THIS IS NOT JUST FILL & FINISH : INSIGHTS FROM A C(D)MO PERSPECTIVE

The added value of fill finish is often regarded as a simple development step while being actually extremely complex in nature. Enough development time for Fill Finish partners selection and technology transfer is usually not accounted and too little time is spent on primary packaging selection which can be detrimental when stabilities issues are discovered late in the process.

THE RIGHT C(D)MO PARTNER

Selection of your **C(D)MO partner** depends on specific and subjective criteria: the **technical characteristics** of the **equipment**, the **expertise** with a specific Drug Substance and manufacturing process and the **reputation** (quality track record) but also the **location**, **business model** and **cultural fit**.

Market reach

- *Local vs global*

Regulatory approvals (US, Japan, …)

- *Supply Chain optimization*

From Drug Substance to Drug Product manufacturing and market release

- *Veterinary, pharma*

Regulatory scrutinity for specific markets (ANVISA)

Drug substance

- *Classification & potency*

Full segreggation or high potent only

- *Sensitivity (O2, T°, light)*

Nitrogen flush online, storage at 2-8°C, change light wavelength

Few example of CMO selection criteria

Packaging capabilities

- *Primary container handling*

Type 1 glass or polymer

Nested or bulk

Ampoules, flexible bags, vials, pre-filled syringes, cartridges,…

- *Secondary packaging*

Carton/carton box or blister/carton, serialization

Device assembly

Manufacturing technology

- *Line loss*

0,1 to 3-5L depending on installation

- *Min/max fill volumes*

From 0,1mL to 5L not on same lines

- *Closure system (PFS)*

Vacuum or mechanical placement of plungers

- *Compounding*

None (WFI) to complex (nanoemulsions)

- *Batch size*

1L to several thousands liters

- *Aseptic or terminal sterilization*
- *DP storage T°*

Available capacity

- *Filling system*

Peristaltic or piston pump

- *Viscosity*

Water to gel

TIMING FOR SELECTION PROCESS

Allocating **enough time for C(D)MO partner(s) selection and technical transfer activities** is key to Drug Product project success. Several factors must be taken into consideration: project assessment, scheduling due diligence visit and quality audit but also C(D)MO planning constrains, primary packaging selection and lead time for delivery, …

Almost **one year** can pass **from initial contact to first GMP batch manufacturing**…

The establishment of a strong Fill & Finish partners network early in the process could save time and money in Drug Product development projects.

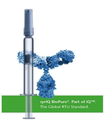
SCHOTT PACKAGING OPTIONS

The choice of **low-risk** primary packaging solutions for **highly-sensitive** drug products/biopharmaceuticals could **optimize Drug Product appearance** and **prevent long term stability issues**.

Schott TopLyo vials

with hydrophobic (silicone-free) internal surface

to prevent „fogging“, enable „elegant lyo-cakes“ and reduce dead volumes after reconstitution, for freeze-dried drug products



Schott syriQ BioPure glass syringes

with reduced silicone amount, tungsten level and adhesive/glue residues

Tight and robust dimensional design for best-fit in autoinjectors/devices

Schott Type I Plus vials

with inert internal quartz-like surface

to prevent drug/container interactions (pH-shift, protein adsorption and/or aggregation…), for liquid formulations

Schott Type I Plus vials plasma coating process