

Sneak Peek

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



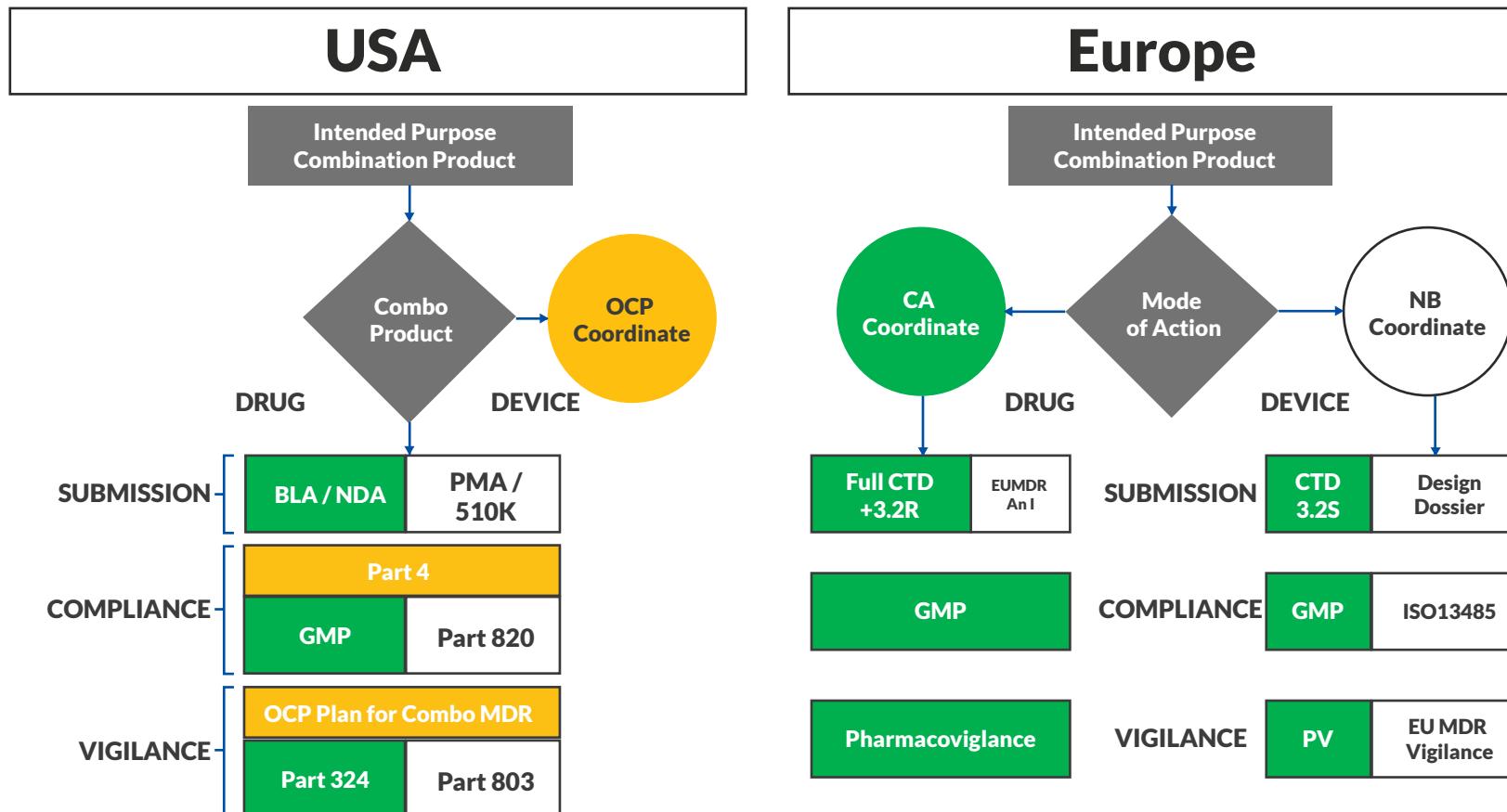
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Health Sciences and Medical
Devices Consultant



SYMMETRIC

Combination Products and How they are regulated – Graphical Summary

01

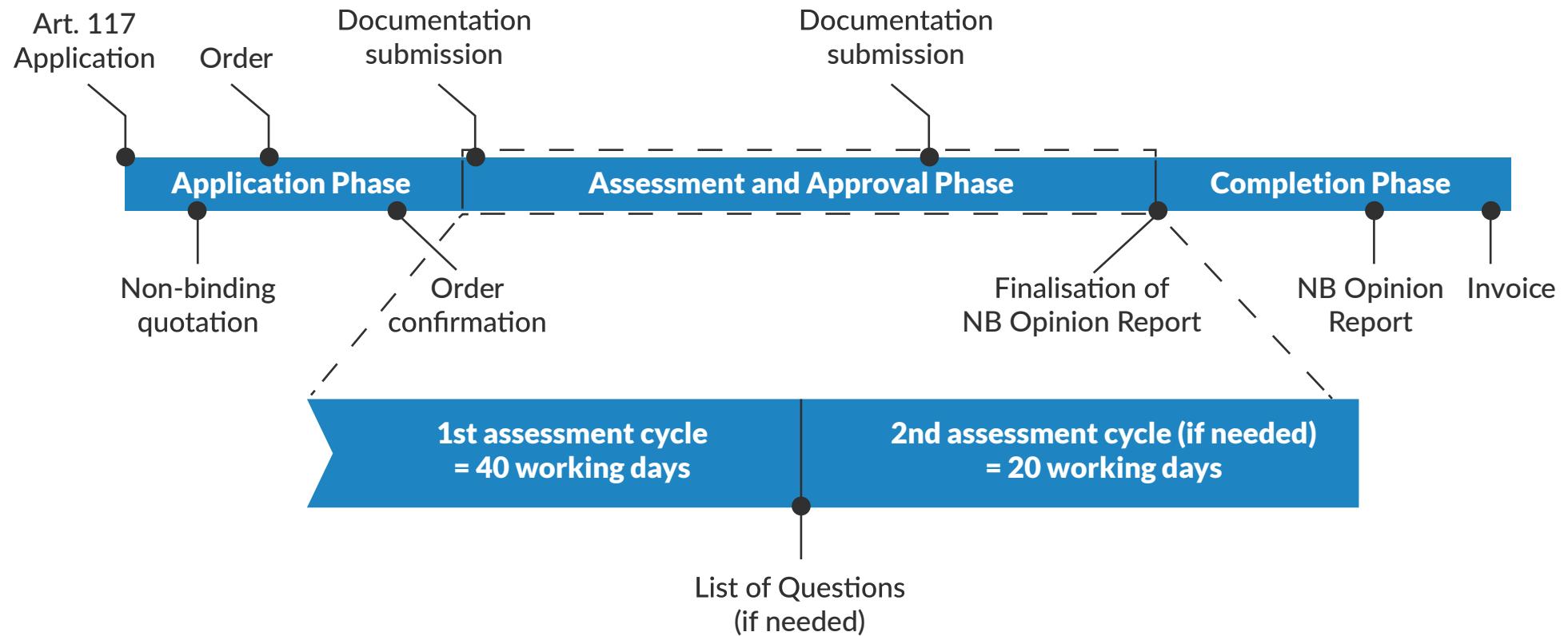


CA = Competent Authority, OCP = Ofcpe of Combination Products, NB = NotiPed Body

Notified body opinion process

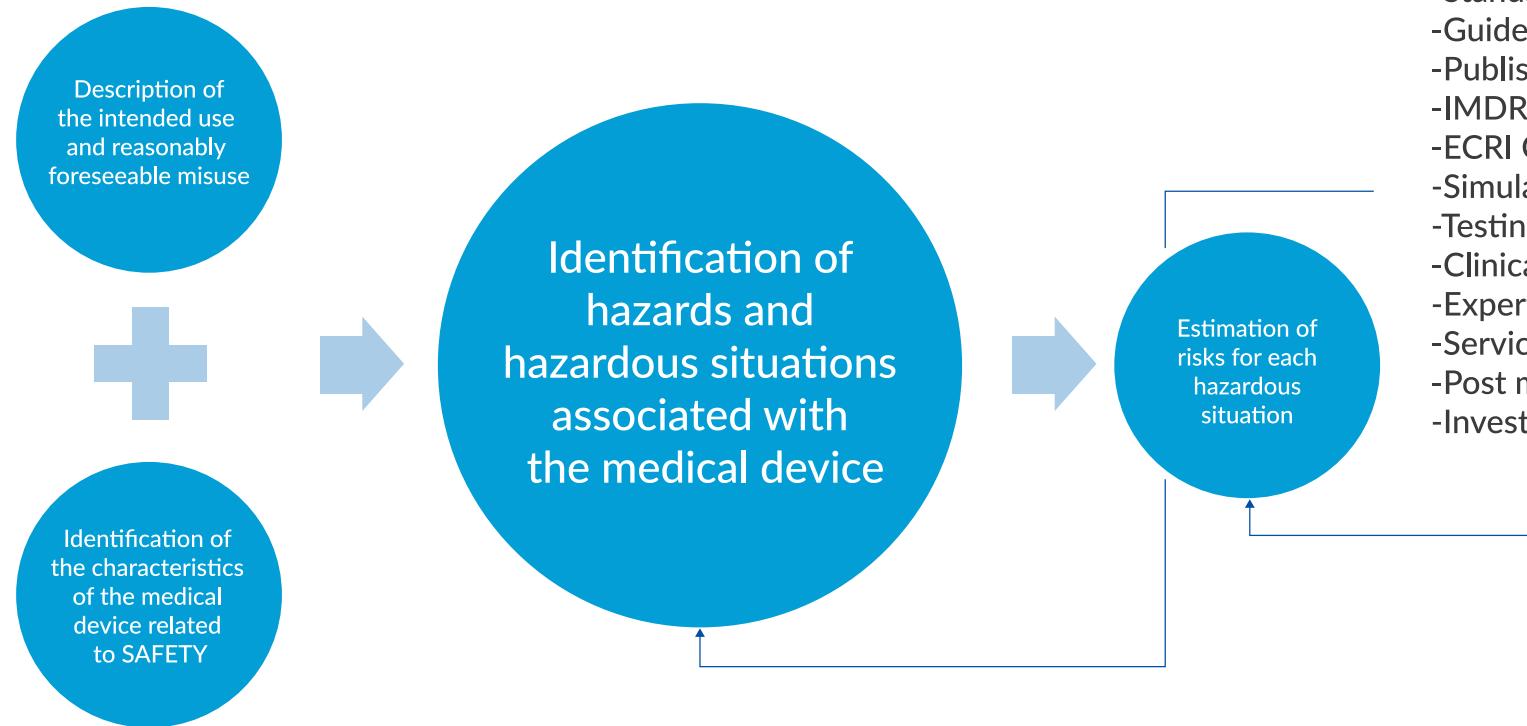
02

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

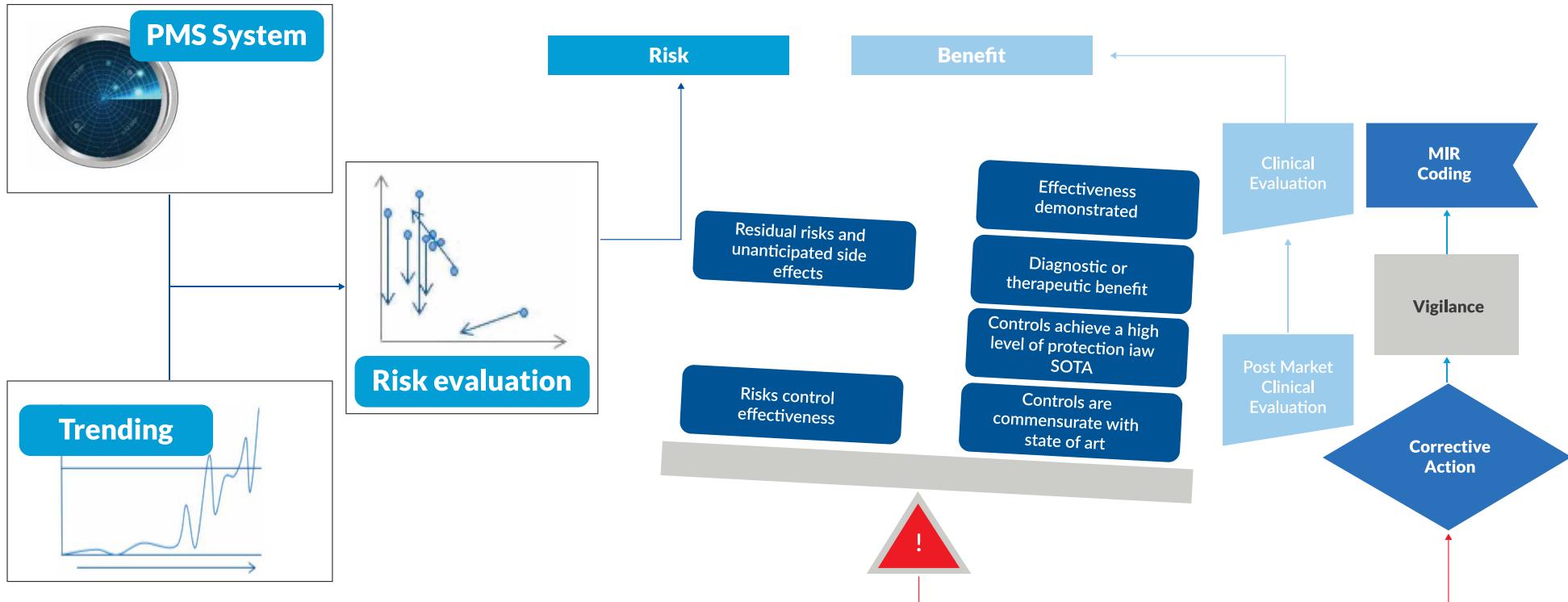


Available information

- Standards
- Guidelines
- Published literature
- IMDRF Coding
- ECRI Coding
- Simulations
- Testing
- Clinical evidence
- Expert evaluation
- Service records
- Post market data
- Investigations

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

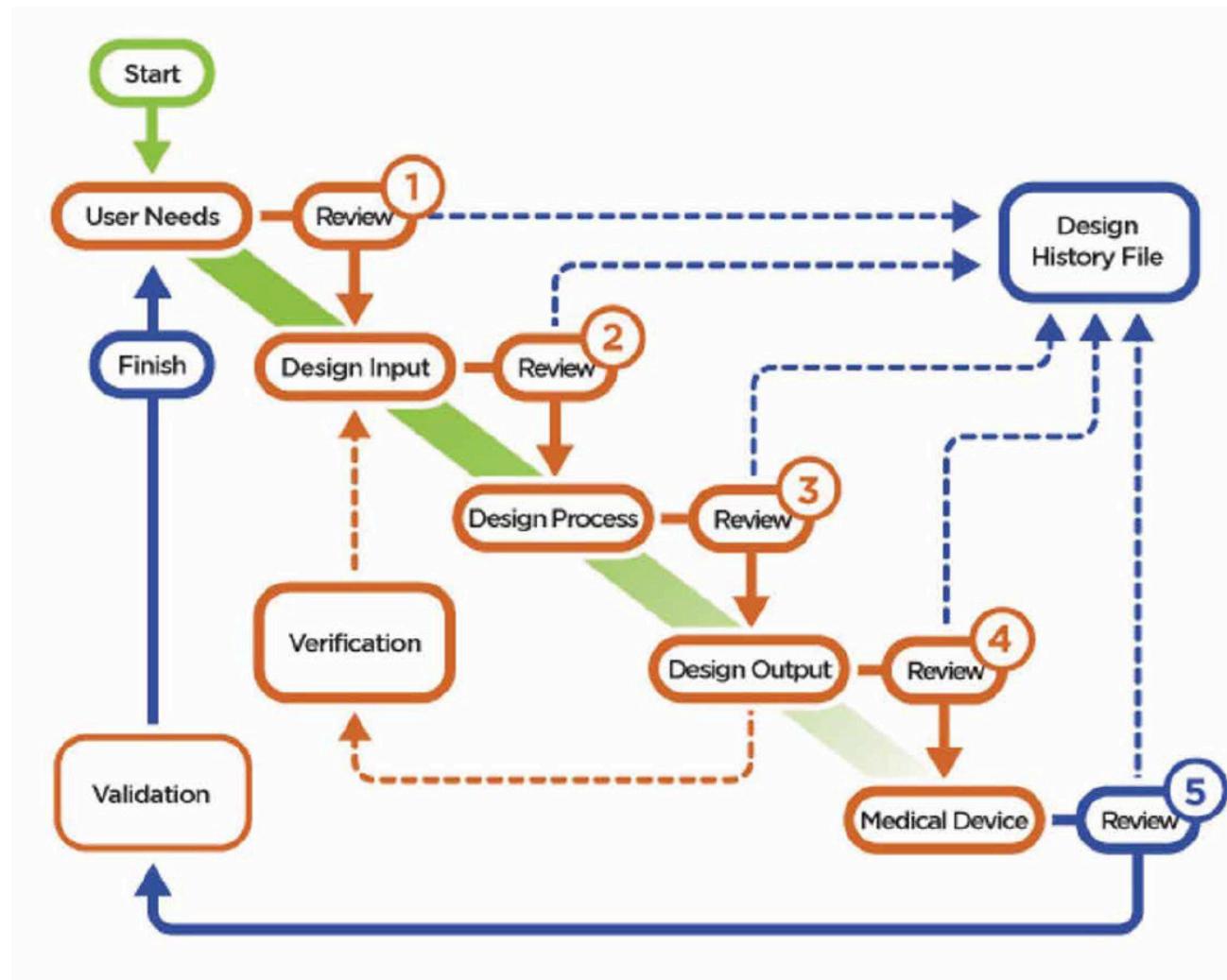
04



DESIGN REVIEW

05

PROCESS



Registration



Sneak Peek

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Notified Body Opinion Process*

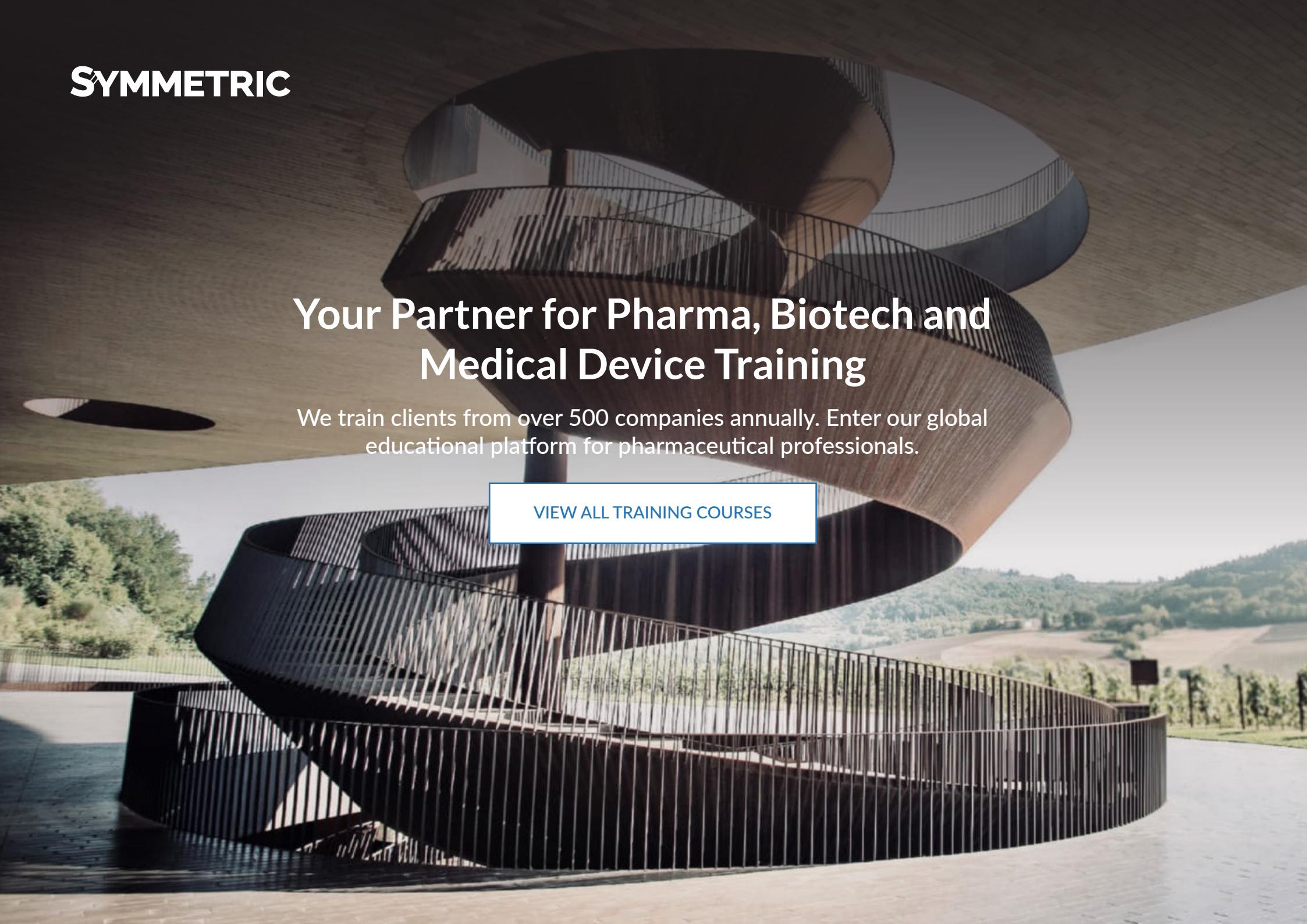


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