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ANNEX TO THE EVALUATION GUIDE FOR GMP REGULATORY COMPLIANCE PROGRAMME– AUDIT CHECKLIST

IMPLEMENTATION OF EU LEGISLATION AND GUIDANCE RELATED TO GMP HUMAN AND VETERINARY – ALL RELEVANT ARTICLES TO BE CHECKED

EU requirement		
Article (Human)	**Subject**	**Article (Veterinary)**
1. Directive 2001/83/EC, as amended by Directive 2004/27/EC – Human Medicinal Products **2. Regulation (EU) 2019/6 – Veterinary Medicinal Products**		
40(1) (2)	Authorisation for manufacture	88
40(3)	Authorisation for import	88(1)(c)
41	Requirements for applicant in order to obtain manufacturing authorisation	89
42	Granting of authorisation	90
43-45	Time limits for the handling of the application	90 and 92
46	Obligations of holder of manufacturing authorisation	93
	(a) Services of the adequate staff	
	(b) Comply with national legislation of the Member State concerned	
	(c) Give prior notice of changes	
	(d) Allow inspections	
	(e) Enable qualified person to carry out its duties	
	(f) Comply with GMP rules	
47	Implementation through Directive and Guidelines / Implementation through implementing acts (to be adopted by January 2025), in meantime Directive 91/412/EC and existing guidelines apply	93(2)

	Guidelines including annexes as published under **EUDRALEX** Volume 4 - Medicinal Products for Human and Veterinary Use : Good Manufacturing Practice (http://pharmacos.eudra.org/F2/eudralex/vol-4/home.htm)	
	Principles of GMP for active substances used as starting materials	
48	Requirement of qualified person	97
49	Conditions of qualification of qualified person and professional background	97
51	Responsibilities of qualified person	97
56	Enforcement of qualified person's obligations	97
53	Application to homeopathic medicinal products	2(5)
111	Detailed Provisions for inspections at premises of manufacturers (please list in detail each aspect of implementation of this article)	123

EU requirement		
Article (Human)	**Subject**	**Article (Veterinary)**
113	MS to ensure that holder of a manufacturing authorisation furnishes proof of the control tests to be carried out in compliance with marketing authorisation (Administrative batch protocol review)	127
114	Official Control Batch Release Testing (May-Provision)	128

Article	**Subject**
2. Directive 2003/94/EC (Human) & Regulation 1252/2014 (Human-API) – and Directive 91/412/EEC (Veterinary) – GMP	
1	Scope of application of GMP rules
2	Repeated inspections by MS
3	Comparable standards to Compilation of Community Procedures (http://www.emea.eu.int/Inspections/GMPCompproc.html)
	• Quality Systems framework
	• Procedures related to Rapid Alerts
	• Procedures related to GMP Inspections
	• Forms used by Regulators (GMP inspection report format, manufacturers authorisation)
	• Procedures related to Centralised Procedures
4	Responsibility of manufacturer and importer
	Compliance of medicinal products and investigational medicinal products manufacturing (in EC or whether imported) with GMP
5	Obligations of the manufacturer:
	• Manufacturing operations in accordance with information in application
	• Adaptation to scientific and technical progress
6	Quality assurance system
7	Qualified personnel at the manufacturing site, job descriptions of qualified personnel, training

	Hygiene programme
8	Premises and equipment
9	Documentation
	• Manufacturing procedures
	• Traceability of batches
	• Protection of data processing systems
10	Production
	• Pre-established procedures, resources
	• Validation
11	Quality control
	• Quality control department
	• Quality control laboratories
	• Final control of finished products
12	Work contracted out
	• Written contract
	• Clearly defined responsibilities
	• No sub-contracting
	• Respect of GPM and allow inspections
13	Implementation of a system for recording and reviewing complaints
	Implementation of a system for product recall
14	Self-inspection

Article	Subject
3. Regulation (EU) No 536/2014 on clinical trials on medicinal products for human use	
61(1) to (4)	Authorisation for total and partial manufacturing of investigational medicinal products
61(2) and 62(1)	Qualified person for investigational medicinal products
63(1) and (3)	GMP for manufacturing and testing of investigational medicinal products

Article	Subject
4. Directive 2005/28/EC Good Clinical Practice	
9	General conditions for a manufacturing and import authorisation
10	Applicant´s requirements to obtain an authorisation
11-12	Obligations of competent authority

13	Obligations of holder of an authorisation
21	Requirements related to inspectors
22	Teams of Inspectors
23	Inspection Procedures (here: only in relation to GMP verification)

Article	Subject
5. Directive 2011/62/EC Falsified Medicines Directive modifying Directive 2001/83/EC (not PIC/S relevant)	
54a	Safety features on prescription medicines
77 (1)	Authorization of wholesalers and introduction in Union database
77 (4)	introduction of authorized wholesalers in Union database
77 (5)	Inspection of the premises of authorized wholesalers and checks on personal employed
85 c	Sale at distance to the public (requirements, conditions common logo, info websites, applicable penalties)