PDA Training Container Closure Systems: literature, references

- European Pharmacopoeia
- Japanese Pharmacopoeia
- United States Pharmacopeia
- Guideline on Plastic Immediate Packaging Materials (CPMP/QWP/4359/03)
- Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use
- Medical Device Directive MDD 93/42/EEC
- Active Implantable Medical Device Directive AIMDD 90/385/EEC
- 21 CFR Part 4 (Docket No. FDA–2009–N–0435) - Current Good Manufacturing Practice Requirements for Combination Products - Final rule, January 22nd, 2013
- 21 CFR 314.420 – Drug Master Files
- FDA Guidance for Industry and FDA Staff: Current Good Manufacturing Practice Requirements for Combination Products (January 2017)
- Guidance for Industry: Container Closure Systems for Packaging Human Drugs and Biologics, 1999
- DIN ISO 2859 Annahmestichprobenprüfung anhand der Anzahl fehlerhafter Einheiten oder Fehler (Attributprüfung)
- Boven K., Knight J., Bader F., Rossert J., Eckhardt K.-U., Casadevall N. Epoetinassociated pure red cell aplasia in patients with chronic kidney disease: solving the mystery, Nephrol. Dial. Transplant, 2005, 20, 33-40
- Duncan, D.: Container Closure Integrity of Sterile Vials During Deep Cold Storage – Presentation on PDA Europe Parenteral Packaging Conference, Prague 2013
- Pfeifer, J:: DPhG Fachgruppentagung Analytics 2003
- Post, E., Container Closure Integrity Test (CCIT), PDA Europe Conference, 07/2013
- Schott - Product brochure type I plus
- EDITIO CANTOR VERLAG, Defect Evaluation List for Containers Made of Moulded Glass, 5th completely revised and enlarged edition 2018