

**SMC<sup>®</sup> Ltd.**

**OVOL**  
MEDICAL TECHNOLOGIES  
An SMC Ltd. Company

**CAMBRIDGE  
PHARMA**  
An SMC Ltd. Company

# Primary and Secondary Packaging - Innovation and Latest Developments

Asmita Khanolkar, Sept 14, 2023

# SMC<sup>®</sup> Ltd.

**SMC<sup>®</sup> Ltd.**



Global Manufacturer of Drug Delivery  
Devices (Injection, Autoinjectors,  
On-body devices, Inhalation & Transdermal)

**oval**  
MEDICAL TECHNOLOGIES  
An SMC Ltd. Company



Specializes in Design, Development  
and Industrialisation of SC/IM  
patient-centric autoinjectors

**CAMBRIDGE  
PHARMA**  
An SMC Ltd. Company



Pharmaceutical Services,  
Fill/Finish, Stability, Clinical &  
Commercial batches

**“End-to-End Services”**

## Primary & Secondary Packaging- Innovation and Latest Trends

# Table of contents

1. Current Pharmaceutical Landscape
2. Novel Therapy Trends
3. Parenterals - New Requirements
4. Paradigm Shift in Packaging Model
5. Packaging Strategies
  - Innovation
  - Integration
  - Digitalization
  - Sustainability
6. Primary and Secondary Packaging Trends

# The Current Landscape



## Drug Discovery

- Rapid evaluation of novel drugs and approaches
- Novel Therapies – Bio therapeutics, Targeted therapies, IV to SC, LAI
- Unknowns – Dose/Route
- New Regulatory Pathways
- Urgency, Speed to clinic

## Clinical Evaluation

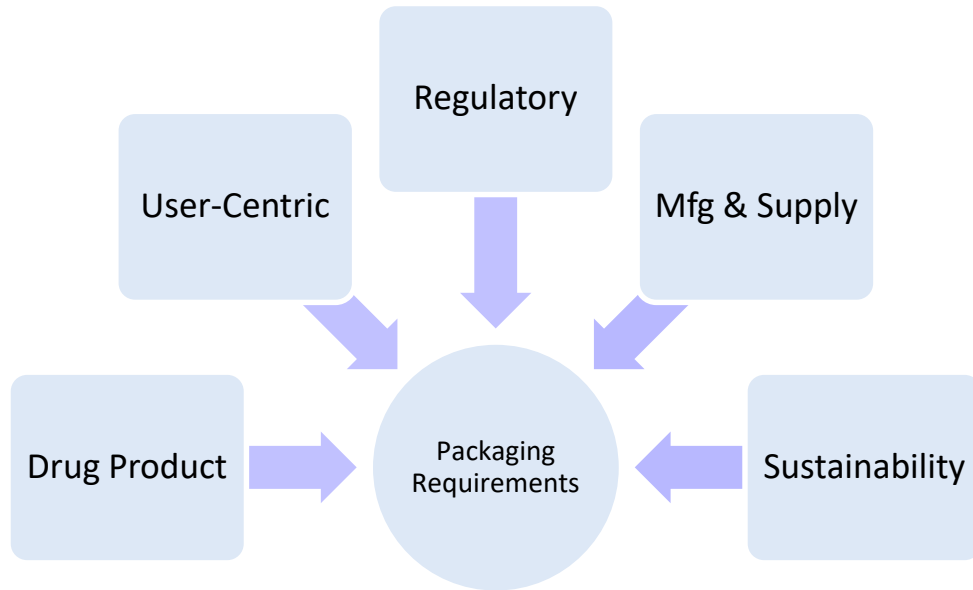
- Decentralization Trends
- Clinical trials at home
- Non-traditional settings
- Self Administration
- Isolation, Remote Care
- Remote training
- Trial Delays, Recruitment difficulty, loss of patients

## Manufacturing & Launch

- Rapid Capacity
- Supply Shortage, Lead times
- Smaller Volumes
- Specialized Processes
- Iterative Scale-Up Strategies
- Single-use technology
- Adaptive Manufacturing
- Automation & Robotics

# Pharmaceutical Packaging Model

Safety > Sterility > Stability



Drug Product Development & Therapy Optimization

## Drug Product Development & Primary Packaging

- Primary Drug Container materials
- Vials, Syringes, Cartridges, Custom PDC
- High Pressure Container Closure Systems
- Ready to Fill Systems
- Sterile Fill-Finish

## Device Assembly & Secondary Packaging

- Drug Handling & Co-packing
- Delivery Optimization
- Device Development & Assembly
- Automation & In-line testing
- Cartons, Blister pack
- IFU, Labeling, Branding

## Final and Tertiary Packaging

- Bulk Packing
- Kitting
- Serialization, Aggregation, Digitization
- Distribution, Track and Trace

# Parenteral Packaging Strategies

## Innovation

- ⑩ New Container Closure Systems
- ⑩ Developing Glass Alternatives
- ⑩ Intuitive Device Design
- ⑩ New Packaging Materials
- ⑩ Cleaner Packaging

## Digitalization

- ⑩ Simulation and 3D Modelling
- ⑩ RFID tags, Counterfeit
- ⑩ Temp, Humidity, Light Sensing
- ⑩ Real Time Monitoring
- ⑩ Labelling, Serialization, QR Codes

## Integration

- ⑩ Pharma 4.0
- ⑩ Automation
- ⑩ Adaptive Manufacturing
- ⑩ Additive Manufacturing, 3D Printing
- ⑩ Emerging and Disruptive Technologies

## Sustainability

- ⑩ Biodegradable Materials
- ⑩ Recycling
- ⑩ Re-use
- ⑩ Minimizing Waste in Production
- ⑩ Improving Efficiencies

# Patient- Centric Device Development

Research potential user groups and use environments Identify key user needs to be addressed

## Early-stage fieldwork

Key functional and user requirements defined  
Develop device design path

## Identify Device Path

Turn inputs into early-stage concepts and identify what works for patients  
Comparative preference testing for multiple options to be evaluated

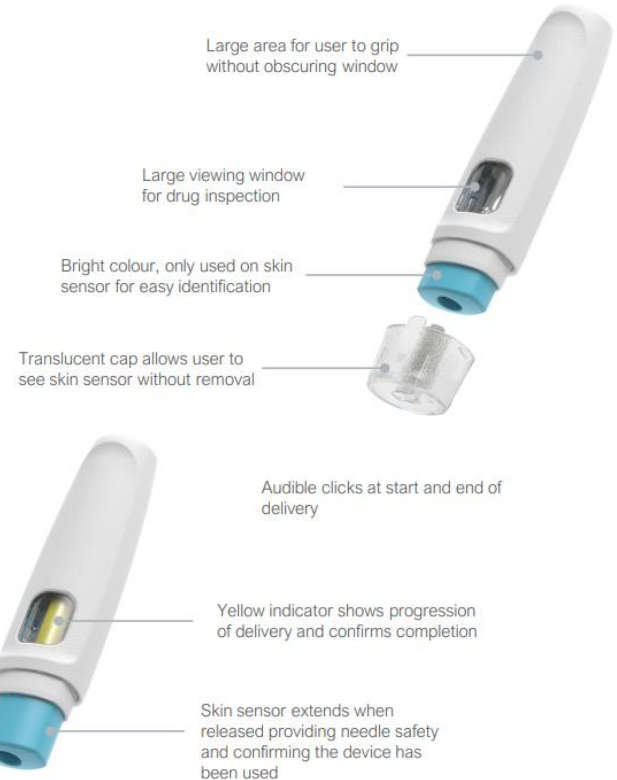
## Formative Evaluation

HF and device development teams work together to ensure functional and user needs are met  
Feedback loop between formative evaluation and device development until device is ready for summative

## Iterate and Refine

Assess identified critical tasks  
HF validation to prove that the device is safe and effective for use

## Summative Evaluation



# Sterility & Stability in Process and Use



## *Formulation*

- Bulk vessels per capacity, Re-usable versus single-use
- Impeller options for homogeneity and sensitive products
- Special requirements shelf, filtration, inert gas head space



## *Filling process*

- Filling process development for new formulations
- Standard versus Custom PDC development
- Stopper position control for downstream assembly



## *Container Closure*

- Closure system selection for custom device and process
- Validation of closures including stability/ shelf life
- Inspection; CCI method development



## *Sterilization*

- Sterilization strategy development
- Bioburden and Sterility Assurance Planning
- Control of primary hermetic closure

## *Device Assembly*

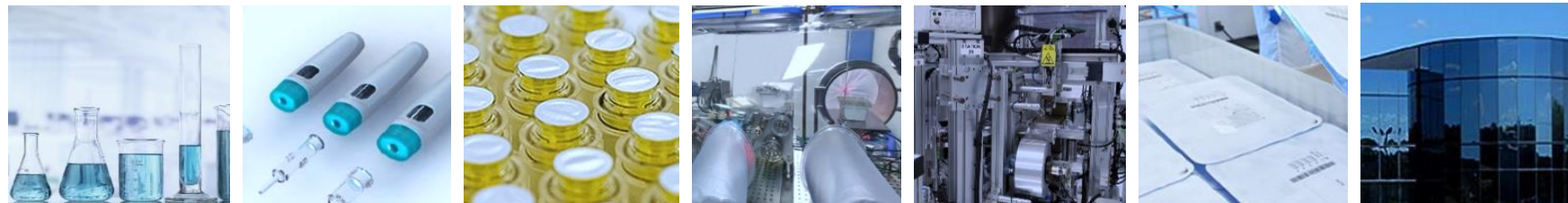
- Assembly steps must not compromise container closures
- Drug paths must be sterilizable and maintain sterility

## *Secondary packaging*

- Secondary packaging developed to align with sterility concept
- Sterile seals identified and validated
- Stability/ shelf life determined



# Supply Chain - Speed to Clinic



Drug Formulation  
& Scale-Up

Device Design &  
Development

Fill-Finish Process  
Development

Clinical Trial  
Manufacturing

Commercial  
Manufacturing

Storage &  
Logistics

Global  
Distribution

Clinical Supply Chain

Commercial Supply Chain

- Innovative Primary Container Closure Systems and Secondary Device Packaging Designs
- Small Batch, Flexible, Adaptive Manufacturing for speed to clinic
- Broad Experience providing solutions for challenging formulations
- Specialized equipment and infrastructure to optimize fill-finish and packaging
- Innovation through single-use systems, automation, non-contact processing, robotic inspection and container closure integrity testing
- Provide modular platforms for early engagement with delivery packaging systems for successful personalized clinical trials

**SMC<sup>®</sup> Ltd.**

**oval**  
MEDICAL TECHNOLOGIES  
An SMC Ltd. Company

**CAMBRIDGE  
PHARMA**  
An SMC Ltd. Company

# THANK YOU!

[asmita.khanolkar@smcltd.com](mailto:asmita.khanolkar@smcltd.com)

[www.smcltd.com](http://www.smcltd.com)  
[www.ovalmedical.com](http://www.ovalmedical.com)  
[www.cambridgepharma.com](http://www.cambridgepharma.com)