



Regulatory Considerations for Licensure

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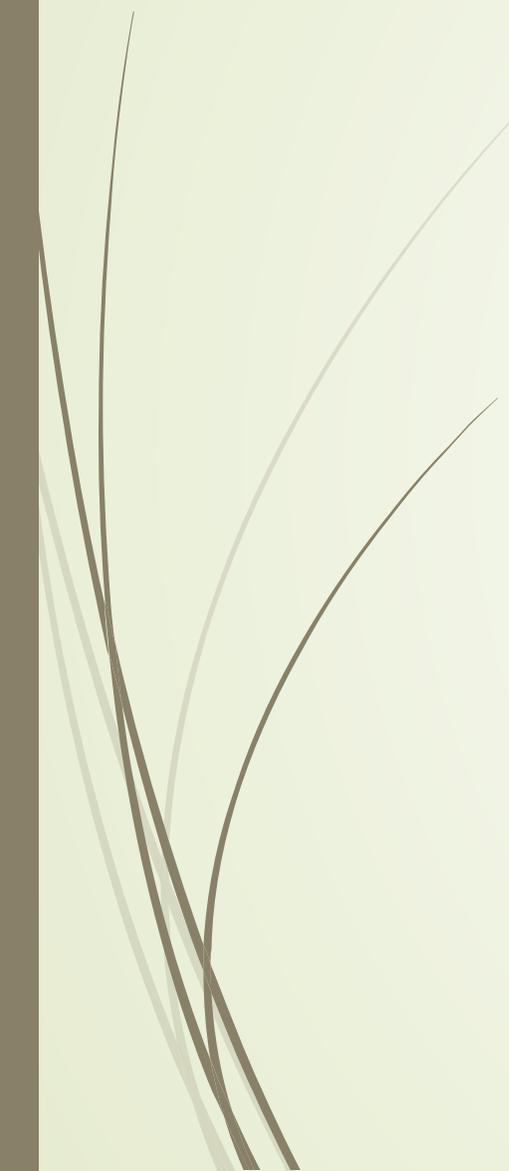


EU regulatory framework for vaccines

- ▶ Marketing authorization-granted after an evaluation of the risk-benefit ratio of the vaccine based on a dossier which presents the data collected during the product development and clinical trials
- ▶ Compliance with good practices in the areas of manufacturing and clinical or laboratory testing is verified by regulatory agencies prior to approval of a marketing authorization
- ▶ During vaccine development, the manufacturer must evaluate the needs of the pediatric population, and if appropriate, propose a pediatric DCP to the European Medicines Agency (EMA)—and then comply with the plan



Regulatory Guidelines



- ▶ Always begin discussions early about your development plan to regulatory by submitting short outlines
- ▶ Request face-to-face meetings early on
- ▶ Try to get written confirmation from your group and the regulators as to what was agreed upon at the meeting
- ▶ Regulators seem to have final say in claims contained in SPC. Usually conservative.
- ▶ Always notify any SAEs ASAP with adequate follow-up and open communications with medical monitor and medical personnel at the regulatory agency.



Registration or licensing

- Centralized Procedure
- Mutual recognition Procedure (MRP)
- National Procedures (for products licensed in one single country)
- Quality assessment-each batch of vaccines must still be assessed for quality before release for use. This is done by both the manufacturer and an official European control laboratory
- Pharmacovigilance-all vaccines and pharmaceuticals are monitored after release onto the market for adverse events. A summary of events is supplied to the registration board to assess if changes need to be made to the SPC
- Additional" stability studies, further confirmatory safety or efficacy trials in populations that have not been studied yet.



Position Papers

- ▶ Publications
 - ▶ Company Web site
 - ▶ Presentations at meetings
 - ▶ Journal and/or TV and radio ads
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