

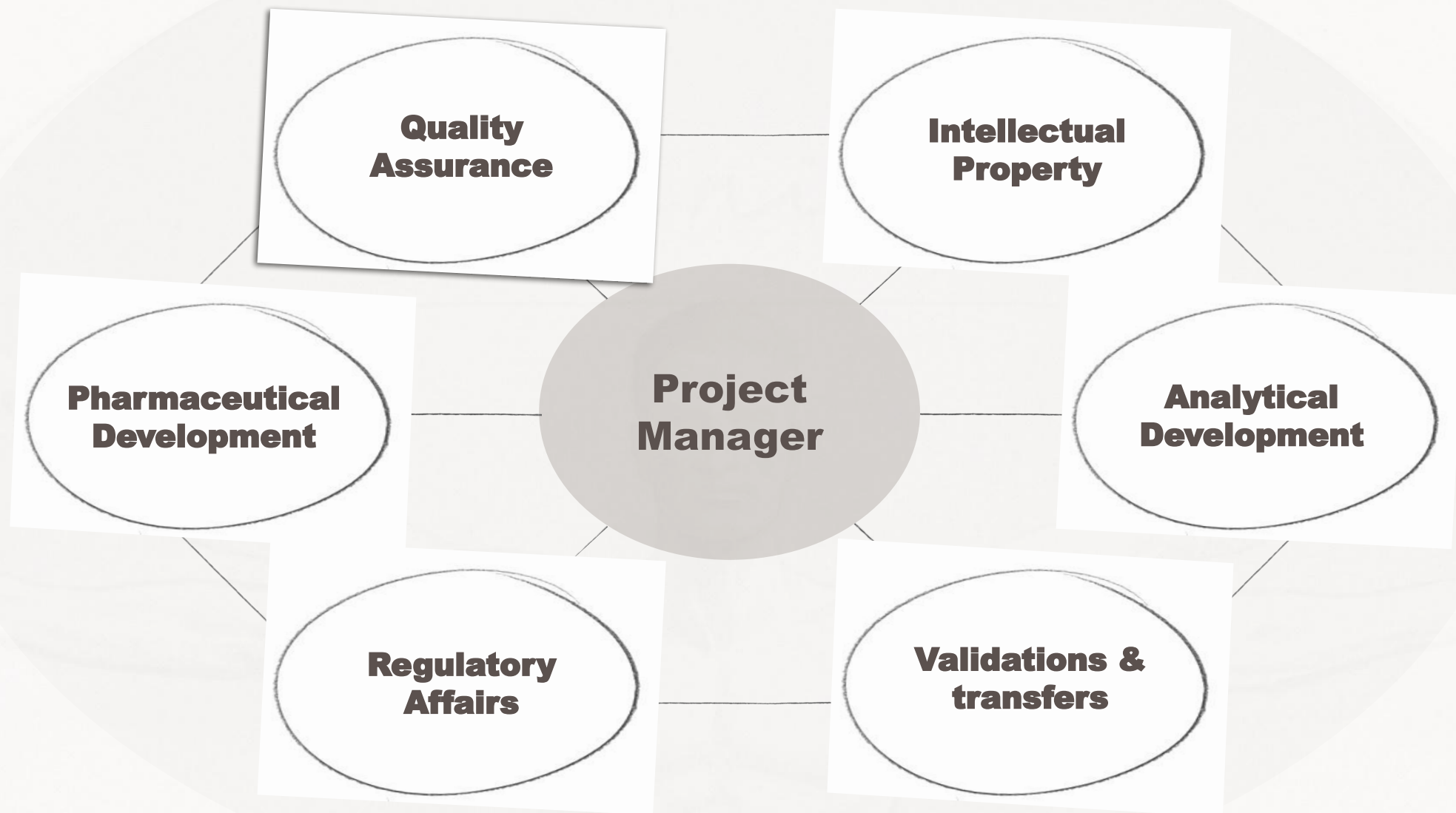
QUALITY ASSURANCE

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Galenicum Health - March 9th 2022

HOW DO WE DEVELOP A NEW PRODUCT?



QUALITY ASSURANCE

Objective is to
prevent **mistakes** and defects
in **manufactured** products
and avoiding **problems** when **delivered** products

According regulations
GMP

Manufacture Good products

Patient Safety and Efficacy

From Factory to Patients, all shelf life

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
Scientific communication with regulatory agencies
Quality systems

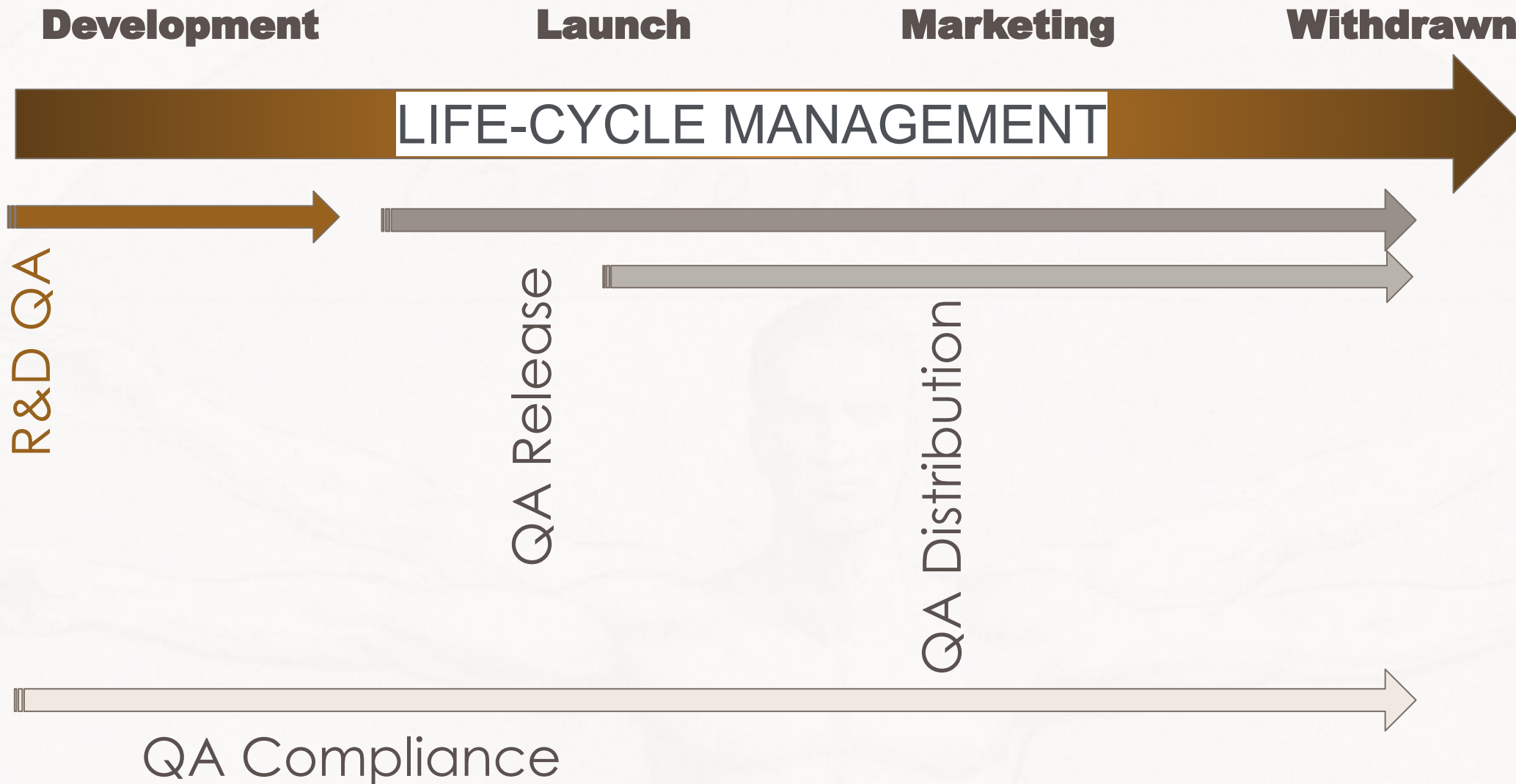


QA officer roles

- 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



Your Profile



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

THANK YOU



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believe in life
Galenicum