Considerations for Primary Vaccine Containers

IFPMA Perspectives: What are the issues?

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The IFPMA in brief

- Non-profit NGO represents the research-based pharmaceutical industry worldwide
- Membership
  - R&D-based biopharmaceutical companies in Europe, India, Japan & USA
  - National Industry Associations, from all 5 continents
- Official observer status with UN in Geneva, including the World Health Organization, WIPO, WTO, etc.
- Advocates policies supporting innovation, high quality standards and sustainable access to medicines for patients around the world
- Provides the Secretariat for the International Conference on Harmonisation (ICH)
General Considerations

Considerations for Primary Vaccine Container Selection

- Technical
- Financial
- Manufacturing

Patient and Practitioner
Manufacturing Considerations

- **Machinability** (How the components run on the line)
- **Supply chain**
  - Assurance of reliable supply of components
  - Standard v. unique components
- **Fill volume**
  - Residual volumes and overfill
  - Splashing for high fill products
- **Validation requirements**
  - Materials, Process, Shipping, Cleaning and Sterilization
- **Compatibility with vision inspection systems**
- **Compatibility with secondary packaging lines**
Technical Considerations

- Stability studies
- Material compatibility
- Container closure integrity
- Extractables and leachables
- Moisture vapor transmission rate in some cases
- Functional performance
- Common issues
  - Coated vs. uncoated stoppers
  - Impact of silicone
  - Thermal stability performance
- Transportation
Financial Considerations

- Direct component costs
- Development costs
  - Stability studies, Container closure integrity, Machinability, Extractables/leachables, Antigen sparing
- Manufacturing costs
  - Capital cost for manufacturing line modification
  - Ongoing line changeover costs to switch between images
  - Geographical/siting
  - Fill volume and overage
- Quality failure financial liability
- Lifecycle Management
  - Suppliers (siting, material, etc), Vaccine manufacturers (standardization, etc), Regulatory mandate

Evaluating technical and manufacturing considerations costs time and money!
Financial Considerations

- **Primary container changes**
  - Similar to new development
  - Stability studies, Container closure integrity, Machinability, Extractables/leachables
  - $1-3MM USD, 1-2 years to market in some cases

- **Syringe vs. vial unit costs**
  - Pre-filled syringe may cost up to 20 times vial cost per single dose

- **Glass vs. plastic vial**
  - “Plastic” tube vials may cost 10 times glass cost per single dose
  - Blow fill seal vials may cost 2 times glass cost per single dose
Patient/Practitioner Considerations

- Product Differentiation
- Counterfeit risk
- Patient safety including injection safety
- Product cost
- Wastage
- Stability performance (expiry / VVM)
- Dose density (cold chain footprint)
- Open vial & storage policies
Secondary Packaging Considerations

- Protect the primary and product
  - Impact, vibration, light, moisture
- Communicate / facilitate use
  - Space for required text
- Labeling
- Overall footprint
- Dose density (# doses per volume)
- Counterfeit risk / security measures
- Machinability
- Sustainability of materials
- Development time & cost
Conclusions

- Complexity and multiplicity of parameters to consider for primary container selection

- Patients and provider’s are the main consideration that drives the decision

- Manufacturing, Technical and Financial viability remain important

- Secondary container requirements are as rigorous as primary