

# Sneak Peek

*Mastering Projects and  
Regulatory Milestones in Generic  
Drug Development*



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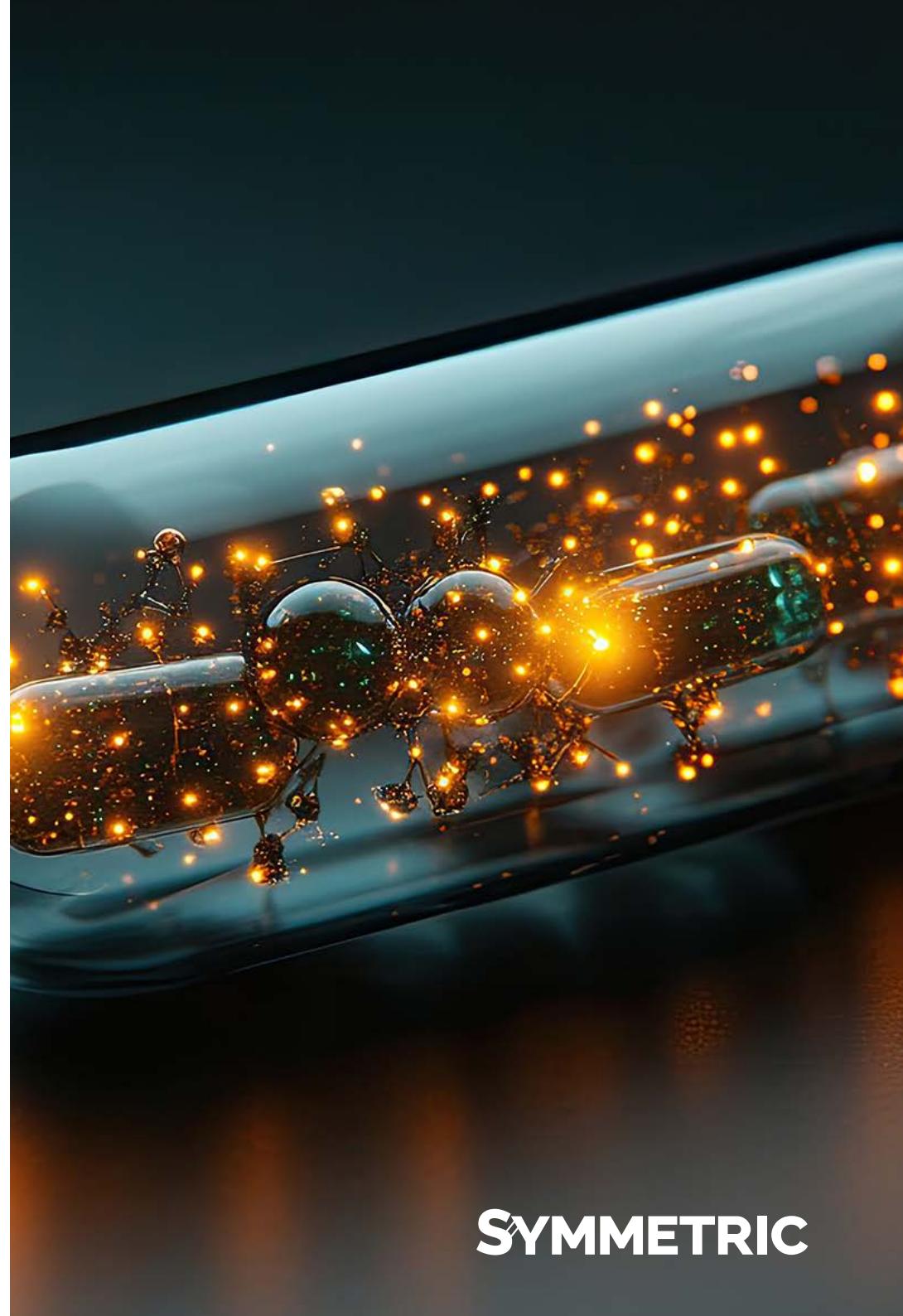


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# Today vs. tomorrow – know your competitive advantage

01

## POSITIONAL ADVANTAGE

Positional advantage may be technical or simply geographical-could include:

- ▶ Salaries
- ▶ Low cost for construction
- ▶ Environment control unregulated

## SPECIAL CAPABILITIES

Special capabilities could include:

- ▶ Patents
- ▶ Special financial agreements
- ▶ Subsidies etc.
- ▶ Privileged tradable assets (business agreements, IP rights)
- ▶ Distinctive competencies (things a company does especially well)

# Criteria for evaluation of product or segmentations

02

## GEOGRAPHIC

- Current geographical **coverage** of competitive products
- **Evolution** of geographical coverage of competitors
- Geographical differences in competitive offering **characteristics**

## DISTRIBUTION

- **Market share** of distribution channels (direct sale, sale through retailer, wholesaler, agent)
- Position within **channel** structure (margins, exclusivities, etc.)

## PRODUCT

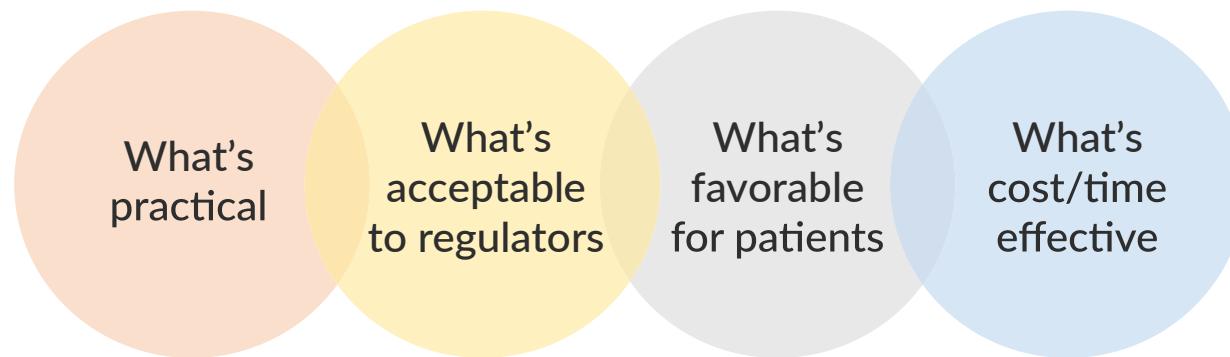
- Complete **overview** of the evolution of product market shares (e.g. by country)
- Product **strategies** for market players
- Manufacturing and distribution **pricing** characteristics of products
- **Regulatory** strategy, marketing authorization application (the EU – MAA), new drug application (US)

## CUSTOMERS / PATIENTS

- Current & future **competitive coverage** of evolving needs in terms of satisfaction level, purchasing criteria and baseline
- Perceived **value** from competitor offerings

# Understanding and Predicting Performance

n3



## Pharma business strategy today - challenges

Digitally integrated quality and manufacturing processes

Focus on operational efficiencies across equipment assets

Real time supply chain management and planning

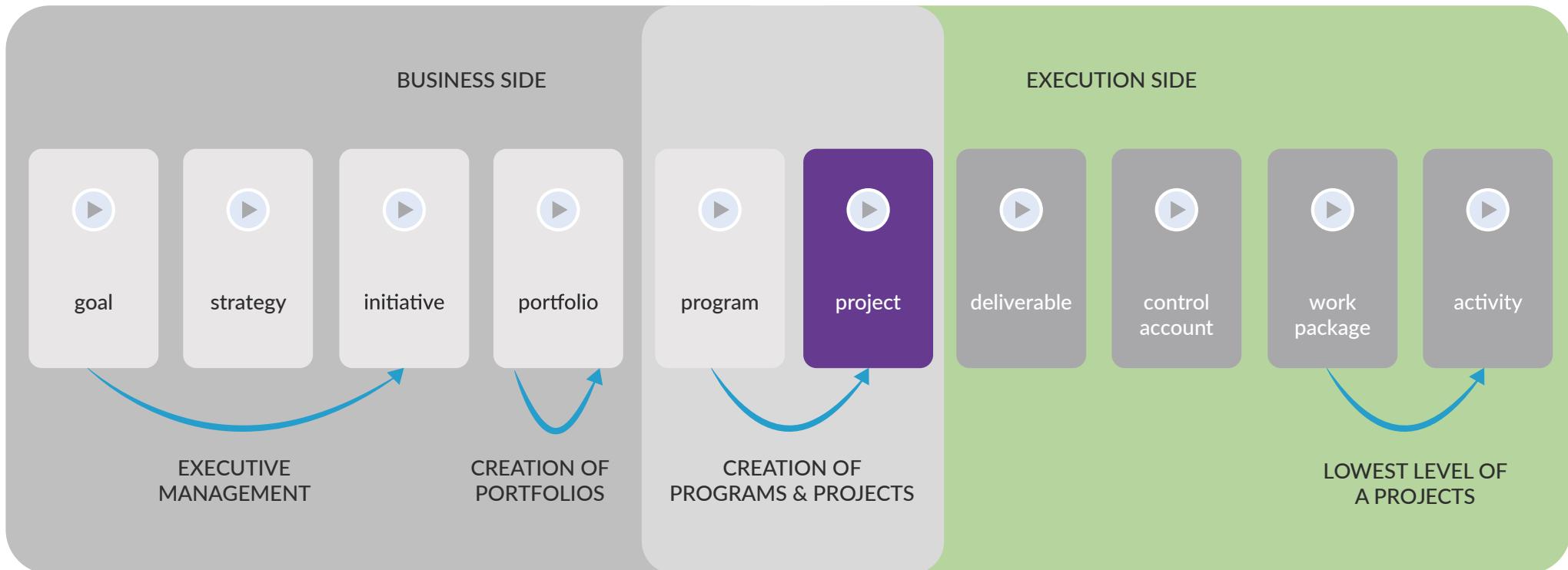
Digital marketing and online presence

Breakthrough therapies with focus on gene therapy, biosimilars and oncology

Development of smaller markets, personalized products and biosimilars

# Business vs. execution

04



# Registration

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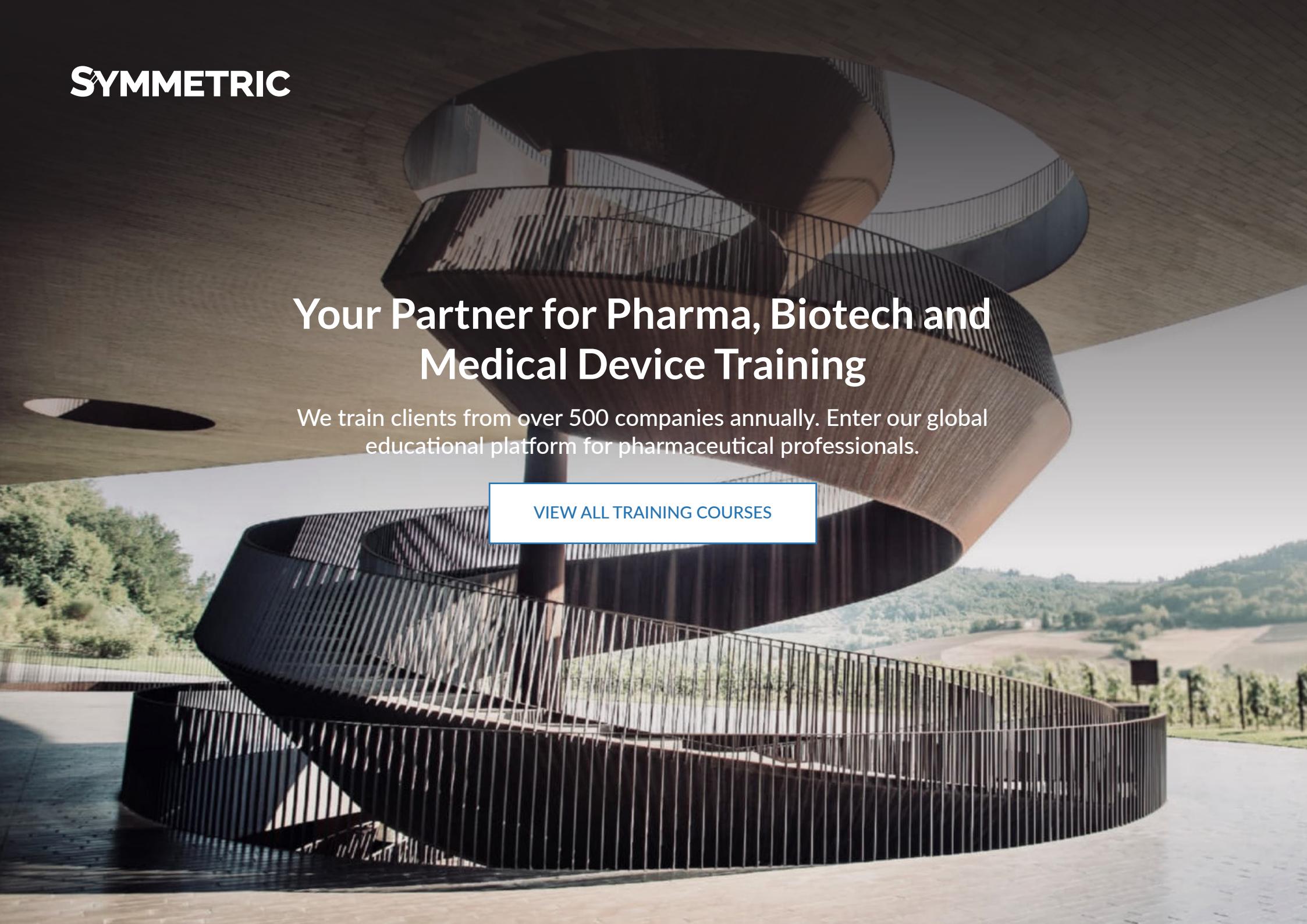


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