Evaluation of nonclinical data for anticancer pharmaceuticals as a part of their regulation process

Varduhi M. Ghazoyan, PhD[*] **,** Mustafa M. Majhool, BS

Eurasia International University Department of Pharmacy, Yerevan, Armenia

[*] ghazoyanvarduhi@gmail.com

Discussion of the structures of CTD Modules 4 and 2.4 is provided, available information is extracted. Main differences between ICH guidelines S6, S9 and M3(R2) were extracted and provided. Mandatory studies and studies conducted on a case-by-case basis, requirements to the GLP certificate, main rules regarding nonclinical studies, as well as differences between nonclinical studies of well-known and new drug products were extracted. applicable statements and layout for Module 4 according to the rules were provided.

Key-words: Regulation, nonclinical studies, Common Technical Document, Module 4, ICH guidelines S6, S9 and M3(R2), GLP certificate, case-by-case studies.