- ***Part I:*** Medicinal Products for Human and Veterinary Use
- ***Part II:*** Basic Requirements for Active Substances used as Starting Materials
- ***Part III:*** Explanatory Notes on the preparation of a Site Master File | Quality Risk Management (ICH Q9) | Pharmaceutical Quality System (ICH Q10) | Internationally harmonised requirements for batch certification | Template for the „written confirmation" for active substances exported to the EU... | Guideline on setting health based exposure limits for use in Risk identification | Guidelines of 19 March 2015 on the formalised risk assessment for ascertaining the appropriate good manufacturing practice for excipients of medicinal products for human use
- ***Part IV:*** Guidelines on Good Manufacturing Practice specific to Advanced Therapy Medicinal Products of 22 Nov 2017
- Annexes 1 to 21