

Arzneimittel- prüfrichtlinien

Sammlung nationaler und internationaler Richtlinien

41. Aktualisierungslieferung 2021

Diese Aktualisierung enthält Richtlinien und Empfehlungen, insbesondere

- zwei neue Dokumente des Arbeitskreises Blut, darunter das aktualisierte Votum zum Verfahren zur Rückverfolgung (Look Back) (gemäß § 19 Transfusionsgesetz) (V48) und die Stellungnahme zum Beratungsergebnis der gemeinsamen Arbeitsgruppe aus Vertretern des AK Blut, des Ständigen Arbeitskreises „Richtlinien Hämotherapie“, des Wissenschaftlichen Beirats der Bundesärztekammer, des Robert Koch-Instituts, des Paul-Ehrlich-Instituts und des Bundesministeriums für Gesundheit „Blutspende von Personen mit sexuellem Risikoverhalten“,
- die aktualisierte EU-Guidance zum Management klinischer Prüfungen während der Corona-Pandemie und die
- EU-Guideline zur Qualität, nichtklinischen und klinischen Aspekten von Arzneimitteln, die genetisch veränderte Zellen enthalten sowie
- Verlautbarungen der Europäischen Arzneimittelagentur (EMA) über die regulatorischen Anforderungen an Impfstoffe zum Schutz vor SARS-CoV-2-Varianten und zur Zulassung von COVID-19 Impfstoffen,
- die aktualisierte Liste zu Produkt-spezifischen Bioäquivalenzleitlinien,
- die revidierte ICH-Leitlinie zu Lösungsmittelrückständen und eine neue zu nichtklinischen Sicherheitstests zur Unterstützung der Entwicklung von pädiatrischen Arzneimitteln,
- die aktualisierte Liste der Substanzen, die nicht von der Verordnung über die Festlegung von Grenzwerten für Tierarzneimittelrückstände in Lebensmitteln (EC No.470/2009) erfasst sind,
- die neue VICH-Leitlinie zur Harmonisierung der Kriterien für Waiver bezüglich der Chargenprüfung mittels Sicherheits-Tierversuchen für Tierimpfstoffe,
- sieben aktualisierte oder neue europäische Pflanzenmonographien,
- einen aktualisierten Überblick über die Produkt-spezifischen Leitlinien für die staatliche Chargenprüfung (EU Official Control Authority Batch Release) für biologische Humanarzneimittel,
- überarbeitete Register.

Inhaltsverzeichnis

Vorwort	1
Inhaltsverzeichnis	1–44
Abkürzungen	1–4

Register

I.	Sachregister.....	1–30
II.	Register EC/EU-Regulations und EC/EU-Directives allgemein nach Codes.....	1–3
III.	Register CHMP / CPMP Guidelines nach Codes	1–9
IV.	Register CHMP/ICH / CPMP/ICH Guidelines nach Codes	1–3
V.	Register ICH Guidelines nach Themen	1–8
VI.	Register CVMP Guidelines nach Codes	1–3
VII.	Register CVMP/VICH Guidelines nach Codes.....	1–2
VIII.	Register VICH Topics nach Themen	1–3
IX.	Register weitere EMA und EMEA Guidelines und andere Committees nach Codes.....	1
X.	Register Community/European Union Herbal Monographs und andere CHMP-Dokumente nach Codes.....	1–5
XI.	Register Community/European Union Herbal Monographs nach Arzneipflanzen.....	1–6

1 Nationale Richtlinien

DE – Arzneimittel-Prüfrichtlinien

1.0	Nationale Richtlinien – Einführung.....	1–3
1.1	Allgemeine Verwaltungsvorschrift zur Anwendung der Arzneimittelprüfrichtlinien (Oktober 2004)	1–55

1.2	Allgemeine Verwaltungsvorschrift zur Registrierung homöopathischer Arzneimittel zur Anwendung bei Tieren (Oktober 2004).....	1–10
1.3	Verordnung zur Anwendung der Arzneimittelprüfrichtlinien, soweit es sich um Arzneimittel handelt, die zur Anwendung bei Tieren bestimmt sind, und zur Ablösung der Allgemeinen Verwaltungsvorschrift zur Anwendung der Tierarzneimittelprüfrichtlinien (Tierarzneimittel-Prüfrichtlinienverordnung – TamPV) (Februar 2010)	1–2
1.4	Verordnung zur Anwendung der Arzneimittelprüfrichtlinien (Arzneimittelprüfrichtlinien-Verordnung – AMPV) (Januar 2016)...	1–2
DE – Andere nationale Vorschriften		
1.5	Verordnung über die Anwendung der Guten Herstellungspraxis bei der Herstellung von Arzneimitteln und Wirkstoffen und über die Anwendung der Guten fachlichen Praxis bei der Herstellung von Produkten menschlicher Herkunft (Arzneimittel- und Wirkstoffherstellungsverordnung – AMWHV) (Februar 2013)	1–53
1.6	Allgemeine Verwaltungsvorschrift zur Durchführung des Arzneimittelgesetzes (AMGVwV) (März 2006)	1–13
DE – Klinische Prüfungen		
1.9	Nationale Umsetzung der Verordnung (EU) Nr. 536/2014 über klinische Prüfungen mit Humanarzneimitteln (Stand Januar 2017)..	1–2
1.10	Verordnung über die Anwendung der Guten Klinischen Praxis bei der Durchführung von klinischen Prüfungen mit Arzneimitteln zur Anwendung am Menschen (GCP-Verordnung – GCP-V) (Oktober 2012).....	1–21
1.11	Verordnung über das Verfahren zur Zusammenarbeit der Bundesoberbehörden und der registrierten Ethik-Kommissionen bei der Bewertung von Anträgen auf Genehmigung von klinischen Prüfungen mit Humanarzneimitteln (Klinische Prüfung-Bewertungsverfahren-Verordnung – KPBV) (12.07.2017).....	1–16
1.13	Bekanntmachung über die Zulassung, Nachzulassung und Registrierung von Arzneimitteln (Empfehlungen der Kommission D nach § 25 Abs. 6 und Abs. 7 des Arzneimittelgesetzes zur Planung und Durchführung homöopathischer Arzneimittelprüfungen) (November 1998).....	1–5
1.14	Kriterien für Erkenntnismaterial zu klinischen Indikationen in der Homöopathie (Oktober 2002).....	1–5
1.20	Prüfung von chemischen Desinfektionsmitteln auf Wirksamkeit gegen Viren in der Humanmedizin (August 2008).....	1–19
1.25	Stabilitätsprüfung bei nach homöopathischen Verfahrenstechniken hergestellten Arzneimitteln (Juni 2006).....	1–5
1.30	BfArM-Bekanntmachung zur Prüfung des Gehalts an Pyrrolizidinalkaloiden zur Sicherstellung der Qualität und Unbedenklichkeit von Arzneimitteln, die pflanzliche Stoffe bzw. pflanzliche Zubereitungen oder homöopathische Zubereitungen aus pflanzlichen Ausgangsstoffen als Wirkstoffe enthalten (März 2016)	1–3
1.35	Mitteilung des BfArM zu Blutegeln in der Humanmedizin – Leitlinie zur Sicherung von Qualität und Unbedenklichkeit – (Juni 2009)	1–9

1.41	Bewertung fixer Kombinationen homöopathischer Einzelmittel – Bekanntmachung über die Zulassung von Arzneimitteln und die Verlängerung von Zulassungen nach § 105 des Arzneimittelgesetzes (Bewertungskriterien der Kommission D nach § 25 Abs. 6 und 7 des Arzneimittelgesetzes für fixe Kombinationen homöopathischer Einzelmittel) (April 1997)	1–5
1.47	Bekanntmachung des BfArM über die Registrierung, Zulassung und Nachzulassung von Arzneimitteln – Duftstoff Moschus Ambrette – (Dezember 1997)	1–2
1.48	Bekanntmachung zu Maßnahmen zur Verminderung der Kontamination von parenteralen Arzneimitteln durch Asbest (November 1993)	1–5
1.49	Bekanntmachung zur Möglichkeit des Ersatzes der Prüfung auf Pyrogene durch die Prüfung auf Bakterien-Endotoxine nach DAB 10 (Parenteralia; Prüfung auf Reinheit) (November 1992)	1–5
1.51	Überwachung von Heilwasserbetrieben und Heilquellen nach § 64 des Arzneimittelgesetzes (November 2007)	1–6
1.59	Herstellung applikationsfertiger Zytostatikalösungen in Apotheken – Zweck und Anwendungsbereich (Mai 1998)	1–13
DE – Blutzubereitungen		
1.60	Bekanntmachung der Richtlinien zur Gewinnung von Blut und Blutbestandteilen und zur Anwendung von Blutprodukten (Hämotherapie) gemäß §§ 12 und 18 des Transfusionsgesetzes (TFG) (Oktober 2017)	1–78
1.61	Übersicht über die Bescheide des Paul-Ehrlich-Instituts im Bereich Hämovigilanz (Stand: 13.08.2020)	1–8
1.81	Bioverfügbarkeit/Bioäquivalenz – Bekanntmachung über die Zulassung nach § 21 des Arzneimittelgesetzes (Bioverfügbarkeit/Bioäquivalenz) (Dezember 2002)	1–3
1.100	Leitlinien des BVL zur Gewinnung, Lagerung, Transport und Verabreichung von Blut und Blutprodukten im Veterinärbereich (Oktober 2010)	1–22
DE – Arbeitskreis Blut		
1.150	Mitteilungen des Arbeitskreises Blut – Einführung	1–6
1.151	Sitzung vom 15.11.1993 (Aufwandsentschädigung für Blut- und Plasmaspender/Ausschluß von Drogenabhängigen aus der Spenderpopulation/Weitergabe von Daten HIV-positiver Spender an andere Blut- und Plasmaspendedienste)	1–2
1.152	Sitzungen am 15.11.1993 und am 24.1.1994 (Effiziente behördliche Kontrolle von Blutspende- und Plasmaspende-Institutionen/Begrenzung der Poolgröße bei der Verarbeitung von Blutplasma/Bewertung des HIV-1-p24-Antigen-Tests bei Blut und Plasmaspenden)	1–2
1.153	Sitzung am 14.3.1994 (Quarantänelagerung von durch frequente Plasmapherese gewonnenem Frischplasma/Anforderungen an Leiter von Blut- und Plasmaspendeeinrichtungen/Chargendokumentation für Albumin/Empfehlungen zur Eigenblutspende/Stellungnahme zur gerichteten Blutspende und Verwandtenspende)	1–3

1.154	Sitzung am 14.3.1994 (Quarantänelagerung von Plasma für die Fraktionierung)	1
1.155	Sitzung am 6.5.1994 (Minderung des Infektionsrisikos bei Blut und Blutprodukten durch optimiertes Screening von Spendern/Chargendokumentation bei der Anwendung von rekombinantem Faktor VIII/ Zehn-Punkte-Empfehlung zur Etablierung eines koordinierten Meldewesens).....	1-4
1.156	Sitzung am 14.7.1994 (Nutzung von PPSB-Präparat Beriplex nur bei vitaler Indikation).....	1
1.157	Sitzung am 19.9.1994 (Verringerung des Übertragungsrisikos von Hepatitis B durch Testung auf Anti-HBc-Antikörper/Kennzeichnung von Blutprodukten zur Erleichterung der Chargendokumentation beim Anwender/Empfehlungen der Ad-hoc-Kommission des Arbeitskreises Blut zum Rückverfolgungsverfahren (look back) für Einzelspender und Kleinpool-Blutpräparate/Mindestvoraussetzungen für Eigenherstellung.....	1-9
1.158	Sitzung vom 9.5.1995 (Verhinderung von bakterieller Kontamination bei Blutkonserven).....	1-2
1.159	Sitzung vom 19.6.1995 (Empfehlungen zum Vorgehen bei reaktiven Screeningtesten auf HIV- oder HCV-Antikörper bzw. HBV-surface-Antigen bei Blut- und Plasmaspenden/Empfehlungen zu Bestellung und Aufgaben von Transfusionsverantwortlichen, Transfusionsbeauftragten, Transfusionskommissionen und Arbeitskreisen für Hämotherapie/ Verwerfen von nicht verwendeten Eigenblut-Spenden und Ablehnung gerichteter Spenden).....	1-6
1.160	Sitzung vom 1.9.1995 (Verbesserung von Screeningtesten für den Nachweis von Infektionserregern und Risikoabwehr/Verantwortlichkeit von fort- und weitergebildeten Ärzten für transfusionsrelevanten Immunhämatologie)	1-2
1.161	Sitzung vom 24.10.1995 (Hyperimmunplasma zur Herstellung von Hyperimmunglobulinen/Vorschläge zu Aufkommen und Verbrauch von Blutkomponenten und Plasmaderivaten mit dem Ziel der Selbstversorgung/Erhöhung der Sicherheit von Plasmapräparaten durch PCR-Testung).....	1-5
1.162	Sitzung vom 23.1.1996 (Stellungnahme zu Rückrufaktionen wegen der Gefahr einer Übertragung der Creutzfeldt-Jakob-Erkrankung durch Blutprodukte).....	1
1.163	Sitzung vom 14.5.1996 (V 13) (Ergänzung zu Empfehlungen des Arbeitskreises Blut zum Vorgehen bei reaktiven Screeningtests auf HIV- oder HCV-Antikörper bzw. HBV-surface-Antigen bei Blut- und Plasmaspenden)	1-5
1.164	Sitzung vom 1.7.1996 (V 14) (Empfehlungen zur Rückverfolgung (look back) infektionsverdächtiger Plasmaspenden für Plasma zur Fraktionierung)	1-3
1.165	Sitzung vom 16.1.1997 (V 15) (Transfusionsmedizinische Ausbildung im Medizinstudium).....	1

1.166	Sitzung vom 5.6.199 (V 16) (Mindestanforderungen zur Sterilitätstestung von Blutkomponenten).....	1-5
1.167	Sitzung vom 3.9.1997 (V 17) (Koordiniertes Meldewesen und Meldebögen: Ergänzung und Aktualisierung der Empfehlung/Empfehlung zu Nachuntersuchungsproben von therapeutischen Blutkomponenten und Rückstellproben von Plasmapools).....	1-4
1.168	Sitzung vom 3.9.1997 (V 18) (Nukleinsäure-Nachweistechniken in der Transfusionsmedizin: Voraussetzungen).....	1-6
1.169	Sitzung vom 19.3.199 (V 19) (Nukleinsäure-Nachweistechniken in der Transfusionsmedizin: Voraussetzungen (Ergänzung)).....	1-2
1.170	Sitzung vom 16.9.1998 (V 20) (Testung von Blutspenden auf Hepatitis-C-Virus mit Nukleinsäure-Nachweis-Techniken).....	1
1.171	Sitzung vom 30./31.8.1999 (V 21) (Ergänzende Empfehlungen zur Testung von Blut- und Plasmaspenden und zum Rückverfolgungsverfahren).....	1-6
1.172	Sitzung vom 16.11.1999 (V 22) (Empfehlung zum Meldewesen nach Transfusionsgesetz § 22 (Epidemiologische Daten))	1-8
1.173	Sitzung vom 16.11.1999 (V 23) (Empfehlung zum Meldewesen nach Transfusionsgesetz § 22 (Epidemiologische Daten): Erratum (V23))	1
1.174	Sitzung vom 8.11.2000 (V 24) (Verfahren zur Rückverfolgung (Look Back) gemäß § 19 Transfusionsgesetz).....	1
1.175	Sitzung vom 1.3.2001 (V 25) (Empfehlung zur Einführung eines neuen Querschnittsbereichs mit Pflichtveranstaltung „Transfusionsmedizin mit Hämostaseologie“ im Rahmen der Novellierung der Approbationsordnung).....	1-2
1.176	Sitzung vom 15./16.10.2001 (V 26) (Zur europäischen Diskussion über die Aufwandsentschädigung für Blut- und Plasmaspender).....	1
1.177	Sitzung vom 26.6.2002 (V 27) (Einführung des „Predonation Sampling“) 1	
1.178	Sitzung vom 6.11.2002 (V 28) (Reduzierung des Zeitraums der Quarantänelagerung für gefrorenes Frischplasma (GFP) von 6 Monaten auf 4 Monate).....	1
1.179	Sitzung vom 6.3.2003 (V 29) (Studentische Ausbildung in Transfusionsmedizin und Hämostaseologie (Hämotherapie))	1-2
1.180	Sitzung vom 1.10.2003 (V 30) (Verzicht auf die Bestimmung der Alanin-Aminotransferase (ALT) als Freigabekriterium für Blutkomponenten zur Transfusion und Plasma zur Fraktionierung)	1-2
1.181	Sitzung vom 17.3.2005 (V 31) (Erhöhung der Sicherheit von zellulären Blutkomponenten und quarantänegelagertem Frischplasma durch Untersuchung der Blut- und Plasmaspenden auf Antikörper gegen das Hepatitis-B-Core-Antigen (Anti-HBc)).....	1-4
1.182	Sitzung vom 17.3.2005 (V 32) (Aktuelle Empfehlungen zur autologen Hämotherapie)	1-4
1.186	Sitzung vom 1.10.2007 (V 36) (Verwechslungssichere Dokumentation durch einheitlichen Kennzeichnungscode für Blutkomponenten in Deutschland)	1
1.187	Sitzung vom 9.6.2008 (V 37) (Meldung von Spendern mit Antikörpern gegen das Hepatitis-B-Core-Antigen (Anti-HBc)).....	1-2

1.188	Sitzung vom 9.6.2008 (V 38) (Festlegung der Haltbarkeitsfrist von Thrombozytenkonzentraten mit dem Ziel der Reduktion lebensbedrohlicher septischer Transfusionsreaktionen durch bakterielle Kontamination).....	1
1.188a	Sitzung vom 9.6.2008 (V 38) (Reduktion des Septikämierisikos bei der Anwendung von Thrombozytenkonzentraten).....	1–6
1.189	Sitzung vom 9.1.2009 (V 39) (Maßnahmen zur Vermeidung der transfusionsinduzierten Lungeninsuffizienz (TRALI)).....	1–2
1.189a	Sitzung vom 30.11.2009 (V 40) Aufrechterhaltung der Blutversorgung bei einer Influenza-Pandemie).....	1–2
1.189b	Sitzung vom 7.6.2010 (V 41) (Verwendung eines einheitlichen Fragebogens für Blut- und Plasmaspender).....	1–2
1.189d	Sitzung vom 7.11.2012 (V 43) (Mindestanforderungen an die mikrobiologische Kontrolle von Blutkomponenten zur Transfusion – Aktualisierung des Votums 16).....	1–4
1.189e	Hygienebedingungen bei Spendeprozessen und deren mikrobiologische Überwachung (s. § 31 Abs. 4 AMWHV*) (V44) (Mai 2015).....	1–6
1.189f	Feststellung der Spendereignung und Spendetauglichkeit von Hämochromatose Merkmalsträgern (V45) (Mai 2015).....	1–3
1.189g	Vorgehensweise bei Variante Creutzfeldt-Jakob-Krankheit (vCJK) im Zusammenhang mit Blut, Plasma und Blutprodukten (V 46) (April 2018).....	1–8
1.189h	Verfahren zur Rückverfolgung (Look Back) (gemäß § 19 Transfusionsgesetz) (V48) (November 2020).....	1–26
1.190	Arbeitskreis Blut: Bewertungen von Krankheitserregern, die durch Blut übertragen werden (Übersicht über alle Stellungnahmen, Stand 13.08.2020).....	1–3
1.190a	Bewertung von Krankheitserregern, die durch Blut übertragen werden (Februar 1998).....	1–2
1.191	Humane T-Zell lymphotrope Viren Typ 1 und 2 (HTLV-I/-II) (November 1998).....	1–13
1.192	Filtration von zellulären Blutpräparaten (September 1998).....	1–5
1.193	Sitzung vom 2. Dezember 1998 (S3) (Stellungnahme zur Frage erhöhter Spendevolumina bei der Plasmapherese).....	1
1.194	Sitzung vom 19. März 1998 (Was bedeutet die neue Variante der Creutzfeldt-Jakob-Krankheit für die Sicherheit von Blutprodukten?).....	1–4
1.195	Stellungnahme: Yersinia enterocolitica (Juli 1999).....	1–16
1.196	Stellungnahme: TT-Virus (Februar 2000).....	1–6
1.197	Stellungnahme: Hepatitis-B-Virus (HBV) (März 2000).....	1–16
1.199	Stellungnahme: Leukozytendepletion (November 2000).....	1–2
1.199a	Stellungnahme: Hepatitis-C-Virus (HCV) (August 2003).....	1–23
1.199b	Stellungnahme: Humanes Immunschwärevirus (HIV) (Mai 2003)...	1–26
1.200	Stellungnahme: Arboviren – durch Anthropoden übertragbare Viren (September 2004).....	1–17
1.201	Stellungnahme: Gerinnungsfaktorpräparat Haemate HS/P 1000 und Risiko der Variante Creutzfeldt-Jakob-Krankheit (Januar 2005).....	1

1.203	Stellungnahme: Variante Creutzfeldt-Jakob-Krankheit (September 2005).....	1–19
1.204	Stellungnahme: Beendigung der Spenderrückstellung nach Kontakt mit tot aufgefundenen Vögeln (Oktober 2006).....	1
1.205	Stellungnahme: Influenzaviren (September 2007)	1–16
1.206	Stellungnahme: Arbobakterien (September 2007).....	1–32
1.208	Stellungnahme: Malaria (Februar 2007).....	1–26
1.209	Stellungnahme: Arboprotzoen (Februar 2008)	1–47
1.210	Stellungnahme: Risiko der Übertragung von vCJK (April 2009)	1–2
1.211	Stellungnahme: Versorgung mit Blutprodukten im Falle einer Influenza-Pandemie (September 2009).....	1–24
1.212	Stellungnahme: Blutversorgung bei Notfällen in Einrichtungen der Krankenversorgung (März 2011).....	1
1.213	Stellungnahme: Sicherheit von Blut und Blutprodukten angesichts aktueller Berichte über die Übertragbarkeit der Alzheimer-Krankheit im Tierexperiment (S11) (Juni 2012).....	1–2
1.214	Stellungnahme: Befristete Rückstellung von der Blutspende bei Personen mit sexuellem Risikoverhalten (S12) (März 2013).....	1–2
1.215	Stellungnahme zur Zulassung von Spendewilligen mit körperlichen und/oder geistigen Einschränkungen (S13) (Februar 2014).....	1–2
1.216	Stellungnahme zur erlaubnisfreie Gewinnung und Anwendung von Blut im Rahmen der maschinellen Autotransfusion (MAT) (S 14) (Februar 2014)	1–3
1. 217	Stellungnahme zur Bewertung von Apherese- und Pool-Thrombozytenkonzentraten (S 15) (März 2015).....	1–4
1.218	Stellungnahme zur Gewinnung und Nutzung von Rekonvaleszentenplasma (RKP) als Therapieoption bei Ausbrüchen schwerer Infektionen (S 16) (Mai 2015)	1–12
1.219	Stellungnahme zu Blutspenden von Personen mit sexuellem Risikoverhalten (S 17) (Oktober 2016).....	1
1.220	Stellungnahme zu Pathogen-Inaktivierungssystemen für Thrombozytenkonzentrate (S18) (April 2018).....	1–42
1.221	Stellungnahme zu Fehlanwendungen von Blutkomponenten (S19) (Mai 2019)	1–6
1.222	Stellungnahme zum SARS-Coronavirus 2 (S20) (März 2020)	1–5
1.223	Stellungnahme zum Einsatz von Hydroxyethylstärke (HES) als Sedimentationsbeschleuniger bei der Gewinnung von Granulozytenkonzentraten (S21) (Februar 2020).....	1–6
1.224	Stellungnahme zur Transfusionsassoziierten Immunmodulation (TRIM) (S22) (Februar 2020).....	1–5
1.225	Stellungnahme zum Beratungsergebnis der gemeinsamen Arbeitsgruppe aus Vertretern des „Arbeitskreises Blut nach § 24 TFG“, des Ständigen Arbeitskreises „Richtlinien Hämotherapie nach §§ 12a und 18 TFG“ des Wissenschaftlichen Beirats der Bundesärztekammer, des Robert Koch-Instituts, des Paul-Ehrlich-Instituts und des Bundesministeriums für Gesundheit „Blutspende von Personen mit sexuellem Risikoverhalten – Darstellung des aktuellen Standes der medizinischen Wissenschaft, Stand 26.05.2021“ (S23) (Juni 2021)	1

2	EU – Richtlinien und Leitlinien (hum und vet)	
2.0	Europäische Union – Einführung	1–4
EU – Richtlinien für Human- und Tierarzneimittel (hum und vet)		
2.1	Directive 2001/83/EC of the European Parliament and of the Council on the Community Code Relating to Medicinal Products for Human Use (November 2012 – consolidated version).....	1–172
2.2	Richtlinie 2002/98/EG zur Festlegung von Qualitäts- und Sicherheitsstandards für die Gewinnung, Testung, Verarbeitung, Lagerung und Verteilung von menschlichem Blut und Blutbestandteilen und zur Änderung der Richtlinie 2001/83/EG (Januar 2003).....	1–21
2.2a	Commission Directive 2004/33/EC Implementing Directive 2002/98/EC of the European Parliament and of the Council as Regards Requirements for Blood and Blood Components (March 2004).....	1–24
2.2b	Commission Directive 2005/61/EC Implementing Directive 2002/98/EC of the European Council as Regards Traceability Requirements and Notification of Serious Adverse Reactions and Events (September 2005).....	1–12
2.4	Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on Clinical Trials on Medicinal Products for Human Use, and Repealing Directive 2001/20/EC (April 2014)	1–94
2.5	Commission Delegated Regulation (EU) No 357/2014 of 3 February 2014 Supplementing Directive 2001/83/EC and Regulation (EC) No 726/2004 as Regards Situations in Which Post-Authorisation Efficacy Studies May be Required (February 2014).....	1–5
2.7	Richtlinie 2005/28/EG der Kommission zur Festlegung von Grundsätzen und ausführlichen Leitlinien der guten klinischen Praxis für zur Anwendung beim Menschen bestimmte Prüfpräparate sowie von Anforderungen für die Erteilung einer Genehmigung zur Herstellung oder Einfuhr solcher Produkte (April 2005).....	1–12
2.8	Directive 2004/23/EC of the European Parliament and of the Council on Setting Standards of Quality and Safety for the Donation, Procurement, Testing, Processing, Preservation, Storage and Distribution of Human Tissues and Cells (March 2004).....	1–18
2.9	Commission Directive 2006/17/EC Implementing Directive 2004/23/EC of the European Parliament and of the Council as Regards Certain Technical Requirements for the Donation, Procurement and Testing of Human Tissues and Cells (February 2006).....	1–17
2.9a	Commission Directive 2006/86/EC Implementing Directive 2004/23/EC of the European Parliament and of the Council as Regards Traceability Requirements, Notification of Serious Adverse Reactions and Events and Certain Technical Requirements for the Coding, Processing, Preservation, Storage and Distribution of Human Tissues and Cells (October 2006).....	1–23

2.10	Directive 2001/82/EC of the European Parliament and of the Council on the Community Code Relating to Veterinary Medicinal Products (July 2009 – konsolidiert).....	1–122
2.11	Verordnung (EU) 2019/6 des Europäischen Parlaments und des Rates vom 11. Dezember 2018 über Tierarzneimittel und zur Aufhebung der Richtlinie 2001/82/EG (Dezember 2018).....	1–183
EU – Leitlinien für Humanarzneimittel (hum)		
2.25	EU-Leitlinien für Humanarzneimittel – Einführung	1–3
2.26	Procedure for European Union Guidelines and Related Documents within the Pharmaceutical Legislative Framework (March 2009)	1–17
2.27a	Similar Biological Medicinal Products Containing Monoclonal Antibodies – Non-clinical and Clinical Issues (May 2012).....	1–17
2.28	Definition of a Potential Serious Risk to Public Health in the Context of Article 29 (1) and (2) of Directive 2001/83/EC (March 2006)	1–4
2.29	Definition of a Potential Serious Risk to Human or Animal Health or for the Environment in the Context of Article 33(1) and (2) of Directive 2001/82/EC (March 2006).....	1–6
2.30	Evaluation of Control Samples in Nonclinical Safety Studies: Checking for Contamination with the Test Substance (March 2005)	1–3
2.31	Non-Clinical Investigation of the Dependence Potential of Medicinal Products (March 2006)	1–12
2.31a	Guideline on the Development of Medicinal Products for the Treatment of Alcohol Dependence (February 2010)	1–17
2.32	Non-Clinical Documentation for Mixed Marketing Authorisation Applications (October 2005)	1–3
2.35	Adjuvants in Vaccines for Human Use (January 2005).....	1–16
2.36	Explanatory Note on Immunomodulators for the Guideline on Adjuvants in Vaccines for Human Use (July 2006).....	1
2.40	Need for Non-Clinical Testing in Juvenile Animals of Pharmaceuticals for Paediatric Indications (January 2008).....	1–9
2.42	Specification Limits for Residues of Metal Catalysts or Metal Reagents (February 2008).....	1–34
2.45	Compassionate Use of Medicinal Products, pursuant to Article 83 of Regulation (EC) No 726/2004 (July 2007)	1–8
2.47	Ethical Considerations for Clinical Trials on Medicinal Products with the Paediatric Population (2007)	1–39
2.48	Scientific Guidance on Post-authorisation Efficacy Studies (October 2016).....	1–15
2.50	Choice of the Non-Inferiority Margin (July 2005)	1–13
2.51	Guideline on the Clinical Investigation of the Pharmacokinetics of the Therapeutic Proteins (January 2007).....	1–12
2.51a	Use of Pharmacokinetics and Pharmacodynamics in the Development of Antimicrobial Medicinal Products (July 2016).....	1–17
2.52	Use of Pharmacogenetic Methodologies in the Pharmacokinetic Evaluation of Medicinal Products (January 2012)	1–22

2.52a	Reporting the Results of Population Pharmacokinetic Analyses (June 2007)	1–12
2.52b	Reporting of Physiologically Based Pharmacokinetic (PBPK) Modelling and Simulation (December 2018)	1–17
2.53	Evaluation of the Pharmacokinetics of Medicinal Products in Patients with Decreased Renal Function (December 2015)	1–11
2.54	Evaluation of the Pharmacokinetics of Medicinal Products in Patients with Impaired Hepatic Function (February 2005)	1–10
2.55	Clinical Development of Fixed Combination Medicinal Products (March 2017)	1–8
2.55a	Clinical Assessment of Fixed Combinations of Herbal Substances/Herbal Preparations (January 2006).....	1–6
2.55b	Non-Clinical Development of Fixed Combinations of Medicinal Products (January 2008)	1–6
2.57	Eignung von Blut- und Plasmaspendern und das Screening von Blutspenden in der Europäischen Gemeinschaft (Juni 1998).....	1–17
2.58	Principles of Regulatory Acceptance of 3Rs (Replacement, Reduction, Refinement) Testing Approaches (December 2016).....	1–6
2.58a	Guidance for Individual Laboratories for Transfer of Quality Control Methods Validated in Collaborative Trials with a View to Implementing 3Rs (November 2017)	1–7
2.59	Repeated Dose Toxicity (March 2010).....	1–9
2.60	Non-clinical Local Tolerance Testing of Medicinal Products (October 2015).....	1–9
2.61	Carcinogenic Potential (July 2002).....	1–7
2.62	Carcinogenicity Evaluation of Medicinal Products for the Treatment of HIV Infection (December 2007)	1–7
2.63	Medicinal Gases (July 2008)	1–13
2.66	Investigation of Bioequivalence (January 2010/November 2011) ...	1–44
2.67	Compilation of Individual Product-specific Guidance on Demonstration of Bioequivalence (April 2015)	1–14
2.67a	Alphabetic List of Product-specific Bioequivalence Guidances (22 November 2020).....	1–2
2.67b	Clinical Requirements For Locally Applied, Locally Acting Products Containing Known Constituents (November 1995)	1–4
2.67c	Equivalence Studies for the Demonstration of Therapeutic Equivalence for Locally Acting Products in the Gastrointestinal Tract – Addendum (October 2018).....	1–13
EU – Qualität (hum)		
2.68	Manufacture of the Finished Dosage Form (July 2017).....	1–6
2.68a	Annex: Start of Shelf Life of the Finished Dosage Form (May 2001)	1
2.69	Quality of Oral Modified Release Products (March 2014).....	1–15
2.70	Quality of Transdermal Patches (October 2014)	1–25
2.71a	Decision Trees for the Selection of Sterilisation Methods (Annex to Note for Guidance on Development Pharmaceuticals) (February 1999)	1–3

2.71b	Development Pharmaceuticals for Biotechnological and Biological Products (Annex to Note for Guidance on Development Pharmaceuticals) (October 1999).....	1–4
2.72	Specifications and Control Tests on the Finished Product (December 1991)	1–10
2.72a	Chemistry of New Active Substances (November 2016)	1–11
2.73a	Declaration of Storage Conditions: A: In the Product Information of Medicinal Products B: For Active Substances (April 2003).....	1–3
2.73c	Stability Testing of Existing Active Substances and Related Finished Products (December 2003)	1–19
2.73d	Stability Testing for Applications for Variations to a Marketing Authorisation (March 2014)	1–16
2.73e	Quality of Combination Herbal Medicinal Products/Traditional Herbal Medicinal Products (June 2008)	1–11
2.74	Quality of Herbal Medicinal Products/Traditional Herbal Medicinal Products (September 2011).....	1–12
2.74a	Specifications: Test Procedures and Acceptance Criteria for Herbal Substances, Herbal Preparations and Herbal Medicinal Product/ Traditional Herbal Medicinal Products (April 2011).....	1–24
2.74b	Good Agricultural and Collection Practice for Starting Materials of Herbal Origin (January 2006).....	1–9
2.74c	Non-Clinical Documentation for Herbal Medicinal Products in Applications for Marketing Authorisation (Bibliographical and Mixed Applications) and in Applications for Simplified Registration (July 2006).....	1–7
2.74d	Assessment of Clinical Safety and Efficacy in the Preparation of EU Herbal Monographs for Well-Established and Traditional Herbal Medicinal Products (September 2017)	1–13
2.74e	Selection of Test Materials for Genotoxicity Testing for Traditional Herbal Medicinal Products/Herbal Medicinal Products (November 2009).....	1–6
2.75	Quality of Water for Pharmaceutical Use (July 2020).....	1–10
2.77	Production and Quality Control of Cytokine Products Derived by Biotechnological Processes (February 1990)	1–11
2.78	Virus Validation Studies: The Design, Contribution and Interpretation of Studies Validating the Inactivation and Removal of Viruses (March 1996)	1–14
2.78a	Contribution to Part II of the Structure of the Dossier for Applications for Marketing Authorization – Viral safety studies (December 1994)	1–6
2.79	Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Human and Veterinary Medicinal Products (March 2011)	1–26
2.79a	Explanatory Note for Medicinal Products for Human Use on the Scope of the Guideline (February 2001).....	1–3
2.79b	Gelatin for Use in Pharmaceuticals: Explanatory Note on the Manufacture of Gelatin (December 2000).....	1

2.79c	Lactose Prepared Using Calf Rennet: Risk Assessment in Relationship to Bovine Spongiform Encephalopathies (BSE) (February 2002)	1
2.79d	Evaluation of Bovine Spongiform Encephalopathies (BSE)-risk via the use of materials of bovine origin in or during the manufacture of vaccines (February 2001).....	1–2
2.79e	Adventitious Agent Safety of Urine-Derived Medicinal Products (May 2015)	1–6
2.79f	Use of Near Infrared Spectroscopy by the Pharmaceutical Industry and the Data Requirements for New Submissions and Variations (January 2014)	1–29
2.79h	Requirements for the Chemical and Pharmaceutical Quality Documentation Concerning Investigational Medicinal Products in Clinical Trials (September 2017).....	1–40
EU – Biotechnologische Arzneimittel (hum)		
2.80	Similar Biological Medicinal Products (October 2014)	1–6
2.80a	Immunogenicity Assessment of Therapeutic Proteins (May 2017)...	1–23
2.80b	Immunogenicity Assessment of Monoclonal Antibodies Intended for In Vivo Clinical Use (May 2012).....	1–11
2.81	Production and Quality Control of Medicinal Products Derived by Recombinant DNA Technology (Revision 1994).....	1–10
2.81b	Non-clinical and Clinical Development of Similar Biological Medicinal Products Containing Recombinant Erythropoietins (June 2018)	1–8
2.81c	Annex to Guideline on Similar Biological Medicinal Products Containing Biotechnology-Derived Proteins as Active Substance: Non-Clinical and Clinical Issues (February 2006)	1–6
2.81d	Similar Medicinal Products Containing Somatropin June (2018).....	1–6
2.81e	Non-clinical and Clinical Development of Similar Biological Medicinal Products Containing Recombinant Human Insulin and Insulin Analogues (February 2015)	1–11
2.81f	Comparability of Biotechnology-Derived Medicinal Products after a Change in the Manufacturing Process (July 2007).....	1–11
2.81g	Non-clinical and Clinical Development of Similar Biological Medicinal Products Containing Low-molecular-weight-heparins (November 2016)	1–8
2.81h	Non-clinical and Clinical Development of Similar Biological Medicinal Products Containing Recombinant Human Follicle Stimulating Hormone (r-hFSH) (February 2013).....	1–7
2.81i	Similar Biological Medicinal Products Containing Interferon Beta (February 2013)	1–8
2.82	Similar Biological Medicinal Products containing Biotechnology-Derived Proteins as Active Substance: Quality Issues (May 2014)...	1–9
2.82a	Similar Biological Medicinal Products Containing Biotechnology-Derived Proteins as Active Substance: Non-clinical and Clinical Issues (December 2014)	1–13
2.83	Production and Quality Control of Animal Immunoglobulins and Immunosera for Human Use (July 2016)	1–13
2.83a	Use of Bovine Serum in the Manufacture of Human Biological Medicinal Products (May 2013)	1–8

2.83b	Development, Production, Characterisation and Specifications for Monoclonal Antibodies and Related Products (July 2016)	1–11
2.83c	Clinical Investigation of Hepatitis B Immunoglobulins (July 2015).	1–10
2.83d	Clinical Investigation of Human Normal Immunoglobulin for Subcutaneous and/or Intramuscular Administration (SCIg/IMIg) (July 2015)	1–9
2.84	Potency Testing of Cell Based Immunotherapy Medicinal Products for the Treatment of Cancer (July 2016).....	1–7
2.84a	Development of Vaccinia Virus Based Vaccines Against Smallpox (June 2002)	1–19
2.84b	Influenza Vaccines – Non-clinical and Clinical Module (July 2016)	1–19
2.85	Influenza Vaccines – Quality Module (July 2017).....	1–36
2.85a	Pharmaceutical and Biological Aspects of Combined Vaccines (July 1998)	1–14
2.86	Preclinical Pharmacological and Toxicological Testing of Vaccines (December 1997)	1–6
2.86b	Validation of Immunoassay for the Detection of Antibody to Human Immunodeficiency Virus (Anti HIV) in Plasma Pools (September 2006).....	1–6
2.86c	Plasma-Derived Medicinal Products (Revision 3, January 2001; ergänzt October 2004).....	1–39
2.86d	Clinical Investigation of Human Normal Immunoglobulin for Intravenous Administration (IVIg) (July 2010).....	1–13
2.86e	Clinical Investigation of Recombinant and Human Plasma-Derived Factor IX Products (May 2015).....	1–21
2.86f	Clinical Investigation of Recombinant and Human Plasma-Derived Factor VIII Products (July 2018).....	1–24
2.86h	Investigation of Manufacturing Processes for Plasma-Derived Medicinal Products with Regard to vCJD Risk (October 2004)	1–11
2.86i	Validation of Immunoassay for the Detection of Hepatitis B Virus Surface Antigen (HBsAg) in Plasma Pools (September 2006).....	1–6
2.86j	Replacement of Rabbit Pyrogen Testing by an Alternative Test for Plasma-Derived Medicinal Products (April 2009)	1–6
2.87	Allergen Products: Production and Quality Issues (November 2008).....	1–20
2.87a	Clinical Development of Products for Specific Immunotherapy for the Treatment of Allergic Diseases (November 2008).....	1–14
2.88	Gene Therapy Products – Quality Aspects in the Production of Vectors and Genetically Modified Somatic Cells (December 1994).	1–10
2.88b	Development and Manufacture of Lentiviral Vectors (May 2005)....	1–7
2.88c	Non-Clinical Testing for Inadvertent Germline Transmission of Gene Transfer Vectors (November 2006).....	1–8
2.88d	Quality, Non-Clinical and Clinical Aspects of Live Recombinant Viral Vectored Vaccines (June 2010)	1–18
2.89	Quality of Biological Active Substances Produced by Transgene Expression in Animals (May 2013)	1–11

2.89a	Quality of Biological Active Substances Produced by Stable Transgene Expression in Higher Plants (July 2008).....	1–12
2.90	Requirements for Quality Documentation Concerning Biological Investigational Medicinal Products in Clinical Trials (September 2017).....	1–19
2.90a	Reflection Paper on the Regulatory Requirements for Vaccines Intended to Provide Protection Against Variant Strain(s) of SARS-CoV-2 (February 2021).....	1–6
2.90b	EMA Considerations on COVID-19 Vaccine Approval (November 2020).....	1–4
EU – Klinische Prüfungen – Allgemein (hum)		
2.91	Inclusion of Appendices to Clinical Study Reports in Marketing Authorisation Applications (June 2004).....	1–2
2.91a	Coordinating Investigator Signature of Clinical Study Reports (October 2001).....	1
2.92	Data Monitoring Committees (July 2005).....	1–8
2.92a	Missing Data in Confirmatory Clinical Trials (June 2010).....	1–15
2.93	Role of Pharmacokinetics in the Development of Medicinal Products in the Paediatric Population (June 2006).....	1–9
2.93a	Investigation of Medicinal Products in the Term and Preterm Neonate (June 2009).....	1–26
2.94a	Strategies to Identify and Mitigate Risks for First-In-Human and Early Clinical Trials with Investigational Medicinal Products (July 2017).....	1–14
2.94b	Pharmacokinetic and Clinical Evaluation of Modified Release Dosage Forms (November 2014).....	1–47
2.94c	Adjustment for Baseline Covariates in Clinical Trials (February 2015)	1–11
2.94d	Risk Proportionate Approaches in Clinical Trials (April 2017).....	1–14
2.94e	Good Pharmacogenomic Practice (February 2018).....	1–19
2.94f	Guidance on the Management of Clinical Trials During the COVID-19 (coronavirus) Pandemic. Version 3 (February 2021).....	1–19
EU – Klinische Prüfungen – Therapeutische Klassen (hum)		
2.95a	Clinical Development of Products for the Treatment of Cystic Fibrosis (October 2009).....	1–28
2.95b	Clinical Evaluation of Antifungal Agents for the Treatment and Prophylaxis of Invasive Fungal Disease (April 2010).....	1–18
2.95c	Clinical Investigation of New Medicinal Products for the Treatment of Acute Coronary Syndrome (July 2017).....	1–17
2.96	Clinical Investigation of Medicinal Products for the Treatment of Chronic Heart Failure (July 2017).....	1–13
2.96a	Clinical Investigation of Medicinal Products for the Treatment of Acute Heart Failure (May 2015).....	1–18
2.96b	Evaluation of Medicinal Products for Cardiovascular Disease Prevention (September 2008).....	1–8
2.96c	Development of Medicinal Products for the Treatment of Smoking (December 2008).....	1–12

2.96d	Evaluation of Drugs for the Treatment of Gastro-Oesophageal Reflux Disease (March 2011)	1–27
2.97	Antiarrhythmics (EMA Status as of November 1995)	1–7
2.97/1	Addendum to the Guideline on Antiarrhythmics on Atrial Fibrillation and Atrial Flutter (July 2010).....	1–10
2.97a	Clinical Investigation of Medicinal Products for the Treatment of Juvenile Idiopathic Arthritis (November 2015)	1–13
2.97b	Clinical Investigation of Medicinal Products for the Treatment of Psoriatic Arthritis (December 2006).....	1–12
2.97c	Clinical Investigation of Medicinal Products Used in the Treatment of Osteoarthritis (January 2010).....	1–14
2.98	Clinical Investigation of Medicinal Products in the Treatment and Prevention of Bipolar Disorder (April 2001).....	1–10
2.98a	Development of New Medicinal Products for the Treatment of Crohn’s Disease (June 2018)	1–19
2.98b	Clinical Investigation of Immunosuppressants for Solid Organ Transplantation (July 2008).....	1–17
2.99	Evaluation of Anticancer Medicinal Product in Man (September 2017)	1–46
2.99/2	Appendix 2 to the Guideline on the Evaluation of Anticancer Medicinal Products in Man. The use of Patient-reported outcome (PRO) Measures in Oncology Studies (April 2016).....	1–19
2.99/4	Appendix 4 to the Guideline on the Evaluation of Anticancer Medicinal Products in Man (December 2015).....	1–22
2.99b	Non-Clinical and Clinical Development of Medicinal Products for the Treatment of Nausea and Vomiting Associated with Cancer Chemotherapy (December 2006)	1–10
2.100	Clinical Investigation of Medicinal Products in the Treatment of Epileptic Disorder (January 2010).....	1–20
2.100a	Clinical Investigation of Medicinal Products for the Treatment of Axial Spondyloarthritis (October 2017)	1–13
2.101	Medicinal Products for the Treatment of Insomnia (February 2011)	1–22
2.101a	Development of Medicinal Products for the Treatment of Post-Traumatic Stress Disorder (PTSD) (July 2008).....	1–11
2.102	Clinical Investigation of Medicinal Products Indicated for the Treatment of Social Anxiety Disorder (SAD) (January 2006)	1–12
2.102a	Clinical Investigation of Medicinal Products for the Prevention of Venous Thromboembolism (VTE) in Non-Surgical Patients (November 2016).....	1–9
2.102b	Clinical Investigation of Medicinal Products for Prevention of Venous Thromboembolism (VTE) in Patients Undergoing High VTE-Risk Surgery (May 2013).....	1–18
2.102c	Clinical Investigation of Medicinal Products for Prevention of Stroke and Systemic Embolic Events in Patients with Non-Valvular Atrial Fibrillation (June 2014)	1–15
2.103	Clinical Investigations of Medicinal Products in the Treatment of Chronic Peripheral Arterial Occlusive Disease (April 2002)	1–16
2.103a	Clinical Investigation of Medicinal Products in the Treatment of Patients with Acute Respiratory Distress Syndrome (September 2006)	1–10

2.103b	Clinical Investigation of Medicinal Products for the Treatment of Sepsis (June 2006).....	1–10
2.104	Clinical Development of Medicinal Products for the Treatment of HIV Infection (April 2016)).....	1–29
2.104a	Clinical Evaluation of Medicinal Products Intended for Treatment of Chronic Hepatitis B (February 2006).....	1–26
2.104b	Clinical Evaluation of Direct Acting Antiviral Agents Intended for Treatment of Chronic Hepatitis C (April 2009).....	1–14
2.105	Trials with Haematopoietic Growth Factors for the Prophylaxis of Infection Following Myelosuppressive or Myeloablative Therapy (March 2007).....	1–11
2.105a	Clinical Development of Medicinal Products Intended for the Treatment of Pain (December 2016).....	1–11
2.105b	Clinical Investigations of Medicinal Products for the Treatment of Pulmonary Arterial Hypertension (October 2009).....	1–9
2.105c	Paediatric Addendum to CHMP Guideline on the Clinical Investigations of Medicinal Products for the Treatment of Pulmonary Arterial Hypertension (December 2011).....	1–7
2.106	Clinical Investigation of Medicinal Products in the Treatment of Hypertension (June 2016).....	1–17
2.106a	Clinical Investigation of Medicinal Products in the Treatment of Lipid Disorders (June 2016).....	1–16
2.106b	Paediatric Addendum to CHMP Guideline on Clinical Investigation of Medicinal Products in the Treatment of Lipid Disorders (September 2012).....	1–6
2.107	Clinical Investigation of Medicinal Products, Including Depot Preparations in the Treatment of Schizophrenia (September 2012) ..	1–24
2.107a	Clinical Investigation of Medicinal Products in the Treatment of Depression (May 2013).....	1–20
2.107b	Clinical Investigation of Medicinal Products for the Treatment of Obsessive Compulsive Disorder (January 2005).....	1–9
2.107c	Clinical Investigation of Medicinal Products Indicated for the Treatment of Panic Disorder (January 2005).....	1–10
2.107d	Clinical Investigation of Medicinal Products Indicated for Generalised Anxiety Disorder (January 2005).....	1–8
2.107e	Clinical Investigation of Medicinal Products for the Treatment of Attention Deficit Hyperactivity Disorder (ADHD) (July 2010)....	1–14
2.107f	Treatment of Premenstrual Dysphoric Disorder (PMDD) (July 2011).....	1–18
2.107g	Clinical Investigation of Medicinal Products to Prevent Development/ slow progression of Chronic Renal Insufficiency (September 2016)	1–12
2.107h	Clinical Investigation of Medicinal Products for the Treatment of Amyotrophic Lateral Sclerosis (ALS) (November 2015).....	1–22
2.108	Clinical Evaluation of Medicinal Products Used in Weight Management (June 2016)).....	1–11
2.108a	Clinical Evaluation of Medicinal Products Used in Weight Control – Addendum on Weight Control in Children (July 2008)....	1–6

2.108b	Evaluation of Medicinal Products for the Treatment of Chronic Constipation (Including Opioid Induced Constipation) and for Bowel Cleansing (June 2015)	1–23
2.109	Postmenopausal Osteoporosis in Women (January 2001)	1–10
2.109b	Clinical Investigation of Medicinal Products for Hormone Replacement Therapy of Oestrogen Deficiency Symptoms in Postmenopausal Women (October 2005)	1–11
2.110	Clinical Investigation of Medicines for the Treatment of Alzheimer’s Disease (February 2018)	1–38
2.110a	Clinical Investigation of Medicinal Products for the Treatment of Venous Thromboembolic Disease (December 1999)	1–7
2.110b	Clinical Investigation of Plasma Derived Antithrombin Products (April 2002)	1–9
2.110d	Clinical Investigation of Plasma Derived Fibrin Sealant Haemostatic Products (July 2004)	1–6
2.110e	Clinical Investigation of Human Plasma Derived Von Willebrand Factor Products (November 2005)	1–15
2.111	Clinical Evaluation of New Vaccines (October 2006)	1–23
2.111a	Clinical Evaluation of New Vaccines – Annex: SPC Requirements (October 2006)	1–5
2.112	Clinical Investigation of Medicinal Products in the Treatment of Parkinson’s Disease (June 2012)	1–16
2.112a	Clinical Medicinal Products Intended for the Treatment of Neuropathic Pain (January 2007)	1–11
2.113	Clinical Investigation of Anti-Anginal Medicinal Products in Stable Angina Pectoris (June 2006)	1–9
2.113a	Clinical Investigation of Medicinal Products for the Treatment of Migraine (January 2007)	1–12
2.114	Clinical Investigation of Medicinal Products for the Treatment of Multiple Sclerosis (March 2015)	1–20
2.114a	Clinical Investigation of Medicinal Products for the Treatment of Urinary Incontinence (June 2013)	1–20
2.114b	Clinical Investigation of Medicinal Products in the Treatment of Chronic Obstructive Pulmonary Disease (COPD) (July 2012)	1–17
2.115	Clinical Investigation of Medicinal Products in the Treatment or Prevention of Diabetes Mellitus (May 2002)	1–26
2.115a	Clinical Investigation of Medicinal Products for Treatment of Asthma (October 2015)	1–9
2.115b	Clinical Investigation of Medicinal Products Indicated for the Treatment of Psoriasis (November 2004)	1–18
2.115c	Clinical Development of Medicinal Products for the Treatment of Allergic Rhino-Conjunctivitis (May 2012)	1–9
2.116	Investigation of Drug Interactions (June 2012)	1–70
2.117	Clinical Investigation of Steroid Contraceptives in Women (July 2005)	1–6
2.117a	Evaluation of Medicinal Products Indicated for Treatment of Bacterial Infections (December 2011)	1–28

2.117b	Addendum to the Guideline on Evaluation of Medicinal Products Indicated for Treatment of Bacterial Infections To Address the Clinical Development of New Agents to Treat Disease Due to Mycobacterium Tuberculosis (July 2017).....	1–16
2.117c	Addendum to the Guideline on the Evaluation of Medicinal Products Indicated for Treatment of Bacterial Infections (October 2013)	1–23
2.118	Clinical Investigation of Human Anti-D Immunoglobulin for Intravenous and/or Intramuscular Use (September 2007)	1–7
2.119a	Clinical Investigation of Human Normal Immunoglobulin for Subcutaneous and Intramuscular Use (July 2002).....	1–7
2.120	Radiopharmaceuticals (November 2008)	1–11
2.124	Paediatric Addendum to the Note for Guidance on the Clinical Investigation on Medicinal Products in the Treatment of Hypertension (February 2015)	1–11
2.125	The Use of Ionizing Radiation in the Manufacture of Medicinal Products (December 1991)	1–5
2.130	Clinical Evaluation of Diagnostic Agents (July 2009)	1–20
2.150	Summary of Requirements for Active Substances in the Quality Part of the Dossier (June 2004).....	1–9
2.152	Investigation of Chiral Active Substances (1993)	1–9
2.154	Active Substance Master File Procedure (June 2012)	1–30
2.155	Additional Guidance on Documents Relating to an Active Substance Master File (September 2012)	1–9
2.156	Clinical Development of Medicinal Products Intended for the Treatment of Chronic Primary Immune Thrombocytopenia (February 2014)	1–17
2.157	Evaluation of Medicinal Products for the Treatment of Irritable Bowel Syndrome (September 2014).....	1–19
2.158	Clinical Investigation of Medicinal Products for the Treatment of Systemic Lupus Erythematosus and Lupus Nephritis (February 2015)	1–16
2.159	Clinical Development of Medicinal Products for the Treatment of Autism Spectrum Disorder (ASD) (November 2017)	1–14
2.159a	Development of New Medicinal Products for the Treatment of Ulcerative Colitis (June 2018)	1–18
2.159b	Clinical Evaluation of Medicinal Products Indicated for the Prophylaxis or Treatment of Respiratory Syncytial Virus (RSV) Disease (October 2018)	1–19
2.159c	Clinical Investigation of Medicinal Products for the Treatment of Rheumatoid Arthritis (December 2017)	1–15
2.159d	Clinical Investigation of Medicinal Products for the Treatment of Gout (November 2019).....	1–15
EU – Tierversuche		
2.160	Richtlinie 2010/63/EU des Europäischen Parlaments und des Rates zum Schutz der für wissenschaftliche Zwecke verwendeten Tiere (September 2010).....	1–70

ICH – Leitlinien für Humanarzneimittel (hum)		
2.200	International Conference on Harmonisation (ICH) – Einführung.....	1–2
2.201	Steps in the ICH Process for Harmonisation of Guidelines.....	1–2
2.202	Stability Testing of New Drug Substances and Products (Revision 2 – February 2003).....	1–21
2.202a	Quality of Biotechnological Products: Stability Testing of Biotechnological /Biological Products (December 1995).....	1–9
2.202b	Stability Testing: Requirements for New Dosage Forms (1996).....	1
2.202c	Bracketing and Matrixing Design for Stability Testing of New Drug Substances and Products (February 2002).....	1–8
2.202d	Evaluation of Stability Data (February 2003).....	1–17
2.202e	Stability Data Package for Registration Applications in Climatic Zones III and IV (June 2006).....	1–2
2.203	Detection of Toxicity to Reproduction for Medicinal Products – ICH S5 (R3) (February 2020).....	1–98
2.204	Studies in Support of Special Populations: Geriatrics (1993).....	1–5
2.205	Validation of Analytical Methods: Definitions and Terminology (November 1994).....	1–5
2.205a	Validation of Analytical Procedures: Methodology (December 1996).....	1–8
2.205b	Bioanalytical Method Validation (nicht ICH) (July 2011).....	1–23
2.206	Pharmacokinetics: Guidance for Repeated Dose Tissue Distribution Studies (1994).....	1–2
2.207	The Extent of Population Exposure to Assess Clinical Safety for Drugs Intended for Long-Term Treatment of Non-Life Threatening Conditions (November 1994).....	1–3
2.208	Dose-Response Information to Support Drug Registration (1994) ...	1–11
2.208a	Duration of Chronic Toxicity Testing in Animals (Rodent and Non Rodent Toxicity Testing) (November 1998).....	1–2
2.209	Toxicokinetics: The Assessment of Systemic Exposure in Toxicity Studies (1994).....	1–11
2.209a	Safety Pharmacology Studies for Human Pharmaceuticals (ICH S74) (November 2000).....	1–9
2.210	Dose Selection for Carcinogenicity Studies of Pharmaceuticals (April 2008).....	1–9
2.210a	Need for Carcinogenicity Studies of Pharmaceuticals – ICH Harmonised Tripartite Guideline [EMA Status as of December 1995].....	1–4
2.210b	Testing for Carcinogenicity of Pharmaceuticals – ICH Harmonised Tripartite Guideline (September 1997).....	1–7
2.211d	Clinical Safety Data Management: Definitions and Standards for Expedited Reporting – ICH Harmonised Tripartite Guideline – ICH E2D (November 2003).....	1–13
2.213	Good Clinical Practice (ICH E6 (R2)) (December 2016).....	1–50
2.214	Structure and Content of Clinical Study Reports – ICH Harmonised Tripartite Guideline [EMA Status as of December 1995] (July 1996)	1–45

2.215	General Considerations for Clinical Trials – ICH Harmonised Tripartite Guideline (September 1997).....	1–13
2.215a	General Principles for Planning and Design of Multi-Regional Clinical Trials (ICH E17) (Dezember 2017).....	1–20
2.216	Statistical Principles for Clinical Trials – ICH Harmonised Tripartite Guideline (March 1998).....	1–41
2.216a	Addendum on Estimands and Sensitivity Analysis in Clinical Trials to the Guideline on Statistical Principles for Clinical Trials – ICH E9 (R1) (February 2020).....	1–20
2.217	Ethnic Factors in the Acceptability of Foreign Clinical Data – ICH Harmonised Tripartite Guideline(March 1998).....	1–15
2.218	Choice of Control Group in Clinical Trials – ICH E 10 (July 2000).	1–32
2.219	Clinical Investigation of Medicinal Products in the Paediatric Population – ICH E 11 (July 2000).....	1–13
2.219a	Clinical Investigation of Medicinal Products in the Paediatric Population – ICH E11(R1) (September 2017).....	1–12
2.220a	Non-clinical Evaluation for Anticancer Pharmaceuticals – ICH Topic S9 (November 2009).....	1–9
2.221	Pharmaceutical Development – ICH Q8 (November 2005).....	1–8
2.221a	Pharmaceutical Development – ICH Topic Q8 Annex (December 2008).....	1–16
2.222	Specifications: Test Procedures and Acceptance Criteria for New Drug Substances and New Drug Products: Chemical Substances (November 1999).....	1–33
2.223	Impurities Testing Guideline: Impurities in New Drug Substances – ICH Topic Q3A (R2) (October 2006).....	1–13
2.224	Impurities in New Drug Products – ICH Topic Q3B (R2) Revision (June 2006).....	1–13
2.224a	Elemental Impurities (ICH Q3D) (July 2016).....	1–73
2.224b	Elemental Impurities in Marketed Products. Recommendations for Implementation (February 2015).....	1–2
2.224c	Implementation Strategy for ICH Q3D Guideline (March 2017).....	1–5
2.225	Impurities: Guideline for Residual Solvents – ICH Q3C (R8) (May 2021).....	1–38
2.225a	Annexes to: CPMP/ICH/283/95 Impurities: Guideline for Residual Solvents & CVMP/VICH/502/99 Guideline on Impurities: Residual Solvents (February 2013).....	1–5
2.227	Photostability Testing of New Active Substances and Medicinal Products [ICH Harmonised Tripartite Guideline] (December 1996).	1–9
2.228	Clinical Evaluation od QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs – ICH Topic E14 (May 2005).....	1–16
2.229	Non-clinical Evaluation of the Potential for Delayed Ventricular Repolarization (QT Interval Prolongation) by Human Pharmaceuticals – ICH S7B (May 2005).....	1–10

2.230	Genotoxicity Testing and Data Interpretation for Pharmaceuticals Intended for Human Use – ICH Guideline S2 (R1) (November 2011).....	1–27
2.230a	Limits of Genotoxic Impurities (nicht ICH) (June 2006).....	1–9
2.231a	Assessment of Genotoxicity of Herbal Substances/Preparations (nicht ICH) (May 2008).....	1–12
2.231b	Photosafety Evaluation of Pharmaceuticals – ICH Topic S10 (January 2014).....	1–16
2.231c	Nonclinical Safety Testing in Support of Development of Paediatric Pharmaceuticals – ICH S11 (April 2020).....	1–53
2.232	Non-Clinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals – ICH Topic M 3 (R2) (June 2009).....	1–27
2.232a	Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk (ICH M7) (September 2014).....	1–29
2.232b	Biopharmaceutics Classification System-based Biowaivers – ICH M9 (February 2020).....	1–16
2.233	Pre-clinical Safety Evaluation of Biotechnology-Derived Pharmaceuticals (ICH Guideline S6 (R1) (July 2011).....	1–23
2.234	Quality of biotechnological products: Derivation and characterisation of cell substrates used for production of biotechnological/biological products – ICH Harmonised tripartite guideline (September 1997).....	1–13
2.235	Quality of Biotechnological Products: Analysis of the Expression Construct in Cells Used for Production of r-DNA Derived Protein Products - ICH Harmonised Tripartite Guideline [EMA Status as of December 1995] (December 1995).....	1–5
2.236	Viral Safety Evaluation of Biotechnology Products Derived from Cell Lines of Human or Animal Origin [ICH Harmonised Tripartite Guideline] (April 1997).....	1–30
2.237	Specifications: Test Procedures and Acceptance Criteria for Biotechnological/biological Products (ICH Harmonised Tripartite Guideline) (March 1999).....	1–18
2.238	Comparability of Biotechnological/Biological Products Subject to Changes in their Manufacturing Process (ICH Q5E) (December 2004).....	1–13
2.239	Immunotoxicity Studies for Human Pharmaceuticals (ICH Topic S 8) (October 2005).....	1–12
2.241	Development and Manufacture of Drug Substances (Chemical Entities and Biotechnological/Biological Entities) (ICH Q11) (May 2012).....	1–30
2.241a	Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management – ICH Q12 (March 2020).....	1–27
2.241b	Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management – ICH Q12 – Annexes (March 2020).....	1–22

2.241c	Note on EU Implementation of ICH Q12 (Guideline on Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management) (March 2020).....	1–2
2.242	Good Manufacturing Practice for Active Pharmaceutical Ingredients (ICH Q7A) (November 2000).....	1–45
2.243	Pharmaceutical Quality System (ICH Q10) (January 2011).....	1–18
2.244	Quality Risk Management (ICH Q9) (January 2011).....	1–20
2.244a	Guideline on Genomic Sampling and Management of Genomic Data (ICH E18) (September 2017).....	1–11
EU – Umweltverträglichkeitsprüfung (ERA) und Risiken durch genetisch veränderte Organismen (GMOs) (hum)		
2.245	Environmental Risk Assessments for Medicinal Products Consisting of or Containing Genetically Modified Organisms (GMOs) (December 2006)	1–15
2.250	Richtlinie des Rates über die Anwendung genetisch veränderter Mikroorganismen in geschlossenen Systemen (90/219/EWG) (April 1990)	1–19
2.251	Richtlinie des Rates über die absichtliche Freisetzung genetisch veränderter Organismen in der Umwelt (90/220/EWG) (April 1990)	1–20
2.252	Richtlinie 2000/54/EG des Europäischen Parlaments und des Rates vom 18. September 2000 über den Schutz der Arbeitnehmer gegen Gefährdung durch biologische Arbeitsstoffe bei der Arbeit (September 2000).....	1–40
2.255	Environmental Risk Assessment of Medicinal Products for Human Use (June 2006)	1–13
2.256	Scientific Requirements for the Environmental Risk Assessment of Gene Therapy Medicinal Products (May 2008)	1–16
EU – Summary of Product Characteristics (SmPC) und Core SPC (hum)		
2.350	Summary of Product Characteristics (SmPC) (September 2009).....	1–33
2.350a	Core SmPC for Radiopharmaceuticals (July 2010).....	1–11
2.353a	Core SPC for Human Normal Immunoglobulin for Subcutaneous and Intramuscular Administration (February 2015)	1–11
2.353b	Core SPC for Human Varicella Immunoglobulin for Intramuscular Use (July 2005).....	1–6
2.353c	Core SPC for Human Rabies Immunoglobulin for Intramuscular Use (July 2005).....	1–6
2.353d	Core SPC for Human Tetanus Immunoglobulin for Intramuscular Use (July 2005).....	1–6
2.353e	Core SPC for Human Tick-Borne Encephalitis Immunoglobulin for Intramuscular Use (July 2005).....	1–6
2.353f	Core SPC for Human Plasma Derived Hepatitis B Immunoglobulin for Intramuscular Use (April 2006)	1–6
2.353g	Core SPC for Human Plasma Derived Hepatitis B Immunoglobulin for Intravenous Use (April 2006).....	1–7
2.354a	Core SPC for Human Plasma Derived Coagulation Factor VII Products (July 2004)	1–6
2.356	Core SmPC for Human Plasma Derived and Recombinant Coagulation Factor IX Products (December 2014)	1–10

2.356a	Core SPC for Human Plasma Derived Antithrombin (January 2002)	1–6
2.356b	Core SPC for Human Plasma-Derived von Willebrand Factor (November 2005).....	1–7
2.359	Core SPC for Human Prothrombin Complex Products (October 2004).....	1–7
2.360	Description of Composition of Pegylated (Conjugated) Proteins in the SPC (July 2003).....	1–2
2.381	Guideline on Core SmPC and Package Leaflet for Fludeoxyglucose (¹⁸ F) (July 2012).....	1–19
2.382	Core SmPC and Package Leaflet for technetium (^{99m} Tc) sestamibi (November 2013).....	1–22
2.383	Core SmPC and Package Leaflet for (99Mo/99mTc) Generator (December 2014).....	1–24
EU – Packmittel und Herstellungsaspekte		
2.400	Plastic Immediate Packaging Materials (May 2005).....	1–11
2.410	Maximum Shelf-life for Sterile Products for Human Use after First Opening or Following Reconstitution (January 1998).....	1–2
2.415	In-Use Stability Testing of Human Medicinal Products (February 2001).....	1–3
2.416	EU Guidelines for Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use – Annex 17: Real Time Release Testing and Parametric Release (December 2018).....	1–6
2.420	Commission Directive 2002/72/EC Relating to Plastic Materials and Articles Intended to Come into Contact with Foodstuffs (August 2002).....	1–49
2.430	Limitations to the Use of Ethylene Oxide in the Manufacture of Medicinal Products (March 2016).....	1–2
2.435	Replacement of Chlorofluorocarbons (CFC) in Metered Dose Inhalation Products (December 1993).....	1–9
2.436	PMS Studies for Metered Dose Inhalers with New Propellants (1995)	1–3
2.437	Pharmaceutical Quality of Inhalation and Nasal Products (March 2006)	1–28
2.438	Requirements for Clinical Documentation for Orally Inhaled Products (January 2009).....	1–29
2.440	Matters Relating to the Replacement of CFCs in Medicinal Products (December 1993).....	1–4
2.445	Commission Decision (2000/22/EC) of 16 December 1999 on the Allocation of Quantities of Controlled Substances Allowed for Essential Uses in the Community in 2000 under Council Regulation (EC) no 3093/94 on Substances that Deplete the Ozone Layer (2000/22/EC)	1–7
2.450	Excipients in the Dossier for Application for Marketing Authorisation of a Medicinal Product (July 2007).....	1–12
2.455	Inclusion of Antioxidants and Antimicrobial Preservatives in Medicinal Products (July 1997).....	1–5
2.460	The Use of Phthalates as Excipients in Human Medicinal Products (November 2014).....	1–12

2.461	The Use of Porcine Trypsin Used in the Manufacture of Human Biological Medicinal Products (February 2014)	1–8
2.525	Conduct of Pharmacovigilance for Medicines used by the Paediatric Population (January 2007).....	1–14
2.540	Exposure to Medicinal Products During Pregnancy: Need for Post-Authorisation Data (November 2005)	1–24
2.541	Risk Assessment of Medicinal Products on Human Reproduction and Lactation: From Data to Labelling (July 2008)	1–20
2.600	Commission Directive 2003/94/EC Laying Down the Principles and Guidelines of Good Manufacturing Practice in Respect of Medicinal Products for Human Use and Investigational Medicinal Products for Human Use (October 2003)	1–8
EU – Leitlinien für Tierarzneimittel (vet)		
2.700	EU-Leitlinien für die Prüfung von Tierarzneimitteln – Einführung ..	1–2
2.702	Statistical Principles for Veterinary Clinical Trials for Veterinary Medicinal Products (Pharmaceuticals) (January 2012)	1–35
2.704	Anticoccidials Used for the Therapy of Coccidiosis in Chickens, Turkeys and Geese (May 1993).....	1–8
2.705	Performance Enhancers (May 1991)	1–4
2.706	Veterinary Medicinal Products for Fluid Therapy in Case of Diarrhoea (September 1992).....	1–4
2.707	Veterinary Medicinal Products Controlling Varroa Destructor Parasitosis in Bees (November 2010).....	1–9
2.708	Demonstration of Efficacy of Ectoparasiticides (September 1994)...	1–7
2.708a	Specific Efficacy Requirements for Ectoparasiticides in Sheep (July 2002)	1–7
2.709	Local Tolerance of Intramammary Preparations in Cows (November 1992)	1–3
2.710	Evaluation of the Safety of Veterinary Medicinal Products for the Target Animals (September 1994)	1–7
2.711	Dossier Requirements for Anticancer Medicinal Products for Dogs and Cats (April 2009)	1–28
2.715	Validation of Analytical Procedures: Methodology (December 1998)	1–9
2.716	Validation of Analytical Procedures: Definition and Terminology (December 1998)	1–5
2.717	Testing and Evaluation of the Efficacy of Antiparasitic Substances for the Treatment and Prevention of Tick and Flea Infestation in Dogs and Cats (July 2016).....	1–17
2.718	Conduct of Efficacy Studies for Intramammary Products for use in Cattle (January 2017).....	1–6
2.719	Demonstration of Efficacy for Veterinary Medicinal Products containing Antimicrobial Substances (January 2016)	1–7
2.725	Conduct of Bioequivalence Studies for Veterinary Medicinal Products (December 2018)	1–31
2.726	Demonstration of Palatability of Veterinary Medicinal Products (November 2014).....	1–7

2.727	Data Requirements for Changes to the Strain Composition of Authorised Equine Influenza Vaccines in Line with OIE Recommendations (November 2014)	1-8
2.730	Pharmaceutical Fixed Combination Products (December 2006).....	1-7
2.738	Data Requirements to Support In-Use Stability Claims for Veterinary Vaccines (March 2010).....	1-4
2.739	Maximum Shelf-Life for Sterile Veterinary Products After First Opening or Following Reconstitution (July 2000).....	1
2.740	In-Use Stability Testing of Veterinary Medicinal Products (February 2002).....	1-4
2.740a	Declaration of Storage Conditions in the Product Information of Pharmaceutical Veterinary Medicinal Products (July 2003).....	1-4
2.740b	Declaration of Storage Conditions for Active Substances (July 2003).....	1
2.741	Excipients in the Dossier for Application for Marketing Authorisation in Veterinary Medicinal Products (February 1999).....	1-6
2.742	Investigation of Chiral Active Substances (June 1997).....	1-10
2.745	Additional Quality Requirements for Products Intended for Incorporation into Animal Feedingstuffs (Medicated Premixes) (December 1996).....	1-4
EU – Pharmacovigilanz (vet)		
2.747a	EU Veterinary Suspected Adverse Reaction Report Form for Veterinarians and Health Professionals (June 2005).....	1-3
2.756	Conduct of Post-Marketing Surveillance Studies of Veterinary Medicinal Products (April 2000).....	1-6
2.759	Pre-Authorisation Studies to Assess the Potential for Resistance Resulting from the Use of Antimicrobial Veterinary Medicinal Products (July 2002).....	1-7
EU – Umweltverträglichkeitsprüfung (ERA) (vet)		
2.760	Determining the Fate of Veterinary Medicinal Products in Manure (March 2011)	1-10
2.761	Environmental Risk Assessment for Veterinary Medicinal Products Consisting of or Containing Genetically Modified Organisms (GMOs) (March 2017).....	1-21
2.764	Environmental Impact Assessment for Veterinary Medicinal Products Phase II (VICH-GL 38) (November 2004).....	1-34
2.765	Environment Risk Assessment for Immunological Veterinary Medicinal Products (July 1996).....	1-7
2.767	Assessment of Environmental Risks of Veterinary Medicinal Products (June 2009)	1-5
2.767a	Assessment of Persistent, Bioaccumulative and Toxic (PBT) or very Persistent and very Bioaccumulative (vPvB) Substances in Veterinary Medicinal Products (September 2015)	1-14
2.767b	Plant Testing Strategy for Veterinary Medicinal Products (March 2017)	1-13
2.767c	Assessing the Environmental and Human Health Risks of Veterinary Medicinal Products in Groundwater (April 2018).....	1-12

EU – Tierarzneimittelrückstände (MRL) (vet)

2.768	Regulation (EC) No 470/2009 of the European Parliament and of the Council Laying down Community Procedures for the Establishment of Residue Limits of Pharmacologically Active Substances in Foodstuffs of Animal Origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council (May 2009)	1–19
2.768a	Commission Regulation (EU) 2017/880 of 23 May 2017 Laying Down Rules on the Use of a Maximum Residue Limit Established for a Pharmacologically Active Substance in a Particular Foodstuff for Another Foodstuff Derived from the Same Species and a Maximum Residue Limit Established for a Pharmacologically Active Substance in One or More Species for Other Species, in Accordance with Regulation (EC) No 470/2009 of the European Parliament and of the Council.....	1–5
2.768b	Commission Regulation (EU) 2018/782 of 29 May 2018 Establishing the Methodological Principles for the Risk Assessment and Risk Management Recommendations Referred to in Regulation (EC) No 470/2009	1–34
2.768c	Biological substances Considered as not Requiring an MRL Evaluation as per Regulation (EU) No. 2018/782, with Regard to Residues of Veterinary Medicinal Products in Foodstuffs of Animal Origin (January 2020)	1–2
2.769	Commission Regulation (EU) No 37/2010 on Pharmacologically Active Substances and their Classification Regarding Maximum Residue Limits in Foodstuffs of Animal Origin (January 2010)	1–97
2.769a	Substances Considered as not Falling within the Scope of Regulation (EC) No. 470/2009, with Regard to Residues of Veterinary Medicinal Products in Foodstuffs of Animal Origin (December 2020).....	1–6
2.770	Guideline on Data to be Provided in Support a Request to Include a Substance in the List of Substances Considered as Not Falling Within the Scope of Regulation (EC) No 470/2009 (November 2010).....	1–8
2.770a	Risk Analysis Approach for Residues of Veterinary Medicinal Products in Food of Animal Origin (January 2001)	1–12
2.771	Establishment of Maximum Residue Limits for Minor Animal Species (November 1997).....	1–5
2.772	Establishment of Maximum Residue Limits for <i>Salmonidae</i> and other Fin Fish (January 1998).....	1
2.774	Risk Characterisation and Assessment of Maximum Residue Limits (MRL) for Biocides (January 2015)	1–20
2.775	Determination of Withdrawal Periods for Edible Tissues (September 2018).....	1–34

EU – Development Pharmaceuticals (vet)

2.778	Development Pharmaceuticals (Veterinary) (August 1999).....	1–9
2.779	Decision Trees for the Selection of Sterilisation Methods – Annex to Note for Guidance on Development Pharmaceuticals (February 2000).....	1–3
2.780	Chemistry of Active Substances for Veterinary Medicinal Products November 2017).....	1–15
2.780a	Quality of Modified Release Dosage Forms for Veterinary Use (July 2003).....	1–11
2.780b	Risk Assessment Requirements to Control Elemental Impurities in Veterinary Medicinal Products (November 2017).....	1–2
2.783	Conduct of Pharmacokinetic Studies in Target Animal Species (March 2000).....	1–6
2.785	Specific Requirements for the Production and Control of Allergen Products (1994).....	1–9
2.791	DNA Vaccines Non-Amplifiable in Eukaryotic Cells for Veterinary Use (March 2000).....	1–6
2.791a	Live Recombinant Vector Vaccines for Veterinary Use (December 2004).....	1–5
2.792	Harmonisation of Requirements for Equine Influenza Vaccines Specific Requirements for Substitution or Addition of a Strain or Strains (November 1998).....	1–6
2.793	Use of Adjuvanted Veterinary Vaccines (November 1998).....	1–4
2.793a	Duration of Protection Achieved by Veterinary Vaccines (October 2000).....	1–4
2.793b	Field Trials with Veterinary Vaccines (June 2001).....	1–6
2.794	Requirements for Combined Vaccines and Associations of Immunological Veterinary Medicinal Products (IVMPs) (July 2013)	1–12
2.794a	Design of Studies to Evaluate the Safety and Efficacy of Fish Vaccines (November 2011).....	1–10
2.794k	Requirements for an Authorisation under Exceptional Circumstances for Vaccines for Emergency Use against Bluetongue (November 2008).....	1–7
2.795	Inclusion of Antimicrobial Preservatives in Immunological Veterinary Medicinal Products (July 1997).....	1–3
2.795a	Requirements and Controls Applied to Bovine Serum Used in the Production of Immunological Veterinary Medicinal Products (November 2005).....	1–7
2.796	Veterinary Medicinal Products for Zootechnical Purposes (March 1992).....	1–3
2.800	Requirements for the Production and Control of Immunological Veterinary Medicinal Products (December 2016).....	1–10
2.802	Assessment of the Effect of Antimicrobial Substances on Dairy Starter Cultures (March 2000).....	1–7
2.805	Conduct of Efficacy Studies for Non-Steroidal Anti-Inflammatory Drugs (January 2014).....	1–10

2.806	Efficacy of Veterinary Medicinal Products for Use in Farmed Aquatic Species (September 1994).....	1–14
2.832	Procedure to be Followed When a Batch of a Vaccine Finished Product is Suspected to be Contaminated with Bovine Viral Diarrhoea Virus (September 2015).....	1–4
2.833	Data Requirements for Removing the Target Animal Batch Safety Test for Immunological Veterinary Medicinal Products in the EU (January 2012).....	1–4
2.835	User Safety for Pharmaceutical Veterinary Medicinal Products (March 2010).....	1–20
2.836	User Safety of Topically Administered Veterinary Medicinal Products (April 2018).....	1–27
EU – Summary of Product Characteristics (SmPC) (vet)		
2.840	Summary of Product Characteristics for Pharmaceutical Veterinary Medicinal Products (July 2006).....	1–20
2.843	Summary of Product Characteristics for Anthelmintics (July 2007).....	1–5
VICH – Leitlinien für Tierarzneimittel – Wirksamkeit		
2.845	International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) – Einführung.....	1
2.845a	VICH Process – The 9-steps of VICH process – The official Organisational Charter.....	1–3
2.845b	Bioequivalence: Blood Level Bioequivalence Study (VICH GL52) (September 2015).....	1–17
2.846	Efficacy of Anthelmintics: Specific Recommendations for Equines (VICH Topic GL 15) (July 2001).....	1–5
2.847	Efficacy of Anthelmintics: Specific Recommendations for Porcines (VICH Topic GL 16) (July 2001).....	1–5
2.848	Efficacy of Anthelmintics: Specific Recommendations for Canines (VICH Topic GL 19) (July 2001).....	1–5
2.849	Efficacy of Anthelmintics: Specific Recommendations for Felines (VICH Topic GL 20) (July 2001).....	1–5
2.850	Efficacy of Anthelmintics: Specific Recommendations for Poultry – Gallus Gallus (VICH Topic GL 21) (July 2001).....	1–4
2.851	Efficacy of Anthelmintics: General Requirements (EAGR) (VICH GL7) (December 1999).....	1–9
2.852	Efficacy of Anthelmintics: Specific Recommendations for Bovines (VICH GL12) (December 1999).....	1–5
2.853	Efficacy of Anthelmintics: Specific Recommendations for Ovines (VICH GL13) (December 1999).....	1–5
2.854	Efficacy of Anthelmintics: Specific Recommendations for Caprines (VICH GL14) (December 1999).....	1–5

EU/VICH – Qualität (vet)

2.855	Stability Testing for Medicated Premixes (VICH GL8) (December 1999)	1–2
2.856	Quality Aspects of Single-Dose Veterinary Spot-on Products (nicht VICH) (January 2009)	1–4
2.857	Impurities in New Veterinary Drug Substances (VICH GL10) (February 2007)	1–13
2.858	Impurities in New Veterinary Medicinal Products (VICH GL11) (February 2007)	1–11
2.858a	Setting Specifications for Related Impurities in Antibiotics (nicht VICH) (June 2012)	1–18
2.859	Impurities: Residual Solvents in New Veterinary Medicinal Products, Active Substances and Excipients – VICH GL18(R) (September 2011)	1–16
2.859a	Testing of Residual Formaldehyde (VICH GL25) (April 2002)	1–5
2.859b	Testing of Residual Moisture (VICH GL26) (April 2002)	1–3
2.859c	Biologicals: Testing for the Detection of Mycoplasma Contamination – VICH GL34 (March 2013)	1–15
2.860	Stability Testing of Biotechnological/Biological Veterinary Medicinal Products (VICH GL17) (June 2000)	1–10
2.861	Stability Testing of New Veterinary Drug Substances and Medicinal Products (VICH GL3) (February 2007)	1–21
2.861a	Quality: Statistical Evaluation of Stability Data – VICH GL51 (March 2013)	1–18
2.862	Stability Testing for New Veterinary Dosage Forms (VICH GL4) (June 1999)	1
2.863	Stability Testing: Photostability Testing of New Veterinary Drug Substances and Medicinal Products (VICH GL5) (June 1999)	1–9
2.864	Quality Aspects of Pharmaceutical Veterinary Medicines for Administration via Drinking Water (nicht VICH) (July 2004)	1–8
2.866	Stability Testing of Existing Active Substances and Related Finished Products (nicht VICH) (August 2008)	1–18
2.867	Quality: Bracketing and Matrixing Designs for Stability Testing of New Veterinary Drug Substances and Medicinal Products (VICH GL45) (April 2010)	1–8

EU/VICH – Tierarzneimittelrückstände (vet)

2.870	Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: General Approach to Establish a Microbiological ADI (VICH GL36) (R2) (March 2019)	1–22
2.870b	Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: General Approach to Establish an Acute Reference Dose (ARfD) (VICH GL54) (December 2016)	1–10
2.870c	Harmonisation of Criteria to Waive Target Animal Batch Safety Testing for Live Vaccines for Veterinary Use (VICH GL55) (June 2017)	1–8
2.871	Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Repeat–Dose (Chronic) Toxicity Testing (VICH GL37) (June 2004)	1–4

2.872	Pre-Approval Information for Registration of New Veterinary Medicinal Products for Food-producing Animals with Respect to Antimicrobial Resistance (VICH GL27) (January 2004)	1–7
2.873	Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: General Approach to Testing (VICH GL33) (April 2009)	1–5
2.873a	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 (VICH GL46) (February 2011)	1–11
2.873b	Studies to Evaluate the Metabolism and Residue Kinetics of Veterinary Drugs in Food-Producing Animals: Laboratory Animal Comparative Metabolism Studies (VICH GL47) (March 2011).....	1–9
2.873c	Studies to Evaluate the Metabolism and Residue Kinetics of Veterinary Drugs in Food-Producing Animals: Marker Residue Depletion Studies to Establish Product Withdrawal Periods (VICH GL48) (February 2015)	1–14
2.873d	Studies to Evaluate the Metabolism and Residue Kinetics of Veterinary Drugs in Human Food-Producing Animals: Validation of Analytical Methods Used in Residue Depletion Studies (VICH GL 49) (February 2015)	1–16
2.873e	Harmonization of Criteria to Waive Target Animal Batch Safety Testing for Inactivated Vaccines for Veterinary Use (VICH GL50) (June 2017)	1–7
2.873k	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 (VICH GL56) (July 2018)	1–8
2.873l	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 (VICH GL57) (March 2019).....	1–11
2.873m	Stability Testing of New Veterinary Drug Substances and Medicinal Products in Climatic Zones III and IV (VICH GL58) (December 2019)	1–6
2.873n	Harmonisation of Criteria to Waive Laboratory Animal Batch Safety Testing for Vaccines for Veterinary Use – (VICH GL59) (December 2020)	1–7
2.874	Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Reproduction Testing (VICH GL22) (July 2001).....	1–5
2.875	Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Genotoxicity Testing (VICH GL23) (November 2014)	1–6
2.876	Safety of Residues: Repeat-Dose (90-Day) Toxicity Testing (VICH Topic GL31) (November 2002)	1–3
2.877	Safety of Residues: Development Toxicity Testing (VICH Topic GL32) (November 2002)	1–4

2.878	Studies to evaluate the Safety of Residues of Veterinary Drugs in Human Food: Carcinogenicity Testing (VICH GL28) (Revision May 2005)	1–4
2.879	Injection Site Residues (October 2004)	1–12
2.880	Good Clinical Practice (VICH GL9) (June 2000)	1–21
2.881	Specifications: Test Procedures and Acceptance Criteria for New Veterinary Drug Substances and New Medicinal Products: Chemical Substances (VICH GL39) (November 2005)	1–34
2.882	Specifications: Test Procedures and Acceptance Criteria for New Biotechnological/Biological Veterinary Medicinal Products (VICH GL 40) (November 2005)	1–19
2.883	Target Animal Safety: Examination of Live Veterinary Vaccines in Target Animals for Absence of Reversion to Virulence (VICH Topic GL 41) (July 2007)	1–6
2.884	Target Animal Safety for Veterinary Pharmaceutical Products (VICH GL 43) (July 2008)	1–16
2.885	Target Animal Safety for Veterinary Live and Inactivated Vaccines (VICH GL 44) (July 2008)	1–9
2.886	Demonstration of Target Animal Safety and Efficacy of Veterinary Medicinal Products Intended for Use in Farmed Finfish (nicht VICH) (May 2011)	1–15
2.890	Environmental Impact Assessment (EIAs) for veterinary medicinal Products (VMPs) – Phase I (VICH GL6) (June 2000)	1–7
2.891	Environmental Impact Assessment For Veterinary Medicinal Products – In Support of the VICH Guidelines GL6 and GL38 (June 2016)	1–72
2.910	Guideline on Requirements for an Authorisation under Exceptional Circumstances for Vaccines for Use in Birds against Avian Influenza (nicht VICH) (April 2007)	1–9
2.915	Data Requirements for Multi-Strain Dossiers for Inactivated Vaccines Against Avian Influenza (AI), Bluetongue (BT) and Foot-And-Mouth Disease (FMD) (nicht VICH) (March 2010) ..	1–7
2.935	Assessor Preparing Assessment Reports for Veterinary Medicinal Products (May 2005)	1–51
EU – Minor Uses or Minor Species (MUMS) (vet)		
2.974	Classification of Veterinary Medicinal Products Indicated for Minor Use Minor Species (MUMS)/Limited Market (October 2017)	1–13
2.975	Quality Data Requirements for Veterinary Medicinal Products Intended for Minor Uses or Minor Species (MUMS/Limited market (December 2016)	1–9
2.977	Efficacy and Target Animal Safety Data Requirements for Veterinary Medicinal Products Intended for Minor Uses or Minor Species (MUMS/Limited Market (December 2016)	1–7
2.980	Safety and Residues Data Requirements for Pharmaceutical Veterinary Medicinal Products Intended for Minor Uses or Minor Species (MUMS/Limited Market (December 2016)e	1–27

2.981	Data Requirements for Immunological Veterinary Medicinal Products Intended for Minor Use or Minor Species (MUMS)/Limited Market (April 2017)	1–10
EU – Orphan Medicinal Products (OMP)		
2.1000	Regulation (EC) No 141/2000 of the European Parliament and of the Council on Orphan Medicinal Products (December 1999)	1–8
2.1001	Commission Regulation (EC) No 847/2000 Laying down the Provisions for Implementation of the Criteria for Designation of a Medicinal Product as an Orphan Medicinal Product and Definitions of the Concepts ‘Similar Medicinal Product’ and ‘Clinical Superiority’ (April 2000)	1–6
EU – Implementierung von GCP (hum)		
2.1010	Clinical Trials in Small Populations (July 2006)	1–12
2.1100	Directive 2001/20/EC of the European Parliament and of the Council on the Approximation of the Laws, Regulations and Administrative Provisions of the Member States Relating to the Implementation of Good Clinical Practice in the Conduct of Clinical Trials on Medicinal Products for Human Use (April 2001)	1–18
2.1101	Regulation (EC) No 1901/2006 of the European Parliament and of the Council on Medicinal Products for Paediatric Use and Amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004 (December 2006) ...	1–31
2.1102	Regulation (EC) No 1902/2006 of the European Parliament and of the Council amending Regulation 1901/2006 on Medicinal Products for Paediatric Use (December 2006)	1–2
2.1105	Investigational Medicinal Products (IMPs) and “Non Investigational Medicinal Products” (NIMPS) (Rev.1, March 2011)	1–12
2.1113	Virus Safety Evaluation of Biotechnological Investigational Medicinal Products (July 2008)	1–10
2.1300	Definitions for Genomic Biomarkers, Pharmacogenomics, Pharmacogenetics, Genomic Data and Sample Coding Categories (ICH Topic E 15) (November 2007)	1–6
2.1310	Genomic Biomarkers Related to Drug Response: Context, Structure and Format of Qualification Submissions (ICH E16) (September 2010)	1–10
EU – Plasma Master File (PMF) und Vaccine Antigen Master File (VAMF)		
2.1500	Scientific Data Requirements for a Plasma Master File (PMF) (November 2006)	1–37
2.1502	Epidemiological Data on Blood Transmissible Infections (February 2016)	1–15
2.1503	Requirements for Plasma Master File (PMF) Certification (February 2004)	1–11
2.1505	Scientific Data Requirements for a Vaccine Antigen Master File (December 2003)	1–5

2.1510	Requirements for Vaccine Antigen Master File (VAMF) Certification (Revision 1 – March 2005)	1–12
2.1515	Plasma Master File (PMF) and Vaccine Antigen Master File (VAMF) “Second Step” (2004).....	1–4
EU – Zellpräparate und Arzneimittel für neuartige Therapien (hum)		
2.1605	Human Cell-Based Medicinal Products (May 2008).....	1–27
2.1610	Xenogeneic Cell-Based Medicinal Products (October 2009).....	1–15
2.1700	Non-Clinical and Clinical Development of Similar Medicinal Products Containing Recombinant Interferon Alfa (April 2009)	1–7
2.1705	Non-Clinical Studies Required Prior to Clinical Use of Gene Therapy Medicinal Products (May 2008).....	1–11
2.1706	Quality, Non-Clinical and Clinical Aspects of Gene Therapy Medicinal Products (March 2018).....	1–47
2.1710	Follow-Up of Patients Administered with Gene Therapy Medicinal Products (October 2009).....	1–14
2.1805	Clinical and Non-Clinical Evaluation During the Consultation Procedure on Medicinal Substances Contained in Drug-Eluting (Medicinal Substance-Eluting) Coronary Stents (May 2008)	1–11
2.1810	Risk-Based Approach According to Annex I, Part IV of Directive 2001/83/EC Applied to Advanced Therapy Medicinal Products (February 2013).....	1–25
2.1815	Good Clinical Practice specific to Advanced Therapy Medicinal Products. C(2019) 7140 final (October 2019)	1–14
2.1820	Guideline on Quality, Non-Clinical and Clinical Aspects of Medicinal Products Containing Genetically Modified Cells (November 2020).....	1–35
EU – Community Herbal Monographs		
2.1995	Community Herbal Monographs – Einführung.....	1
2.1996	Documentation to be Submitted for Inclusion into the ‘Community List of Herbal Substances, Preparations and Combinations thereof for Use in Traditional Herbal Medicinal Products’ (Revision July 2007)	1–4
2.1997	Glossary on Herbal Teas (July 2010).....	1–6
2.2000	Procedure for the Preparation of Community Monographs for Herbal Medicinal Products with Well-Established Medicinal Use (January 2007)	1–10
2.2002	European Union Herbal Monograph on <i>Senna alexandrina</i> Mill. (<i>Cassia senna</i> L.; <i>Cassia angustifolia</i> Vahl)1, Fructus (September 2018).....	1–10
2.2003	Community Herbal Monograph on <i>Linum usitatissimum</i> L., Semen (March 2015)	1–8
2.2004	Community Herbal Monograph on <i>Plantago afra</i> L. et <i>Plantago Indica</i> L., Semen (May 2013)	1–11
2.2005	Community Herbal Monograph on <i>Plantago ovata</i> Forssk., Semen (May 2013)	1–10
2.2006	Community Herbal Monograph on <i>Plantago ovata</i> Forssk., Seminis Tegumentum (May 2013).....	1–11

2.2007	European Union Herbal Monograph on <i>Rhamnus frangula</i> L., Cortex (September 2019).....	1–9
2.2008	Community Herbal Monograph on <i>Foeniculum vulgare</i> Miller Subsp. <i>Vulgare</i> Var. <i>dulce</i> (Miller) Thellung, Fructus (July 2007).....	1–6
2.2009	Community Herbal Monograph on <i>Foeniculum vulgare</i> Miller Subsp. <i>Vulgare</i> Var. <i>vulgare</i> , Aetheroleum (July 2007).....	1–6
2.2010	Community Herbal Monograph on <i>Foeniculum vulgare</i> Miller Subsp. <i>Vulgare</i> Var. <i>Vulgare</i> , Fructus (July 2007).....	1–6
2.2011	Community Herbal Monograph on <i>Primula veris</i> L. and/or <i>Primula</i> <i>elatior</i> (L.) Hill, Flos (September 2012).....	1–5
2.2012	Community Herbal Monograph on <i>Primula veris</i> L. and/or <i>Primula</i> <i>elatior</i> (L.) Hill, Radix (September 2012).....	1–7
2.2013	European Union Herbal Monograph on <i>Mentha x piperita</i> L., Aetheroleum (January 2020).....	1–11
2.2014	Community Herbal Monograph on <i>Passiflora incarnata</i> L., Herba (September 2007).....	1–5
2.2015	Community Herbal Monograph on <i>Melissa officinalis</i> L., Folium (May 2013).....	1–6
2.2016	European Union herbal monograph on <i>Rhamnus purshiana</i> DC., Cortex (May 2020).....	1–9
2.2017	European Union Herbal Monograph on <i>Rheum palmatum</i> L. and <i>Rheum officinale</i> Baillon, Radix (May 2020).....	1–8
2.2018	Community Herbal Monograph on <i>Thymus vulgaris</i> L. and <i>Thymus</i> <i>zygis</i> L., Herba (October 2007).....	1–7
2.2019	Community Herbal Monograph on <i>Pimpinella anisum</i> L., Aetheroleum (July 2007).....	1–5
2.2020	Community Herbal Monograph on <i>Pimpinella anisum</i> L., Fructus (July 2007).....	1–5
2.2021	European Union Herbal Monograph on <i>Cassia senna</i> L. and <i>Cassia</i> <i>angustifolia</i> Vahl, Folium (September 2018).....	1–10
2.2022	Community Herbal Monograph on <i>Valeriana officinalis</i> L., Radix (February 2016).....	1–6
2.2023	Community Herbal Monograph on <i>Equisetum arvense</i> L., Herba (February 2016).....	1–6
2.2024	European Union Herbal Monograph on <i>Melilotus officinalis</i> (L.) Lam., Herba (November 2017).....	1–5
2.2025	European Union Herbal Monograph on <i>Verbascum thapsus</i> L., V. <i>densiflorum</i> Bertol. and V. <i>phlomoides</i> L., Flos (March 2018).....	1–4
2.2026	European Union Herbal Monograph on <i>Sambucus nigra</i> L., Flos (March 2018).....	1–4
2.2027	European Union Herbal Monograph on <i>Echinacea purpurea</i> (L.) Moench, Herba recens (November 2014).....	1–6
2.2028	European Union Herbal Monograph on <i>Calendula officinalis</i> L., Flos (March 2018).....	1–6
2.2029	Community Herbal Monograph on <i>Eleutherococcus senticosus</i> (Rupr. et Maxim.) Maxim., Radix (March 2014).....	1–6
2.2030	Community Herbal Monograph on <i>Humulus lupulus</i> L., Flos (May 2014).....	1–6

2.2031	European Union Herbal Monograph on <i>Betula pendula</i> Roth and/or <i>Betula pubescens</i> Ehrh., Folium (November 2014).....	1–6
2.2032	European Union Herbal Monograph on <i>Ruscus aculeatus</i> L., Rhizoma (November 2018)	1–6
2.2033	Community Herbal Monograph on <i>Avena sativa</i> L., Herba (September 2008).....	1–5
2.2034	Community Herbal Monograph on <i>Avena sativa</i> L., Fructus (September 2008).....	1–4
2.2035	Community Herbal Monograph on <i>Peumus boldus</i> Molina, Folium (November 2016).....	1–5
2.2036	Community Herbal Monograph on <i>Centaurium erythraea</i> Rafn, Herba (November 2015)	1–5
2.2037	Community Herbal Monograph on <i>Harpagophytum procumbens</i> D.C. and/or <i>Harpagophytum Zeyheri</i> Decne, Radix (July 2016).....	1–7
2.2038	European Union Herbal Monograph on <i>Mentha X piperita</i> L., Folium (January 2020)	1–6
2.2039	Community Herbal Monograph on <i>Polypodium vulgare</i> L., Rhizoma (November 2008).....	1–5
2.2040	European Union Herbal Monograph on <i>Salix</i> [various species including <i>S. purpurea</i> L., <i>S. daphnoides</i> Vill., <i>S. fragilis</i> L.], Cortex (January 2017)	1–7
2.2041	Community Herbal Monograph on <i>Solidago virgaurea</i> L., Herba (September 2008).....	1–5
2.2042	Community Herbal Monograph on <i>Urtica dioica</i> L. and <i>Urtica urens</i> L., Herba (September 2008).....	1–7
2.2043	European Union Herbal Monograph on <i>Artemisia absinthium</i> L., Herba (March 2020).....	1–6
2.2044	Community Herbal Monograph on <i>Althaea officinalis</i> L., Radix (July 2016)	1–6
2.2045	European Union Herbal Monograph on <i>Curcuma longa</i> L., Rhizoma (September 2018).....	1–6
2.2046	European Union Herbal Monograph on <i>Echinacea pallida</i> (Nutt.) Nutt., Radix (June 2018).....	1–4
2.2047	European Union Herbal Monograph on <i>Gentiana lutea</i> L., Radix (November 2018).....	1–5
2.2048	Community Herbal Monograph on <i>Hamamelis virginiana</i> L., Cortex (September 2019).....	1–7
2.2049	Community Herbal Monograph on <i>Hamamelis virginiana</i> L., Folium et Cortex aut Ramunculus Destillatum (November 2009).....	1–6
2.2050	Community Herbal Monograph on <i>Hamamelis virginiana</i> L., Folium (November 2009).....	1–7
2.2051	European Union Herbal Monograph on <i>Aesculus hippocastanum</i> L., Semen (January 2020)	1–8
2.2052	Community Herbal Monograph on <i>Hypericum perforatum</i> L., Herba (Well-Established Medicinal Use) (November 2009).....	1–8
2.2053	Community Herbal Monograph on <i>Hypericum perforatum</i> L., Herba (Traditional Use) (November 2009)	1–9

2.2054 European Union Herbal Monograph on <i>Salvia officinalis</i> L., Folium (September 2016).....	1–7
2.2055 Community Herbal Monograph on <i>Potentilla erecta</i> (L.) Rausch., Rhizoma (November 2010)	1–7
2.2056 European Union Herbal Monograph on <i>Tanacetum parthenium</i> (L.) Schulz Bip., Herba (July 2020).....	1–5
2.2057 European Union Herbal Monograph on <i>Cimicifuga racemosa</i> (L.) Nutt., Rhizoma (March 2018).....	1–5
2.2058 Community Herbal Monograph on <i>Urtica dioica</i> L.; <i>Urtica urens</i> L., Folium (January 2010).....	1–6
2.2059 European Union Herbal Monograph on <i>Vitis vinifera</i> L., Folium (May 2017)	1–7
2.2060 Community Herbal Monograph on <i>Orthosiphon stamineus</i> Benth., Folium (March 2010).....	1–5
2.2061 Community Herbal Monograph on <i>Arctium lappa</i> L., Radix (September 2010).....	1–6
2.2062 Community Herbal Monograph on <i>Leonurus cardiaca</i> L., Herba (September 2010).....	1–6
2.2063 Community Herbal Monograph on <i>Thymus vulgaris</i> L., <i>Thymus zygis</i> Loeffl. ex L., Aetheroleum (September 2010)	1–7
2.2064 European Union Herbal Monograph on <i>Valeriana officinalis</i> L., Radix and <i>Humulus lupulus</i> L., Flos (September 2019).....	1–8
2.2065 European Union Herbal Monograph on <i>Ribes nigrum</i> L., Folium (September 2017).....	1–5
2.2066 Community Herbal Monograph on <i>Cola nitida</i> (Vent.) Schott et Endl. and its varieties and <i>Cola acuminata</i> (P. Beauv.) Schott et Endl., Semen (November 2011)	1–5
2.2067 Community Herbal Monograph on <i>Chamaemelum nobile</i> (L.) All., Flos (November 2011).....	1–5
2.2068 Community Herbal Monograph on <i>Agropyron repens</i> (L.) P. Beauv., Rhizoma (November 2011).....	1–5
2.2069 Community Herbal Monograph on <i>Capsella bursa-pastoris</i> (L.) Medikus, Herba (July 2011)	1–5
2.2070 Community Herbal Monograph on <i>Commiphora molmol</i> Engler, gummi-resina (July 2011).....	1–6
2.2071 Community Herbal Monograph on <i>Syzygium aromaticum</i> (L.) Merrill et L. M. Perry, floris aetheroleum (September 2011).....	1–6
2.2072 Community Herbal Monograph on <i>Cynara scolymus</i> L., Folium (July 2011)	1–6
2.2073 Community Herbal Monograph on <i>Fumaria officinalis</i> L., Herba (September 2011).....	1–6
2.2074 European Union Herbal Monograph on <i>Achillea millefolium</i> L., Herba (September 2020).....	1–6
2.2075 Community Herbal Monograph on <i>Achillea millefolium</i> L., Flos (July 2011)	1–6
22.2076 Community Herbal Monograph on <i>Filipendula ulmaria</i> (L.) Maxim., Flos (July 2011)	1–5

2.2077 Community Herbal Monograph on <i>Filipendula ulmaria</i> (L.) Maxim., Herba (July 2011)	1-6
2.2078 Community Herbal Monograph on <i>Cinnamomum verum</i> J.S. Presl, Cortex (May 2011).....	1-6
2.2079 European Union Herbal Monograph on <i>Vitex agnus-castus</i> L., Fructus (March 2018)	1-6
2.2080 Community Herbal Monograph on <i>Cinnamomum verum</i> J.S. Presl, Corticis aetheroleum (May 2011).....	1-4
2.2082 Community Herbal Monograph on <i>Taraxacum officinale</i> Weber ex Wigg., Folium (November 2019).....	1-6
2.2083 Community Herbal Monograph on <i>Taraxacum officinale</i> Weber ex Wigg., Radix cum herba (November 2009).....	1-6
2.2084 European Union Herbal Monograph on <i>Hedera helix</i> L., Folium (November 2017).....	1-5
2.2085 Community Herbal Monograph on <i>Trigonella foenum-graecum</i> L., semen (January 2011)	1-6
2.2086 European Union Herbal Monograph on <i>Echinacea purpurea</i> (L.) Moench, Radix (May 2017).....	1-5
2.2087 Community Herbal Monograph on <i>Juniperus communis</i> L., Pseudo-fructus (November 2009).....	1-7
2.2088 Community Herbal Monograph on <i>Quercus robur</i> L., <i>Quercus petraea</i> . (Matt.) Liebl., <i>Quercus pubescens</i> Willd., Cortex (November 2010)	1-6
2.2089 Community Herbal Monograph on <i>Rosmarinus officinalis</i> L., Folium (July 2010)	1-7
2.2090 Community Herbal Monograph on <i>Ilex paraguariensis</i> St. Hilaire, Folium (May 2010).....	1-6
2.2091 Community Herbal Monograph on <i>Rosmarinus officinalis</i> L., Aetheroleum (July 2010)	1-6
2.2092 Community Herbal Monograph on <i>Viola tricolor</i> L. and/or subspecies <i>Viola arvensis</i> Murray (Gaud) and <i>Viola vulgaris</i> Koch (Oborny), herba cum flore (November 2010).....	1-5
2.2093 Community Herbal Monograph on <i>Juniperus communis</i> L., Aetheroleum (November 2010).....	1-6
2.2094 Community Herbal Monograph on <i>Glycyrrhiza glabra</i> L. and/or <i>Glycyrrhiza inflata</i> Bat. and/or <i>Glycyrrhiza uralensis</i> Fisch., Radix (May 2012)	1-8
2.2095 Community Herbal Monograph on <i>Tilia cordata</i> Miller, <i>Tilia platyphyllos</i> Scop., <i>Tilia x vulgaris</i> Heyne or their mixtures, Flos (May 2012)	1-7
2.2096 Community Herbal Monograph on <i>Fraxinus excelsior</i> L. or <i>Fraxinus</i> <i>angustifolia</i> Vahl, Folium (March 2012)	1-6
2.2097 Community Herbal Monograph on <i>Lavandula angustifolia</i> Miller, Aetheroleum (March 2012)	1-5
2.2098 Community Herbal Monograph on <i>Lavandula angustifolia</i> Miller, Flos (March 2012)	1-5
2.2099 Community Herbal Monograph on <i>Zingiber officinale</i> Roscoe, Rhizoma (March 2012)	1-6
2.2100 Community Herbal Monograph on <i>Echinacea angustifolia</i> DC., Radix (March 2012)	1-6

2.2101	Community Herbal Monograph on <i>Rhodiola rosea</i> L., Rhizoma et Radix (March 2012)	1–5
2.2102	European Union Herbal Monograph on <i>Olea europaea</i> L., Folium (January 2017)	1–4
2.2103	European Union Herbal Monograph on <i>Oenothera biennis</i> L.; <i>Oenothera lamarckiana</i> L., Oleum (June 2018)	1–4
2.2104	European Union Herbal Monograph on <i>Arctostaphylos uva-ursi</i> (L.) Spreng., Folium (January 2018)	1–6
2.2105	Community Herbal Monograph on <i>Plantago lanceolata</i> L., Folium (January 2014)	1–8
2.2106	Community Herbal Monograph on <i>Levisticum officinale</i> Koch, Radix (November 2012)	1–5
2.2107	Community Herbal Monograph on <i>Solanum dulcamara</i> L., Stipites (January 2013)	1–5
2.2108	European Union Herbal Monograph on <i>Pelargonium sidoides</i> DC and/or <i>Pelargonium reniforme</i> Curt., Radix (June 2018)	1–4
2.2109	Community Herbal Monograph on <i>Aesculus hippocastanum</i> L., Cortex (May 2012)	1–5
2.2110	Community Herbal Monograph on <i>Urtica dioica</i> L., <i>Urtica urens</i> L., their hybrids or their mixtures, Radix (September 2012)	1–6
2.2111	Community Herbal Monograph on <i>Grindelia Robusta</i> Nutt., <i>Grindelia squarrosa</i> (Pursh) Dunal, <i>Grindelia Humilis</i> Hook. et Arn., <i>Grindelia camporum</i> Greene, Herba (November 2012)	1–5
2.2112	Community Herbal Monograph on <i>Cichorium intybus</i> L., Radix (January 2013)	1–5
2.2113	Community Herbal Monograph on <i>Paullinia cupana</i> Kunth ex H.B.K. var. <i>sorbilis</i> (Mart.) Ducke, Semen (January 2013)	1–5
2.2114	Community Herbal Monograph on <i>Cucurbita pepo</i> L., Semen (November 2012)	1–5
2.2115	Community Herbal Monograph on <i>Eucalyptus globulus</i> Labill., Folium (April 2013)	1–6
2.2116	Community Herbal Monograph on <i>Thymus vulgaris</i> L. and <i>Thymus zygis</i> L., Herba and <i>Primula veris</i> L. and <i>Primula elatior</i> (L.) Hill, Radix (April 2016)	1–8
2.2117	Community Herbal Monograph on <i>Marrubium vulgare</i> L., Herba (July 2013)	1–6
2.2118	Community Herbal Monograph on <i>Juglans regia</i> L., Folium (July 2013)	1–5
2.2119	Community Herbal Monograph on <i>Phaseolus vulgaris</i> L., Fructus sine Semine (November 2013)	1–5
2.2120	Community Herbal Monograph on <i>Origanum dictamnus</i> L., Herba (January 2014)	1–6
2.2121	Community Herbal Monograph on <i>Rubus idaeus</i> L., Folium (January 2014)	1–6
2.2122	Community Herbal Monograph on <i>Curcuma xanthorrhiza</i> Roxb. (<i>C. xanthorrhiza</i> D. Dietrich), Rhizoma (January 2014)	1–5
2.2123	Community Herbal Monograph on <i>Panax ginseng</i> C.A.Meyer, Radix (March 2014)	1–8

2.2124 Community Herbal Monograph on <i>Eucalyptus globulus</i> Labill., <i>Eucalyptus polybractea</i> R.T. Baker and/or <i>Eucalyptus smithii</i> R.T. Baker, Aetheroleum (March 2014)	1–9
2.2125 Community Herbal Monograph on <i>Ononis spinosa</i> L., Radix (March 2014)	1–5
2.2126 European Union Herbal Monograph on <i>Hieracium pilosella</i> L., Herba cum radice (May 2015)	1–5
2.2127 Community Herbal Monograph on <i>Arnica montana</i> L., Flos (May 2014)	1–5
2.2128 Community Herbal Monograph on <i>Fucus vesiculosus</i> L., Thallus (May 2014)	1–5
2.2129 Community Herbal Monograph on <i>Rosa gallica</i> L., <i>Rosa centifolia</i> L., <i>Rosa damascena</i> Mill., Flos (July 2014)	1–5
2.2130 European Union Herbal Monograph on <i>Sisymbrium officinale</i> (L.) Scop., Herba (September 2014)	1–6
2.2131 European Union Herbal Monograph on <i>Melaleuca alternifolia</i> (Maiden and Betch) Cheel, <i>M. linariifolia</i> Smith, <i>M. dissitiflora</i> F. Mueller and/or Other Species of <i>Melaleuca</i> , Aetheroleum (November 2014)	1–8
2.2132 European Union Herbal Monograph on <i>Cetraria islandica</i> (L.) Acharius s.l., Thallus (November 2014)	1–8
2.2133 European Union Herbal Monograph on <i>Eschscholzia californica</i> Cham., Herba (January 2015)	1–5
2.2134 European Union Herbal Monograph on <i>Capsicum annuum</i> L. var. minimum (Miller) Heiser and Small Fruited Varieties of <i>Capsicum</i> <i>frutescens</i> L., Fructus (May 2015)	1–9
2.2135 European Union Herbal Monograph on <i>Symphytum officinale</i> L., Radix (May 2015)	1–5
2.2136 European Union Herbal Monograph on <i>Agrimonia eupatoria</i> L., Herba (January 2015)	1–7
2.2137 European Union Herbal Monograph on <i>Ginkgo biloba</i> L., Folium (January 2015)	1–9
2.2138 European Union Herbal Monograph on <i>Aloe barbadensis</i> Mill. and on <i>Aloe</i> (various species, mainly <i>Aloe ferox</i> Mill. and its hybrids), Folii succus siccatus (November 2016)	1–9
2.2139 European Union Herbal Monograph on <i>Glycine max</i> (L.) Merr., Oleum raffinatum (January 2017)	1–6
2.2140 European Union Herbal Monograph on <i>Prunus africana</i> (Hook f.) Kalkm., Cortex (July 2016)	1–5
2.2141 European Union Herbal Monograph on <i>Species diureticae</i> (March 2017)	1–8
2.2142 European Union Herbal Monograph on <i>Silybum marianum</i> (L.) Gaertn., Fructus (June 2018)	1–5
2.2143 European Union Herbal Monograph on <i>Allium sativum</i> L., Bulbus (July 2017)	1–6
2.2144 European Union Herbal Monograph on <i>Fragaria vesca</i> L., <i>Fragaria</i> <i>moschata</i> Weston, <i>Fragaria viridis</i> Weston and <i>Fragaria x ananassa</i> (Weston) Duchesne ex Rozier, Folium (November 2018)	1–5

2.2145	European Union Herbal Monograph on <i>Malva sylvestris</i> L., Flos (November 2018).....	1–5
2.2146	European Union Herbal Monograph on <i>Malva sylvestris</i> L. and/or <i>Malva neglecta</i> Wallr., Folium (November 2018).....	1–5
2.2147	European Union Herbal Monograph on <i>Menyanthes trifoliata</i> L., Folium (May 2021).....	1–6
2.2148	European Union Herbal Monograph on <i>Species sedativae</i> (November 2020).....	1–5
2.2149	European Union Herbal Monograph on <i>Species amarae</i> (November 2020).....	1–7
2.2150	European Union Herbal Monograph on <i>Herniaria glabra</i> L., <i>H. hirsuta</i> L., <i>H. incana</i> Lam., Herba (July 2020).....	1–4
EU – Kinderarzneimittel		
2.5000	Pharmaceutical Development of Medicines for Paediatric Use (August 2013).....	1–27
2.5001	Standard Paediatric Investigation Plan for Non-Adjuvanted or Adjuvanted Pandemic Influenza Vaccines During a Pandemic (March 2010).....	1–10
2.5005	EMA/PDCO Standard Paediatric Investigation Plan for Allergen Products for Specific Immunotherapy (February 2015).....	1–16
2.5006	Paediatric Investigation Plan: Expected Key Elements and Requirements for a New DTaP Containing Combination Vaccine Seeking Marketing Authorisation (September 2014).....	1–4
2.5007	Paediatric Addendum on the CHMP Guideline on Clinical Investigation of Medicinal Products for the Treatment of Acute Heart Failure (November 2016).....	1–9
2.5007a	Evaluation of Anticancer Medicinal Products in Man. Addendum on paediatric Oncology (July 2003).....	1–7
2.5008	Clinical investigation of Medicinal Products for the Treatment of Duchenne and Becker Muscular Dystrophy (December 2015).....	1–21
2.5015	Format and Content of Applications for Agreement or Modification of a Paediatric Investigation Plan and Requests for Waivers or Deferrals and Concerning the Operation of the Compliance Check and on Criteria for Assessing Significant Studies (2014/C 338/01) ..	1–21
2.5016	European Medicines Agency Decision CW/0001/2015 on Class Waivers, in Accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council (July 2015).....	1–16
2.5020	Revised Priority List for Studies on Off-Patent Paediatric Medicinal Products (August 2013).....	1–14

3 Resolutionen des Europarates
--

3.0	Europarat – Einführung	1–2
3.1	Quality Control of Drugs.....	1–4
3.2	Preparation and Quality Control of Radiopharmaceuticals	1–4

3.3	Concerning Medical Research on Human Beings – Recommendation No. R (90) 3 (February 1990).....	1–4
3.10	Responsibilities of Health Authorities in the Field of Blood Transfusion Recommendation No. R (88) 4 (March 1988).....	1–4
3.11	Europäisches Übereinkommen über den Austausch therapeutischer Substanzen menschlichen Ursprungs (Übersetzung) (Dezember 1958)	1–37
3.13	Concerning Clinical Trials Involving the Use of Components and Fractionated Products Derived from Human Blood or Plasma Recommendation No. R (93) 4 (March 1993).....	1–6
3.14	Plasma Products and European Self-Sufficiency Recommendation No. R (90) 9 (1990).....	1–4
3.50	Certification of Suitability to the Monographs of the European Pharmacopoeia – Revised version (Resolution AP-CSP (07) 1) (February 2007)	1–7
3.51	Certification of Suitability to the Monographs of the European Pharmacopoeia – Terms of Reference (PA/PH/CEP (01)1,11 R Cor) (July 2019)	1–9
3.80	Übereinkommen zum Schutz der Menschenrechte und der Menschenwürde im Hinblick auf die Anwendung von Biologie und Medizin: Übereinkommen über Menschenrechte und Biomedizin (April 1997)	1–12
3.80a	Erläuternder Bericht zu dem Übereinkommen zum Schutz der Menschenrechte und der Menschenwürde im Hinblick auf die Anwendung von Biologie und Medizin: Übereinkommen über Menschenrechte und Biomedizin (Mai 1997)	1–35
3.81	Zusatzprotokoll zum Übereinkommen zum Schutz der Menschenrechte und der Menschenwürde im Hinblick auf die Anwendung von Biologie und Medizin über das Verbot des Klonens von menschlichen Lebewesen (Januar 1998)	1–3
3.82	Additional Protocol to the Convention on Human Rights and Biomedicine Concerning Biomedical Research (January 2005).....	1–14
3.85	Protection of the Human Rights and Dignity of Persons with Mental Disorder (September 2004).....	1–13

<p>4 European Directorate for the Quality of Medicines & Health Care (EDQM) – Official Control Authority Batch Release (OCABR)</p>

4.1	Official Control Authority Batch Release (OCABR) for Human Biologicals: Vaccines, Blood and Plasma Derivatives – Background and Legal Framework – (April 2014).....	1–2
4.5	OCABR Network Human Biologicals Guidelines and Procedures – Preface (September 2017).....	1–2

4.10	EU Administrative Procedure for Official Control Authority Batch Release – Human Vaccine and Blood Derived Medicinal Products (October 2019).....	1–35
4.15	EU Administrative Procedure for Official Control Authority Batch Release (OCABR) of Centrally Authorised Immunological Medicinal Products for Human Use and Medicinal Products Derived from Human Blood and Plasma (May 2010).....	1–2
4.20	EU Official Control Authority Batch Release for Human Biological Medicines – Overview of Products Specific Guidelines (August 2020)	1–4
4.25	Official Control Authority Batch Release (OCABR)/Official Batch Protocol Review (OBPR) for Immunological Veterinary Medicinal Products (IVMPs) (April 2014).....	1–3
4.30	VBRN Procedures and Technical Guidelines – Preface (August 2017)	1–2
4.35	EU Administrative Procedure for a Harmonised Application of Article 81 for Official Batch Protocol Review of Immunological Veterinary Medicinal Products (November 2012).....	1–11
4.40	EU Administrative Procedure for Application of Article 82 for Official Control Authority Batch Release of Immunological Veterinary Medicinal Products (September 2017).....	1–13
4.45	Guidelines for EU Official Control Authority Batch Release (OCABR)/EU Official Batch Protocol Review (OBPR) for Immunological Veterinary Medicinal Products IVMPs – Products Specific Guidelines (July 2015).....	1–2

<p>5 Richtlinien der Pharmazeutischen Inspektions-Convention/ Co-Operation Scheme (PIC/S)</p>
--

5.0	Pharmazeutische Inspektions-Convention (PIC), PIC Scheme (PIC/S), MRA und ACAA – Einführung	1–4
5.5	Pharmaceutical Inspection Co-Operation Scheme (PIC Scheme) – List of PIC/S Participating Authorities & Partners (August 2020)....	1–8

<p>6 Richtlinien der Organization for Economic Cooperation and Development (OECD) und sonstige GLP-Vorschriften</p>
--

6.0	Organization for Economic Cooperation and Development (OECD) – Einführung	1–3
6.1	Grundsätze der Guten Laborpraxis (GLP) – GLP-Konsensdokument Nummer 1 (Neufassung Mai 1997)	1–2
6.2	Allgemeine Verwaltungsvorschrift zum Verfahren der behördlichen Überwachung der Einhaltung der Grundsätze der Guten Laborpraxis (ChemVwV-GLP) (November 2011).....	1–16
6.20	Revised Guidance for the Conduct of Laboratory Inspections and Study Audits – Environment Monograph No. 111 – Guidance for GLP Monitoring Authorities (Guidance No. 3) (1995)	1–16

6.25	Leitfaden zur Harmonisierung des GLP-Überwachungsverfahrens in der Bundesrepublik Deutschland (April 2007).....	1–9
6.30	Revised Guides for Compliance Monitoring Procedures for Good Laboratory Practice – Environment Monograph No. 110 – Guidance for GLP Monitoring Authorities (Nr. 2) (1995).....	1–16
6.40	Directive 2004/10/EC of the European Parliament and of the Council on the Harmonisation of Laws, Regulations and Administrative Provisions Relating to the Application of the Principles of Good Laboratory Practice and the Verification of their Applications for Tests on Chemical Substances (codified version) (February 2004)...	1–22
6.41	Directive 2004/9/EC of the European Parliament and of the Council on the Inspection and Verification of Good Laboratory Practice (GLP) (Codified version) (March 2009).....	1–21
6.42	Qualitätssicherung und GLP – GLP-Konsensdokument Nummer 4 (überarbeitet, 1999).....	1–7
6.43	Einhaltung der GLP-Grundsätze durch Lieferanten – GLP-Konsensdokument Nummer 5 (überarbeitet, 1999).....	1–4
6.44	Anwendung der GLP-Grundsätze auf Freilandprüfungen – GLP-Konsensdokument Nummer 6 (überarbeitet, 1999).....	1–11
6.45	Anwendung der GLP-Grundsätze auf Kurzzeit-Prüfungen – GLP-Konsensdokument Nummer 7 (überarbeitet, 1999).....	1–11
6.46	Rolle und Verantwortlichkeiten des Prüfleiters bei GLP-Prüfungen – GLP-Konsensdokument Nummer 8 (überarbeitet, 1999).....	1–7
6.48	Anwendung der OECD GLP-Grundsätze auf Organisation und Management von Multi-Site-Prüfungen – Konsensdokument der Arbeitsgruppe GLP Nummer 13 (2002).....	1–11
6.49	Anwendung der OECD GLP-Grundsätze auf <i>in vitro</i> Prüfungen – Beratungsdokument der Arbeitsgruppe GLP Nummer 14 (2004).....	1–12
6.50	Einrichtung und Betrieb von Archiven in Übereinstimmung mit den Grundsätzen der Guten Laborpraxis – Beratungsdokument der Arbeitsgruppe GLP Nummer 15 (2007).....	1–16
6.51	GLP Requirements for Peer Review of Histopathology – Consensus Document 16 (December 2014).....	1–5
6.52	Application of GLP Principles to Computerised Systems – Consensus Document 17 (April 2016).....	1–29
6.53	Advisory Document of the Working Group on Good Laboratory Practice on the Management, Characterisation and Use of Test Items – Document 19 (April 2018).....	1–11

7	Richtlinien der Weltgesundheitsorganisation (WHO)
----------	--

7.0	Weltgesundheitsorganisation (WHO) – Einführung.....	1
7.1	WHO Guidelines: Production, Quality Control, Inspections, Related Regulatory Standards – Overview (August 2020).....	1–8

7.2	WHO Recommendations, Guidelines and other Documents Related to the Manufacture and Quality Control of Biological Substances Used in Medicine Overview (February 2017)	1–4
7.5	WHO – Good Manufacturing Practices for Pharmaceutical Products: Main Principles (2014)	1–48
7.30	Anforderungen an die Entnahme, Verarbeitung und Qualitätskontrolle von Blut, Blutbestandteilen und Plasmabestandteilen (Anforderungen an biologische Substanzen Nr. 27, überarbeitet 1992) (Dezember 1995)	1–68
7.52	Good Manufacturing Practices: Supplementary Guidelines for the Manufacture of Pharmaceutical Excipients (1999)	1–18

8 Richtlinien nationaler Fachgesellschaften

8.5	Empfehlungen zur Bewertung der Qualifikation von Prüfern und Geeignetheit von Prüfstellen durch Ethik-Kommissionen bei klinischen Prüfungen nach dem AMG (August 2009).....	1–7
8.17	Richtlinie zur Gewinnung von Spenderhornhäuten und zum Führen einer Augenhornhautbank (Erste Fortschreibung – August 2017).....	1–38
8.30	Ergänzende Empfehlungen zu den Richtlinien zur Blutgruppenbestimmung und Bluttransfusion der Bundesärztekammer über Eigenblutspende und Eigenbluttransfusion (1994).....	1–4
8.33	Richtlinie zur Herstellung und Anwendung von hämatopoetischen Stammzellzubereitungen (BÄK – 2014).....	1–52
8.35	Richtlinien für die Herstellung von Plasma für besondere Zwecke (Hyperimmunplasma) (BÄK/PEI – 2000).....	1–16
8.52	Richtlinie der GendiagnostikKommission (GEKO) für die Beurteilung genetischer Eigenschaften hinsichtlich ihrer Bedeutung für die Wirkung eines Arzneimittels bei einer Behandlung gemäß § 23 Abs. 2 Nr. 1b GenDG	1–7

9 Richtlinien internationaler Fachgesellschaften

9.1	WMA – Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects (World Medical Association) (2008).....	1–6
-----	--	-----

10 Richtlinien sonstiger Herkunft