

# TOPRA: Key Regulatory Competences



## Human Medicines: Regulatory Competences

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

### Human Medicines: OTC Products

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

### Medical Devices

26. Knowledge and application of the Medical Devices legislation (EU Directives) and guidelines (MEDDEVs), awareness of Global Harmonisation Task Force (GHTF) documents
27. Knowledge and application of emerging technologies for medical devices
28. Knowledge and application of Device Vigilance Cosmetics and Borderline Products
29. Knowledge and application of the Cosmetics Directive (76/68/EC) and associated legislation
30. Knowledge and application of the borderline between Cosmetics, Medicines and Medical Devices

### Chemicals

31. 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

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

### Pesticides and Biocides

33. 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

34. Knowledge and application of principles of Good Laboratory Practice (GLP) and its application in clinical studies used in veterinary medicinal product applications
35. Knowledge and application of the requirements for veterinary feed additives for farm animals
36. Knowledge and application of the clinical requirements for veterinary medicinal products for large animals
37. Knowledge and application of the clinical requirements for veterinary medicinal products for companion animals
38. Knowledge and application of principles of Good Manufacturing Practice (GMP), the Qualified Person their legal duties and role
39. Knowledge and application of user safety requirements for veterinary products
40. Knowledge and application of environmental risk assessment of veterinary medicinal products
41. Knowledge and application of advertising and promotional material clearance

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

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

IT Competences will include knowledge and application of:

49. Word processing
50. Spreadsheets
51. Presentations
52. Project management
53. Document Management Systems,
54. Publishing/eCTD etc

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

55. Negotiation and influencing skills
56. Presentation skills for regulators
57. Team working in a global environment
58. Project management and strategic thinking
59. Time management
60. Leadership skills
61. Performance management
62. Marketing for regulators
63. Crisis management