

Lecturas recomendadas

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Tema 1

Repetto Manuel y Repetto Guillermo. Desarrollo y evolución histórica de la toxicología. Toxicología Fundamental. 4ª ed. Madrid : Díaz de Santos, D.L. 2009.

Tema 2

- ✓ Food and Drug Administration. Guidance for Industry. Estimating the Maximum Safe Starting Dose in Initial Clinical Trials for Therapeutics in Adult Healthy Volunteers [en línea] 2005. [Consulta: 23-9-2021]. Disponible en:
- ✓ European Medicines Agency. Guideline on strategies to identify and mitigate risks for first-in-human and early clinical trials with investigational medicinal products [en línea] 2017. [Consulta: 23-9-2021]. Disponible en:

<https://www.fda.gov/media/72309/download..>

https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-strategies-identify-mitigate-risks-first-humanearly-clinical-trials-investigational_en.pdf

Tema 3

- ✓ European Medicines Agency. Note for guidance on toxicokinetics: the assessment of systemic exposure in toxicity studies (ICH S3A)[en línea] 2017. [Consulta: 23-9-2021]. Disponible en:

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- ✓ Food and Drug Administration. Guidance for industry. M3(R2) Nonclinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals [en línea] 2010. [Consulta: 23-9-2021]. Disponible en:

<https://www.fda.gov/media/71542/download>

Organisation for Economic Co-operation and Development (OECD) Guidelines: 471, 474, 475, 476 y 489.

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- ✓ OECD 476: In Vitro Mammalian Cell Gene Muta-on Tests using the Hprt and xprr genes [en línea] 2016. [Consultado:23-9-2021]. Disponible en: [hWps://www.oecdilibrary.org/docserver/9789264264809-en.pdf?expires=1632398727&id=id&accname=guest&checksum=A1B45361407349A55EEBB43EA44D3BC8](https://www.oecdilibrary.org/docserver/9789264264809-en.pdf?expires=1632398727&id=id&accname=guest&checksum=A1B45361407349A55EEBB43EA44D3BC8))
- ✓ OECD 474.: Mammalian Erythrocyte Micronucleus Test [en línea] 2016. [Consultado:23-9-2021]. Disponible en: <https://www.oecdilibrary.org/docserver/9789264264762-en.pdf?expires=1632398943&id=id&accname=guest&checksum=9557311F967E31444D10788FB38B2A9D>
- ✓ OECD 489.: In Vivo Mammalian Alkaline Comet Assay [en línea] 2016. [Consultado:23-9-2021]. Disponible en: <https://www.oecdilibrary.org/docserver/9789264264885-en.pdf?expires=1632399102&id=id&accname=guest&checksum=345A2C2694143A7AB4E15F7C9BE1172B>

Tema 7

- ✓ IARC: Agents Classified by the IARC Monographs, Volumes 1–129 [en línea]. [Consultado: 23-9-2021]. Disponible en: <https://monographs.iarc.who.int/agents-classified-by-the-iarc/>
- ✓ OECD 451.: Carcinogenicity Studies [en línea] 2018. [Consultado:23-9-2021]. Disponible en: <https://www.oecd-ilibrary.org/docserver/9789264071186->

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Tema 8

- ✓ ICH. DETECTION OF TOXICITY TO REPRODUCTION FOR MEDICINAL PRODUCTS & TOXICITY TO MALE FERTILITY S5(R2) [en línea] 2005. [Consulta:23-9-21]. Disponible en: <http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.738.3248&rep=rep1&type=pdf>.
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- ✓ Agencia Española de Medicamentos y Productos Sanitarios(AEMPS). ÁCIDO VALPROICO: NUEVAS MEDIDAS PARA EVITAR LA EXPOSICIÓN DURANTE EL EMBARAZO.[en línea] 2018. [Consulta el 23-9-21]. Disponible en https://www.aemps.gob.es/informa/notasinformativas/medicamentosusohumano-3/seguridad-1/2018/ni-muh_fv_3-acido-valproico/