

# TOPRA: Key Regulatory Competences



## *Human Medicines: Regulatory Competences*

1. Knowledge about the discovery and development of pharmaceutical products
2. Knowledge about emerging technologies for dosage form design, delivery systems
3. Knowledge and application of current procedures for obtaining approval to carry out clinical trials in the European Union (CTAs, IMPDs and other supporting documentation)
4. Knowledge and application of current procedures for obtaining approval in other countries as appropriate to carry out clinical trials
5. Knowledge and application of principles of Good Clinical Practice (GCP)
6. Knowledge and application of principles of Good Manufacturing Practice (GMP), the Qualified Person their legal duties and role
7. Knowledge and application of registration procedures in Europe (Centralised, Mutual Recognition, Decentralised) for MA approvals, variations, extensions and renewals
8. Knowledge and application of the registration procedures in other markets as appropriate for approvals, changes and updates
9. Knowledge and application of the technical, chemical, pharmaceutical and biological requirements for registration of chemical entities
10. Knowledge and application of the technical requirements for registration of biological and biotechnological products
11. Knowledge and application of the nonclinical requirements for registration of chemical, biological and biotechnological products
12. Knowledge and application of the clinical requirements for registration of chemical, biological and biotechnological products
13. Knowledge and application of the content and format of registration files (Common Technical Document and eCTD)
14. Knowledge and application of Pharmacovigilance and the qualified person
15. Knowledge and application of requirements for information for promotion, labelling (SPC, PIL, user acceptance testing, Braille labelling)
16. Knowledge and application of requirements for risk management (clinical, quality)
17. Knowledge and application of regulatory compliance with the approved registration file/change control
18. Knowledge and application of environmental risk assessment for human medicinal products
19. Knowledge and application of reimbursement and economic assessment (for prescribability)
20. Knowledge and application of advertising and promotional material clearance



### ***Human Medicines: OTC Products***

21. Knowledge and application of legislation for changing legal supply classification (e.g. prescription to pharmacy sale)
22. Knowledge and application of advertising and promotional material clearance

### ***Medical Devices***

23. Knowledge and application of the Medical Devices legislation (EU Directives) and guidelines (MEDDEVs), awareness of Global Harmonisation Task Force (GHTF) documents
24. Knowledge and application of emerging technologies for medical devices
25. Knowledge and application of Device Vigilance

### ***Cosmetics and Borderline Products***

26. Knowledge and application of the Cosmetics Directive (76/68/EC) and associated legislation
27. Knowledge and application of the borderline between Cosmetics, Medicines and Medical Devices

### ***Chemicals***

28. Knowledge and application of the new proposed EU regulatory framework for Registration, Evaluation and Authorisation of Chemicals (REACH), and the transition Research Implementation Projects (RIPs)

### ***Food Additives***

29. Knowledge and application of legislation and submissions for authorisation of additives permitted in foodstuffs

### ***Pesticides and Biocides***

30. Knowledge and application of requirements under 91/414/EEC (or as amended) The Plant Protection Products Directive and 98/8/EC (The Biocidal Products Directive) and how to apply them.

### ***Veterinary Medicines***

31. Knowledge and application of principles of Good Laboratory Practice (GLP) and its application in clinical studies used in veterinary medicinal product applications
32. Knowledge and application of the requirements for veterinary feed additives for farm animals
33. Knowledge and application of the clinical requirements for veterinary medicinal products for large animals
34. Knowledge and application of the clinical requirements for veterinary medicinal products for companion animals



35. Knowledge and application of principles of Good Manufacturing Practice (GMP), the Qualified Person their legal duties and role
36. Knowledge and application of user safety requirements for veterinary products
37. Knowledge and application of environmental risk assessment of veterinary medicinal products
38. Knowledge and application of advertising and promotional material clearance

***Competences specific for Regulatory Affairs Professionals working in National Competent Authorities (Agencies) and the EMEA***

39. Knowledge and application of regulatory legislation and the legal implications of regulatory decisions
40. Knowledge and application of the management of regulatory procedures
41. Knowledge and application of preparation of Assessment Reports (quality, non-clinical, and clinical)
42. Knowledge and application of the review of Product Information translations
43. Knowledge and application of the principles of Quality Management Systems
44. Knowledge and application of regulatory guidance and regulatory precedents
45. Knowledge and application of QRD rules on leaflets and readability

***IT Competences will include knowledge and application of:***

46. Word processing,
47. Spreadsheets,
48. Presentations,
49. Project management,
50. Document Management Systems,
51. Publishing/eCTD etc

***Competences may include knowledge and application of some of the following 'Soft Skills':***

52. Negotiation and influencing skills
53. Presentation skills for regulators
54. Team working in a global environment

55. Project management and strategic thinking
56. Time management
57. Leadership skills
58. Performance management
59. Marketing for regulators
60. Crisis management

