

# 20th Annual Pharmaceutical and Medical Device Compliance Congress

Mini Summit XXI: Medical Device Asset Management Risk Considerations

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# Medical Device Asset Management Risk Considerations

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## Speakers:

### **Punkaj T. Amin, MS, MBA**

Compliance Officer, US Wound Management and US Privacy Officer  
Smith & Nephew  
Fort Worth, TX

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### **Heather Young, JD**

Compliance Officer – Director for Olympus Corporation of the Americas;  
Philadelphia, PA

The logo for Olympus, featuring the word "OLYMPUS" in a bold, blue, sans-serif font with a registered trademark symbol, positioned above a thick, horizontal yellow brushstroke.

## Moderator:

### **Kamleh J. Nicola, LLB**

Partner, Baker & McKenzie LLP  
Toronto, Canada

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# What Are Field Assets & What Are They Used For?

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- Field Assets = Both Capital Equipment & Single-Use (Disposable) Products
  - Non-revenue generating assets:
    - For demonstration (non-patient use) or evaluation (patient use)
    - Usually provided free of charge
    - **Requires proper tracking**
  - Revenue generating assets:
    - “Trunk Stock” disposable sales and capital equipment rental income
    - Placed capital (no charge) with revenue generated from accompanying disposable sales
    - Consigned product placement and sales
    - **Requires proper tracking**

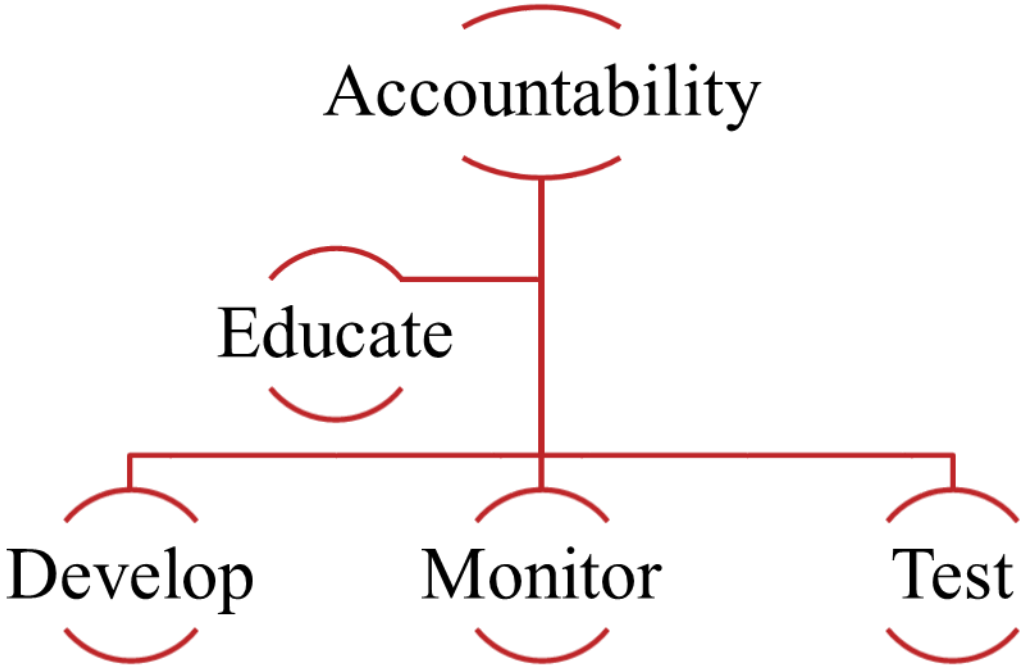
# What is "Asset Management"?

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- What is the primary objective of "Asset Management"? What do you look to achieve?
- Why is it important?
  - What does an effective "Asset Management" program look like?
  - At what stage of the device's pathway is asset management engaged? When does it start?
    - When devices are in development? prototype? in field? commercialized?

# Asset Management Matrix

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# Getting Buy-In and Driving Accountability

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- How do you get buy-in from Leadership Team?
  - *Education* - Understanding that medical assets are “Company assets” and where potential risk exists.
  - *Accountability* - Need Leadership buy-in for allocation of resources necessary to develop and implement program
- What are the drivers to getting buy-in? What resonates with your Leadership Teams?
- Once you have Leadership buy-in and the required resources to proceed, what is next?

# Educate The Business

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- How do you educate the business on the risks (and benefits) of asset management?
  - Initiate two-way dialogue with key business stakeholders to illustrate importance and value to the Company
  - Agree upon what the Company's assets are
- *Risk assessment* – identify, rank and prioritize risks to provide road map for development of your program.
  - Risks are Multi-Faceted:
    - Lost revenue
    - Lost inventory & inventory write-offs
    - Debt write-offs
    - Improper inducements
    - Inaccurate financials
    - Fraud by reps, etc.
    - Inventory variances
    - Sunshine Act violations
    - Fines

# Develop / Deploy Program

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- What are the key factors to development of an asset management program?
  - Stakeholder buy in – Commercial, Finance, Supply Chain, IT
  - Comprehensive and practical business and compliance controls covering Company assets
  - Development of a robust, validated tracking protocol
  - Leverage existing business processes
- How can the Company best mitigate/control risks?
  - Written agreements
  - Monitoring and reporting
  - Field audits and exit audits
  - Invoicing and payment collection
- Consideration of data capture for compliance and business benefit – What are the barriers that may be encountered? Or the obstacles to overcome?
- How do you build-in and socialize accountability across the Company? How best to ensure cross-organizational deployment?



# Monitor the Program

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- How best to monitor program and ensure compliance?
- How to engage and socialize Business Units to self-monitor?
  - How important is self-monitoring?
  - What the business gains – efficiency /cost cutting, business analysis, resource allocation
  - Avoiding external and reputational costs
- KPI development based on agreed upon objectives
  - Compliance controls
  - Efficiency / cost / resource allocation
  - Activity tracking / effectiveness

# Test For Gaps

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- Why is it important to test the asset management program?
- How do you audit your program to identify compliance gaps and improve/manage/remediate risk control?
- What is the Compliance Team's role?
- How do you ensure a "mindset of continuous improvement"?

# Conclusion

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- What do you see as the biggest threat to implementation and socialization of asset management program through out all levels of an organization?
- What is the biggest lesson learned during your time in this role of asset management and compliance?

# Questions?

# Thank you!

Smith+Nephew

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