Managing Quality at your CMOs

Contract Pharma Annual Conference

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Managing quality at your CMOs

- **Background and Perspective**
  - Virtual Global Pharma

- **Quality and Compliance Strategy**

- **CMO Quality and Operational Plan**
  - Map the Product Supply Chain
  - CMO Selection Process
  - Negotiating a Quality Agreement
  - Quality Organization
  - On-going management and monitoring

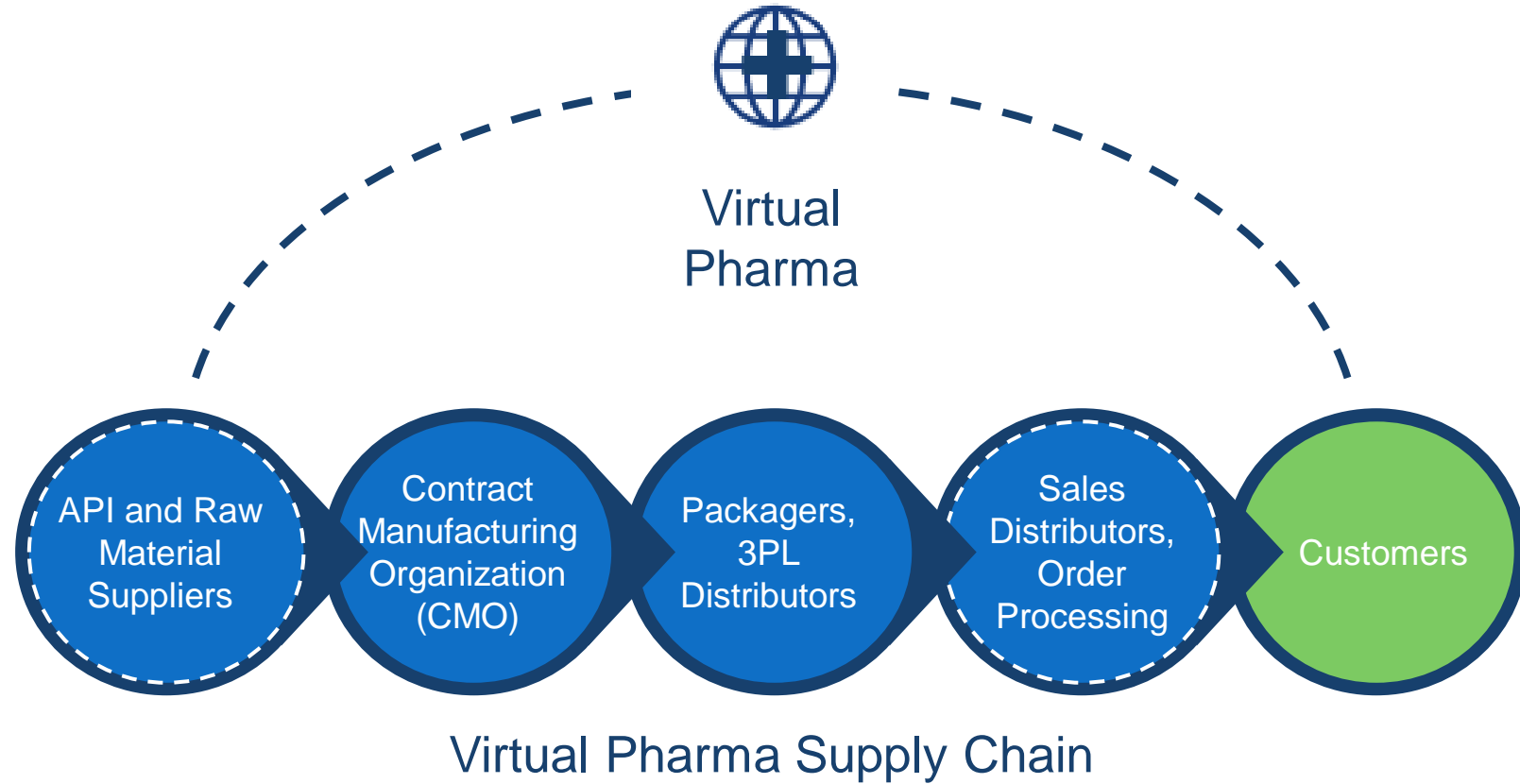- **Building & Maintaining the "Relationships"**

- **KPI's for Managing CMO's**

Background and Perspective

Background

Virtual Pharma

Virtual Pharma Supply Chain

- API and Raw Material Suppliers
- Contract Manufacturing Organization (CMO)
- Packagers, 3PL Distributors
- Sales Distributors, Order Processing
- Customers

Denotes functional areas that can be both outsourced to partners and also can have some direct internal control

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Background and perspective for this discussion

Virtual Global Pharma

CMO's located in US, Canada, EU, Asia (India & China)

Functions involved in managing quality include – Quality Assurance, Quality Control, Compliance, Technical Operations, Manufacturing, Supply Chain, Planning, Project Management, Regulatory, IT

CMO Types include API's, Development, Clinical Supplies, Packaging, Commercial Products

Dosage forms - Tablets, Capsules, SR Capsules, Sterile Injectables, Semi-Solids, Oral Suspensions

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Quality and Compliance Strategy

Quality and compliance strategy

Quality and Compliance Strategy

- Determine what selection requirements to adhere to in setting a minimum standard for a CMO to meet:

  - Quality, Regulatory and Compliance history

- Your Strategy should take into account the entire CMO performance at HQ and the plant site:

  - Corporate QA Systems

  - Specific history at the plant

  - Perform a comprehensive audit

  - Past Track Record = Future Performance

Quality and compliance strategy

Selection Process

- Qualify CMO candidates for a product before the RFQ

- Take into account past Quality, Regulatory, Compliance

- Perform a Comprehensive Audit

- Inquire as to the CMO's other customers at the site

- Dosage forms - Is the product dosage form one that this CMO and the site technical people have a lot of expertise?

- Quality to Quality meetings are separate as well as the Quality Agreement

- Allow QA a veto on a CMO selection

- Build your requirements for the Formal RFQ

- Run the Formal RFQ

- Selection Process must include Business Fit, Quality & Regulatory Performance, Equipment & Capacity and Pricing
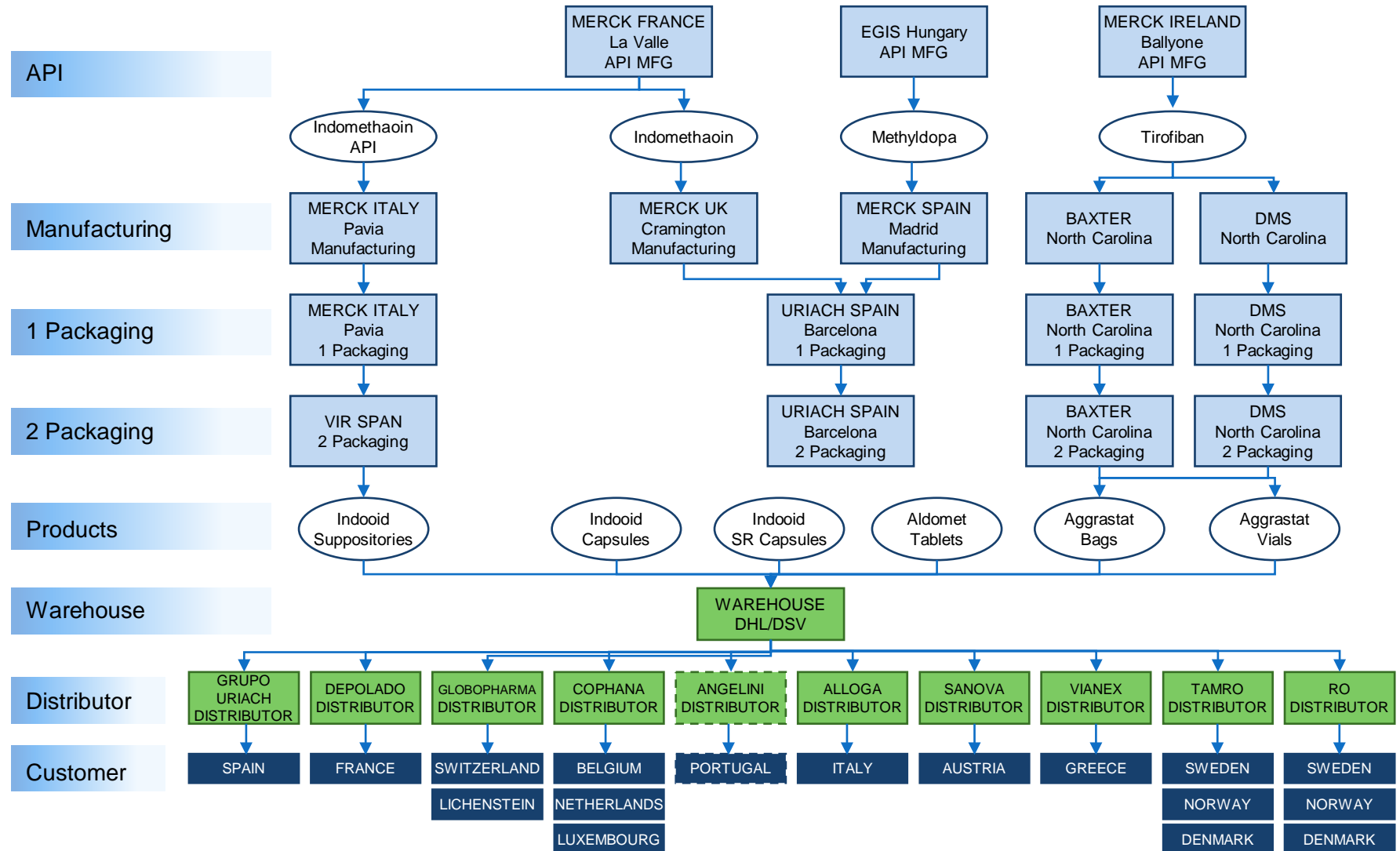
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CMO Quality and Operational Plan

Strategy and supply chain

- Strategy and supply chain

- Quality focus on "nodes" & "links"

Negotiating a Quality Agreement

Key checklist for quality

- Quality and regulatory history

- Regulatory agency approvals

- Quality systems

- Batch record review process

- Manufacturing deviations

- Quality agreement

- Quality audits

- Critical data and trending

- Annual product reviews

- QC testing capabilities and requirements

- Types of products currently manufactured and how that can impact quality at the site

- Product release responsibilities

- Quality organization

- Monthly CMO review by quality

Negotiating a quality agreement

- Most CMO's will try to have the customer use their contract template. Some are good, but some are filled with language written from a CMO perspective. Use your contract template as the base agreement to avoid changes to balance the language in the CMO contract template

- Simple quality agreements can take 2 months and complicated ones can take 3 to 5 months

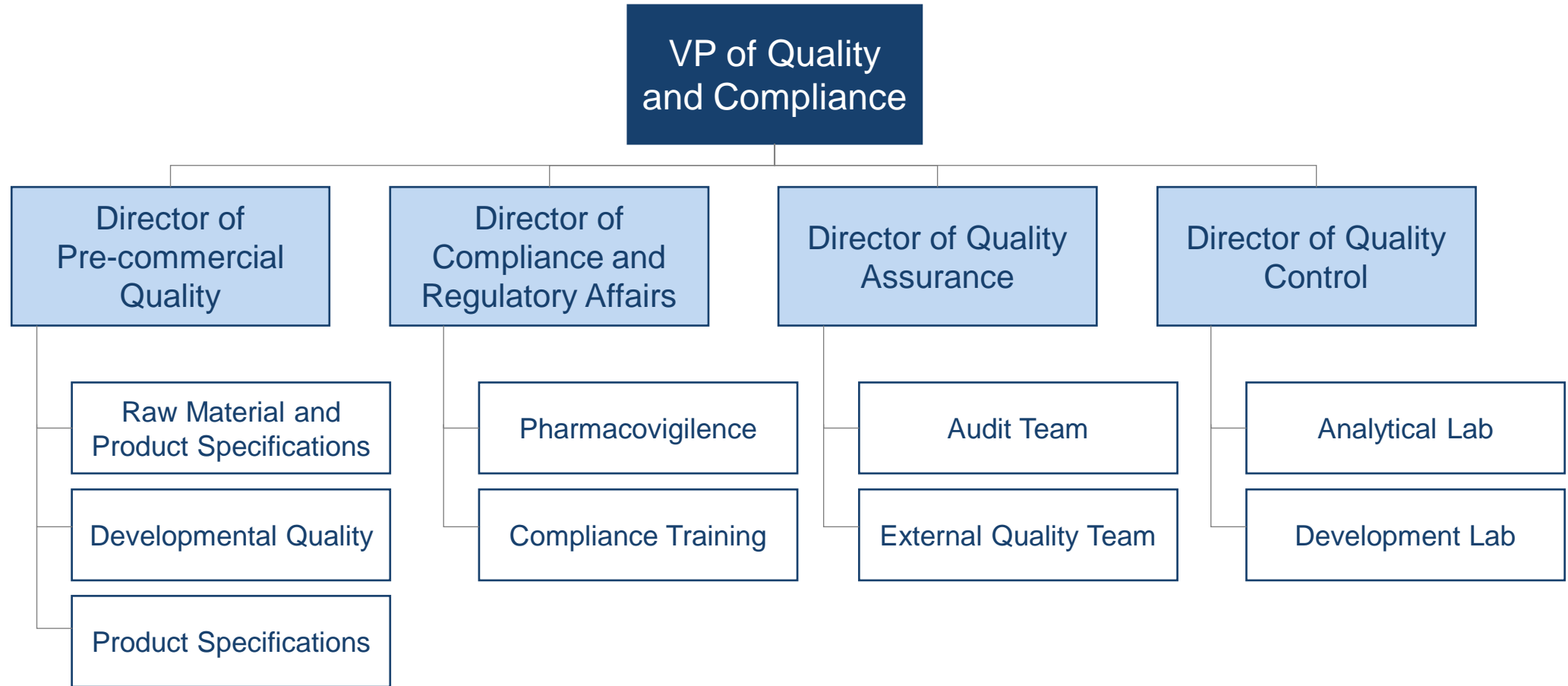- Clearly identify who is responsible for what!

Quality Organization

Sample pharma quality department

VP of Quality and Compliance

- Director of Pre-commercial Quality
  - Raw Material and Product Specifications
  - Developmental Quality
  - Product Specifications
- Director of Compliance and Regulatory Affairs
  - Pharmacovigilence
  - Compliance Training
- Director of Quality Assurance
  - Audit Team
  - External Quality Team
- Director of Quality Control
  - Analytical Lab
  - Development Lab

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CMO Organizational Structure Questions

- Is there a site head located at the plant?

- Who is the top Quality person at the site and do they report into the plant manager or to HQ QA?

- Was there a review of the quality systems and training records during the RFQ process?

- Who is responsible for product release?

- What are the change control procedures and SOP's and what is required to go through the process?

- Are the systems validated?

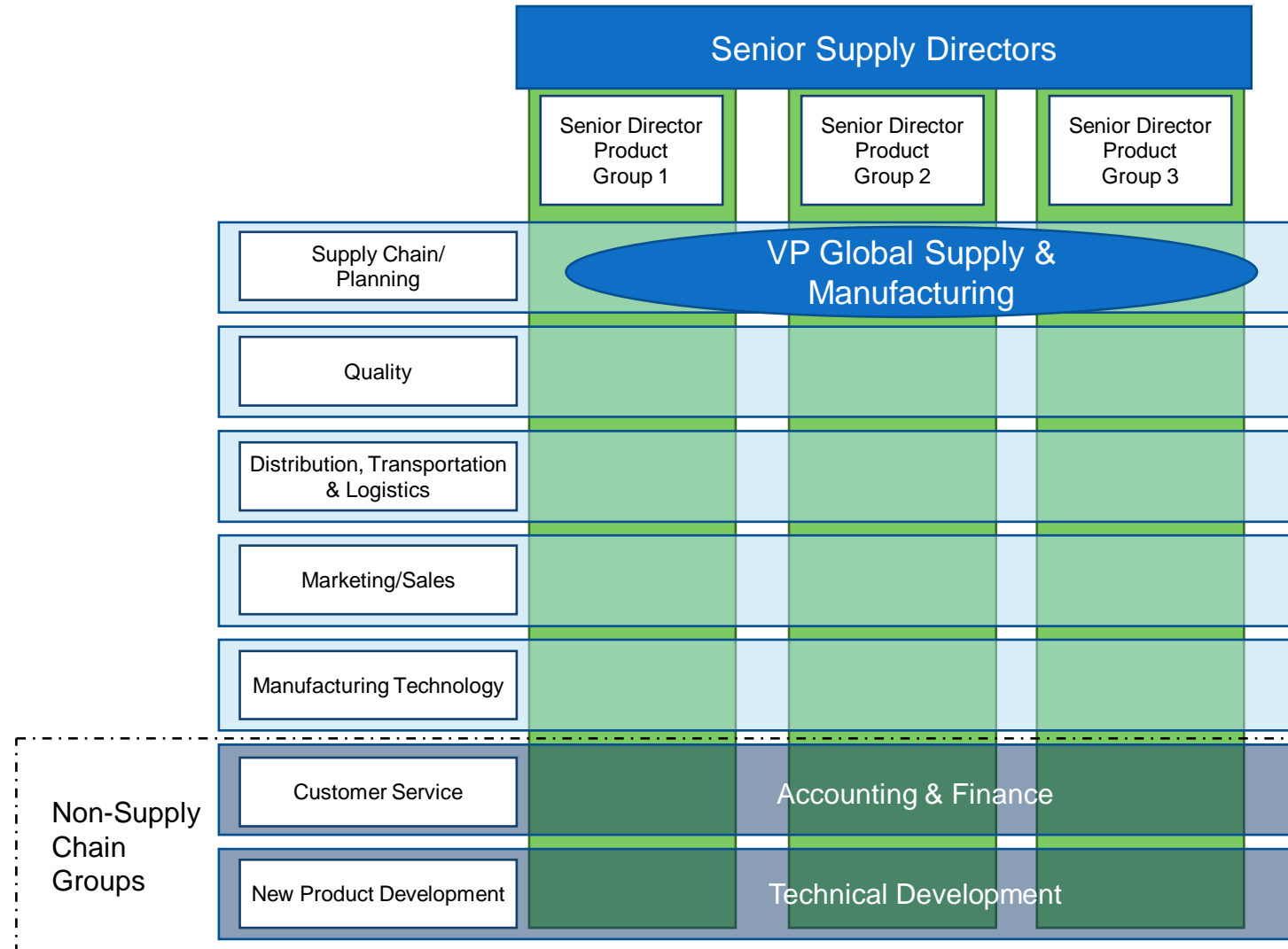# Building and Maintaining the "Relationships"

Building and maintaining the "relationships"

- Build the CMO network of high-quality partners one relationship at a time –

  - Good fit: at the business, technical, quality, cultural and management levels

  - How easy are they to do business with

  - Multiple sites for one high quality CMO
    - When it works well, try more products with that CMO

  - Multiple CMO's for one product
    - Internal risk assessment may dictate the need for a secondary source but need the same level of quality

Matrix organization example

Building and maintaining the "relationships"

- Set up framework for successful management

- Lead person from both sides manage the overall relationship – single point of contact

  - Functional leads contact each other directly on normal matters, exceptions go through contact point

    - Quality to Quality, SC to SC, Tech Ops to Tech Ops, etc.

  - Develop a comprehensive scorecard and collect critical data for use by quality in trending analysis and APR's as well as supply chain and financial data

  - Set up automatic data exchange to improve accuracy and timeliness of data and information exchange with the CMO

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Building and maintaining the "relationships"

- Quality and Master agreements set the rules, but the goal should be to build a strong relationship and rarely refer to the contracts

- Monthly cross-functional conference calls and quarterly site visits -- standing agenda starting with a review of quality Issues

- Monthly review of performance metrics:

  - Batches shipped on time, deviations, quality issues, planning changes within frozen period, yields, invoicing accuracy, inventory accuracy

KPIs for Managing CMOs

KPIs for managing CMOs

Manufacturing	Quality	Order Attributes	Warehouse
Average no. of days late	No. of "major" quality issues monthly	% correct quantity delivered	% of damaged goods and claims
% of batches shipped on-time	No. of "minor" quality issues monthly	% of "perfect" orders shipped	% of stock-outs
% of shipments delivered in full	Cost of quality	Correct price invoiced	% of accidents, lost hours
Pieces per batch (yield)	No. of returned products	Accuracy of documents	Warehouse cost as % of COGS
% of batches delayed due to quality issues	Frequency of quality holds	Frequency of order errors	Inventory accuracy
Batch failure frequency	Right "first time" measurement	% of partial orders/ total orders shipped	Overtime hours worked

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Finding a high quality CMO to partner with…

… is like finding a great building contractor to renovate your mother's house, giving you confidence to smile and enjoy the results.

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