

# Sneak Peek

*Extractables and Leachables  
Control Strategies*



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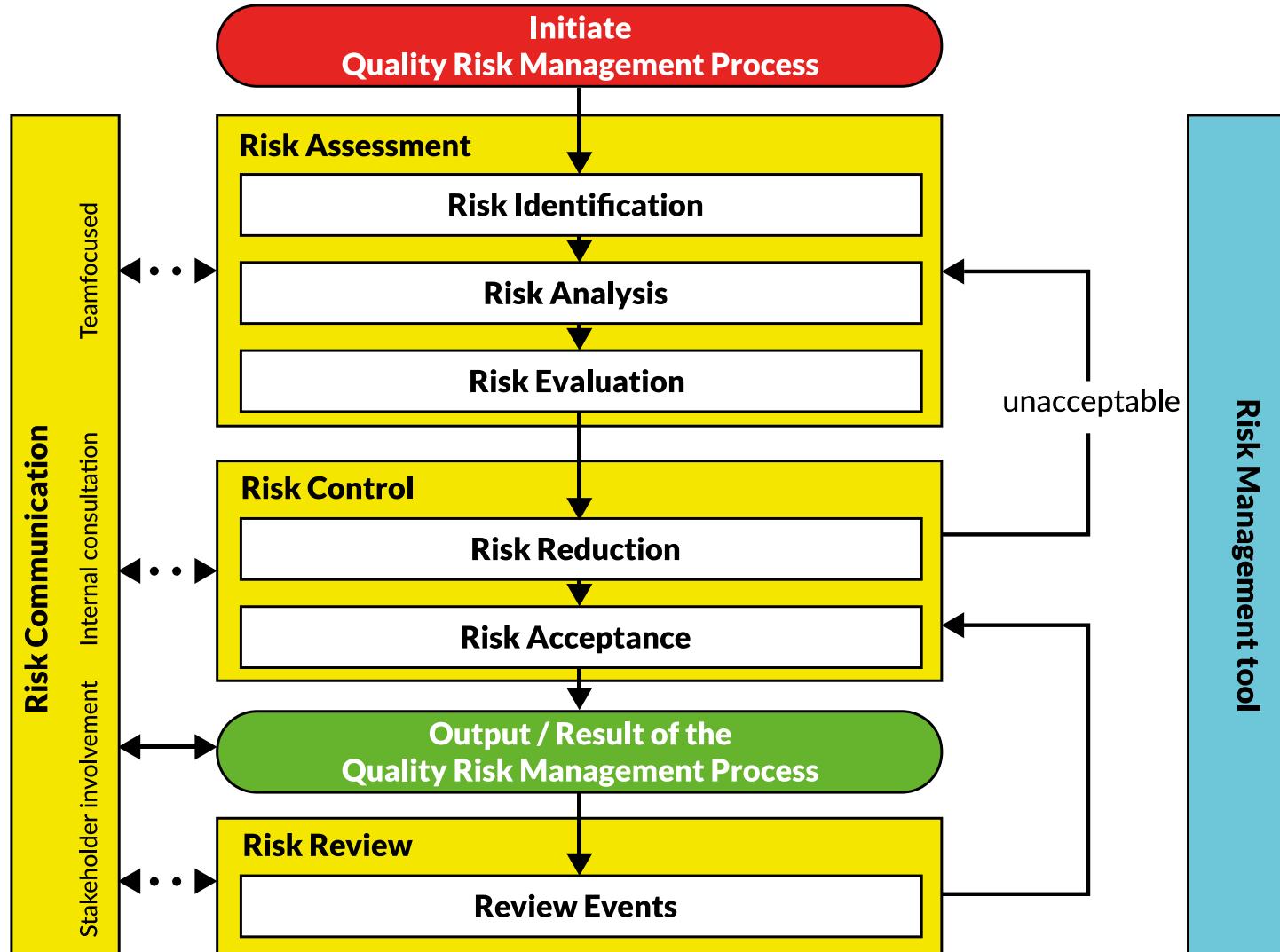
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# Risk Management Process

01



# Risk Assessment

02

## Consider:

- What might go wrong?
- What is the likelihood (probability) it will go wrong?
- What are the consequences (severity)?



Severity is often easier to assess than likelihood

# Risk Assessment Tools: FMEA

03

- FMEA (Failure Modes and Effects Analysis) is an analysis tool that helps to identify potential problems related to a product or process during their life cycle
- It addresses:
  - Potential failure modes
  - The effects of those failures
  - Prioritisation of failure modes for mitigation
- It is an important tool in risk management

# When to use FMEA

04

- When a process:
  - Is being developed or changed
  - Is to be applied in a new way
  - Requires improvement
  - Is being investigated because of failures
- Before developing control strategies for new or modified processes
- Periodically throughout the life cycle of the process (continuous improvement)

# When to use FMEA

05

- Assemble a cross-functional team with knowledge of the process, product or service
  - Brainstorming
  - Fishbone diagrams
- Define the scope of the FMEA
  - Use flowcharts to identify the scope and to make sure every team member understands it

# Registration

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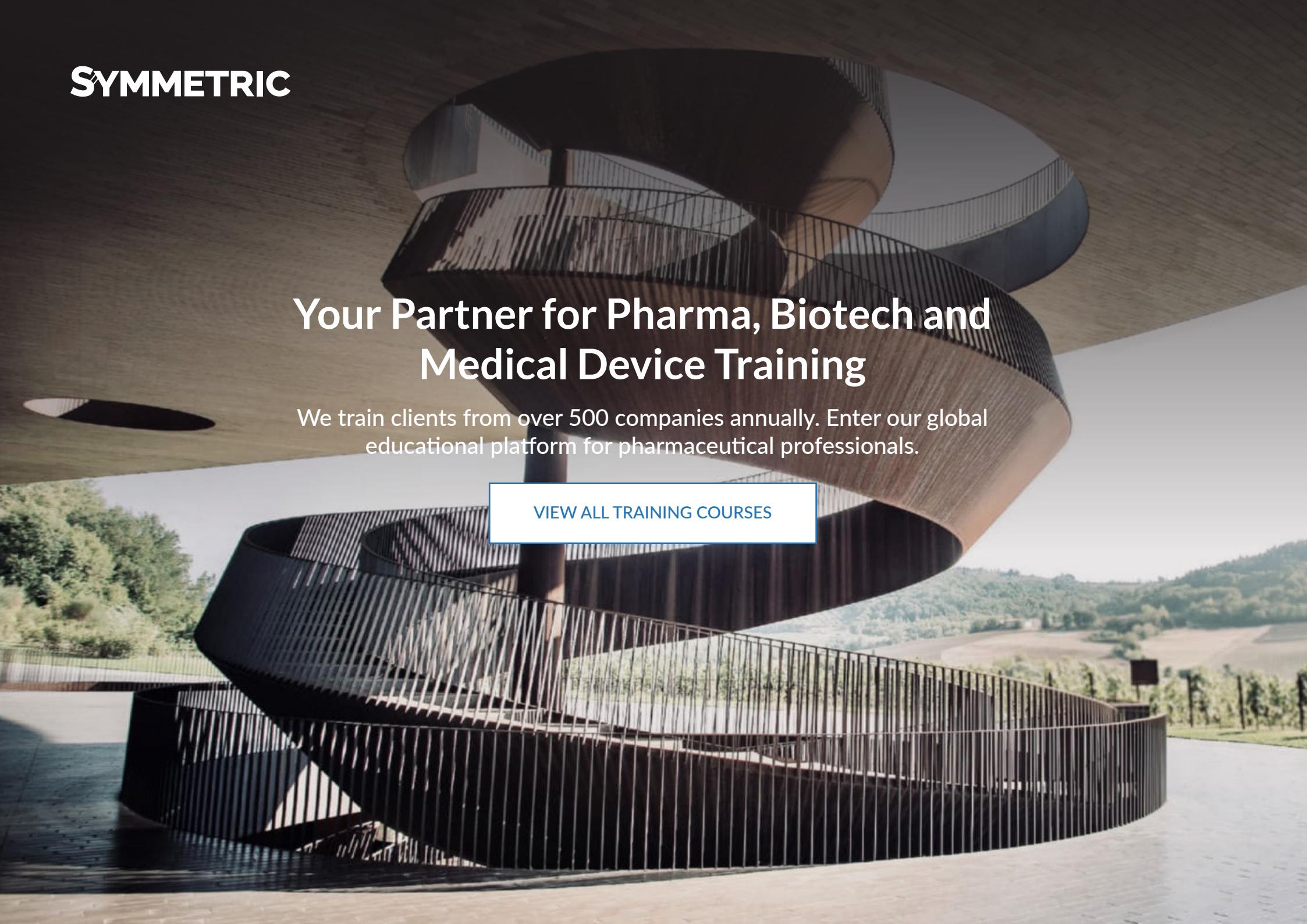
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