Last update: October 5th, 2018

Nonclinical Guidelines

NOTE: This document should only be used as a first orientation and was created with utmost caution and great care. However, we do neither claim completeness nor timeliness of data published (yearly update). For further information visit the EMA website: http://www.ema.europa.eu/ema/. This document contains links to external websites no liability for any content of any external site is taken. The content of external sites belongs to the sphere of responsibility of its respective publisher.

HINWEIS: Dieses Dokument soll der ersten Orientierung dienen und wurde von uns mit größtmöglicher Sorgfalt erstellt. Wir erheben jedoch keinen Anspruch auf Vollständigkeit und Aktualität (jährliches Update). Weiterführende Informationen finden Sie auf der EMA Website: http://www.ema.europa.eu/ema/. Dieses Dokument enthält Links zu externen Webseiten Dritter, auf deren Inhalte wir keinen Einfluss haben. Deshalb können wir für diese fremden Inhalte keine Gewähr übernehmen.

	Pharmaceuticals	Biological and Biotechnological Products
General Information	• Guideline on strategies to identify and mitigate risk for first-in-human clinical trials with investigational medicinal products EMEA/CHMP/SWP/28367/07 Rev.1 • Guideline on non-clinical safety studies for the conducts of human clinical trials and marketing authorisation for pharmaceuticals (ICH M3(R2)) EMA/CPMP/ICH/286/1995 • Questions and answers to ICH guideline M3(R3) EMA/CHMP/ICH/507008/2011	
		• Preclinical safety evaluation of biotechnology-derived pharmaceuticals (ICH S6 (R1)) EMA/CHMP/ICH/731268/1998
Drug Interaction	• Guideline on the investigation of drug interactions CPMP/EWP/560/95/Rev. 1 Corr**	

	Pharmaceuticals	Biological and Biotechnological Products
Toxicology	• Toxicokinetics: A guidance for assessment of systemic exposure in toxicity studies (ICH S3A) CPMP/ICH/384/95 • Guideline on the evaluation of control samples for non-clinical safety studies: Checking for contamination with the test substance CPMP/SWP/1094/04 • Pharmacokinetics: Repeated dose tissue distribution studies (ICH 3SB) CPMP/ICH/385/95 • Guideline on repeated dose toxicity CPMP/SWP/1042/99 Rev 1 Corr	
Genotoxicity and Carcinogenicity	• Guideline on genotoxicity testing and data interpretation for pharmaceuticals intended for human use (ICH S2 (R1)) CHMP/ICH/126642/08 • The need for carcinogenicity studies of pharmaceuticals (ICH S1A) CPMP/ICH/140/95 • Carcinogenicity: Testing for carcinogenicity of pharmaceuticals (ICH S1B) CPMP/ICH/299/95 • Dose selection for carcinogenicity studies of pharmaceuticals (ICH S1C) EMEA/CHMP/ICH/383/1995 • Assessment and control of DNA reactive (mutagenic) impurities in pharmaceuticals to limit potential carcinogenic risk (ICH M7) EMA/CHMP/ICH/83812/2013	• Preclinical safety evaluations of biotechnology-derived pharmaceuticals S6 (R1)
Pharmacology and Safety Pharmacology	• Safety pharmacology studies for human pharmaceuticals (ICH S7A) CPMP/ICH/539/00	
	• The nonclinical evaluation of the potential for delayed ventricular repolarization (QT interval prolongation) by human pharmaceuticals (ICH S7B) CPMP/ICH/423/02	

	Pharmaceuticals	Biological and Biotechnological Products
Other Toxicological Studies	• Guideline on non-clinical local tolerance testing of medicinal products EMA/CHMP/SWP/2145/2000 Rev. 1, Corr. 1* • Detection of toxicity to reproduction for medicinal products and toxicity to male fertility (ICH S5 (R2)) CPMP/ICH/386/95 • Guideline on the need for non-clinical testing in juvenile animals on human pharmaceuticals for pediatric indications EMEA/CHMP/SWP/169215/2005 • Guideline on risk assessment of medicinal products on human reproduction and lactation: from data to labelling EMEA/CHMP/203927/2005 • Guidance on photosafety evaluation of pharmaceuticals (ICH S10) EMA/CHMP/ICH/752211/2012	
	• Note for guidance on duration of chronic toxicity testing in animals (rodents and non-rodent toxicity testing) (ICH S4) CPMP/ICH/300/95 • Note for guidance on immunotoxicity studies for human pharmaceuticals (ICH S8) CHMP/167235/2004	
Environmental Risk Assessment	• Guideline on the environmental risk assessment of medicinal products for human use EMEA/CHMP/SWP/4447/00 corr 2*	
		• Guideline on environmental risk assessments for medicinal products consisting of, or containing, genetically modified organisms (GMOs) EMEA/CHMP/BWP/473191/2006 - Corr

Additional Guidelines

ATMPs

- Non-clinical studies required before first clinical use of gene therapy medicinal products EMEA/CHMP/GTWP/125459/2006
- Non-clinical testing for inadvertent germline transmission of gene transfer vectors EMEA/273974/2005
- Guideline on scientific requirements for the environmental risk assessment of gene-therapy medicinal products EMEA/CHMP/GTWP/125491/2006