL53	Electronic File Format	Electronic exchange of documents: File format requirements	EFF	Step 7	Nov. 2013	Jan. 2014	Jan. 2015	Feb. 2015	Feb. 2016
GL54	Safety: Acute Reference Dose (ARfD)	Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: General Approach to Establish an Acute Reference Dose (ARfD)	Safety	Step 7	Dec. 2014	Feb 2015	Sept 2016	Nov. 2016	Nov. 2017

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GL 55	Biologicals: TABST Live vaccines	Harmonisation of criteria to waive target animal batch safety testing for live vaccines	Biologicals	Step 7	Sept. 2015	Oct 2015 Re-signed in Feb 2016	April 2017	May 2017	May 2018
GL 56	MRK: Residues in Honey	Studies to evaluate the Metabolism and Residue Kinetics of Veterinary Drugs in Food-producing Species: Study Design Recommendations for Residue Studies in Honey for establishing MRLs and Withdrawal Periods	MRK	Step 7	Oct. 2016	Jan. 2017	June 2018	June 2018	June 2019
GL 57	MRK: Residues in Fish	Studies to evaluate the Metabolism and Residue Kinetics of veterinary drugs in food-producing species: Marker residue depletion studies to establish product withdrawal periods in aquatic species	MRK	Step 7	Nov. 2017	Dec. 2017	February 2019	February 2019	February 2020
GL 58	Stability: Climatic Zones III and IV	Stability Testing of New Veterinary Drug Substances and Medicinal Products in Climatic Zones III and IV	Quality	Step 7	June 2018	June 2018	October 2019	November 2019	November 2020
GL 59	Biologicals: LABST Veterinary vaccines	Harmonisation of criteria to waive laboratory animal batch safety testing for vaccines for veterinary use	Biologicals	Step 7	June 2019	Oct. 2019	October 2020	November 2020	November 2021
GL 60	Quality: GMP for API	Good Manufacturing Practice for Active Pharmaceutical Ingredients used in Veterinary Medicinal Products	Quality	Step 4	August 2023	Sept. 2023			
GL 61	Quality: Pharmaceutical Development	Pharmaceutical Development for veterinary medicinal products	Quality	Step 4	January 2024	February 2024			
GL 62	Biologicals: TAS Evaluation for VMAP	Target Animal Safety Evaluation for Veterinary Monoclonal Antibody Products	Biologicals	Step 2	June 2025	August 2025			

2/ VICH Revised Guidelines at Step 9

GL3	Stability 1	Stability testing of new drug substances and products	Quality	Step 7	April 2005	May 2005	Dec. 2006	Jan 2007	Jan 2008

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GL7	Anthelmintics General	Efficacy of anthelmintics: general requirements	Anthelmintics	Step 4	March 22	May 22	Sept 24	October 24	October 25
GL10	Impurities substances	Impurities in new veterinary drug substances	Quality	Step 7	April 2005	May 2005	Dec. 2006	Jan 2007	Jan 2008
GL11	Impurities products	Impurities in new veterinary medicinal products	Quality	Step 7	April 2005	May 2005	Dec. 2006	Jan 2007	Jan 2008
GL 12	Anthelmintics bovine	Efficacy of anthelmintics: specific recommendations for bovines	Anthelmintics	Step 7	March 22	May 22	Sept 24	October 24	October 25
GL13	Anthelmintics ovine	Efficacy of anthelmintics: specific recommendations for ovines	Anthelmintics	Step 7	March 22	May 22	Sept 24	October 24	October 25
GL14	Anthelmintics caprine	Efficacy of anthelmintics: specific recommendations for caprines	Anthelmintics	Step 7	March 22	May 22	Sept 24	October 24	October 25
GL15	Anthelmintics equine	Efficacy of anthelmintics: specific recommendations for equines	Anthelmintics	Step 7	March 22	May 22	Sept 24	October 24	October 25
GL16	Anthelmintics porcine	Efficacy of anthelmintics: specific recommendations for porcines	Anthelmintics	Step 7	March 22	May 22	Sept 24	October 24	October 25
GL18	Impurities: Residual Solvents	Impurities: residual solvents in new veterinary medicinal products, active substances and excipients	Quality	Step 7	Feb. 2010	April 2010		July 2011	June 2012
GL18 Rev 2	Impurities: Residual Solvents	Impurities: residual solvents in new veterinary medicinal products, active substances and excipients	Quality	Step 7	Oct 21	Nov 21	March 23	April 2023	April 2024
GL19	Anthelmintics canine	Efficacy of anthelmintics: specific recommendations for canine	Anthelmintics	Step 7	March 22	May 22	Sept 24	October 24	October 25
GL20	Anthelmintics feline	Efficacy of anthelmintics: specific recommendations for feline	Anthelmintics	Step 7	March 22	May 22	Sept 24	October 24	October 25
GL21	Anthelmintics poultry	Efficacy of anthelmintics: specific recommendations for poultry	Anthelmintics	Step 7	March 22	May 22	Sept 24	October 24	October 25
GL23	Safety: genotoxicity	Studies to evaluate the safety of residues of veterinary drug in human food: genotoxicity testing	Safety	Step 7	October 2012	Dec 2012	August 2014	Sept. 2014	Oct. 2015

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GL28	Safety: Carcinogenicity	Studies to evaluate the safety of residues of veterinary drug in human food: carcinogenicity testing	Safety	Step 7		May 2004 (part only)	March 2005	March 2005	March 2006
GL33 Rev 2	Safety: General approach to testing	Studies to evaluate the safety of residues of veterinary drugs in human food: General approach to testing	Safety	Step 7				Feb 2009	Feb 2010
GL34 Rev 1	Biologicals: Mycoplasma	Test for the detection of Mycoplasma contamination	Biologicals	Step 7				Nov. 2025	April 2026
GL35 Rev 1	Pharmacovigilance: ESTD	Pharmacovigilance: Electronic Standards for Transfer of Data	Pharmacovigilance	Step 7			Feb 2023	March 2023	March 2024
GL36	Safety: microbiological ADI	Studies to evaluate the safety of residues of veterinary drugs in human food: General Approach to establish a microbiological ADI	Microbiological ADI	Step 7	January 2011	February 2011 (at the 25th SC)	April 2012	May 2012	June 2013
GL36 Rev 2	Safety: microbiological ADI	Studies to evaluate the safety of residues of veterinary drugs in human food: General Approach to establish a microbiological ADI	Microbiological ADI	Step 7				February 2019	August 2019
GL42 Rev 1	Pharmacovigilance: Data elements	Pharmacovigilance: Data Elements for Submission of Adverse Events Reports	Pharmacovigilance	Step 7			Feb 2023	March 2023	March 2024
GL 48	MRK: Marker Residue Depletion Studies	Studies to evaluate the Metabolism and Residue Kinetics of Veterinary Drugs in Food-producing Animals: Marker Residue Depletion Studies to establish Product Withdrawal Periods	MRK	Step 7			Sept 2014	Jan 2015	Jan 2016
GL 49 Rev 1	MRK: Method used in Residue Depletion Studies	Guidelines for the Validation of Analytical Methods used in Residue Depletion Studies	MRK	Step 7			Sept 2014	Jan 2015	Jan 2016
GL 50 Rev 1	Biologicals: TABST	Harmonization of criteria to waive target animal batch safety testing (TABST) for inactivated vaccines for veterinary use	Biologicals	Step 7		Feb. 2016	April 17	May 2017	May 2018

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3/ VICH Guidelines under Revision - Step 9

GL8	Stability premixes	Stability testing for medicated premixes	Quality	Step 4	October 24	November 24			
GL22 Rev 1	Safety reproduction	Studies to evaluate the safety of residues of veterinary drugs in human food: reproduction studies	Safety	Step 6	December 23	January 24	June 25		
GL23 Rev 2	Safety: genotoxicity	Studies to evaluate the safety of residues of veterinary drugs in human food: genotoxicity testing	Safety	Step 6	April 24	May 24	June 25		
GL24	Pharmacovigilance	Pharmacovigilance of veterinary medicinal products: management of Adverse Event Reports (AERs)	Pharmacovigilance	Minor revision	ON HOLD				
GL29	Pharmacovigilance : PSU	Pharmacovigilance of Veterinary Medicinal Products: Management of Periodic Summary Update Reports (PSUs)	Pharmacovigilance	Minor revision	ON HOLD				
GL 47	MRK: Comparative Metabolism Studies	Studies to evaluate the Metabolism and Residue Kinetics of Veterinary Drugs in Food-producing Animals: Comparative Metabolism Studies in Laboratory Animals	MRK	Step1					
GL 49 Rev 2	MRK: Method used in Residue Depletion Studies	Guidelines for the Validation of Analytical Methods used in Residue Depletion Studies	MRK	Step 1					