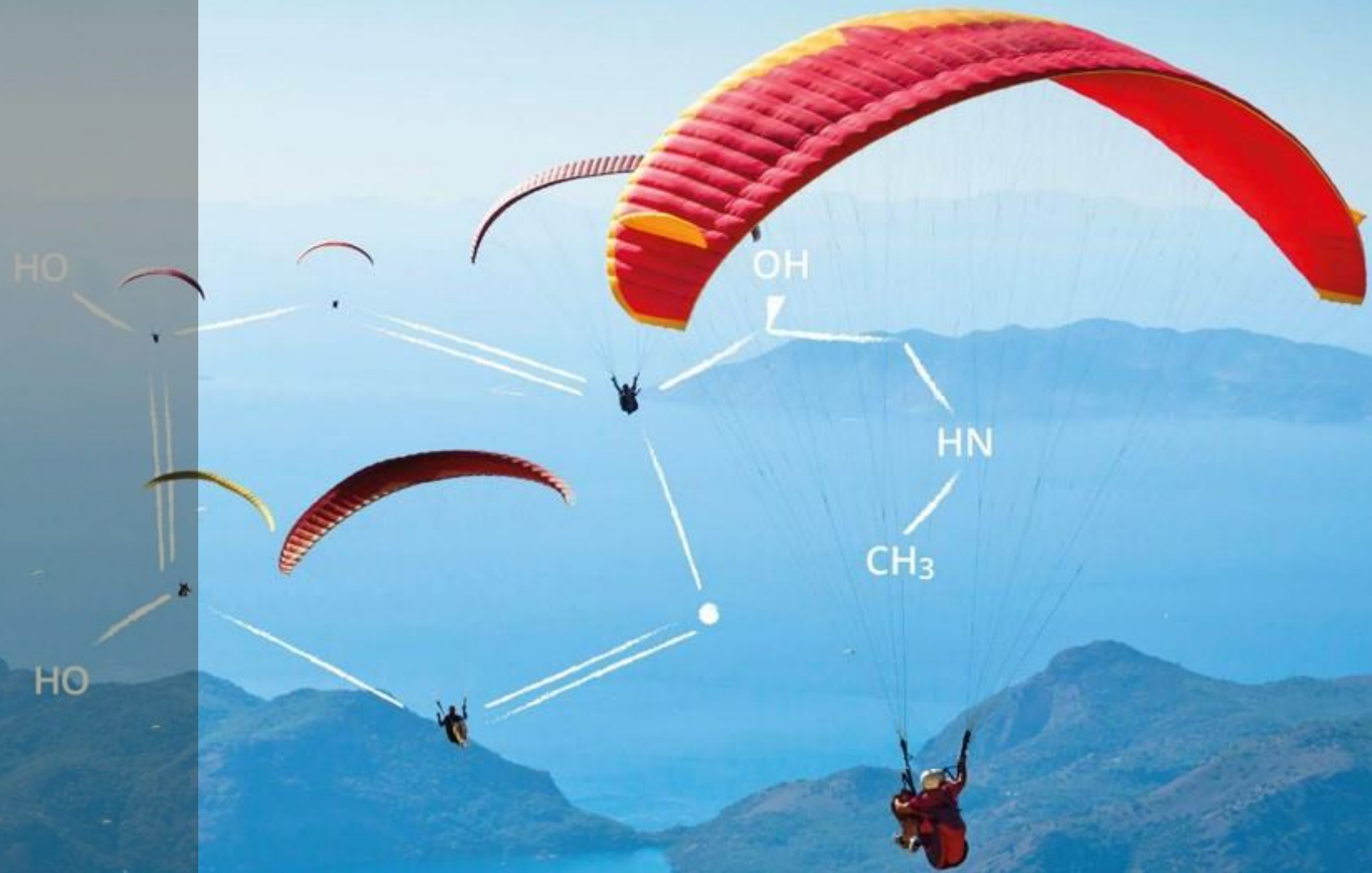


DARE TO FLY

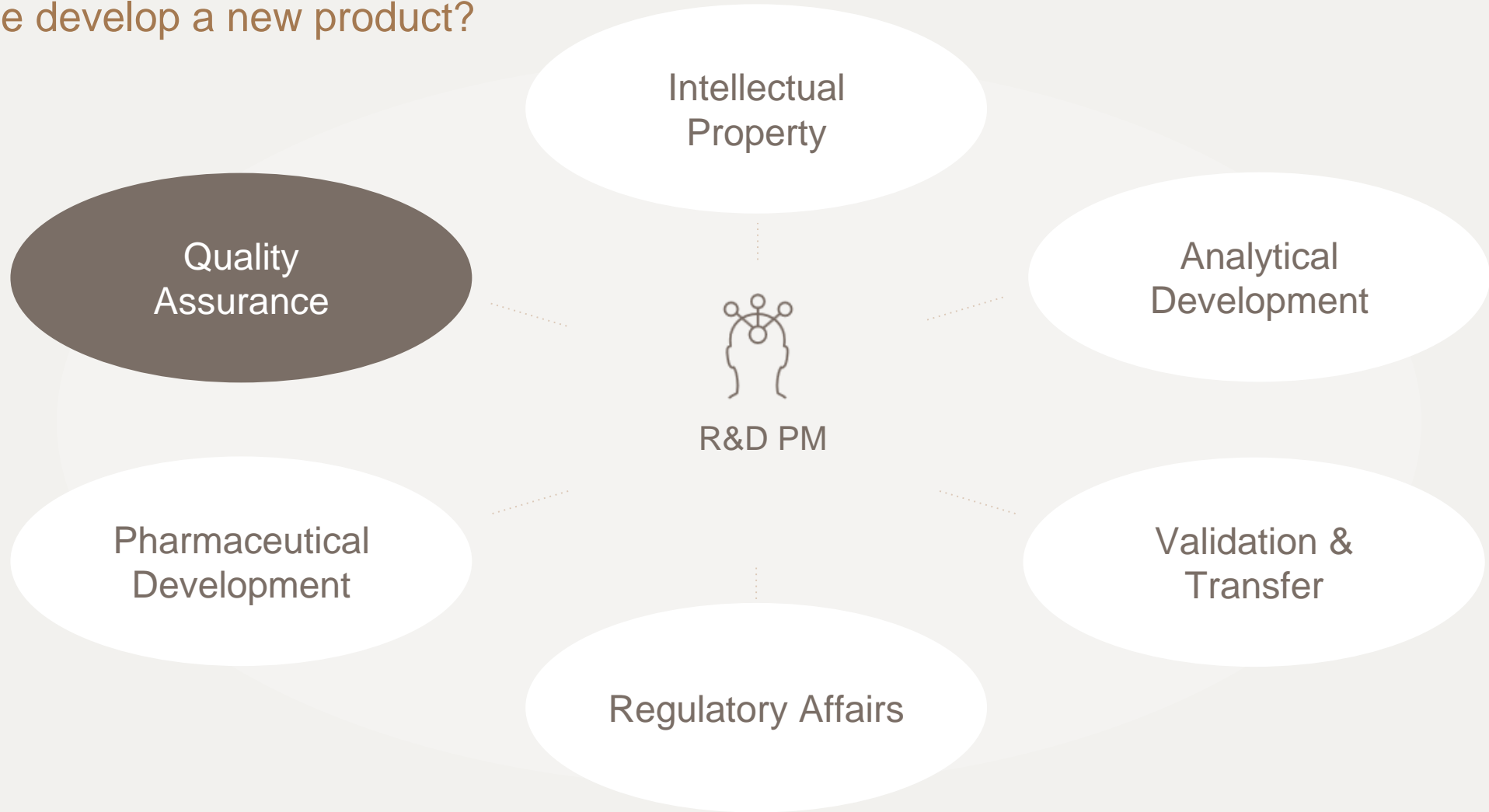
QUALITY ASSURANCE

VICTORIA JULIÀ
QUALITY ASSURANCE
GALENICUM VITAE

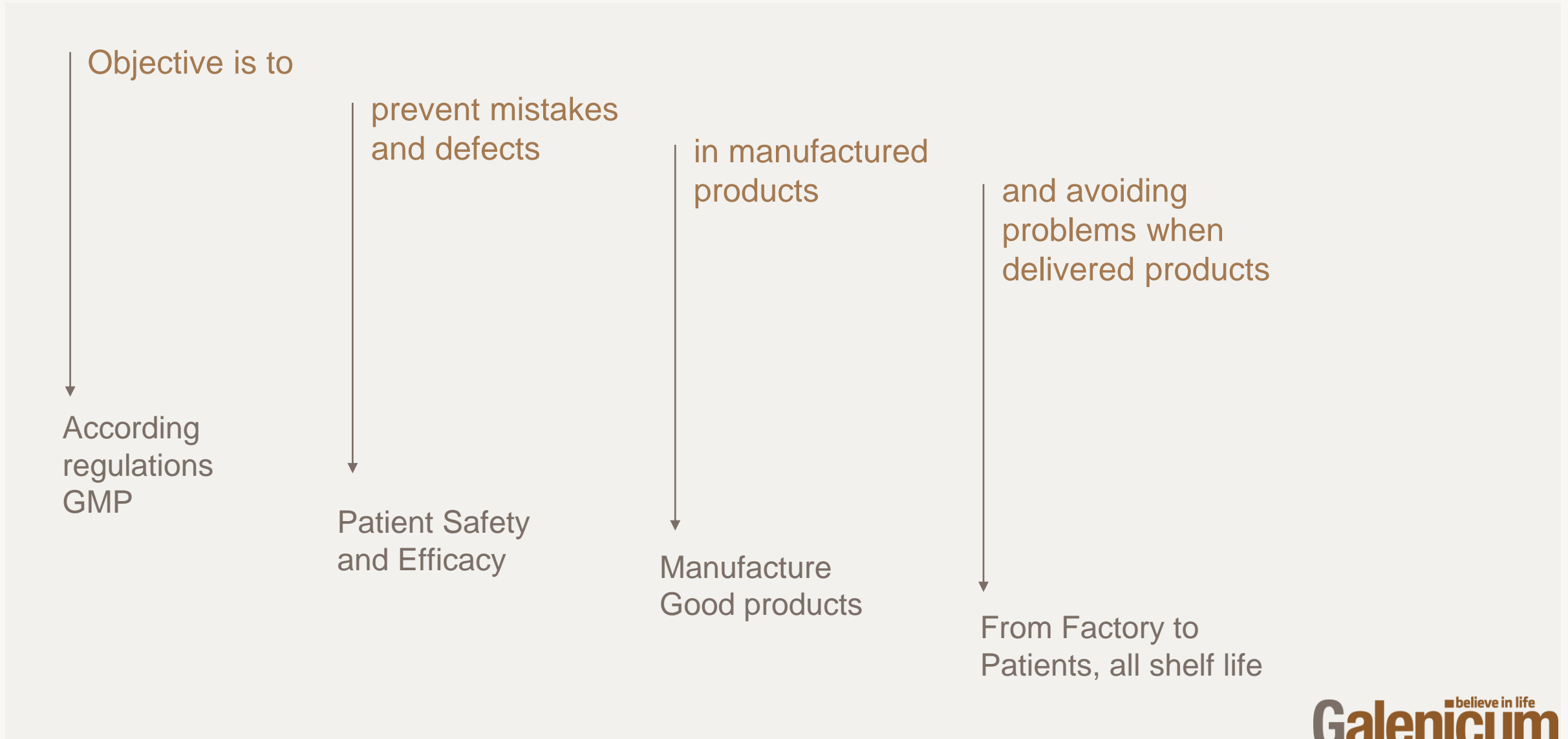


ROLE WITHIN THE INDUSTRY

How do we develop a new product?



QUALITY ASSURANCE



ONE DAY IN THE OFFICE



Deviations.

CAPA (Corrective & preventive actions).

Complaints.

Product Quality Review (PQR).

Risk Analysis.

Release of batches.

Product Development.

Real use Product knowledge.

Optimal study designs.

Time to Market strategies.

Scientific discussion with regulatory agencies.

Quality Systems.

QA OFFICER ROLES

QA Compliance

- PQR → Statistical
- Change Control
- Computer System Validation
- Audit Management (Self inspections - Suppliers)

R&D QA

QA Release

- Manufacturing Deviations
- Release of Batches
- Complaints

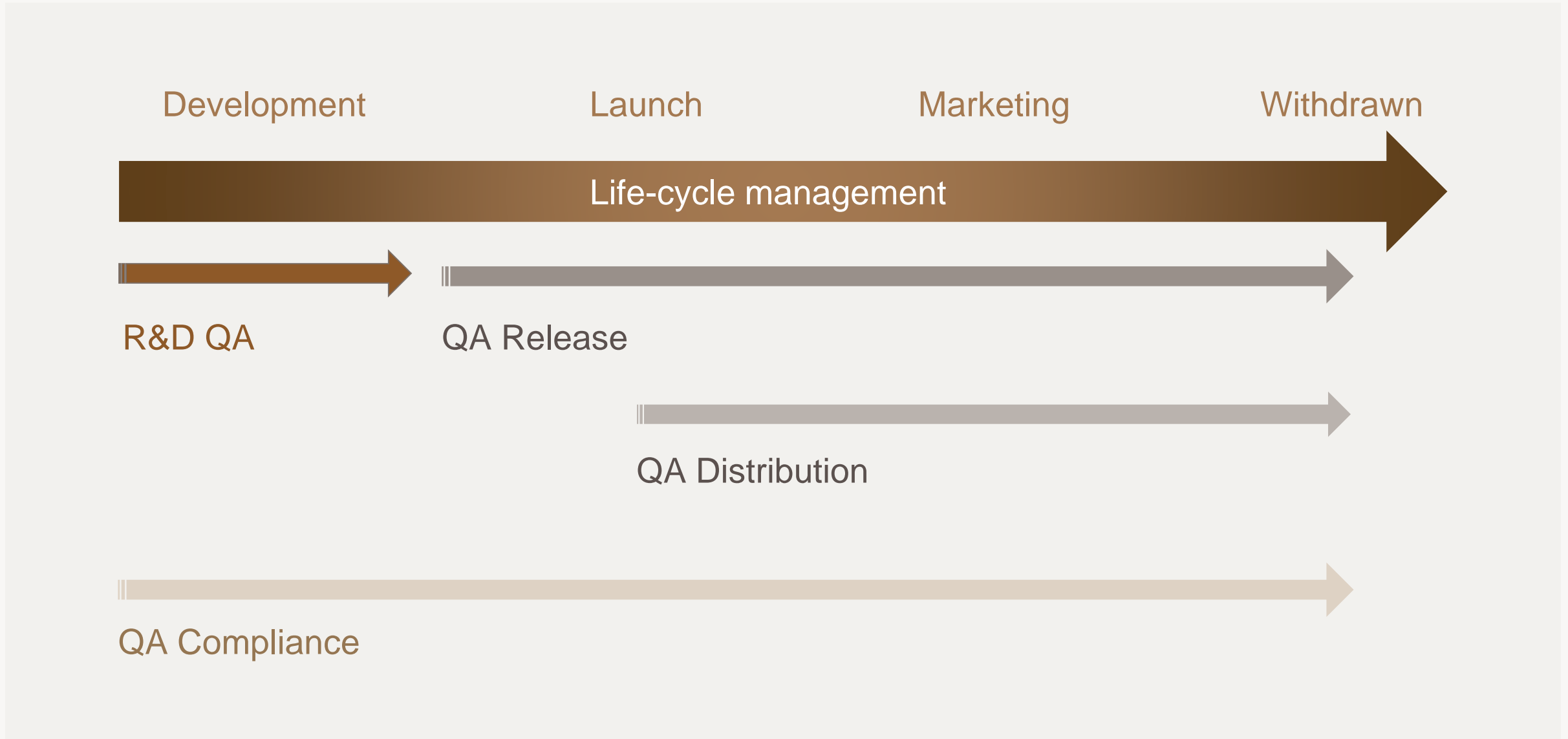
Wholesalers (GDP)

QA Laboratories

- OOS Management



QUALITY ASSURANCE



WHAT IS THE MARKET LOOKING FOR



Soft Skills

- Systematic
- Responsible
- Common sense
- Curious & Perseverant
- Autonomous when needed
- Time management
- Problem solver
- Negotiation Skills



Technical Skills

- GxP guidelines
- ICH guidelines



Languages

- Fluent in English

MERCI

THANK YOU

GRACIAS

GRÀCIES