Overview of Part VIII

**Patentability**
- Invention disclosure
- Patentability requirements met?
- Patent grant

**Manufacturing**
- Influenza vaccines
- From eggs to cell cultures
- Monovalent vaccine production

**FDA**
- Demonstration of safety and effectiveness
- Licensing
- General biological product standards

**EMA**
- Centralised and decentralised procedure
- Marketing authorisation application
- Pharmacovigilance

**US veterinary vaccines**
- Application for US license
- Specific requirements
- Field safety studies

**EU veterinary vaccines**
- National application
- Centralised procedure – application to the EMA
- Committee for Veterinary Medicinal Products
The way from a feasibility study to a product launch is time- and cost-intensive. A successful new vaccine is the culmination of many carefully planned different steps in laboratory under GLP, patent and marketing department, and, last but not least, finally the application for marketing authorization. The proof of concept demonstrates that the candidate vaccines work in principle. Successful clinical studies according to international GCP guidelines are the basis for a license. The GMP controlled manufacturing process, including periodic facility inspections, is part of the licensure. Vaccine safety is controlled post marketing by pharmacovigilance.

**Patentability.** Both the USA and China dominate first (earliest priority) and second (a subsequent family member) patent filings claiming active ingredients of vaccines against infectious diseases, with Europe and Australia rising to dominance for second patent filings in the vaccine field. Claims reciting a medical indication using a known or new vaccine composition must be inventive and sufficiently disclosed. The EPC limits the ability of an applicant to claim aspects of a vaccine identified as a method of treatment, surgery, or diagnosis in view of various public policies underlying the patentability exclusion under Article 53(c) EPC 2000.

**Manufacturing.** The development and the production of influenza vaccines are based on a complex manufacturing process starting with the selection and development of optimal candidate vaccine viruses, and it requires various dynamic interactions with regulatory authorities and health-care officials. Most influenza vaccine production is based on classical egg-based technology, a technology that has been used to produce seasonal vaccine for more than 30 years. Novel cell-culture technologies can offer various advantages over egg-based manufacturing methods and most likely will supplement the current egg-based technology.

**FDA regulations for human vaccines.** Vaccine licensure is based on a demonstration of safety and effectiveness, as well as the ability of the license holder to manufacture the product in a consistent manner within the defined and agreed upon specifications. After licensure, monitoring of the vaccine and production activities, including periodic facility inspections, must continue as long as the manufacturer holds a license for the product.

**EMA regulations for human vaccines.** Although the European pharmaceutical legislation does not provide a formal definition, vaccines are typically considered medicinal products containing one or more immunogenic antigens intended for prophylaxis against infectious disease. Medicinal products containing one or more immunogenic antigens for the treatment of disease, e.g., chronic HIV infection, chronic hepatitis B or C infection, cancer, or Alzheimer’s disease, are typically referred to as therapeutic vaccines or active immunotherapy.

**Vet vaccines in the USA.** The Center for Veterinary Biologics (CVB), United States Department of Agriculture (USDA), located in Ames, Iowa, has regulatory jurisdiction over veterinary biologics in the USA for the diagnosis, prevention, and treatment of animal diseases. All veterinary vaccines sold within the USA must have either a US Veterinary Biological Product License, produced within a licensed establishment, or a US Veterinary Biological Permit.
Veterinary vaccines must be authorized by the relevant competent authorities in the EU. An application for a Marketing Authorization (MA) must be submitted, and this should include a dossier that demonstrates the quality of the vaccine and the safety and efficacy in the target species. It should be noted that safety must also be demonstrated for the user, the environment, and the consumer.