



Outsourcing, Technology Transfer & CMO-Client Relationships

Introduction

*Contract Manufacturing / Outsourcing
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Your team today



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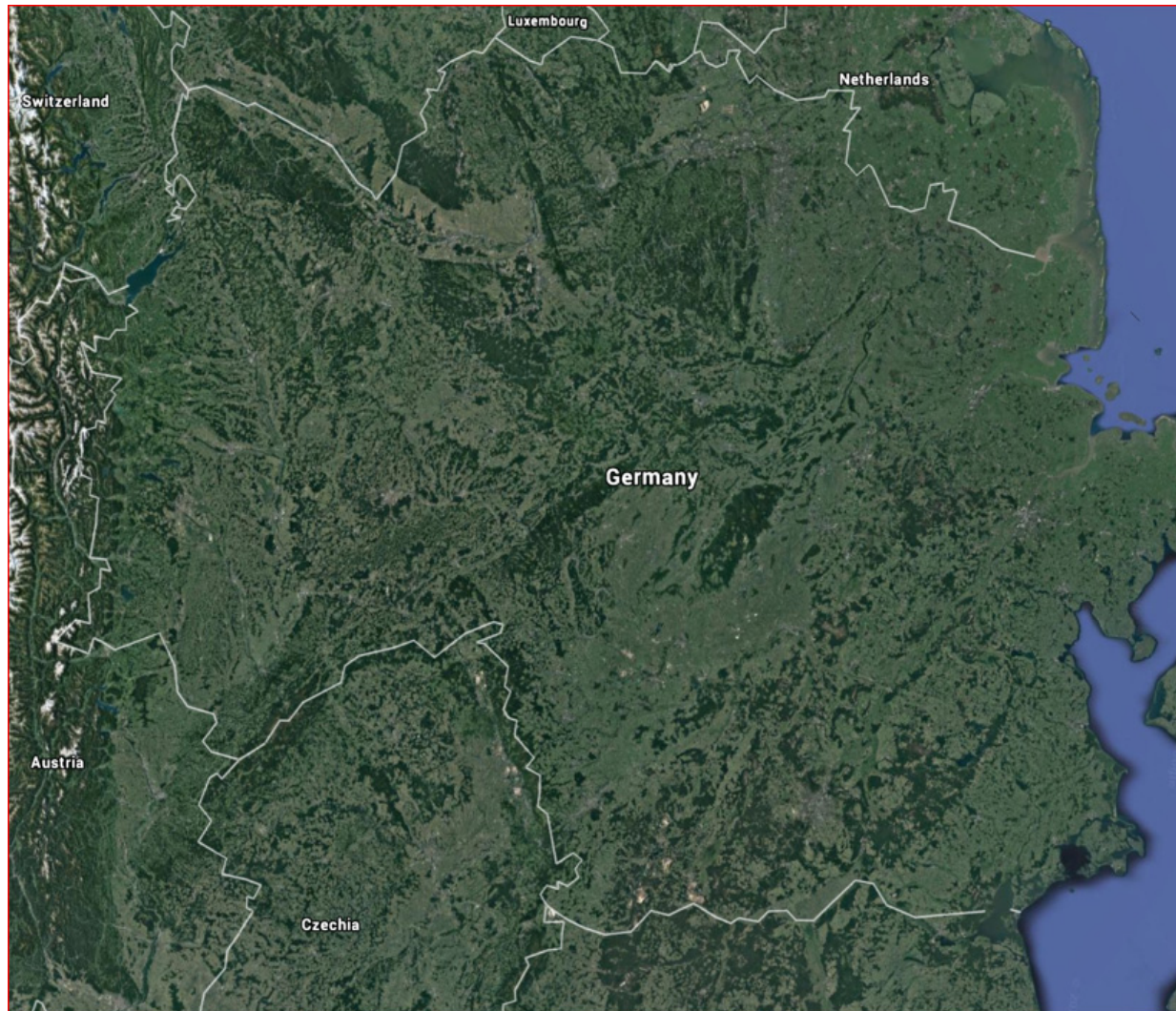
Take Home Message

Outsourcing is a resource demanding activity for both the contract giver and the CMO

A well-structured approach and thorough planning and efficient communication are key for successful outsourcing

Outsourcing should be based on a partnership approach, with a focus on open and honest exchange of information, and a profound will to collaborate and find solutions

No CMO or Client is perfect, but a structured and collaborative approach will make a successful project









Expectations for a Project

- Make a safe product that meets medical needs
- Bring the product forward as fast as possible
- Manufacture product that can be sold /used for clinical trials – generate revenue to the project owner
- Develop a robust process that works every time
- No deviations
- Meet high quality standards in all aspects of the manufacture and release process
- Make a process that regulators can easily approve
- Meet agreed timelines
- Low Cost of Goods

SUCCESSFUL PROJECT



Customer expectations from a CMO

- Tox and/or GMP material within a few months from project start – aggressive timelines
- CMO takes liability for successful project execution
- Timely delivery
- Contractual binding slot bookings
- Flexibility in meeting project changes
- Low and transparent prices
- Meeting budget
- Experienced partner providing knowhow
- High level of compliance

**WE SIGN
YOU DELIVER**



- Realistic timelines
- Include at least one Engineering batch
- Thorough tech transfer
- Adequate development and scale up program
- Customer acknowledges project ownership and responsibility
- Target protein characteristics
- Specification and targets
- No (minimal) last minute process changes
- Freedom to operate
- Mutual decision making

**COMMITMENT
ACTIVE PARTICIPATION**



Dating



Wedding



Marriage



First F2F



Contract



Project execution

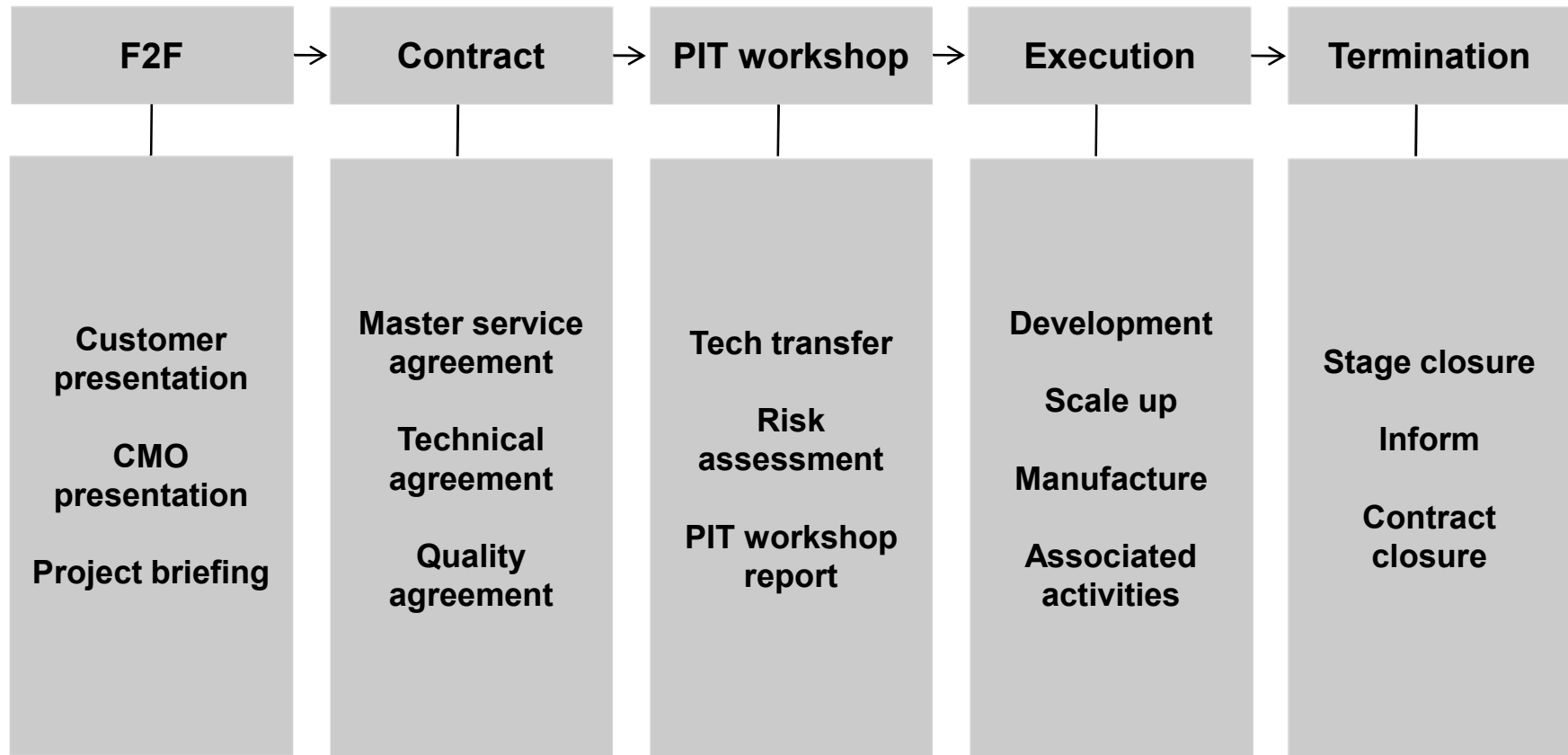


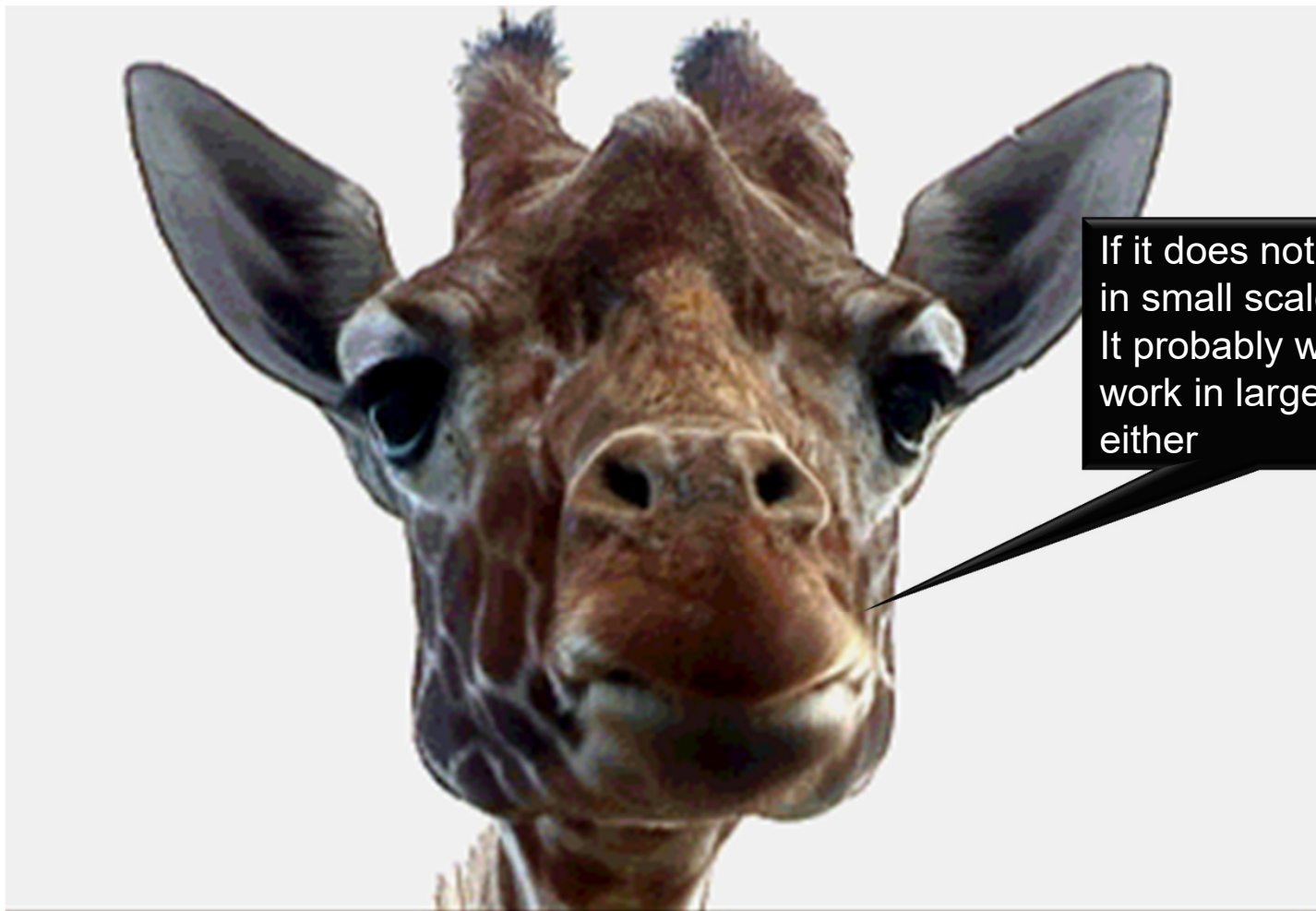
Contract Manufacturing
Arrangements for Drugs:
Quality Agreements
Guidance for Industry

Key message

- The guideline is only FDA's recommendations – but!
- The guideline only covers marketed products – but!
- GMP responsibility cannot be outsourced
- Sponsor are expected to have own quality unit for testing and quality assessment
- Separate quality and commercial/technical agreements
- A structured knowledge transfer plan as well as an detailed communication plan are expected
- Do not describe the format for a Quality Agreement, but should be used as a check list

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Center for Veterinary Medicine (CVM)
November 2016
Pharmaceutical Quality/Manufacturing Standards (CGMP)





If it does not work
in small scale!
It probably won't
work in large scale
either

- Lack of communication
- Nothing is obvious
- Define assumptions
- Insufficient process development
- Warnings from small scale and technical batches ignored
- Lack of trust
- Decision making not clearly defined
- Late or not well controlled process changes
- Insufficient decision making
- Lack of commitment
- Lack of win – win approach

Failed to
ALIGN EXPECTATIONS



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