Aseptic processing during the manufacturer of pharmaceuticals, medical devices, and combination products is coming under increasing scrutiny over the last few years. From 2004 to 2010, three quarters of drug product recalls involved sterile drug products, and of these sterile product recalls, approximately 80% were due to lack of sterility assurance. The manufacturing of sterile drug products has consistently remained challenging, and industry is always seeking ways to improve and remain compliant with global regulations.

In March, 2014, IVT hosted the "Advances in Aseptic Processing conference," where participants were updated on regulatory expectations and had the opportunity to benchmark with peers. Taken from these presentations, below is a list of international regulations and guidance for aseptic processing. Knowledge of these requirements and resources will guarantee compliance with international regulatory agencies and lean, efficient aseptic processing.

**US Food and Drug Administration**

2. [Code of Federal Regulations Title 21 Part 211](http://www.ivtnetwork.com) (Specifically, 211.113, 211.42, 211.67, 211.63, 211.167, 211.165, 211.192, 211.194, 211.22, 211.25, 211.28, 211.65, 211.103, 211.84, 211.46, 211.166, 211.13), read it here.
4. [Code of Federal Regulations Title 21 Part 606](http://www.ivtnetwork.com), read it here.
5. [Code of Federal Regulations Title 21 Part 177](http://www.ivtnetwork.com), read it here.
8. [Process Validation: General Principles and Practice](http://www.ivtnetwork.com), read it here.
9. [Technical Considerations for Pen, Jet, and Related Injectors Intended for Use with Drugs and Biological Products](http://www.ivtnetwork.com), read it here.
11. [Submissions for Postapproval Modifications to a Combination Product Approved Under a BLA, NDA, or PMA](http://www.ivtnetwork.com), read it here.
12. [Classification of Products as Drugs and Devices and Additional Product Classification Issues](http://www.ivtnetwork.com), read it here.
13. [Interpretation of the Term "Chemical Action” in the Definition of Device Under Section 201(h) of the Federal Food, Drug, and Cosmetic Act](http://www.ivtnetwork.com)
14. How to Write a Request for Designation (RFD), read it here.


16. New Contrast Imaging Indication Considerations for Devices and Approved Drug and Biological Products, read it here.

17. Devices Used to Process Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps), read it here.

18. Minimal Manipulation of Structural Tissue (Jurisdictional Update), read it here.

19. Early Development Considerations for Innovative Combination Products, read it here.

20. Application User Fees for Combination Products, read it here.


22. Submission and Resolution of Formal Disputes Regarding the Timeliness of Premarket Review of a Combination Product, read it here.

23. Guidance for Industry: Manufacturing, Processing, or Holding APIs, read it here.

24. ORA: ORA-Lab.5.3; Facilities and Environmental Conditions, read it here.

International Conference for Harmonisation

25. ICH Q10, Pharmaceutical Quality System, read it here.

26. ICH Q8, Pharmaceutical Development, read it here.

27. ICH Q9, Quality Risk Management, read it here.

Medicines and Healthcare Products Regulatory Agency


European Union

27. EudraLex - Volume 4 Good manufacturing practice, Annex 1 (specifically, Annex 1.4, 1.42, 1.55, 1.61, 1.56), read it here.


United States Pharmacopeia

29. USP <1116> Microbiological control and monitoring of aseptic processing environments.

30. USP 36-NF 31, read it here.

31. USP <71>, Sterility Tests.

32. USP <B7>, Biological Reactivity Test, In Vitro.

33. USP <B8>, Biological Reactivity Test, In Vivo.

International Organization for Standardization

34. ISO 14644, Cleanrooms and associated controlled environments, read it here.


39. ISO 11040, Prefilled syringes, read it here.


41. ISO 11137, Sterilization of health care products -- Radiation, read it here.

42. ISO 11135, Sterilization of health care products -- Ethylene oxide, read it here.

43. ISO 17665, Sterilization of health care products -- Moist heat, read it here.

44. ISO 20857, Sterilization of health care products -- Dry heat -- Requirements for the development, validation and routine control of a sterilization process for medical devices, read it here.
Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme

46. Recommendation on the Validation of Aseptic Processes, read it here.
47. Isolators Used for Aseptic Processing and Sterility Testing, read it here.

World Health Organization


Parenteral Drug Association


Media/Other

65. Collected pieces from Rizwan Sharnez, read them here.

Also See:

|JVT: Understanding, Preventing, and Remediating Mold in Cleanrooms|