



Ensure excellence: Effective  
supplier management in pharma  
outsourcing

Strategies, Challenges and  
Learnings

Lars Stubberud, Dusseldorf, June 5, 2025

# Short introduction

**Lars Stubberud**

VP Technical Operations



- Master of Science (cand. pharm.) and PhD in Pharmaceutical Science from the University of Oslo, Norway.
- Experienced global line manager with >30 years experience from the pharmaceutical Industry. Significant expertise within the broader CMC area, including Formulation Sciences, Product Development, Technology Transfer/Technical Stewardship, Regulatory Affairs- CMC and Quality Assurance, Manufacturing and Supply, as well as Contactor Management.
- Joined Calliditas Therapeutics in 2020, a biopharmaceutical company with a commercially launched product in the nephrology space
- Calliditas Therapeutics was acquired by Asahi Kasei in September 2024, and now is part of the Asahi Kasei family of companies, which includes Veloxis Pharmaceuticals

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# Topics

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**About Calliditas  
Therapeutics AB and its  
journey from a small  
start up to fully  
commercialized  
company**



**Outsourcing**



**Working with  
Partners &  
Suppliers  
(Supplier mgt)**



**Challenges &  
Learnings**



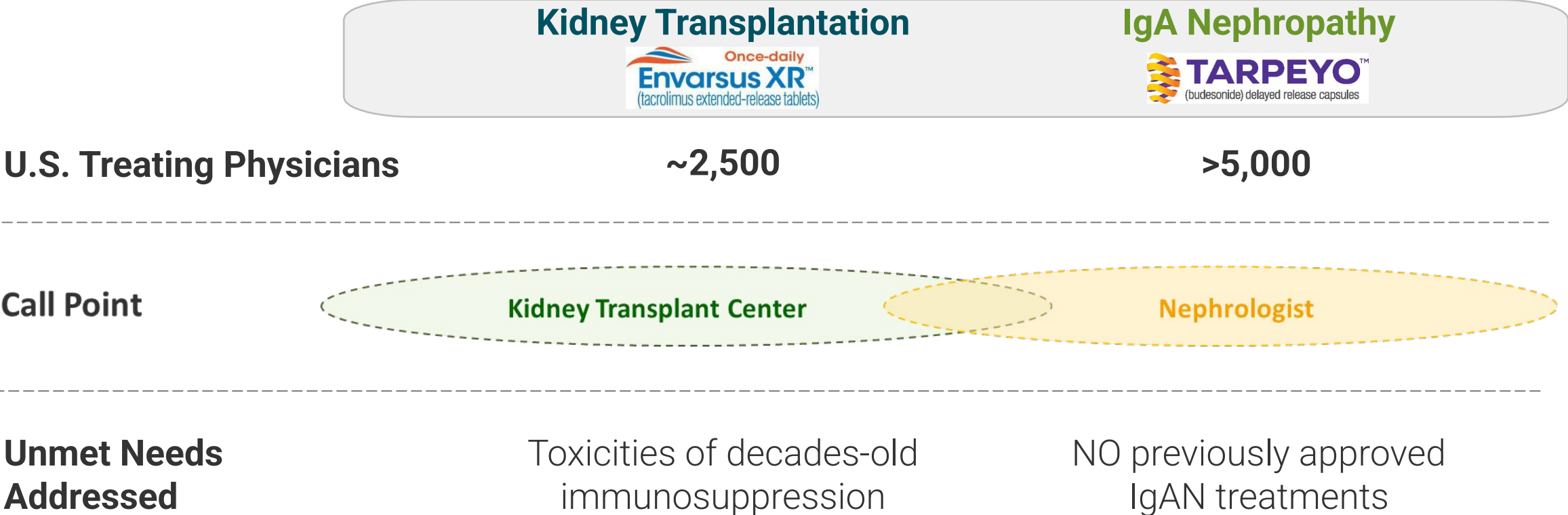
**Q&A**



# Company overview









Acquisition of Calliditas by AsahiKasei

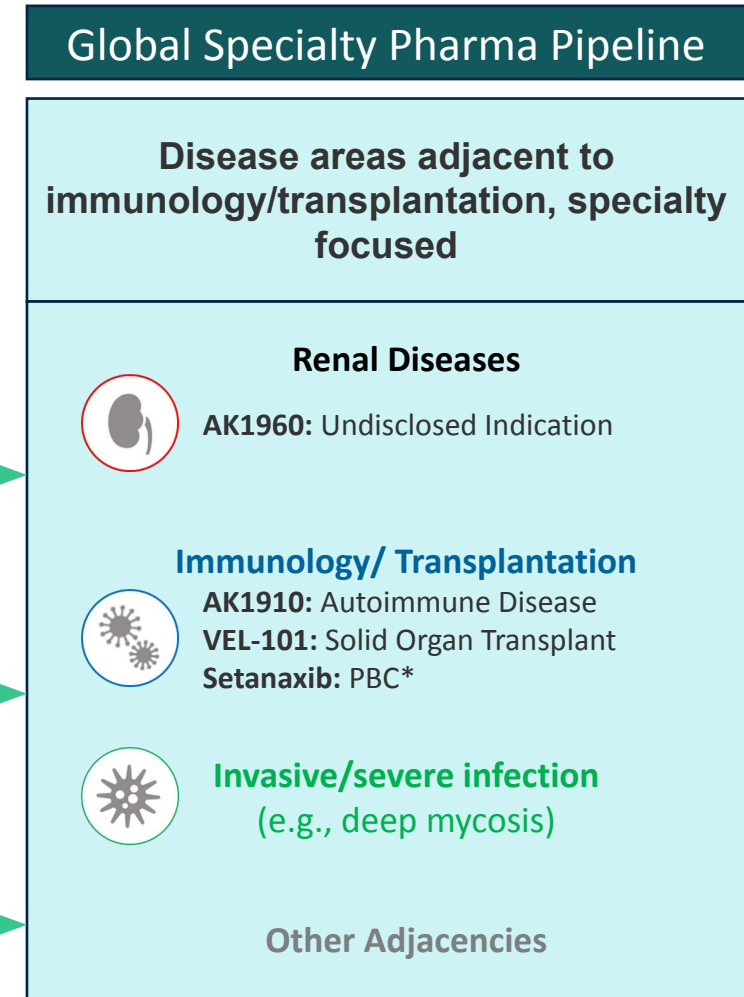
# The combination of Calliditas and Veloxis paves the way for becoming a leading nephrology biotech



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# The combination of Calliditas and Veloxis/Asahi Kasei paves the way for becoming a leading nephrology biotech, and expansion of footprint to deliver innovation globally to patients

Region	Core Disease Areas	Products	
Asahi Kasei			
Japan 	Orthopedics		<ul style="list-style-type: none"> <li>• TERIBONE (Osteoporosis)</li> <li>• RECLAST (Osteoporosis)</li> </ul>
	Critical Care / Hospital Based		<ul style="list-style-type: none"> <li>• CRESEMBA (Aspergillosis, Mucormycosis)</li> <li>• RECOMODULIN (DIC)</li> </ul>
	Immunology		<ul style="list-style-type: none"> <li>• KEVZARA (RA)</li> <li>• PLAQUENIL (CLE &amp; SLE)</li> <li>• BREDININ (Nephrotic Syndrome, LN, RA)</li> </ul>
Veloxis Pharmaceuticals			
U.S. 	Transplantation		<ul style="list-style-type: none"> <li>• ENVARUSUS XR (Prophylaxis of organ rejection)</li> </ul>
Calliditas Therapeutics			
U.S. 	Renal Disease		<ul style="list-style-type: none"> <li>• TARPEYO (IgA Nephropathy)</li> </ul>



\*Also includes Alport Syndrome, IPF, and Solid Tumors

# The history and evolution of Calliditas

Three guys and a dog.  
Engelbrekts kyrkogata 7B



15 guys and a dog.  
Wallingatan 22B



160 guys and a dog.  
World Trade Center Stockholm  
+ several other locations



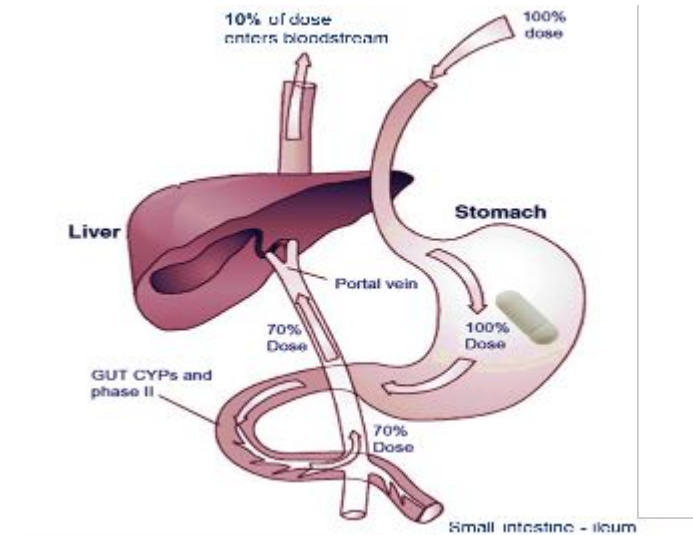
Lilly – the V.I.P. dog



# Nefecon – the product, designed to target the presumed origin of the disease

## Drug product based on known active ingredient

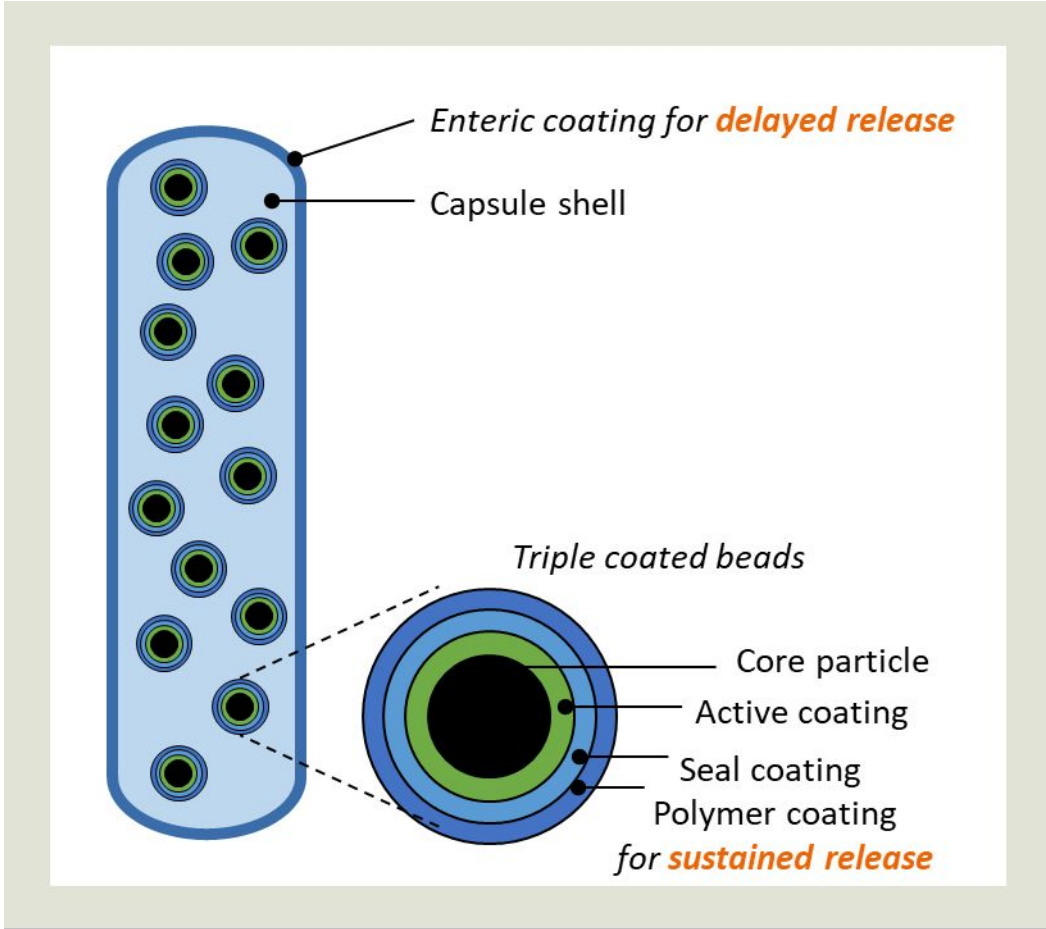
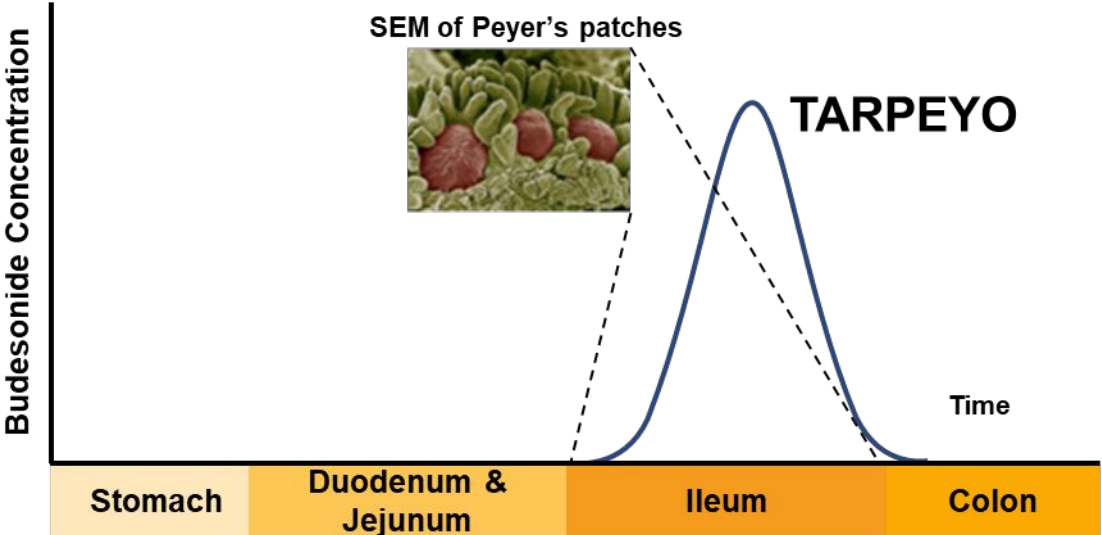
- Active ingredient is budesonide – a highly potent, topical, **locally acting immunomodulator**
- **90% cleared in first pass metabolism** by liver, with the view of minimizing systemic side effects
- No clinically relevant adverse effects on metabolic or cardiovascular system. No prophylaxis needed. Predominantly mild to moderate AEs, reversible upon discontinuation



# Nefecon – the product, designed to target the presumed origin of the disease

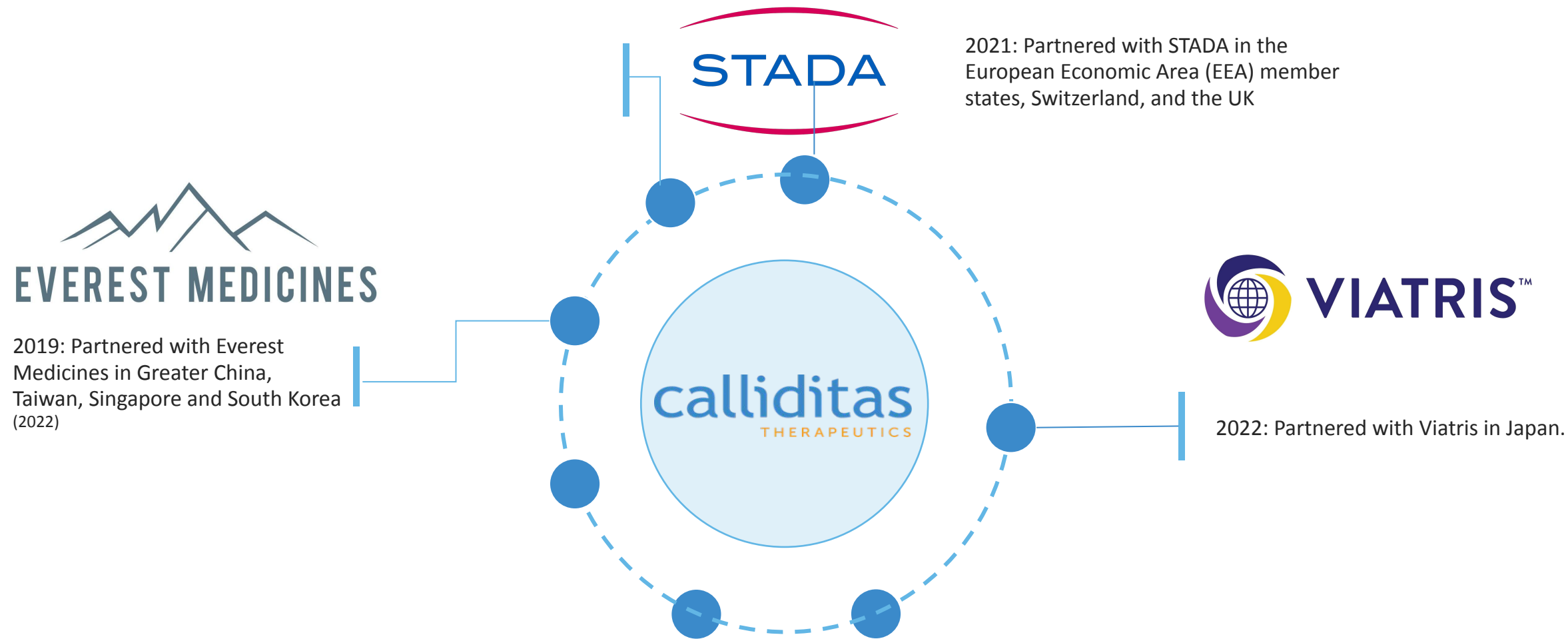
## Novel targeted release profile

- Designed to deliver a targeted and highly potent dose directly to **Peyer's patches in the ileum**
- Differentiated release profile
  - pH-governed delayed disintegration of the capsule until it reaches the ileum
  - Potent, sustained exposure throughout the ileum



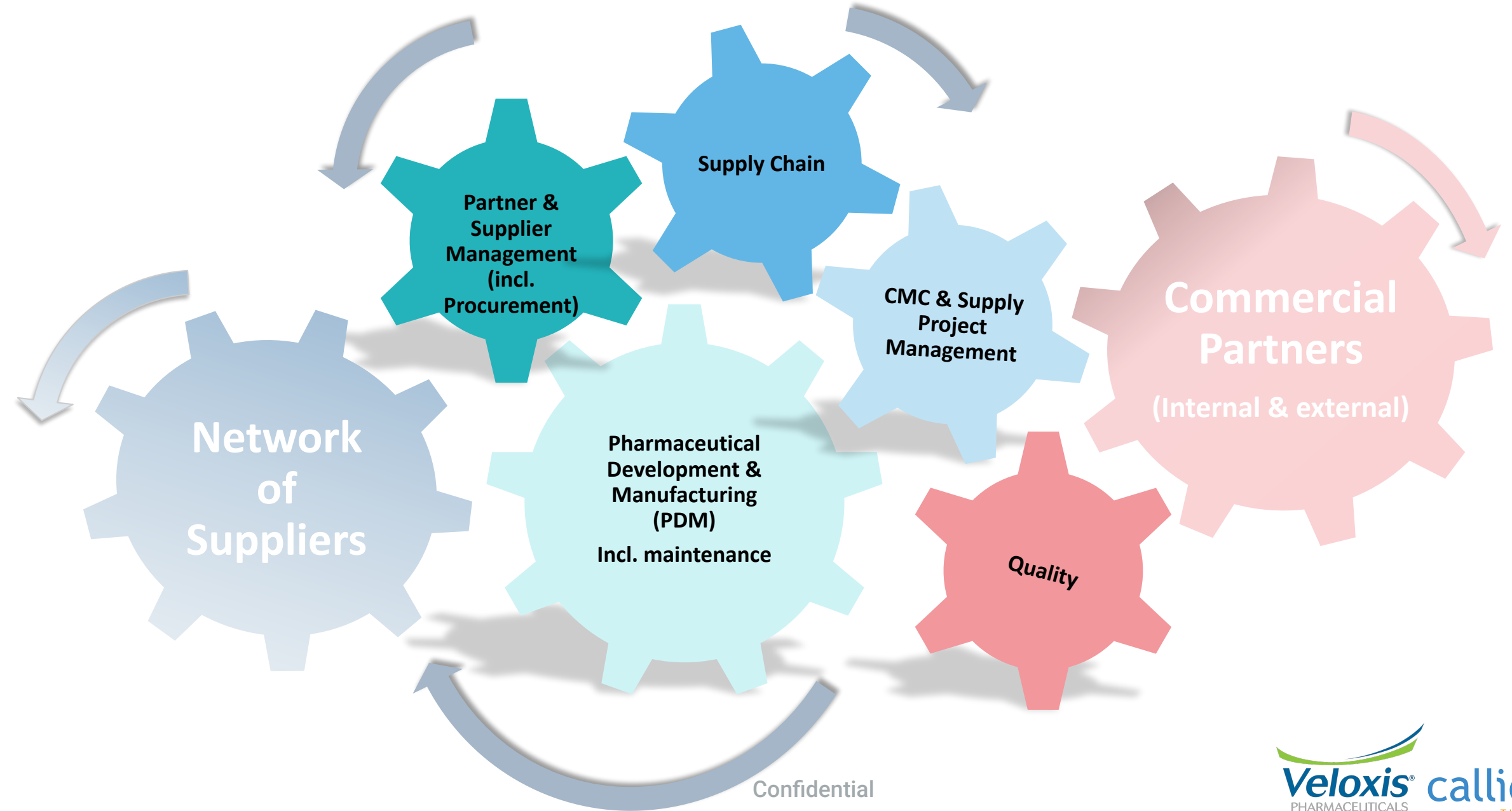
# Commercial Partnerships

## Effective partner/supplier management is one of the key factors to success



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# The virtual world of Technical Operations



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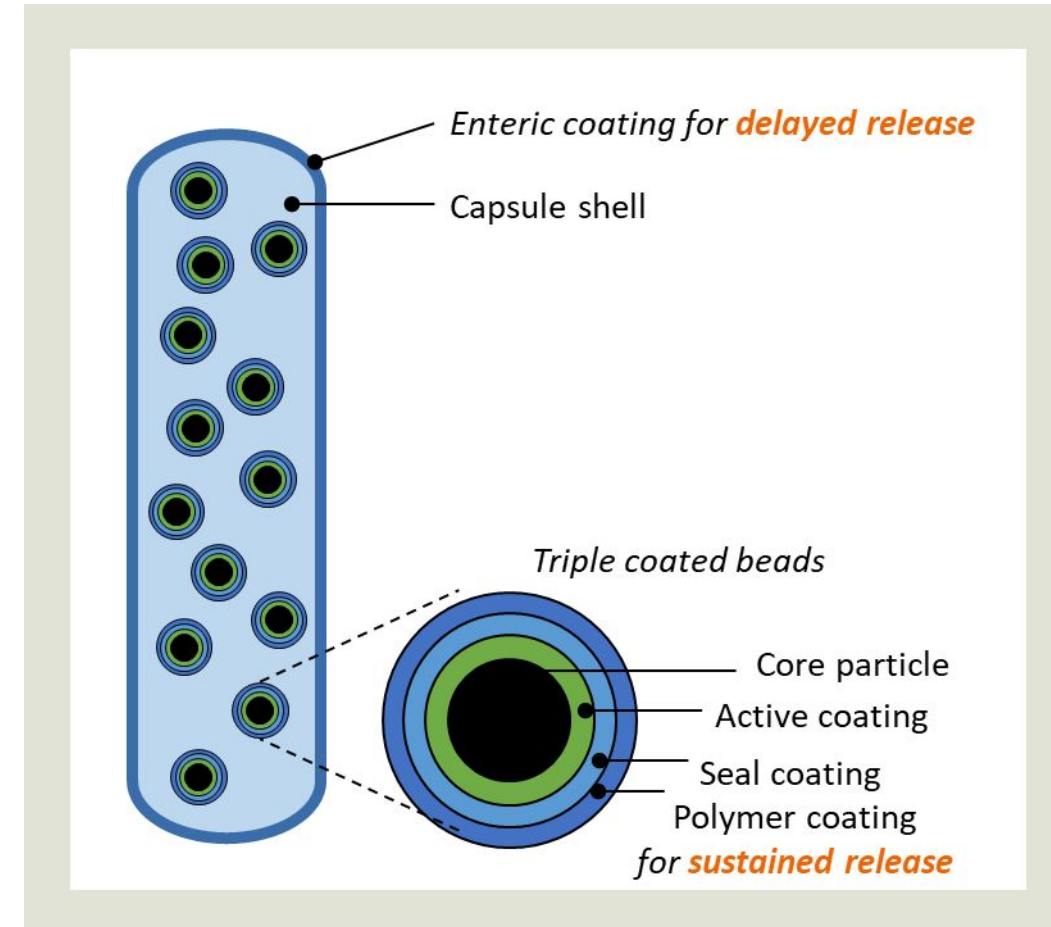


# Outsourcing

# The importance of the right supplier!

## Development, IMP, Validation, Manufacturing, Supply

- Technically advanced manufacturing
- Unique process
- Limited number of suppliers with right technology
- BioTech and small start-ups – traps!
- CAPEX
- The one you chose from start vs. the cost and time of a change
- The "strategic fit"

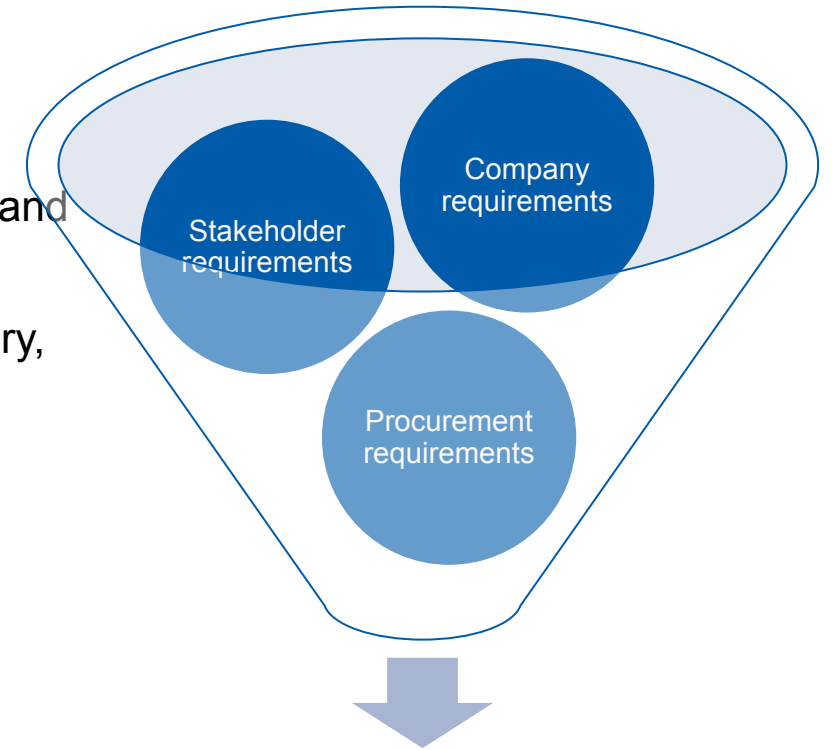


Introduction of “The SPET” – an evaluation tool for Supplier selection, development and management

# From a holistic company view to a business case for management decision

## Supplier Performance Evaluation Tool - The "SPET"

- Neutral evaluation with focus on your company's best business interest, The criteria should be based upon requirements from the following key areas and stakeholders;
  - Company specific requirements: e.g. Code of Conduct, Ethics, Anti-bribery, Environmental requirements
  - Quality & Regulatory.: e.g. GxP, Market specific requirements
  - Technical Operations: e.g. capability, competence and equipment
  - Procurement: e.g. financial position, quality of cooperation, COGS & TCO



## Key Criteria

The criteria should be a supportive part of the Procurement Management Process. This includes the RFx, the negotiation, the evaluation, selection and the contract. Each criteria should have a clearly stated definition. The definition could vary between different types of Procurements.

# Standardized criteria of Supplier Evaluation - examples

## Company criteria

- ▶ Code of conduct
- ▶ Environmental systems & efforts
- ▶ Global or local presence

## Procurement Criteria

- ▶ Financial Position
- ▶ Total cost
- ▶ Share of business revenue
- ▶ Management attention
- ▶ Quality of cooperation

## Stakeholder Criteria

- ▶ Requirement Specification or Scope
- ▶ Supplier competency
- ▶ Technological competitive position
- ▶ Capacity flexibility
- ▶ Lead time
- ▶ Supply accuracy
- ▶ Quality of Performance
- ▶ Communication and interface
- ▶ Regulatory impacts

## Stakeholders:

Technical development/PDM, Quality, Supply Chain, Regulatory and others depending on the Scope

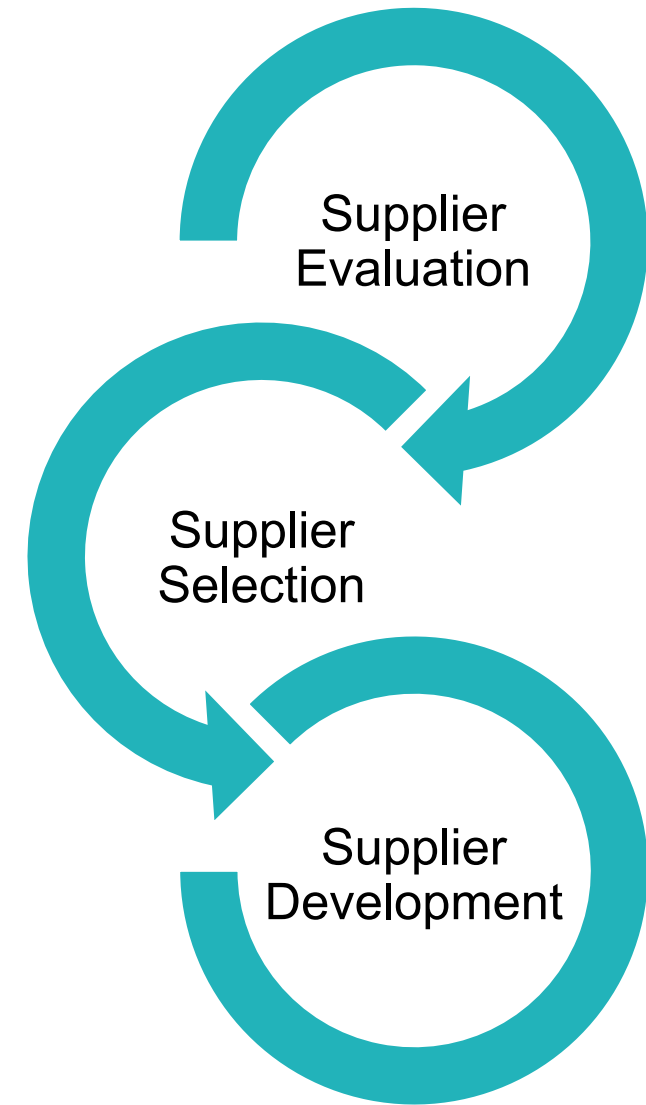
A joint evaluation committee as a evaluation body, and to focus and agree upon:  
 - Best fit for purpose supplier

**Jointly align on the recommendation to be summarized in a Business Case for Management decision**

# The SPET

## When to use the tool

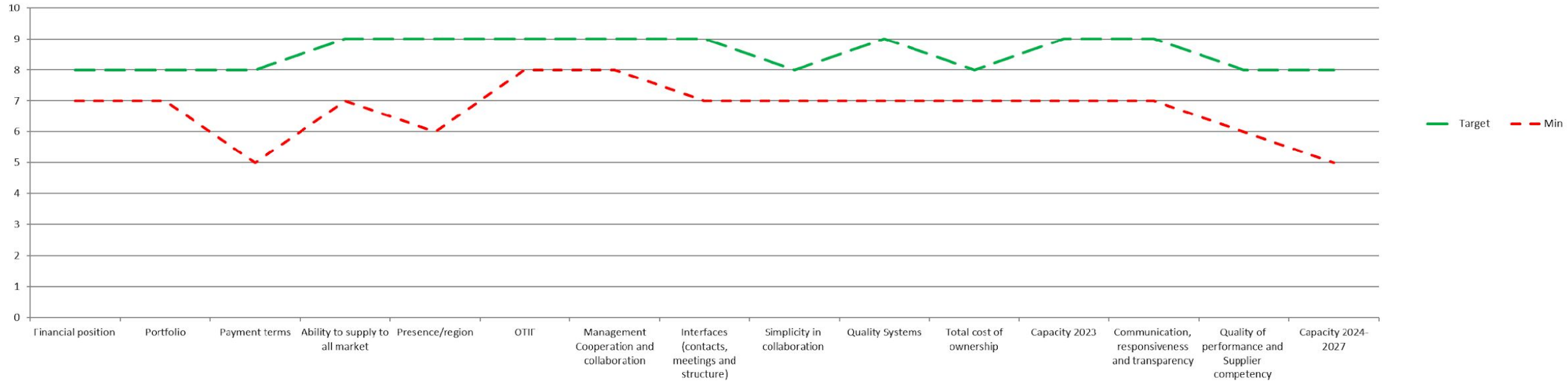
- Supplier Evaluation and Selection process
  - During preparation and planning for outsourcing
    - Identify right CDMO for development, manufacturing and/or supply
  - For RFI/RFP preparation and submission
  - For proposal evaluation
    - To be evaluated by an Evaluation Committee with stakeholders
  - During negotiation
  - Supplier recommendations and business case summary
- For continuous Supplier follow-up and development
  - Business Review Meetings
  - Specific project reviews



# The SPET

The tool visualize and identifies the Supplier profile and gaps

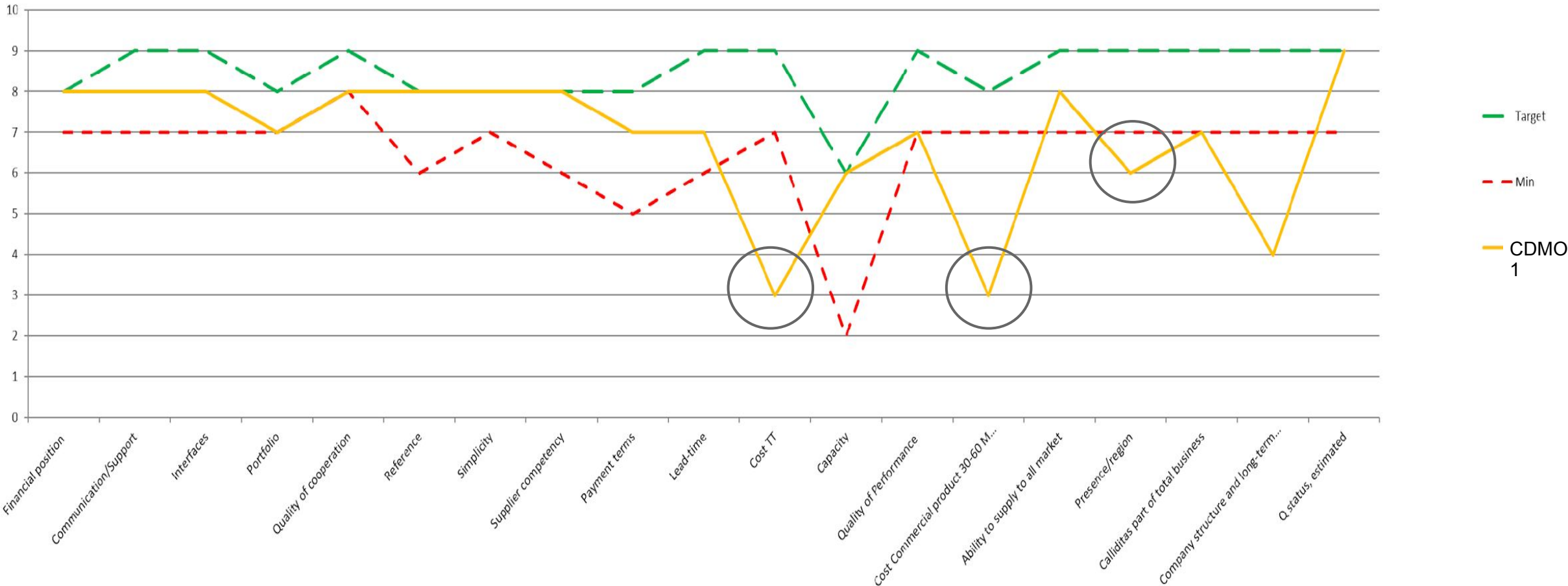
- Defined minimum and target levels
- Visualizes the strengths and weaknesses of the supplier
- The supplier's actual profile and gaps will be evaluated
- Easy to add suppliers for comparisons



# SPET evaluation of manufacturer

**Gaps**  
- Identified gaps to be highlighted and mitigated if needed

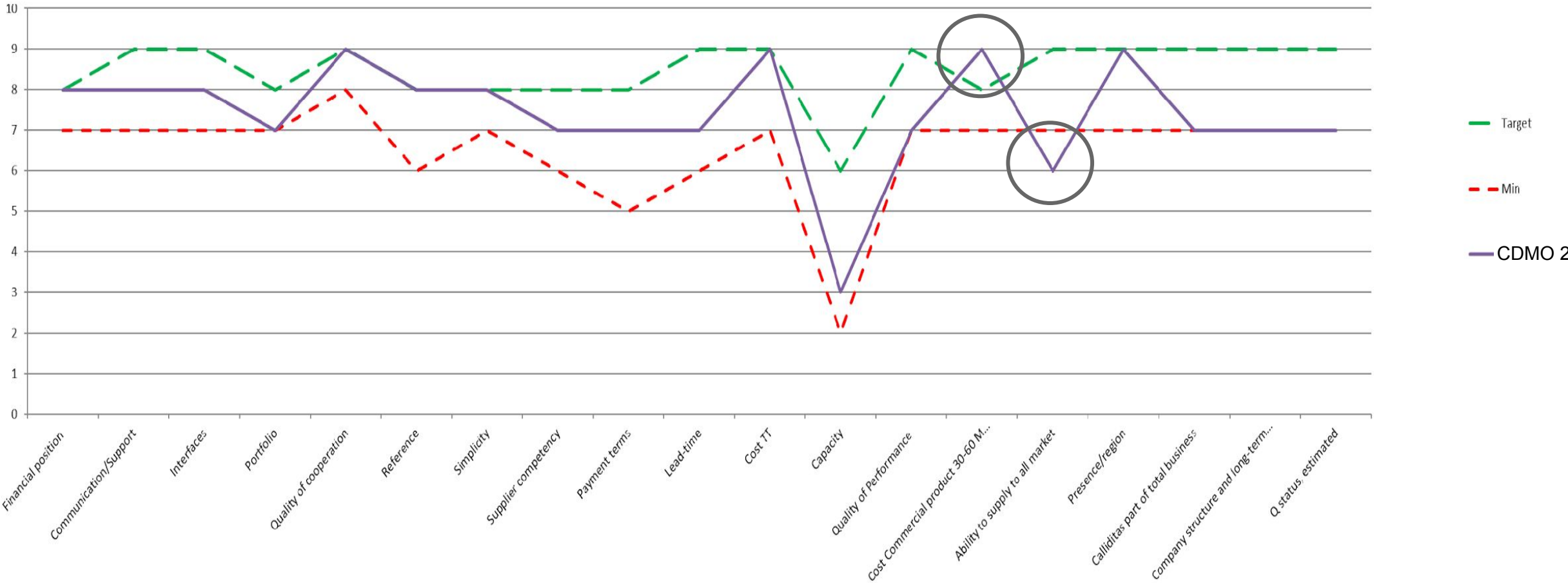
CDMO 1



# SPET evaluation of manufacturer

**Gaps**  
- Identified gaps to be highlighted and mitigated if needed  
+ Gaps could be positive

CDMO 2

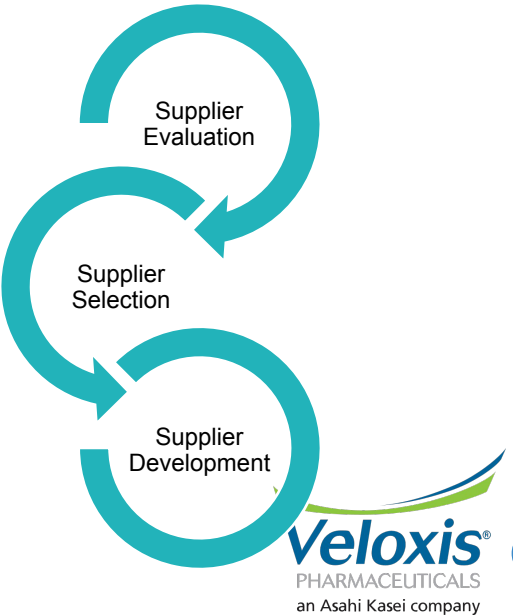
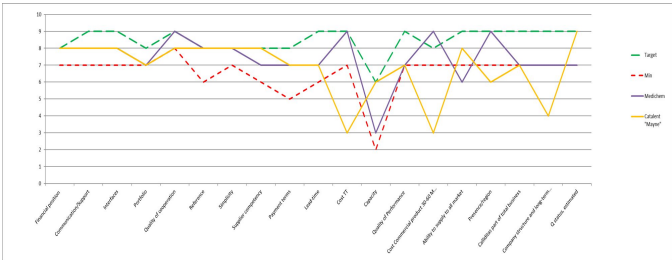
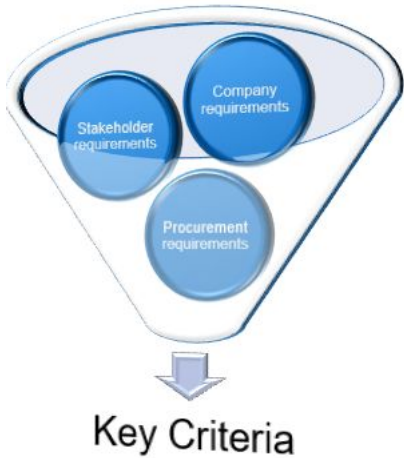


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# SPET

## Summary

- The purpose
  - Align with company requirements
  - Objective & Strategic supplier selection
  - Identifying and driving improvements
  - Supplier performance assessments
  - Visualizing the supplier's evaluation, performance & gaps
- When to use the tool
  - During Procurement preparation and planning
  - For RPI/RFP preparation and submission
  - For RFI/RFP evaluation and supplier recommendations
  - For negotiation and supplier selections and business case summaries
  - **For supplier development and management**
- Other fields of application
  - Suits all kind of procurement scopes and supplier development projects



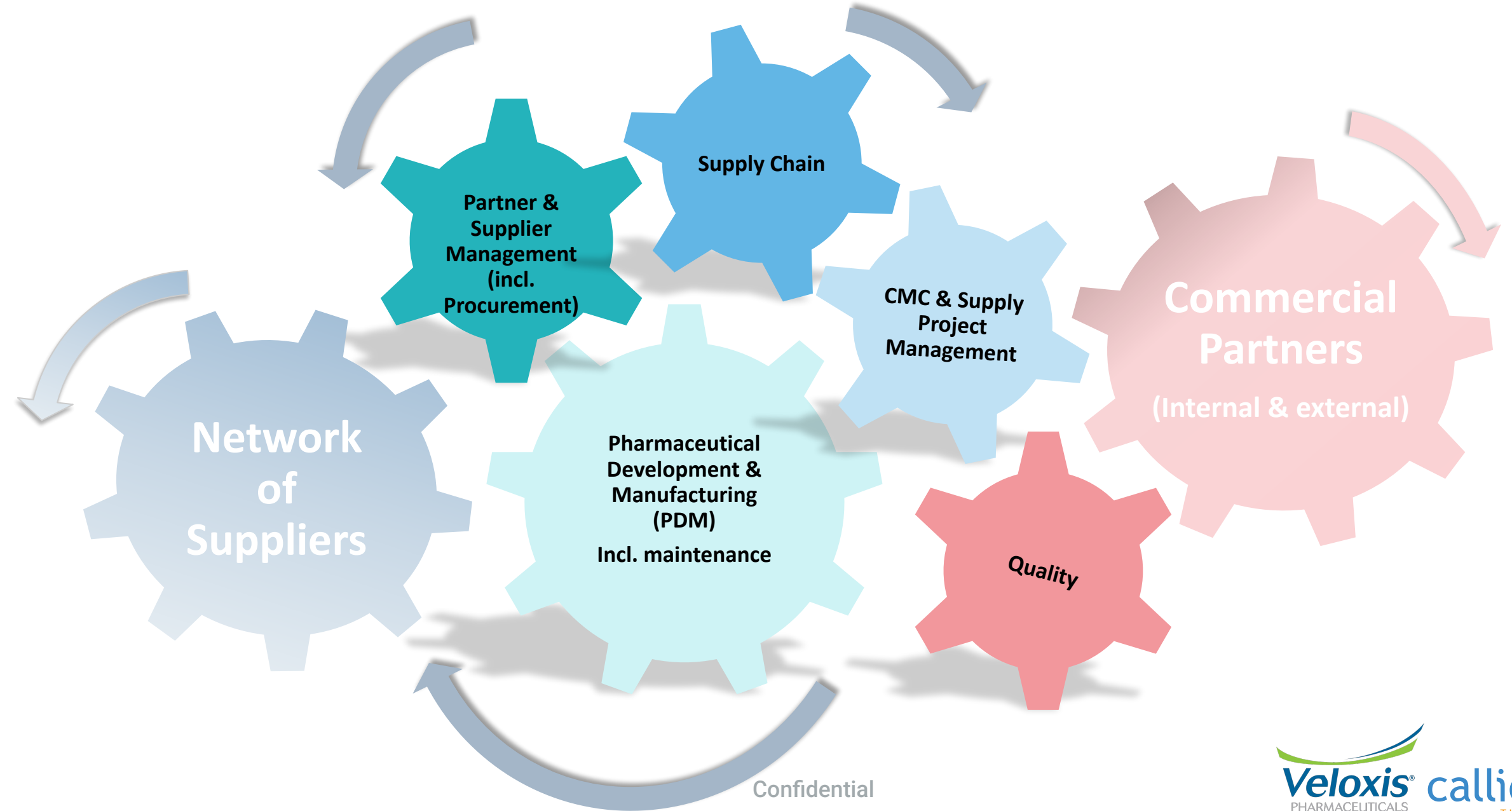


**calliditas**  
THERAPEUTICS

The logo for Calliditas Therapeutics features the word "calliditas" in a bold, lowercase sans-serif font, with "THERAPEUTICS" in a smaller, all-caps sans-serif font below it.

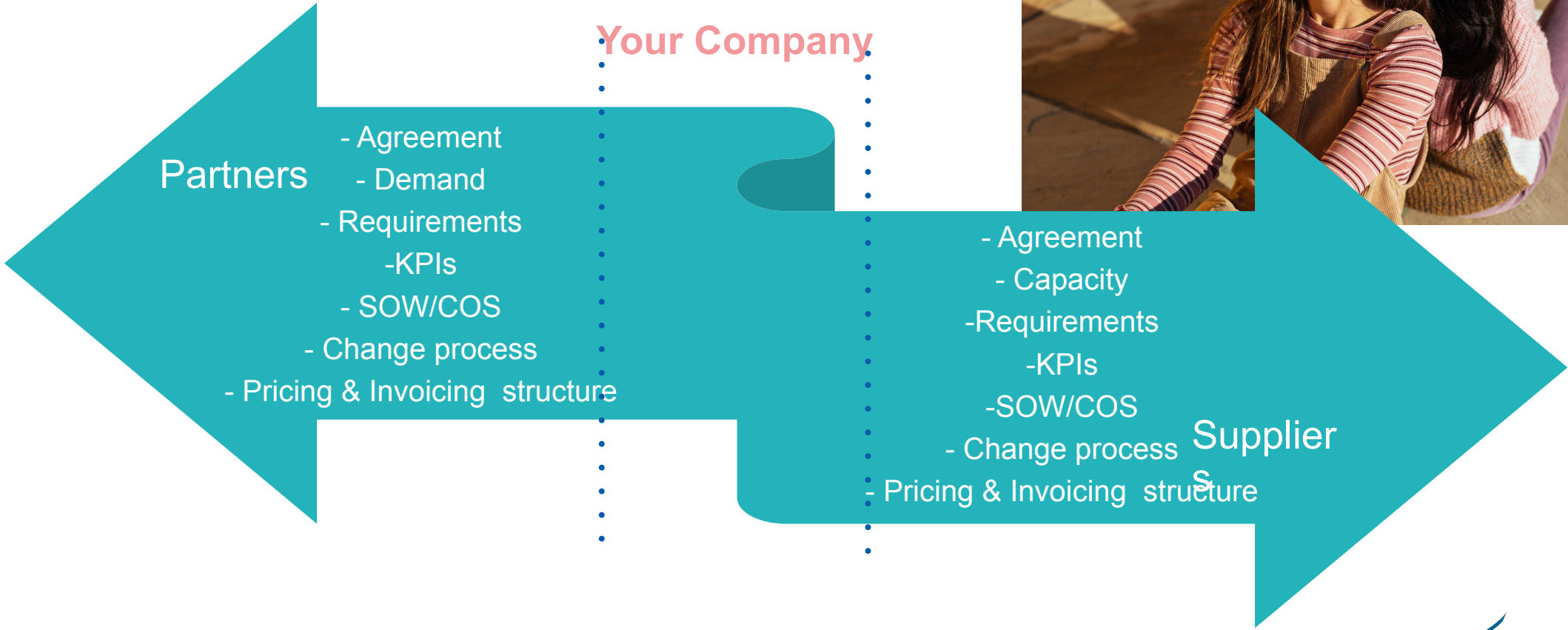
# Working with Partners & Suppliers

# The virtual world of Technical Operations



Effective supplier mgt is about to ensure

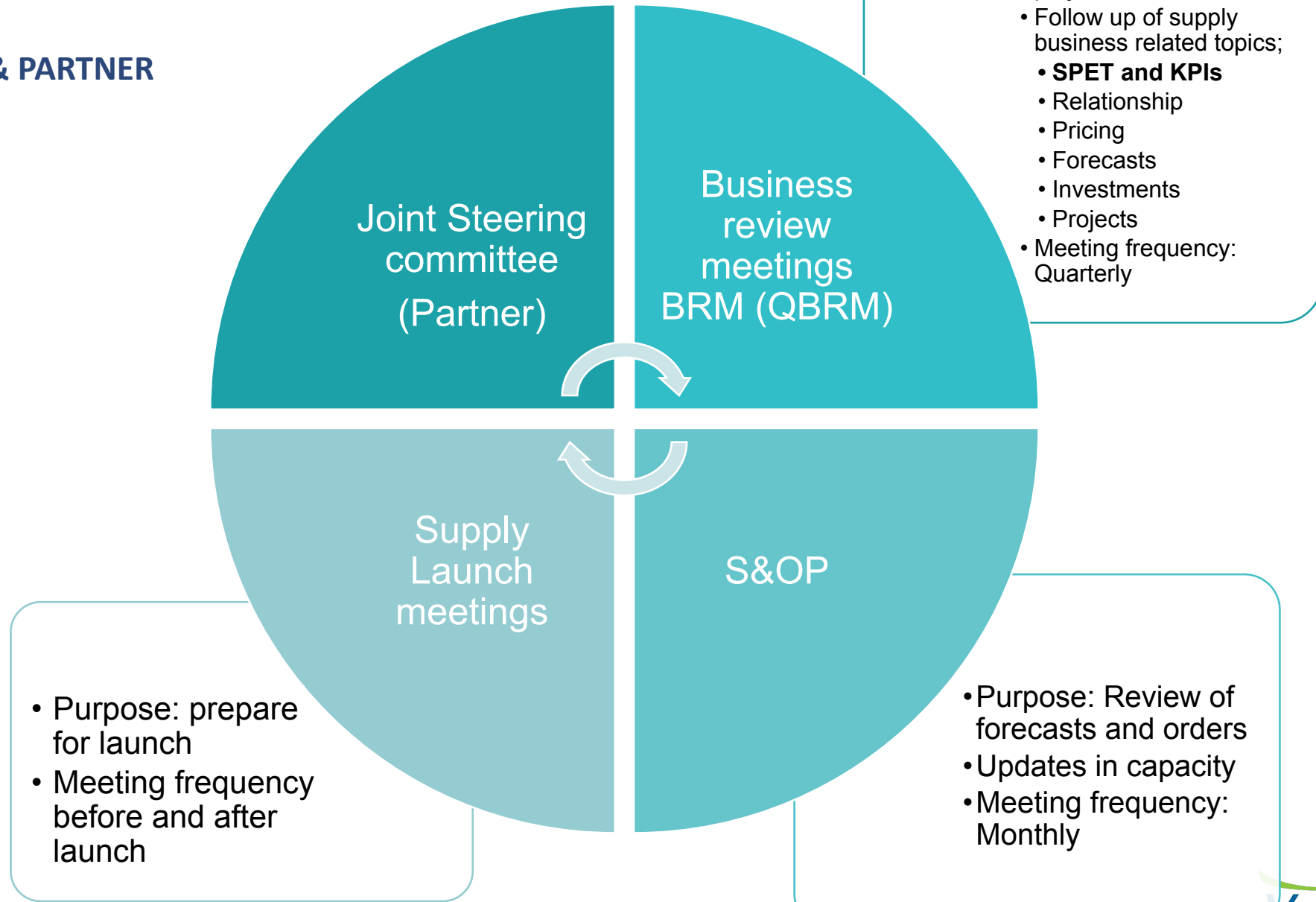
# “Back-to-back” business model and structure



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# Governance Structure

## SUPPLIER & PARTNER



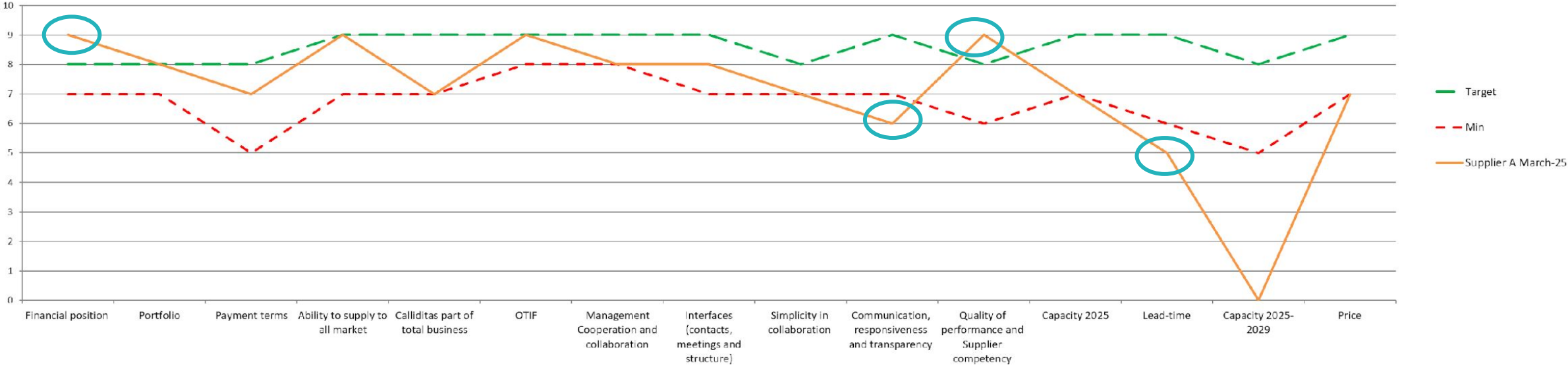
# SPET March. vs. May-25 performance overview (Supplier "A" - real example)

**Identified GAPS:**

- + Financial position
- + Quality of Performance and supplier competency
- Lead time
- Communication, responsiveness and transparency (legal matters)

Negative gaps need an improvement plan

## March -2025



O = not evaluated

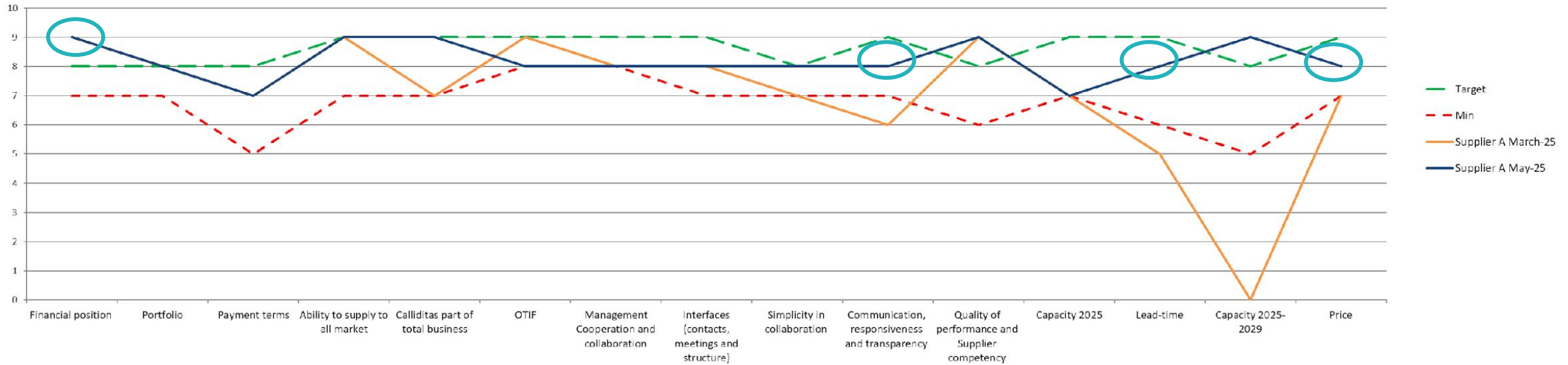
# SPET March. vs. May-25 performance overview (Supplier "A" - real example)

**Identified GAPs:**

- + Financial position
- + Quality of Performance and supplier competency
- + Lead time
- + Communication, responsiveness and transparency

No negative GAP's!

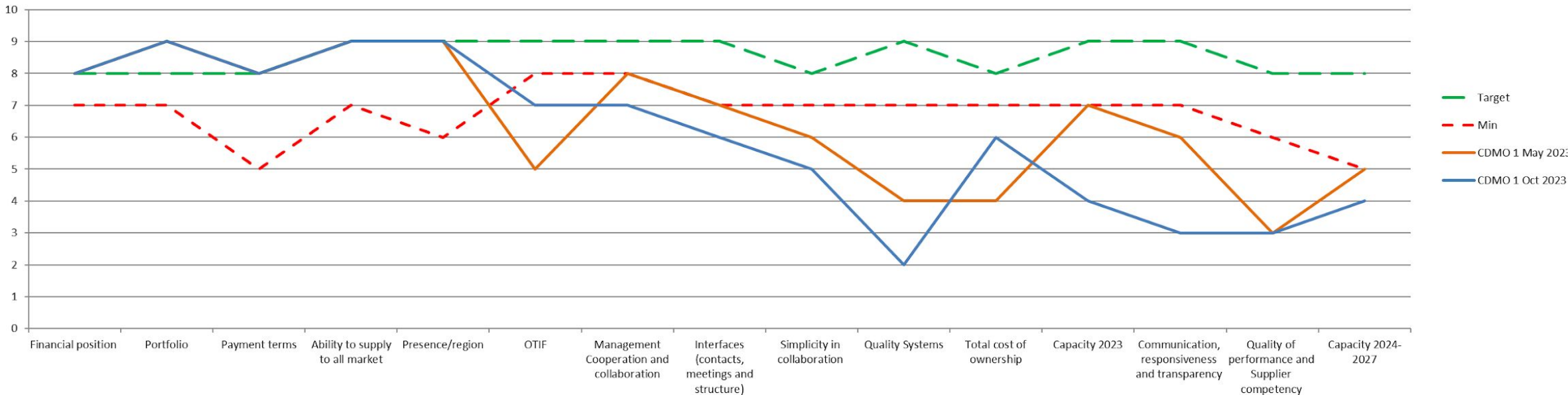
## May -2025



O = not evaluated

# SPET Oct. vs. May-23 performance overview (CDMO “1” - real example)

- Identified GAPS:**
- Gaps to be discussed and plan for mitigation
  - Negative trends identified, evaluated and discussed
  - Positive trends identified and highlighted





# Challenges & Learnings

# Challenges and Learnings

## From a start up from 3 guys and a dog through commercialization and Partner relations

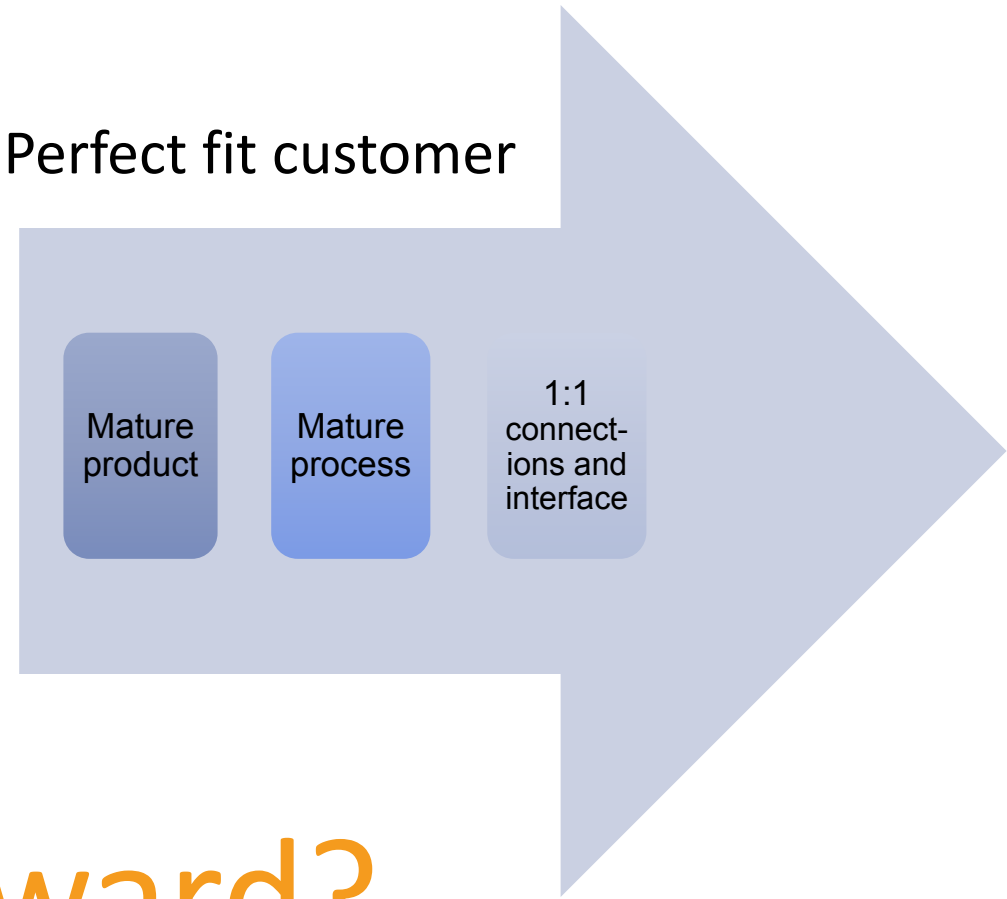
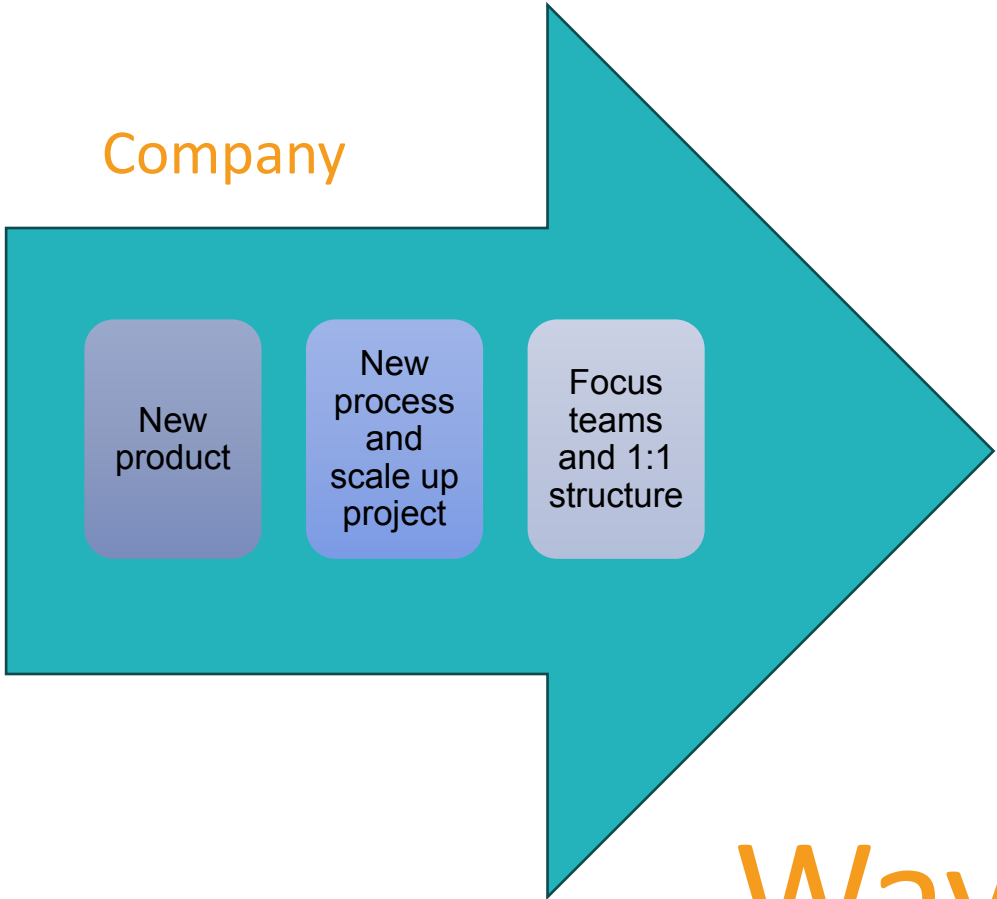
### Challenges:

- Going from start-up to commercialization
  - Interactions with suppliers –how to get your voice heard and supply chain running
- Advanced product/process
  - The fine balance between expertise and micromanagement
- Management of both Partners & Suppliers (CDMOs)

### Learnings:

- Going from start-up to commercialization & Interactions with suppliers –how to get your voice heard and supply chain running
  - Supplier selection process
  - Visualise your view of the supplier (SPET)
  - Regular F2F BRM at Supplier site
- Advanced product/process
  - Product/Process SMEs
  - Present at manufacturing site/s
- Management Partners vs Suppliers (CDMOs)
  - Strong business & supply team
  - Assure "Back-to Back" models
- Through the process
  - SPET –as a supporting tool

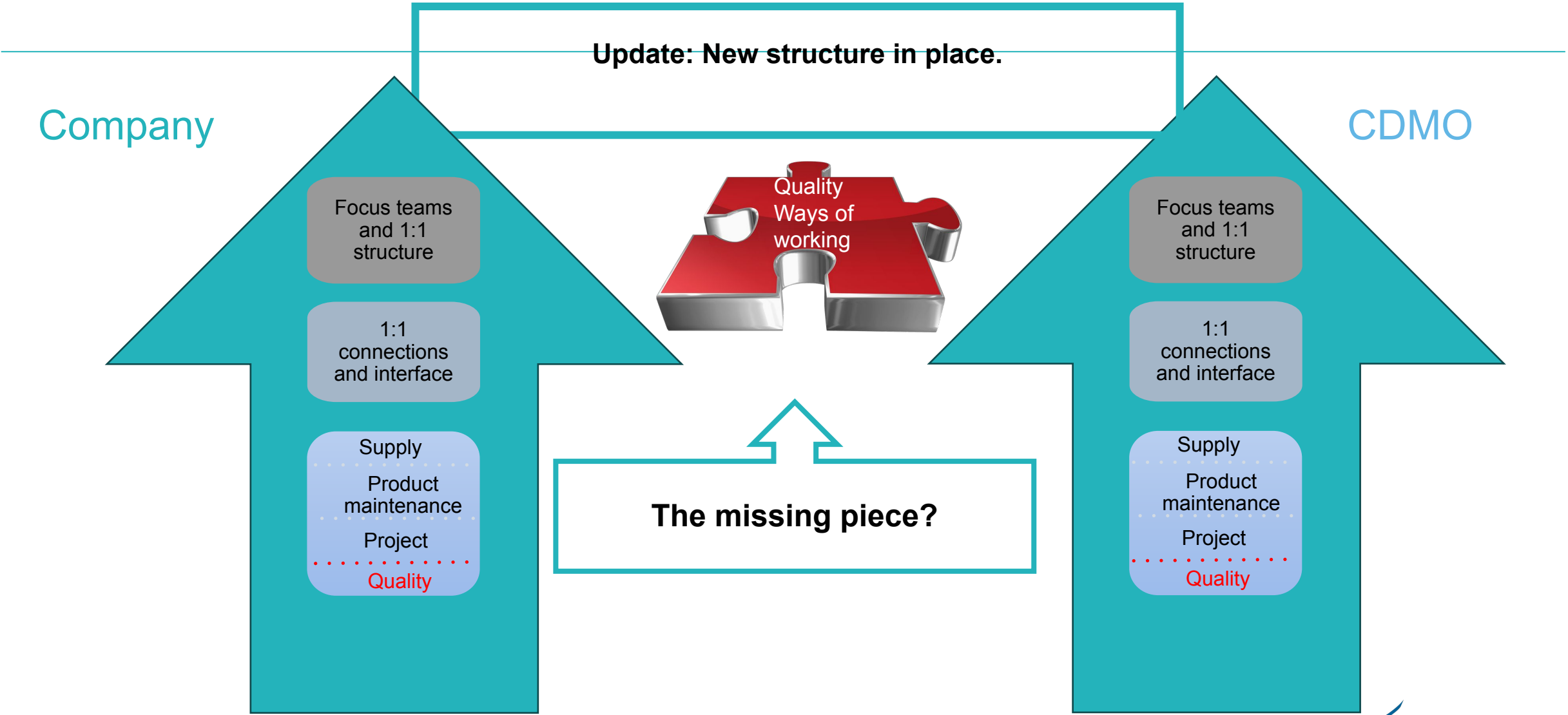
# Perfect fit supplier? – Or, perfect fit customer...



# Way forward?

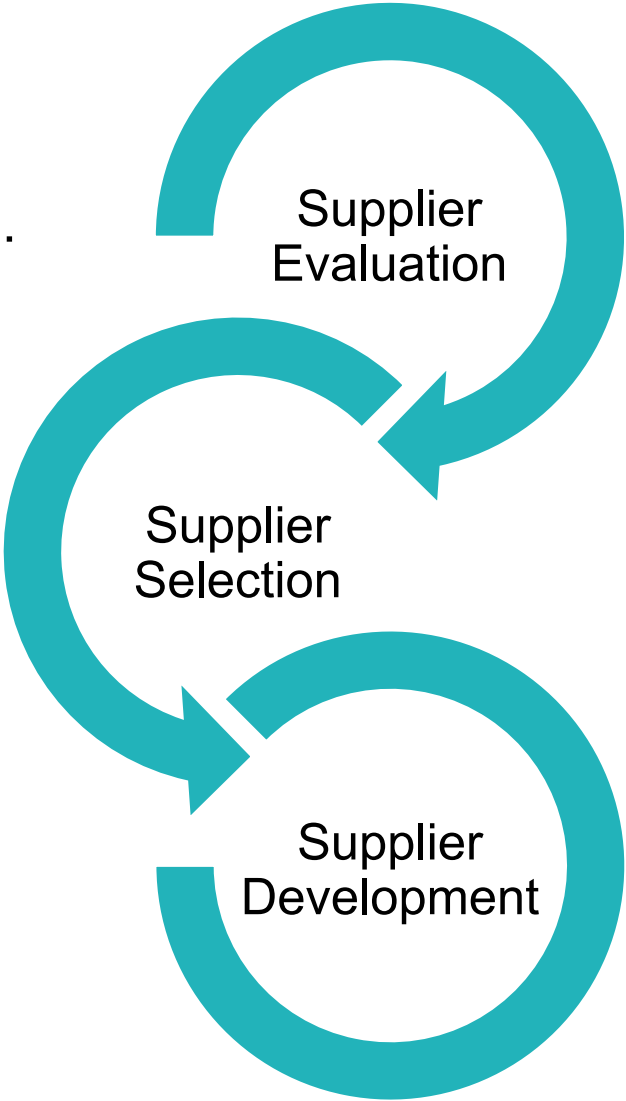
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# Collaboration and way of working – improvements



# Conclusion/Summary

Competence, tool and process to find your perfect fit Supplier...



...and you need a dog!



## Q&A