

HOW TO ASSURE QUALITY WHEN ENGAGING IN EXTERNAL PARTNERSHIPS

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Dermatology
beyond the skin

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Agenda

Quality Perspective

- Introduction
- Complexity of Supply Chain
- Contracts
- Responsibilities
- Onboarding of a new CMO
- CMO Governance
- Quality Level



Cost Perspective

- Outsourcing of activities
- Choosing the right CMO
- From the CMOs perspective



Quality Perspective

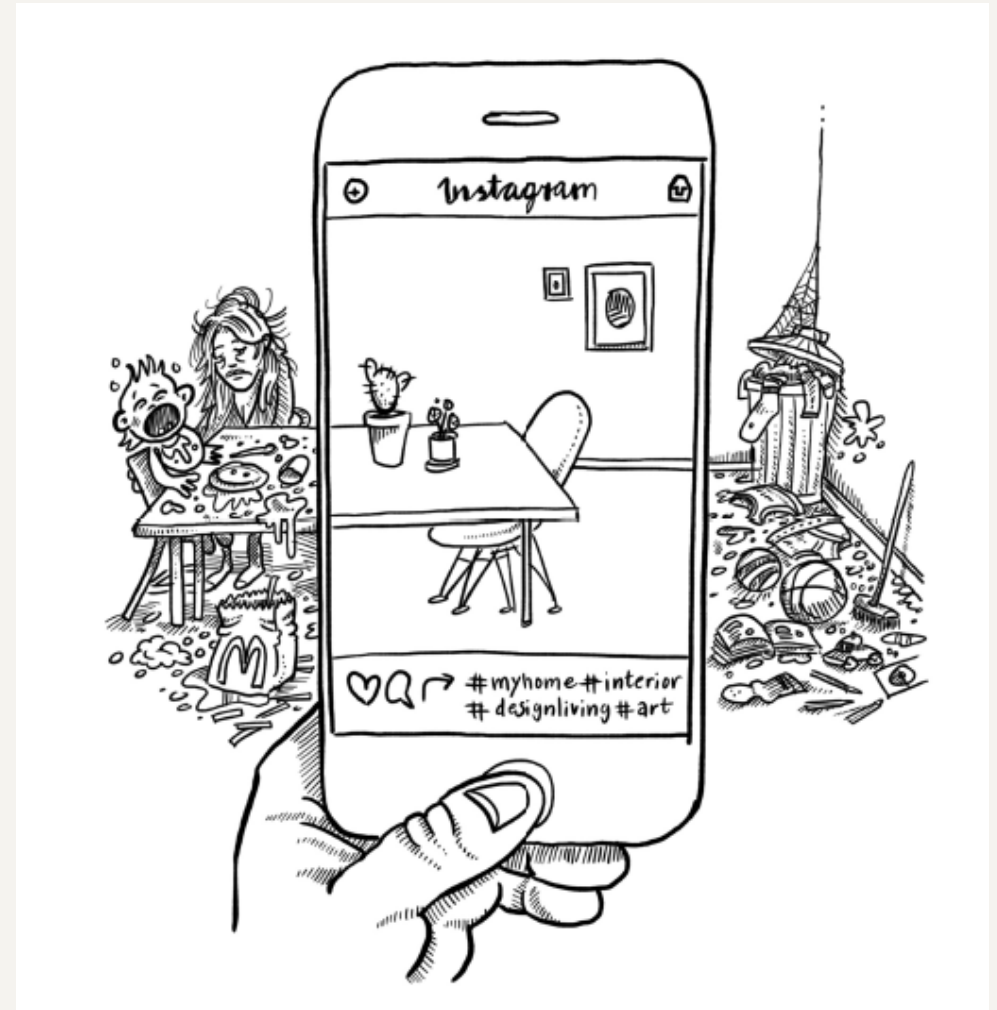
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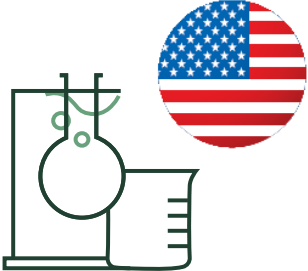
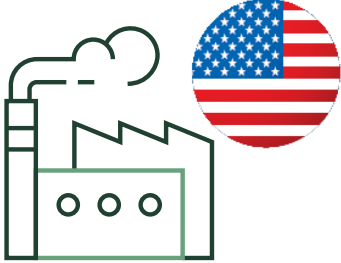


Do Not Expect the CMO will share Everything with you



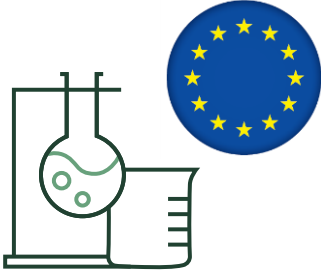
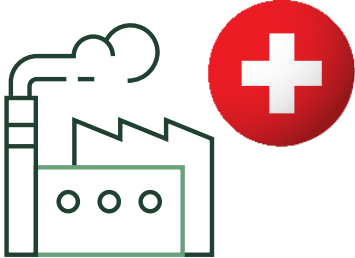
Complexity of Supply Chains

Drug Substance

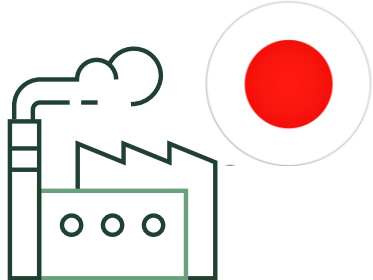
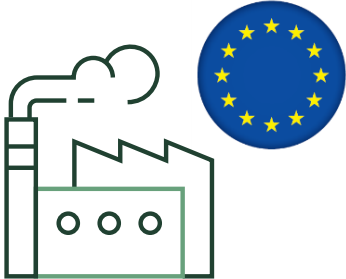


QC Testing

Drug Product



Packaging



Contracts

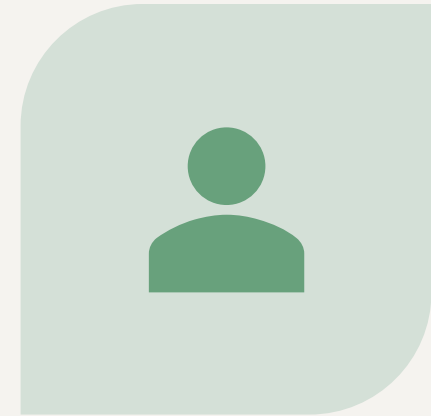
Between CMO and Marketing Authorization Holder, MAH



THE CONTRACTS ARE THE
FOUNDATION OF THE
COLLABORATION



QUALITY AGREEMENT
(GMP)



MASTER SERVICE AGREEMENT
(BUSINESS)

MAH vs QP Responsibility

01

The MAH has the ultimate responsibility for the process and the product

02

QP Certification can be outsourced to the CMO → GMP and regulatory responsibility

03

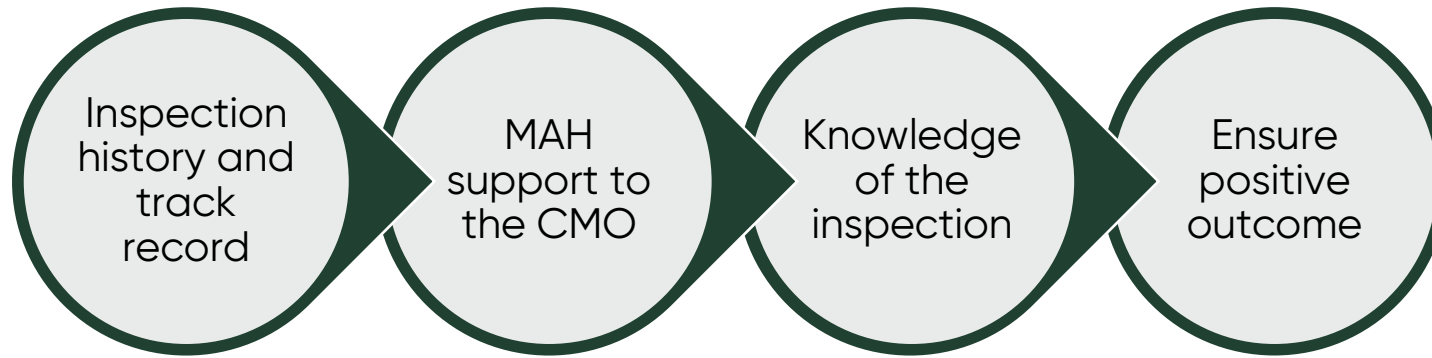
Describe the responsibilities in your contract

04

As MAH you **cannot** outsource your responsibility for product quality and safety

Inspections and Audits

Inspection by Health Authorities



Audits Schedule by MAH



Onboarding of a new CMO



Evaluation of a new CMO

- CMO's inspection history
- CMO's quality management system
- MAH should perform a due diligence audit
- Experience with manufacturing technology



Cost for tech transfer and PPQ

- Manufacturing lines are fit for purpose
- Qualification and validation protocols and reports
- Failed PPQ is very expensive and time consuming

CMO Governance

Ensure timely risk mitigation

Establish a meeting structure

Quality Meeting Review &
Business Review Meeting

KPI Review

Person in plant

Yearly CMO re-evaluation

PQR

Audit program incl. For Cause
Audit

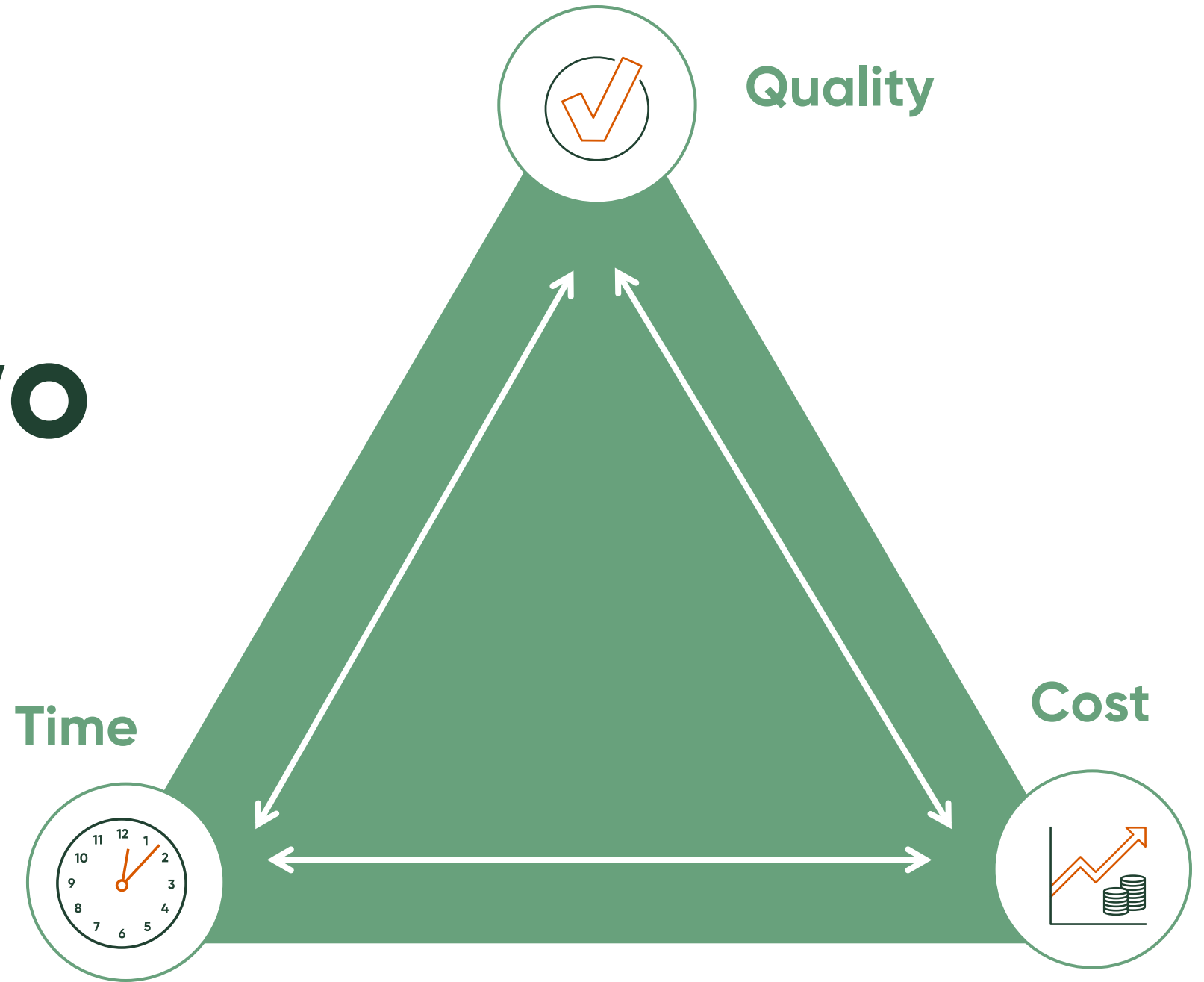


Level of Quality – a Joint Responsibility

Ensures a good partnership



Pick two



Cost Perspective

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Outsourcing is not an Easy Fix

Points to consider



Process understanding and oversight



Resource demanding



Workload



Complexity of supply chain



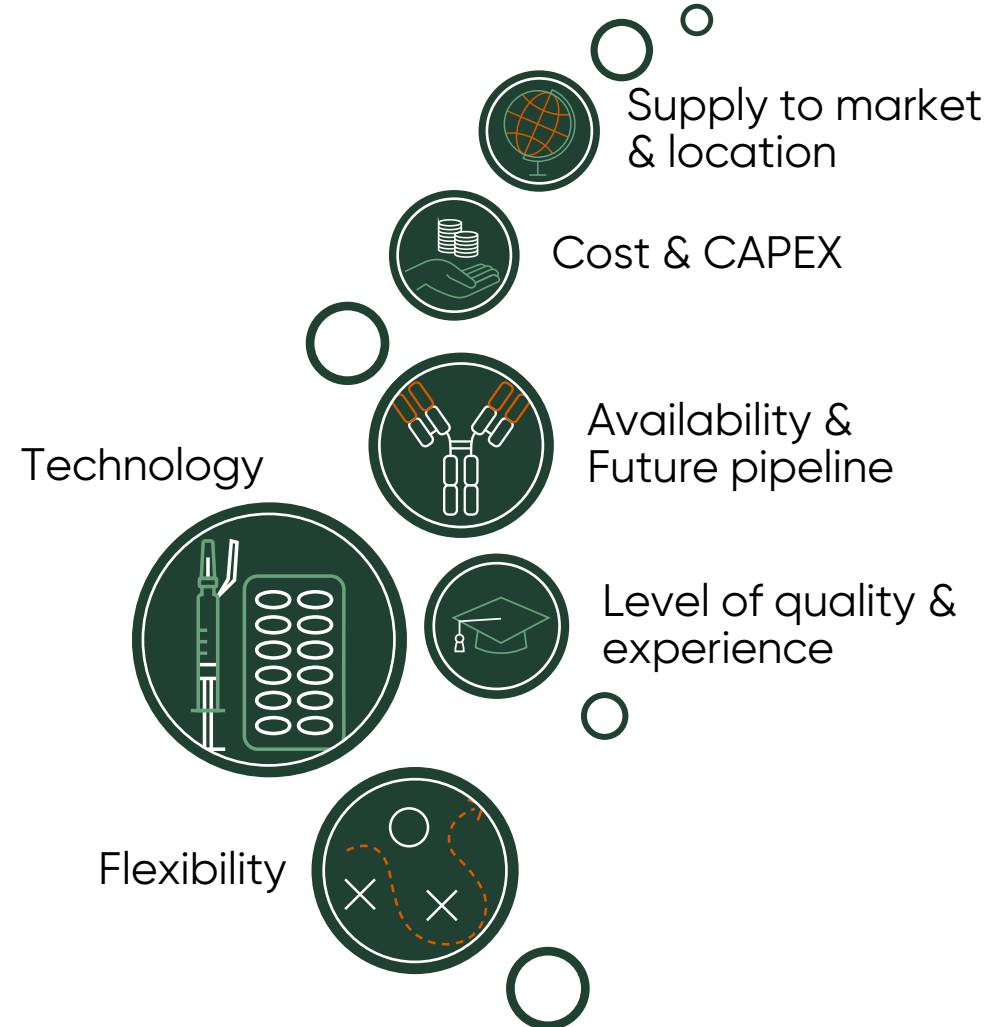
Fixed production schedules



Decreased agility and flexibility

Choosing the Right CMO

Ensure clear selection criteria



Complexity of Supply Chain

Pros and Cons with externally manufactured products and dual sourcing



Pros

- Risk mitigation
- Capacity
- Technology platforms
- Avoid investments
- Support your pipeline



Cons

- Cost of several suppliers with small volumes
- Quality oversight of suppliers
- Increased complexity = Increased lead times
- Less flexible, fixed forecasts, standard delivery timelines

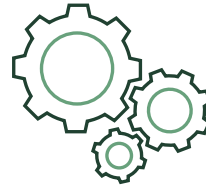
From the CMO's Perspective

All costumers cannot get a tailored solution



CMOs have many clients

Increased complexity
Reduced customization
Use the CMO's standard setup



Rely on the CMO's QMS

Change to standard ways of working will be expensive.



A good CMO can say no

Knowing your own limitations will ensure a robust process and organization

Take Home Messages



- Ensure written agreements are in place for the activities performed
- Continuously monitor the collaboration in order to perform mitigations in due time
- It is expensive not be in compliance

Questions?

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THANK YOU!

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