

Sneak Peek

*Drug-Device Combination
Products: Notified Body
Opinion Process*

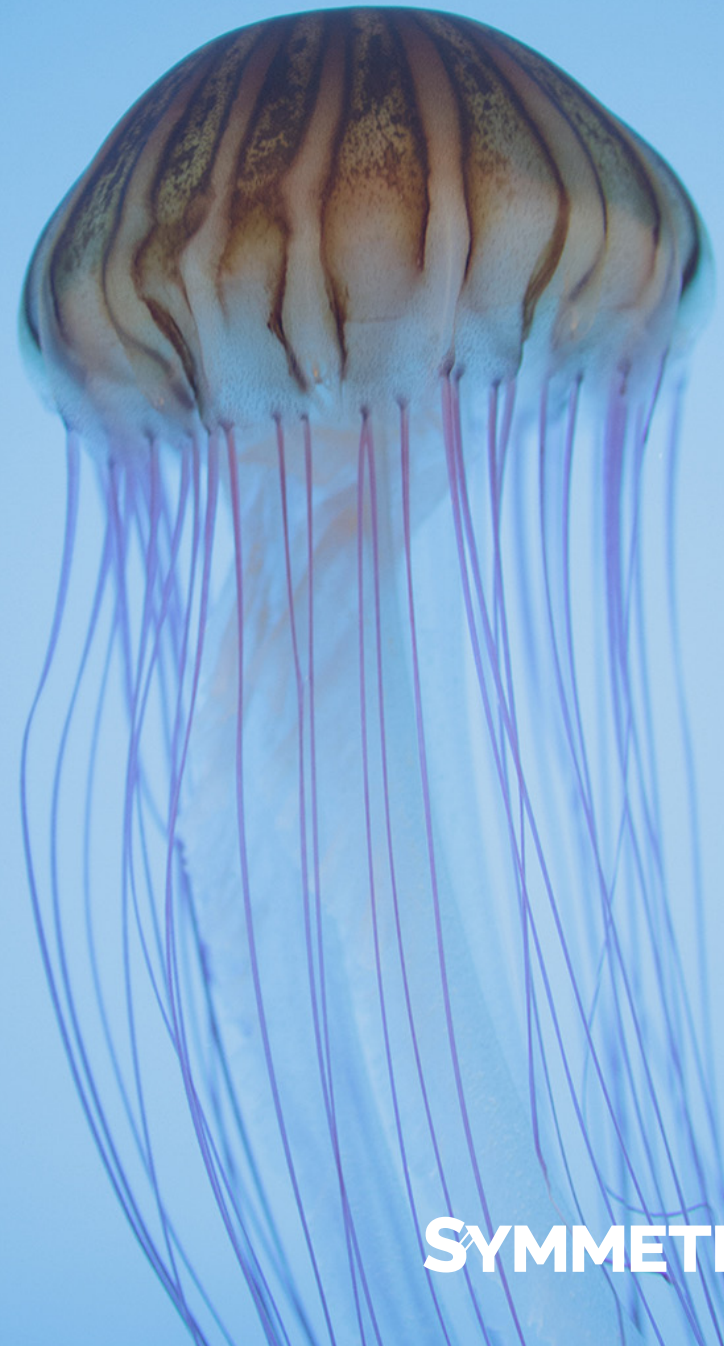


James Pink

Health Sciences and Medical
Devices Consultant



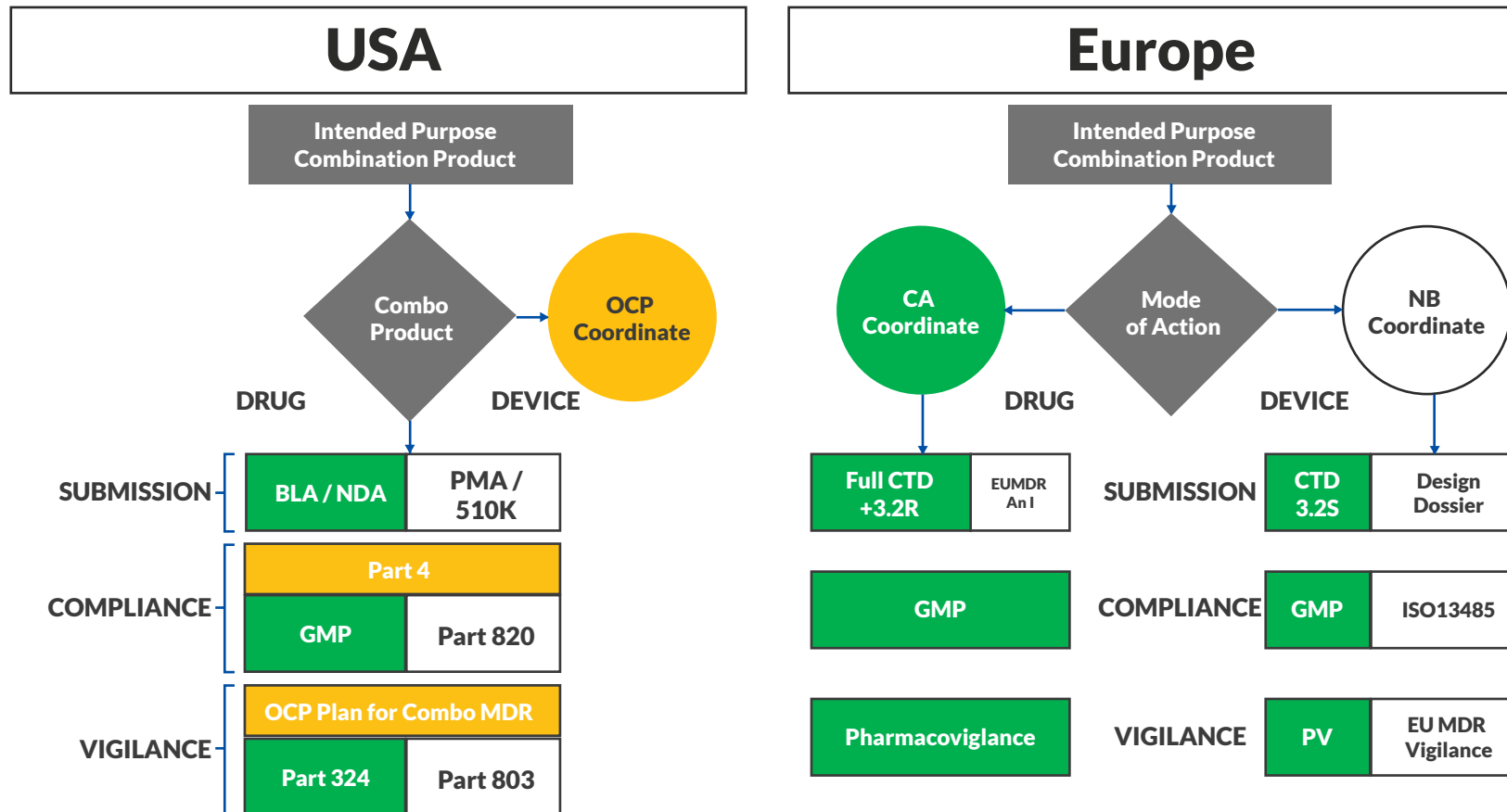
ONLINE
TRAINING



SYMMETRIC

Combination Products and How they are regulated – Graphical Summary

01

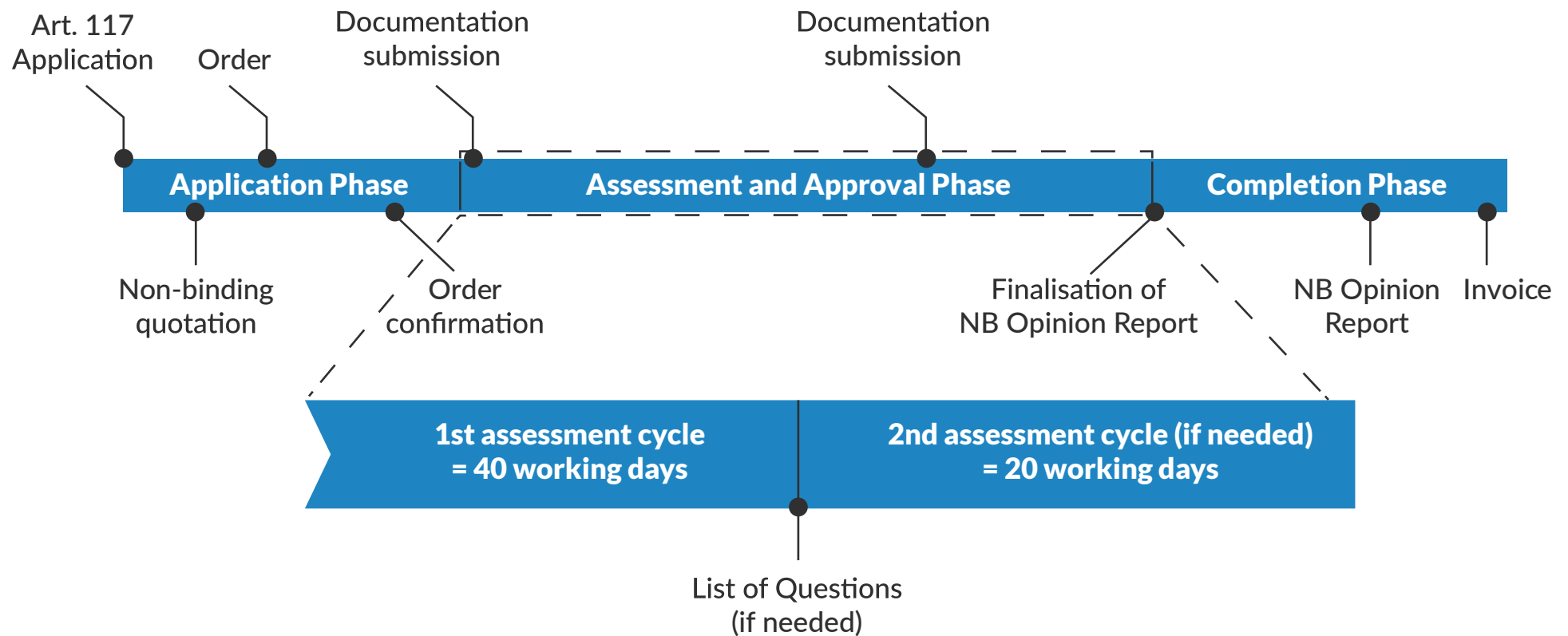


CA = Competent Authority, OCP = Office of Combination Products, NB = Notified Body

Notified body opinion process

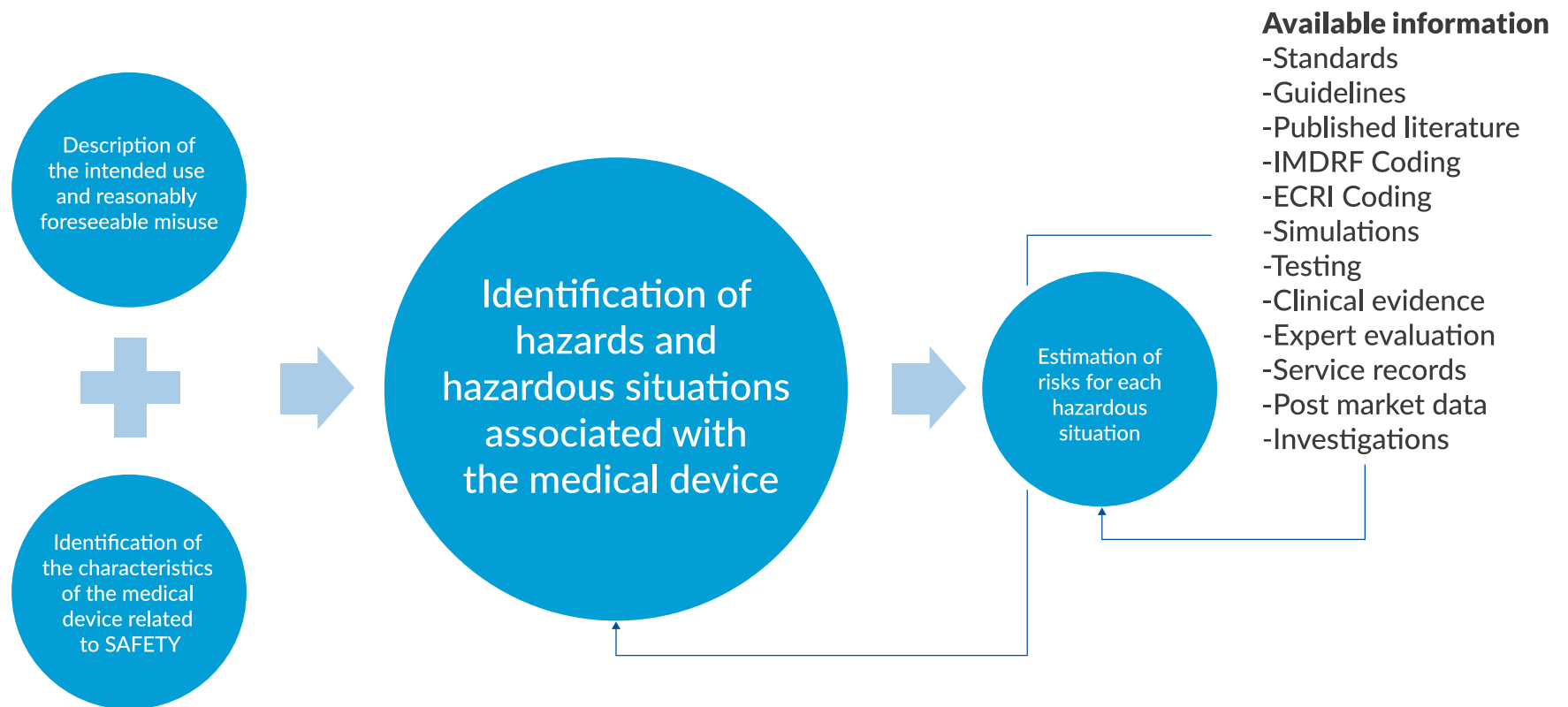


TÜV SÜD Article 117 Examination Process

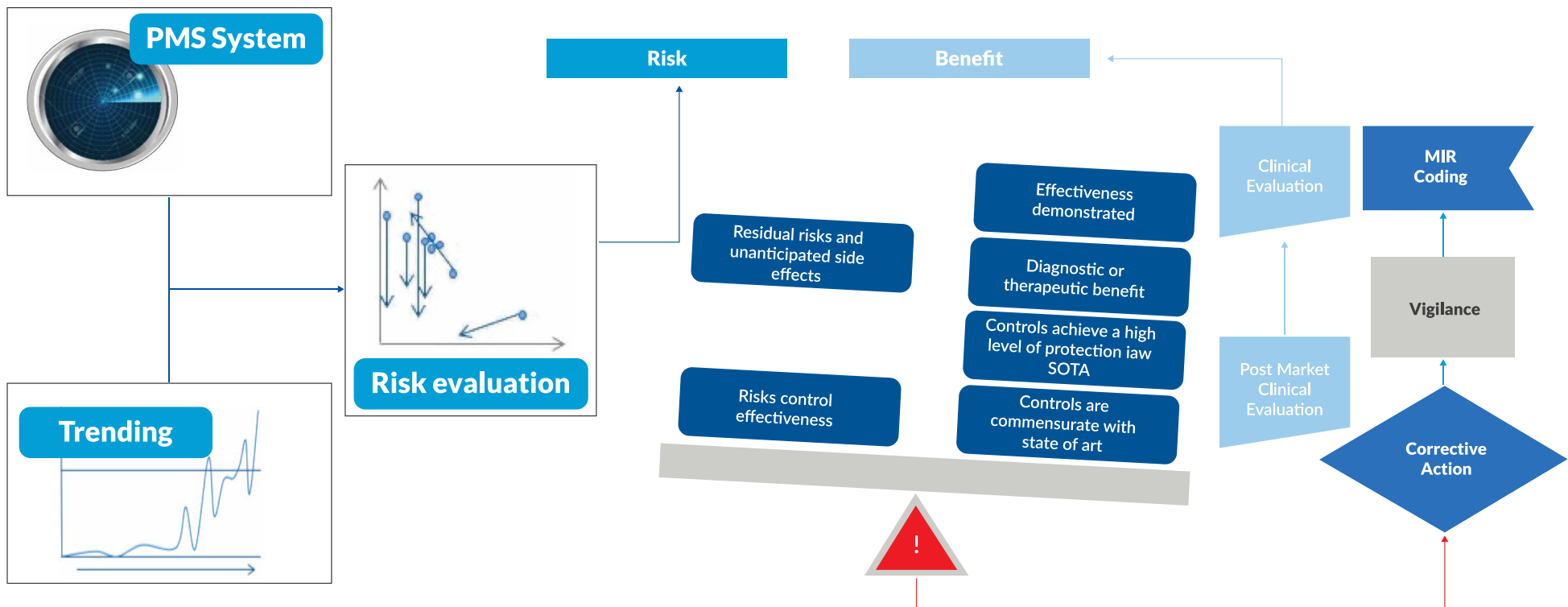


Risk analysis (clause 5 of EN ISO 14971)

Systematic use of available information to identify hazards and to estimate risk



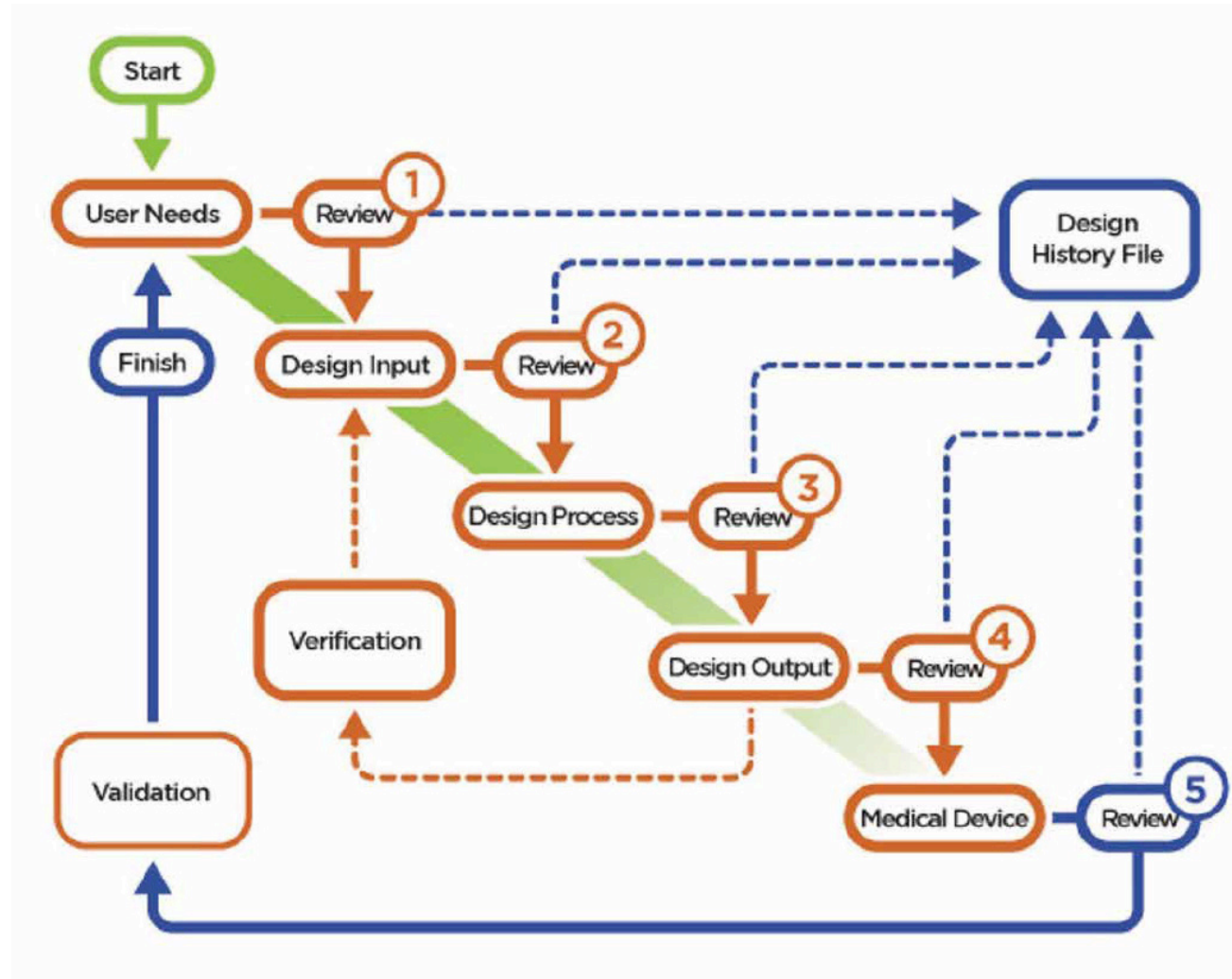
EU MDR Post-market Annex I s3-5, s8 and Article 88



DESIGN REVIEW

PROCESS

05



Registration

Sneak Peek

Drug-Device Combination Products: Notified Body Opinion Process



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