

# Negotiating Medical Device, Pharmaceutical, and Biotechnology Product Sales Contracts

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# Speaker

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# Agenda

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- Introduction
- Understanding the Buyer
- Key Negotiation Points
- Best Practices for Manufacturers

# **Introduction: The Complex Landscape of Medical Product Sales**

# The Complex Landscape of Medical Product Sales

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- **Buyer Priorities and Stakeholder interests**
  - Buyers: GPOs, IDNs, Hospitals
  - Stakeholders: Legal/Compliance, Sales, Finance
- **Regulatory Compliance Complexity**
  - Highly regulated; compliance requirements (pricing transparency, anti-kickback statutes, etc.) add complexity
  - Align with legal and regulatory frameworks AND be competitive and responsive to buyer needs
- **Negotiation Strategies**
  - Manufacturers should align teams, anticipate buyer needs, and prepare for competitive bidding processes.
- **Building Sustainable Industry Partnerships**
  - Effective negotiations foster long-term partnerships enhancing growth and patient care objectives.

# Understanding the Buyer

# Buyer Profiles and Considerations

BUYER	KEY PRIORITIES	NEGOTIATION FOCUS
<b>Group Purchasing Organizations (GPOs)</b>	Cost savings, access to technology	Competitive bidding, standardized terms
<b>Integrated Delivery Networks (IDNs)</b>	System-wide standardization, efficiency	Long-term contracts, uniform specifications
<b>Hospitals/Clinics</b>	Budget, clinical effectiveness	Flexible pricing, implementation support



# Key Negotiation Points

# Competitive and Compliant Pricing

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- Pricing models must balance competitiveness with compliance to legal frameworks like the Federal Anti-Kickback Statute (“AKS”)
  - Structure pricing discount and rebate models within the Discount Safe Harbor of the AKS.
- Risk Management and Reporting
  - Proper tracking and reporting systems reduce legal risks for both manufacturers and buyers.
  - Ask: “Can we implement this?”
    - Establish logistics and procedures to implement and maintain model
    - Failure to do so could place the arrangement outside the protection of the Discount Safe Harbor, increasing the risk of running afoul of the AKS.

# Competitive and Compliant Pricing: *Tiered Pricing Strategies*

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- **GPOs and IDNs**
  - Tiered pricing models based on future purchase volumes
  - Clearly defined thresholds at each level
  - May take the form of rebate structures or volume-based discounts
- Tiered pricing and volume-based discounts is a method for maintaining transparency

# Term & Termination:

## *Contract Duration and Renewal Options*

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- “Evergreen” Agreements not Recommended
  - Term should be for an established length
  - Capped renewal periods subject to both parties’ agreement
  - Market and regulatory shifts
  - Changes within manufacturer’s organization
  - Contracts usually last one to three years (longer terms may be negotiated)
- Renewal Options
  - Renewals generally occur upon agreement to allow an opportunity to review and potentially renegotiate terms based on changes in the market or regulatory landscape, as well as shifts within the manufacturer organization, such as leadership and prioritized business stances.



# Term & Termination:

## *Termination Clause Essentials*

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- Termination clauses specifying early exit conditions should be clearly defined
  - Without cause
  - Breach
  - Regulatory actions
  - Bankruptcy
- Termination Notice Periods
  - Reasonable
  - Buyer may want a longer termination notice period

# Term & Termination:

## *Force Majeure*

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- Another way that a contract may end
- Events outside a party's control:
  - Natural disasters
  - Supply chain disruptions
  - Employee strikes/lockouts
  - Riots, war
  - Since 2020: Epidemic / pandemic provisions / government shutdowns
- Caution: Too much detail could be taken literally



# Compliance & Regulatory Requirements

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- Buyers expect assurances:
  - Products have received the appropriate approvals or clearances by the United States Food and Drug Administration (FDA)
  - Products meet all applicable regulatory requirements
  - Necessary state licenses
  - Plans for mandatory/voluntary recalls, safety notices, or adverse events

# Most Favored Nation (MFN)

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- GPOs and larger IDNs:
  - Assurances that contract terms/pricing are as good as, or better, than other buyers.
- Negotiating MFN provisions:
  - Ensure comparable terms and pricing are extended to similarly situated, non-governmental buyers purchasing a similar mix of products at like volumes.
  - Special considerations for government buyers
  - Ensure internal processes are in place to track pricing/terms offered to buyers before accepting
    - Ask: "Can we track this?"



# Product Supply

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- Buyers expect reliable supply and logistics performance
- Be prepared to negotiate and define:
  - Delivery timelines
  - Order minimums
  - Inventory management practices
  - Mitigation plans for backorders or supply chain disruptions
  - Business Continuity Plans / Disaster Recovery Plans
    - Supply chain and manufacturing continuity



# Limited Warranties

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- In all product sales contracts:
  - Limited product warranty(ies), and
  - Disclaimer for all other warranties, express or implied
- Larger IDNs and GPOs:
  - Often require additional (or alternative) warranty language
    - Manufacturers should carefully review and consider before accepting
    - Do not assume warranty obligations that cannot be met

# Manufacturer Best Practices

# Best Practices for Manufacturers

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- **Engage cross-functionally within organization**
  - Manufacturer sales teams should engage with the company's relevant business and legal teams to ensure alignment on key business stances before contract discussions begin, as well as throughout the negotiation process.
- **Leverage real-world data**
  - Provide evidence to buyers that demonstrates product value in patient outcomes and workflow efficiency for providers.



# Best Practices for Manufacturers, cont'd.

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- **Develop a Contract Negotiation Playbook**
  - Outlines ideal and fallback positions on prioritized business stances, along with its best alternative to a negotiated agreement
  - Empowers stakeholders throughout the business to take an active role in supporting the contract negotiation process with previously approved positioning to move the contract forward more efficiently

# Best Practices for Manufacturers, cont'd.

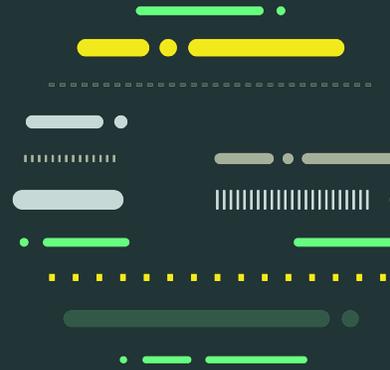
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- **Contract Templates**

- Incorporates preferred terms aligned with the company's legal and business standards
- Accelerates negotiation process
- Establishes a favorable starting point
- Mitigates risk by avoiding inconsistent or ad hoc language across customer agreements



Questions?



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