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The "Consistency Approach": Concept and Progress Since the 2015 Congress European Commission Joint Research Centre; Ispra (VA), Italy

The consistency approach aims to ensure the uninterrupted release of safe and efficacious products. Vaccine batches / lots are regarded as one of a series. DeMattia et al (2011) defined the consistency approach as follows: "The consistency approach is a concept which includes the strict application of GMP rules and guidelines, process validation and in process and final product tests and is aimed at verifying if a manufacturing process produces final batches which are consistent with one that fulfils all the criteria of Quality, Safety and Efficacy as defined in the marketing authorization, ultimately resulting in replacement of routinely used in vivo tests."

The presentation will give an overview on the consistency approach, current discussions and recent developments towards its implementation for established vaccines (e.g. IMI2 VAC2VAC project).

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*Hendriksen C, Arciniega JL, Bruckner L et al. The consistency approach for the quality control of vaccines. *Biologicals* 2008; 36(1): 73-77.*

*De Mattia F, Chapsal JM, Descamps J et al. The consistency approach for quality control of vaccines - a strategy to improve quality control and implement 3Rs. *Biologicals* 2011; 39(1):59-65.*

*De Mattia F, Hendriksen C, Buchheit K-H et al. The Vaccines Consistency Approach Project: an EPAA initiative: *Pharmeuropa Bio&SN* | May 2015 30-58.*

