Sneak Peek

Design Control and Risk Management For Combination Products

James Pink
Health Sciences and Medical Devices Consultant

ONLINE
TRAINING

SYMMETRIC

Design plan - inputs

01

	Pen Injector	Transdermal Patch	Metred dose inhaler
Regulatory requirements **FDA / EU / Guidance**	US Product code NSC ISO 7864 ISO 9626 ISO 23908	US Product code QIX	US Product code QKS
Product Standards • International / EU / Consensus (US) / 510K data • Industry standards	SO 11608-4	?	ISO 20072 ISO 27427
Process / Material Standards	ISO 20069 USP39_NF34<85> ISO 10993-1, 5, 10 ISO 11608-2 ASTM F1929098 ISTA 3A	ISO 20069 ISO 11135	ISO 20069
	Risk analysis	Risk analysis	Risk analysis

Design Input

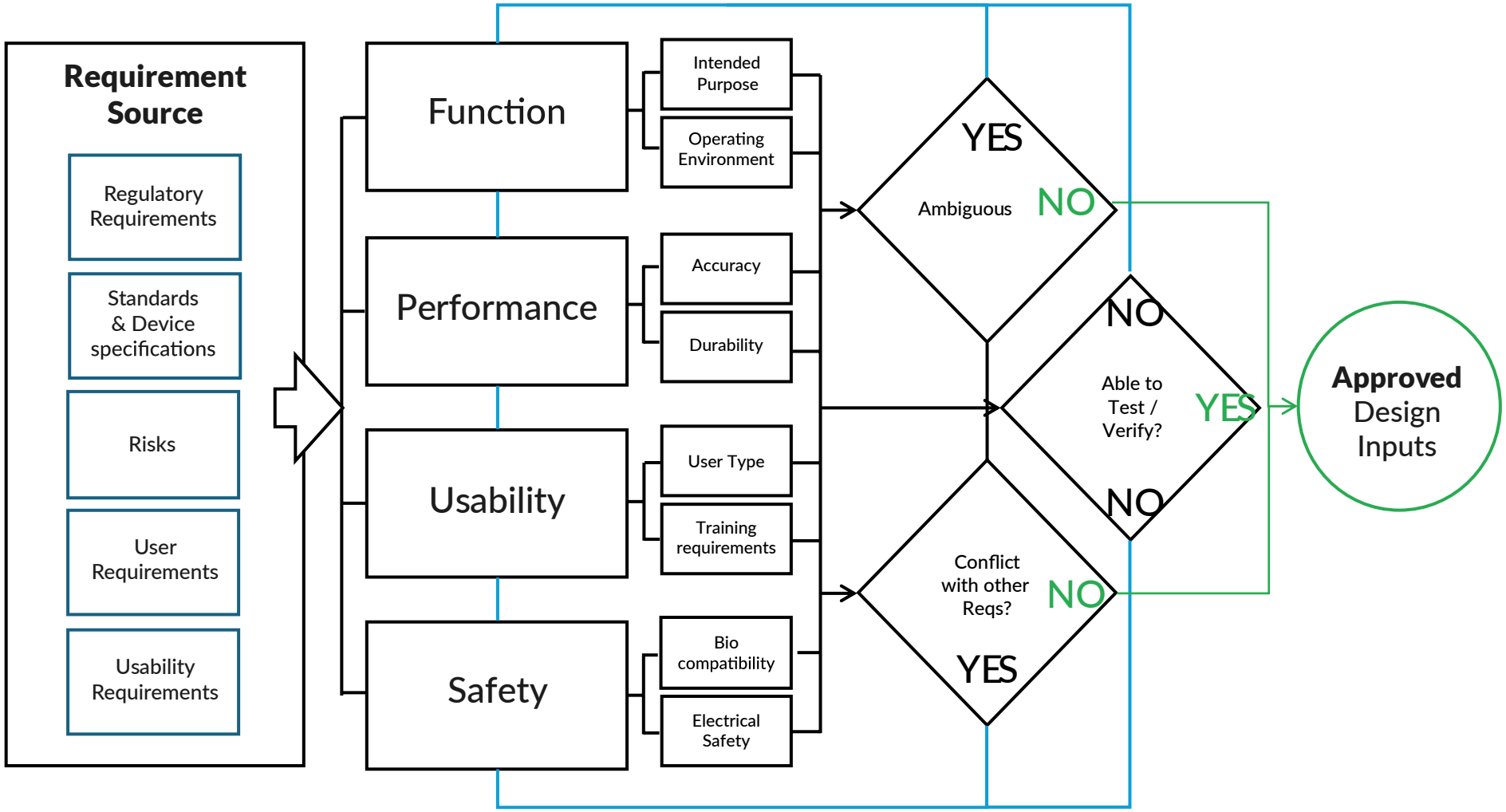


Figure 3 : Determining sources of requirements and translating to approved design input

Requirements – best practice

Objective	Example
Provide the source of the requirement	Standard number and clause, marketing, risk management activity
Be specific	Component / Phase / User step
Use imperatives	Shall or Must
Ensure the requirement is testable	Describe an expected outcome i.e. compliance to a standard test method.
Structure the requirement to be consistent	ID, Type, Component, Phase, Output etc
Don't be subjective	Avoid words like "normal, strengthen, enhance, user-friendly". Opt for precise and measurable terms.

Risk management in combination products

04

- **Failure to actuate, use-related failures**

The purpose of this letter is to inform you that the administration of EpiPen® 0.3 mg and EpiPen Jr® 0.15 mg Auto-Injectors and the authorized generic versions (referenced collectively as EpiPen in the remainder of this letter) may be delayed or prevented during an emergency due to:

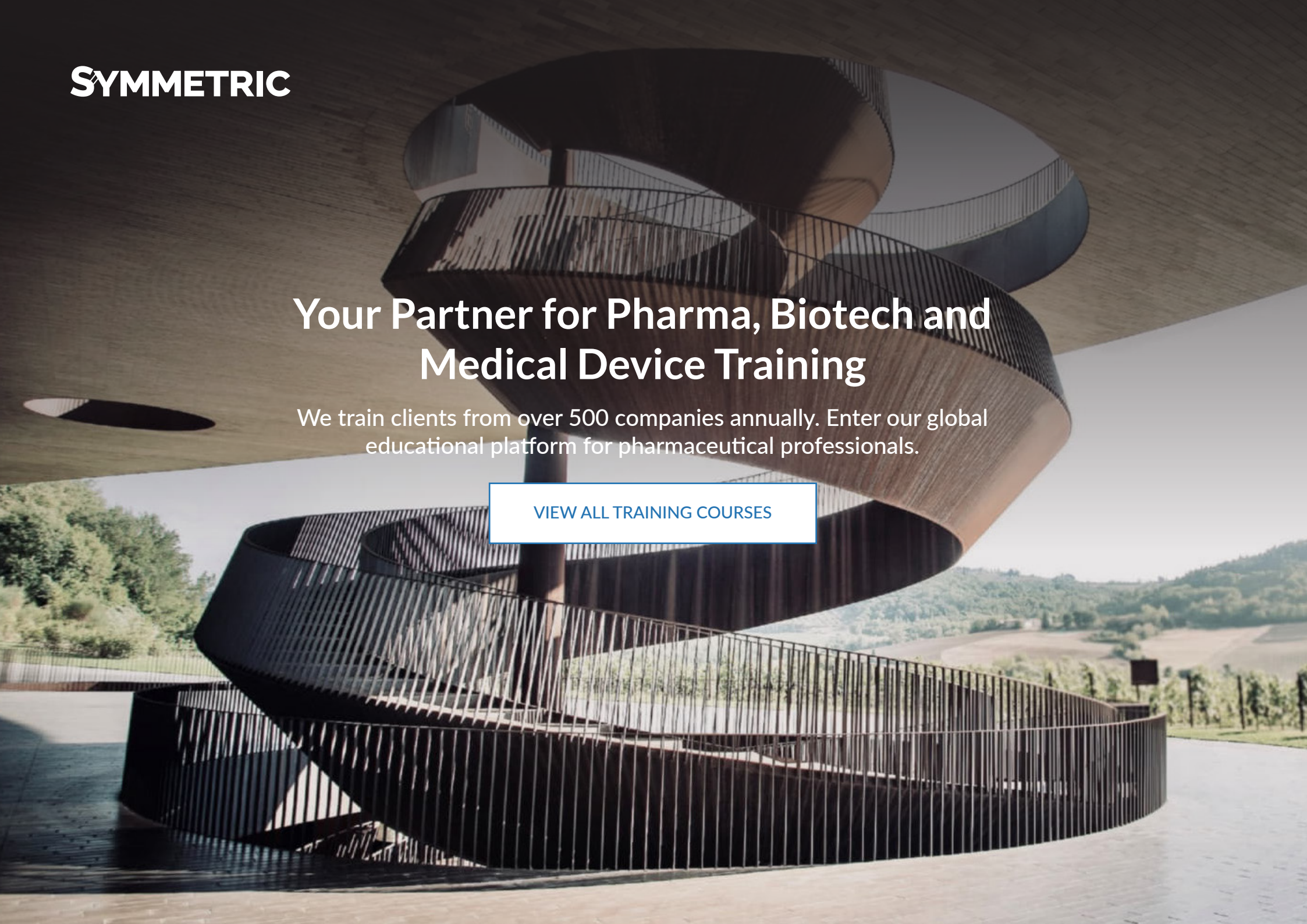
1. Device failure from spontaneous activation caused by using a sideways force to remove the blue safety release.
2. Device failure from inadvertent or spontaneous activation due to a raised blue safety release
3. Difficulty removing the device from the carrier tube.
4. Certain identified use errors.

Registration

Sneak Peek

Design Control and Risk Management
For Combination Product

Mliekarenská 9, 821 09
Bratislava, Slovak Republic
ID: 47 068 124
VAT no: SK2023741973
Office: +421 948 262 346


SYMMETRIC
Your Partner for Pharma, Biotech and Medical Device Training
We train clients from over 500 companies annually. Enter our global educational platform for pharmaceutical professionals.
VIEW ALL TRAINING COURSES