DRUG / DEVIVE DEVELOPMENT COURSE

Reference Course Material

DRUGS - GENERAL

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3. https://www.fda.gov/forpatients/approvals/drugs/ucm405622.htm
4. https://ec.europa.eu/health/documents/eudralex_en
5. https://www.ich.org/home.html
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7. https://www.fda.gov/training-and-continuing-education/fda-learning-portal-students-academia-and-industry
8. https://www.ivowen.com/regulatory-affairs-common-abbreviations-acronyms/ ABBREVIATIONS).
9. https://ascpt.onlinelibrary.wiley.com/doi/epdf/10.1111/cts.12567 GOOD on mAb
10. https://www.nuventra.com/resources/blog/path-to-ind-study-design-and-dosing/
11. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6342261/ (FIH GOOD)
12. CDER Small Business & Industry Assistance (SBIA) | FDA
13. European Medicines Agency - YouTube

STARTING DOSE IN HUMANS:

14. https://www.ema.europa.eu/en/documents/presentation/calculation-minimum-anticipated-biological-effect-level-mabel-1st-dose-human-jennifer-sims_en.pdf
15. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4804402/ Dose calculation.
16. http://www.lasa.co.uk/PDF/LASA-NC3RsDoseLevelSelection.pdf
17. Strategies for selecting the first dose for human clinical tri.indd (certara.com)

EARLY STAGE START-UPS :

18. FDA: Orientation for Early Stage Startups (ycombinator.com) GOOD QUICK OVERVIEW FOR START-UPS

CMC:

19. The Challenge of CMC Regulatory Compliance for Biopharmaceuticals - John Geigert - Google Books (GOOD CMC COVERAGE)

mAb:

20. https://ascpt.onlinelibrary.wiley.com/doi/epdf/10.1111/cts.12567 (on mAb)

PRECLINICAL:

21. From Bench to Clinic - The Chronology of Preclinical Studies - ITR Laboratories Canada Inc.

22. https://www.nuventra.com/resources/blog/path-to-ind-study-design-and-dosing/
23. https://hrcak.srce.hr/file/166090 Dose calculation.
24. https://journal.emwa.org/preclinical-studies/an-introduction-to-little-known-aspects-of-nonclinical-regulatory-writing/ Click to download

MANAGING CULTURAL DIVERSITY :

25. https://www.youtube.com/c/MultiCulturalBusinessSolutions (Week 6 Lionel Laroche).

CLINICAL TRIAL REGULATIONS IN EU:

26. https://youtu.be/GXEVYUdbkcs (CTR and CTIS by Irish HPRA).....Good.

IVDR:

27. https://youtu.be/1x1pVBe_oK8 (IVDR HPRA).

CTIS :

28. https://youtu.be/rrld9_JLIIs (CTIS)
29. https://youtu.be/xxpc-HPKN28 (Statistics)....
30. https://youtu.be/MD0cl_SIQrg (Regulatory Science EMA)
31. https://youtu.be/GXEVYUdbkcs (CTR HPRA Ireland Webinar)
32. https://youtu.be/6_G_o1KPYyk (Birth of the Pharmaceutical industry
33. https://youtu.be/Oq0zUVyF1Tc (EMA FDA Parallel Scientific Advice).
34. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6342261/ (Good article starting dose)
35. https://toolbox.eupati.eu/resources/setting-the-first-in-human-dose/
36. How to Determine First-in-Human Dose for Clinical Studies (nuventra.com)
37. Strategies and Recommendations for Using a Data-Driven and Risk-Based Approach in the Selection of First-in-Human Starting Dose: An International Consortium for Innovation and Quality in Pharmaceutical Development (IQ) Assessment - Leach - 2021 - Clinical Pharmacology & Therapeutics - Wiley Online Library
38. **https://ispe.org/pharmaceutical-engineering/march-april-2017/eu-clinical-trials-regulation-application-process**
39. https://www.advarra.com/blog/understanding-the-eu-clinical-trials-regulations-updates/ (New and good)

MEDICAL DEVICE - GENERAL

40. http://www.imdrf.org/ DEVICES
41. https://toolbox.eupati.eu/resources/types-of-study-in-early-clinical-development/ (Preclinical GOOD)
42. https://youtu.be/zqLkBeGp8g8 (FDA Dose finding good overview.)
43. https://youtu.be/6TyRktLsL5o (FIH FDA GOOD OVERVIEW)

INTELLECTUAL PROPERTY RIGHTS

44. Intellectual Property (efpia.eu)
45. IP - IFPMA