From design to prototype, certification till massproduction.

"Dedicated to Medical Devices"

Your boutique one-stop shop
for Medical devices

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1988 established

privately owned

80 FTE

14 M€ turn over

+70 customers

+250 products

CE/UL products

ISO 7 clean room

FDA registered

MDD → MDR Certification

One piece flow

Scale-up

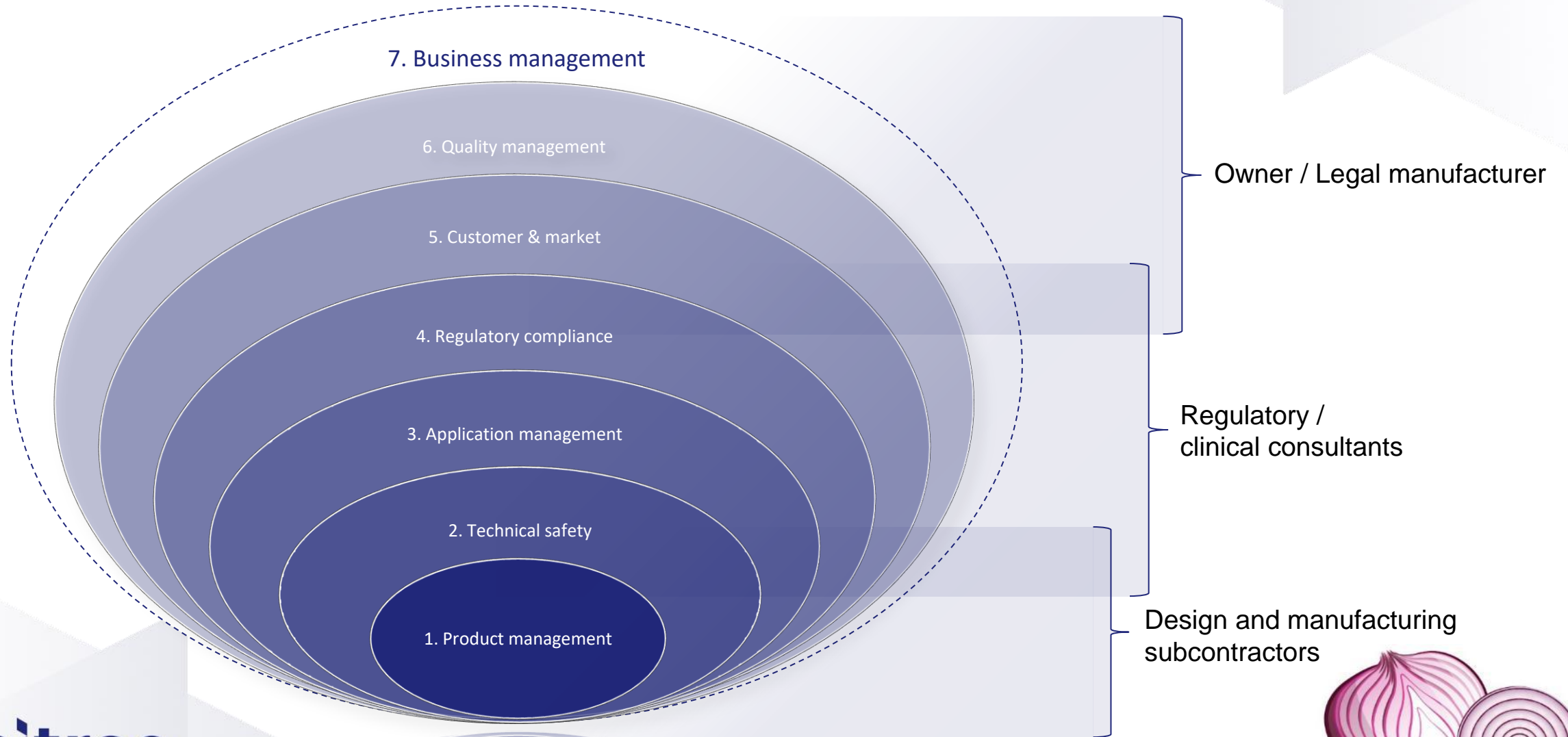**High-volume & Total solution**

iba

ViCentra
Home of Kaleido.

PHILIPS
RESPIRONICS

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Keywords: Validated production line, Sharing knowledge, Partnership, Service provider, Commitment, ISO13485, One stop shop, Ambition, IEC 60601, IEC 62304, IEC 62366, ISO14791, CDMO

The various layers of medical device compliance
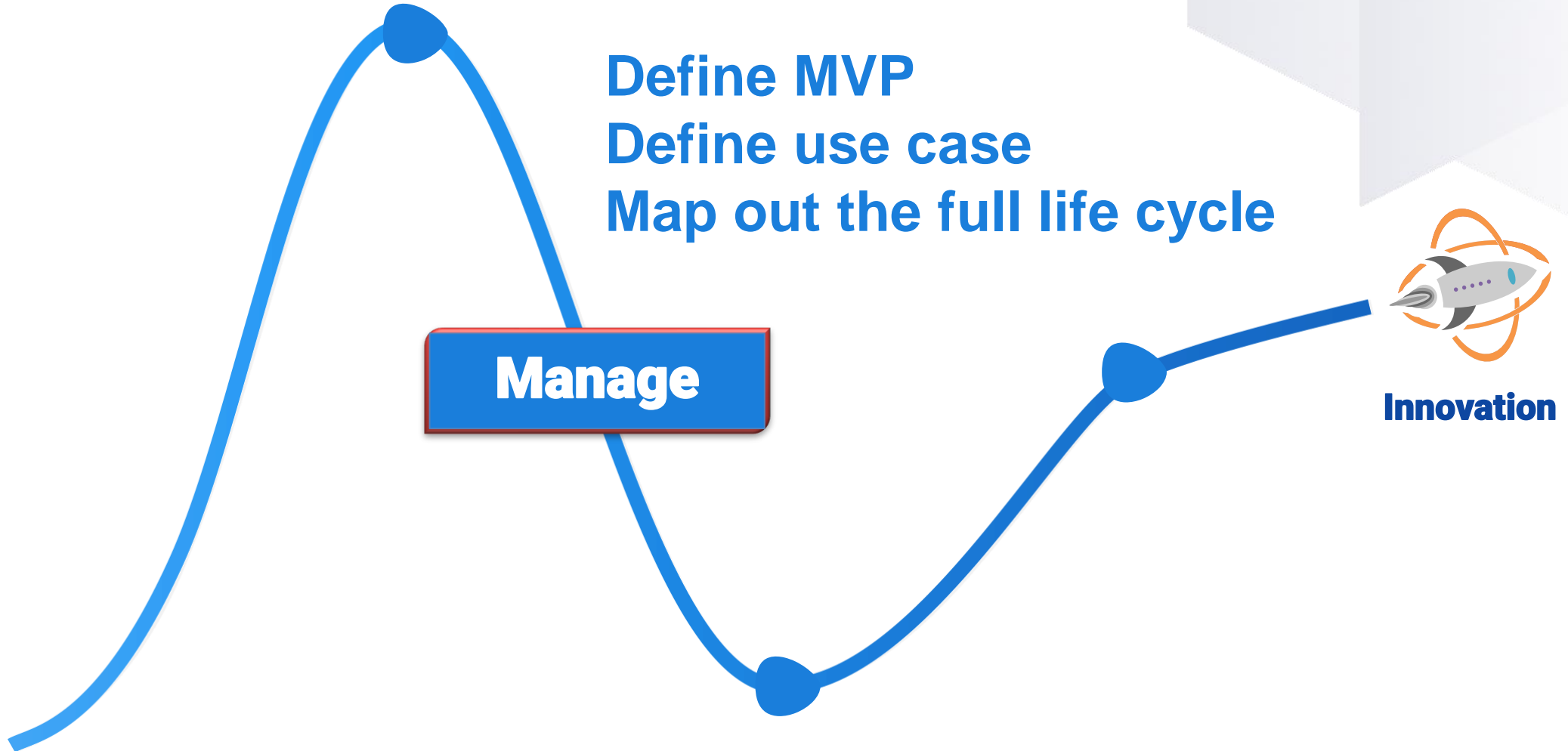
7. Business management

6. Quality management

5. Customer & market

4. Regulatory compliance

3. Application management

2. Technical safety

1. Product management

Owner / Legal manufacturer

Regulatory / clinical consultants

Design and manufacturing subcontractors

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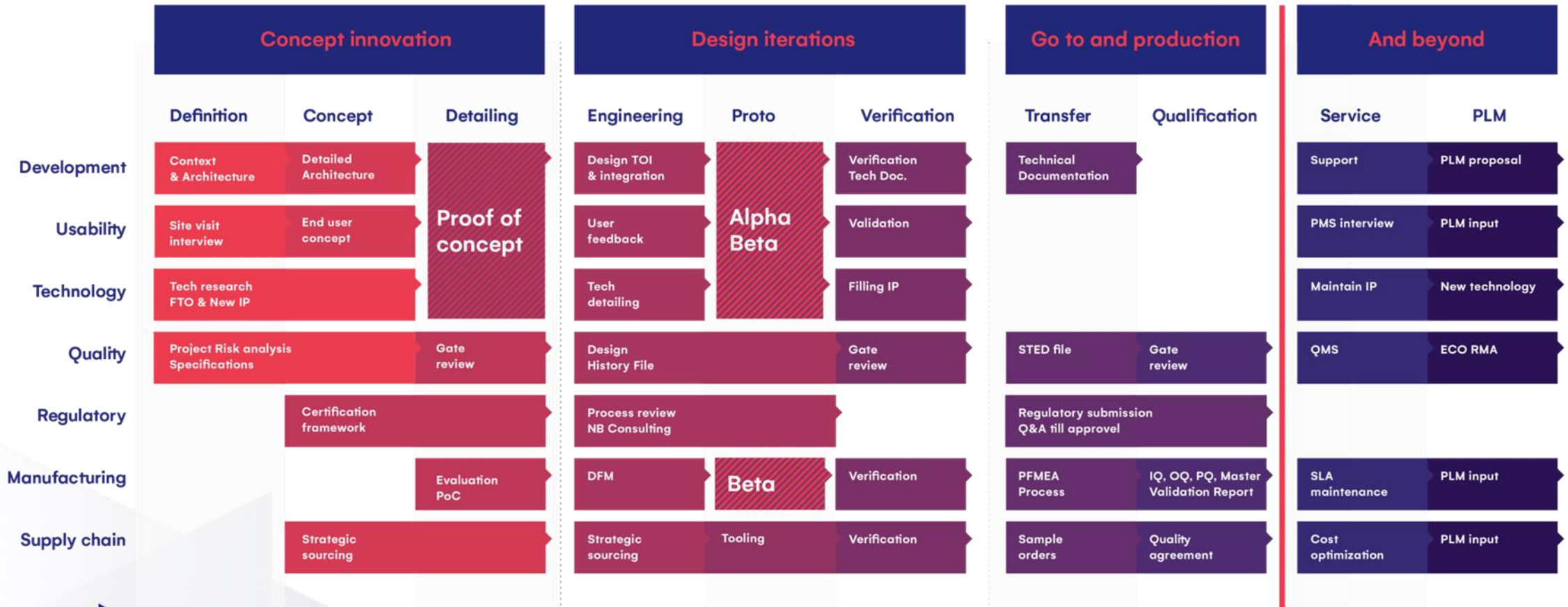
Some standards that can help

QMS-related:
- ISO 13485 + MDR - quality management

Product related:
- ISO 14971 - risk management
- IEC 62304 - software development
- IEC 82304-1 - standalone software
- IEC 62366-1 + IEC 60601-1-6 - usability
- IEC 60601-1 - electrical safety and EMC
- ISO 10993 series - biocompatibility
- MDCG 2020-13 + MDCG 2020-6 - clinical evaluation (formerly MEDDEV 2.7/1 rev. 4)

User information related:
- ISO 15223-1 - medical device symbols
- ISO 20417 - information to be supplied by the manufacturer
- Incorporated in several standards

Production process related:
- ISO 11135 / ISO 11137-1 - sterilization
- ISO 11607-1/2 - packaging

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Process approach - example

Product delivery

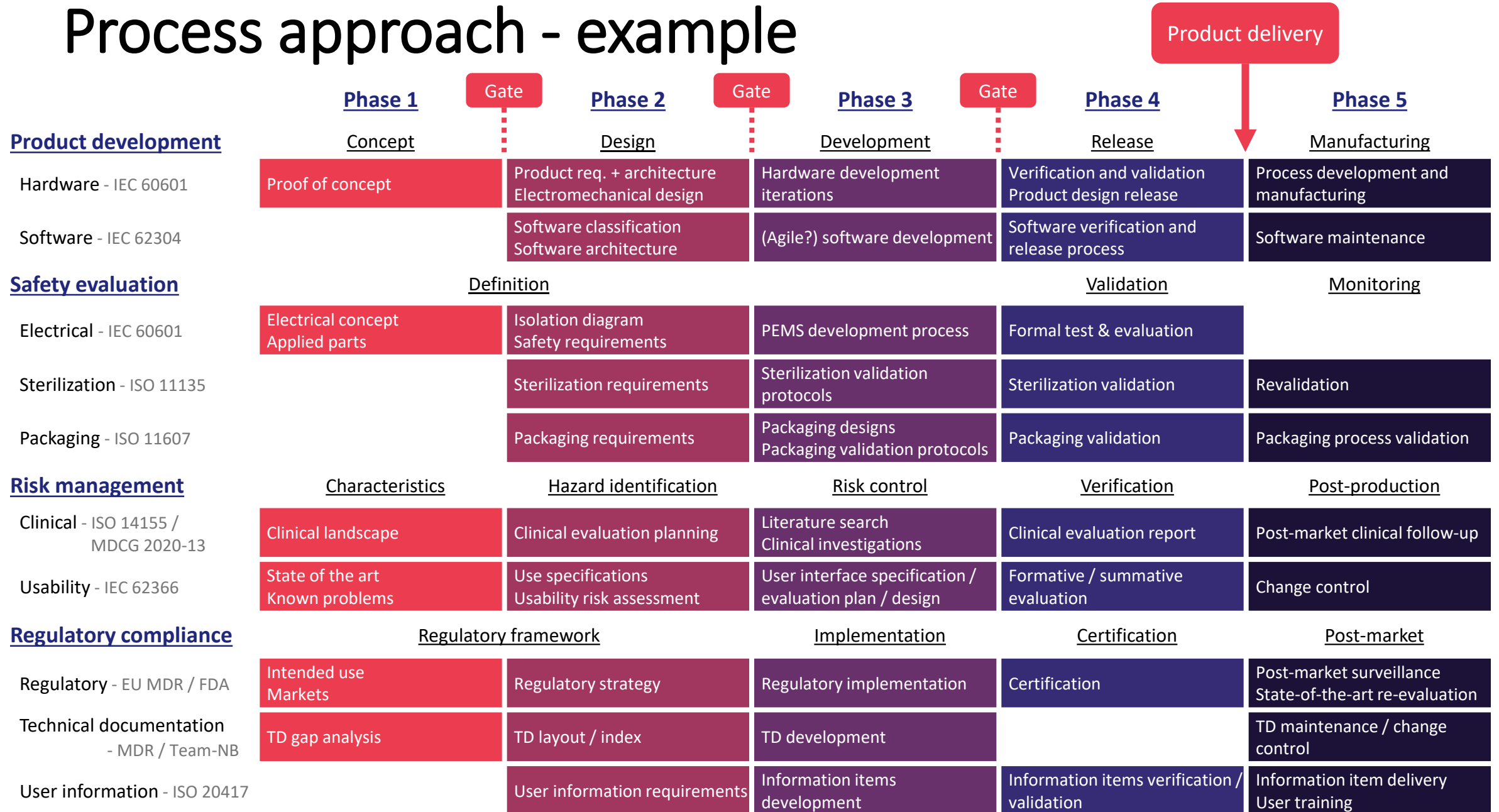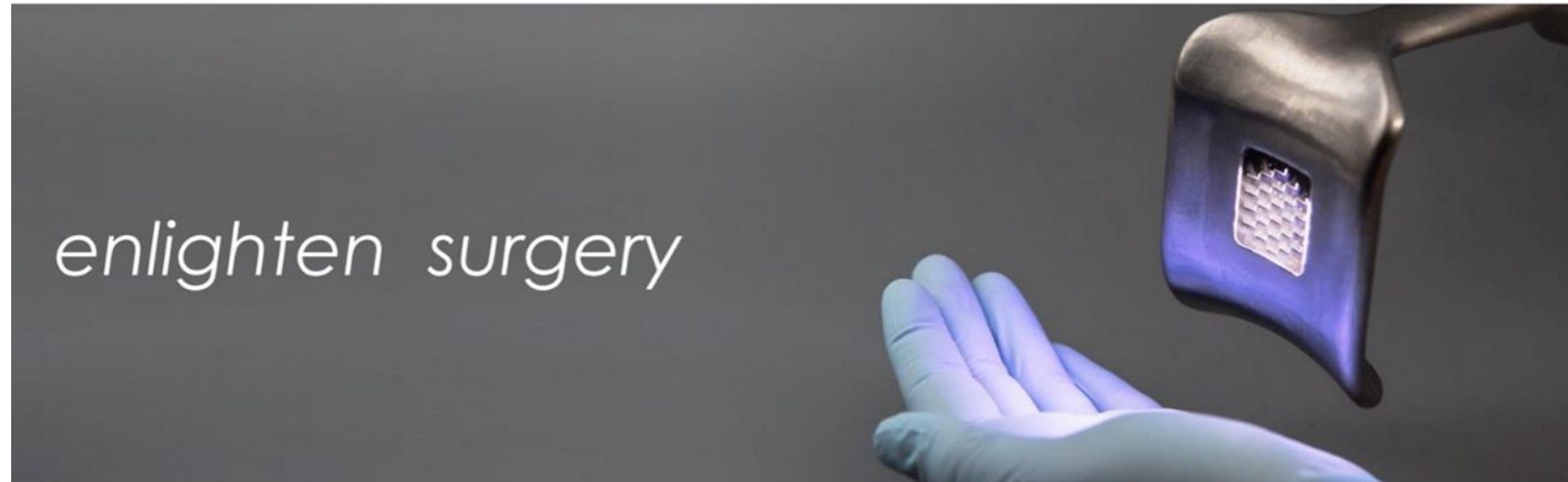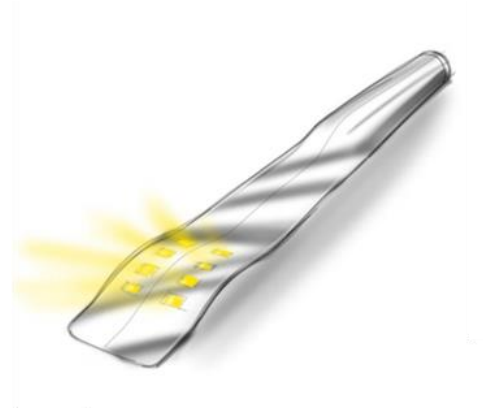|	**Phase 1**	Gate	**Phase 2**	Gate	**Phase 3**	Gate	**Phase 4**	**Phase 5**
Product development	Concept		Design		Development		Release	Manufacturing
Hardware - IEC 60601	Proof of concept		Product req. + architecture / Electromechanical design		Hardware development iterations		Verification and validation / Product design release	Process development and manufacturing
Software - IEC 62304			Software classification / Software architecture		(Agile?) software development		Software verification and release process	Software maintenance
Safety evaluation	Definition						Validation	Monitoring
Electrical - IEC 60601	Electrical concept / Applied parts		Isolation diagram / Safety requirements		PEMS development process		Formal test & evaluation	
Sterilization - ISO 11135			Sterilization requirements		Sterilization validation protocols		Sterilization validation	Revalidation
Packaging - ISO 11607			Packaging requirements		Packaging designs / Packaging validation protocols		Packaging validation	Packaging process validation
Risk management	Characteristics		Hazard identification		Risk control		Verification	Post-production
Clinical - ISO 14155 / MDCG 2020-13	Clinical landscape		Clinical evaluation planning		Literature search / Clinical investigations		Clinical evaluation report	Post-market clinical follow-up
Usability - IEC 62366	State of the art / Known problems		Use specifications / Usability risk assessment		User interface specification / evaluation plan / design		Formative / summative evaluation	Change control
Regulatory compliance	Regulatory framework				Implementation		Certification	Post-market
Regulatory - EU MDR / FDA	Intended use / Markets		Regulatory strategy		Regulatory implementation		Certification	Post-market surveillance / State-of-the-art re-evaluation
Technical documentation - MDR / Team-NB	TD gap analysis		TD layout / index		TD development			TD maintenance / change control
User information - ISO 20417			User information requirements		Information items development		Information items verification / validation	Information item delivery / User training

Regulatory in product development, a practical case

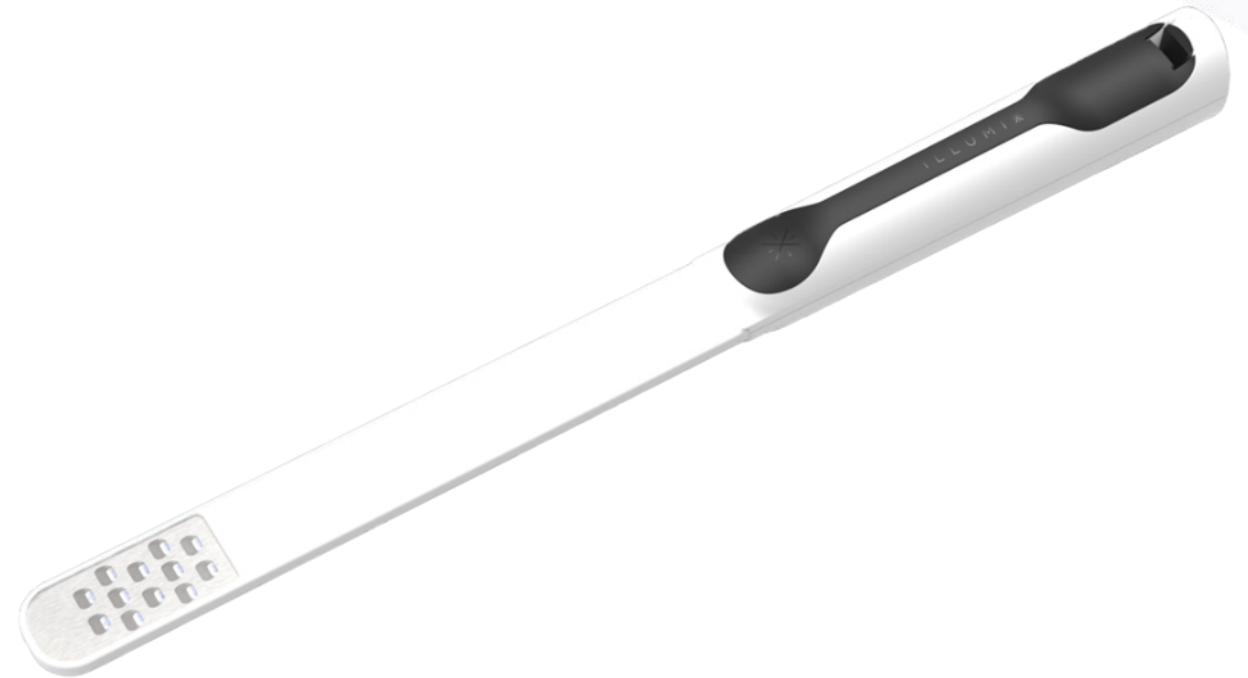# Regulatory in product development, a practical case

Regulatory in product development, a practical case

Regulatory in product development, a practical case

- ✓ Scope and use of device

- ✓ Biocompatibility and correct classification of device

- ✓ Define sterilisation method

- ✓ Temperature stability and hotspots… 41 °C….

- ✓ Color temperature, choice of LED's

- ✓ Requirements

- ✓ Risk Management

- ✓ Packaging

- ✓ Reach and Rohs, supplier check

- ✓ Purchasing all components

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Regulatory in product development - a practical case

Small numbers

Big numbers

Small numbers and start new project for version 2

Investment in the right resources
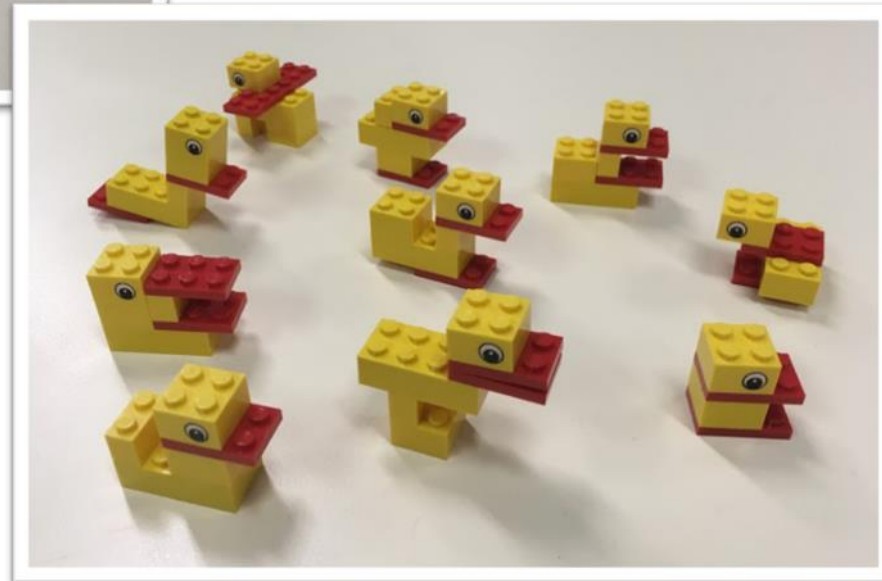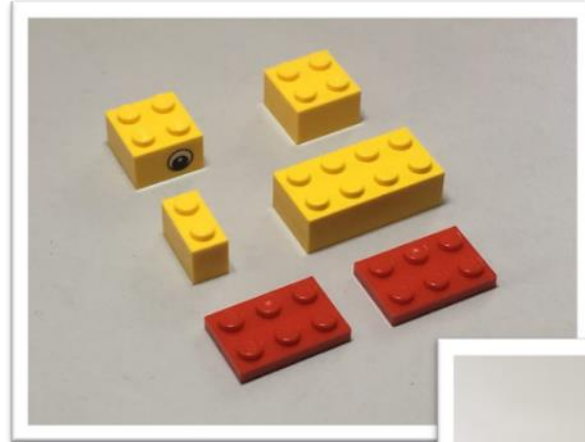
proces

tooling

suppliers

partners

logistics

FDA

MDR

Legal manufacturer

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Take-Home Message

Source: http://www.legoengineering.com/build-a-duck/

conclusion

- Start with *Why*
- Define and plan *processes* for each topic / subject
- Make sure you have the right *cross-discipline expertise* in your team
- Create the correct *scope*
- allow *iterations and interactions* with other processes / subjects
- Think ahead: what is the *next step* in your development, launch or future plan?

Act → Plan → Do → Check → Act

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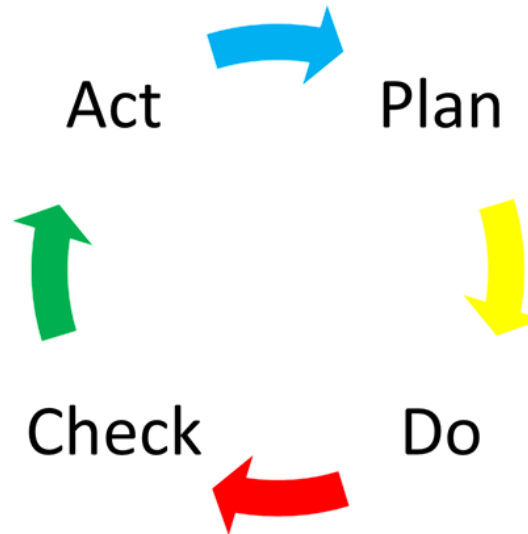
Thank you for your attention

ANY QUESTIONS ?

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