Connecting People, Science and Regulation

Technological Development Updates on Glass Containers for Pharmaceuticals

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OMPI

Ompi | New Portfolio

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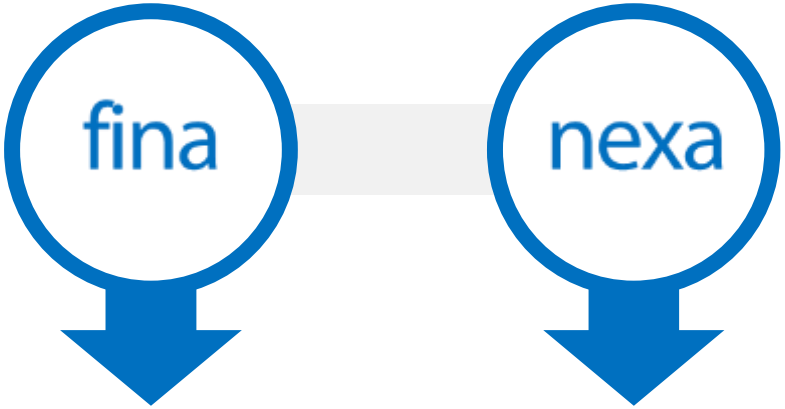


Optimized for parenterals

Best in class for the most demanding products

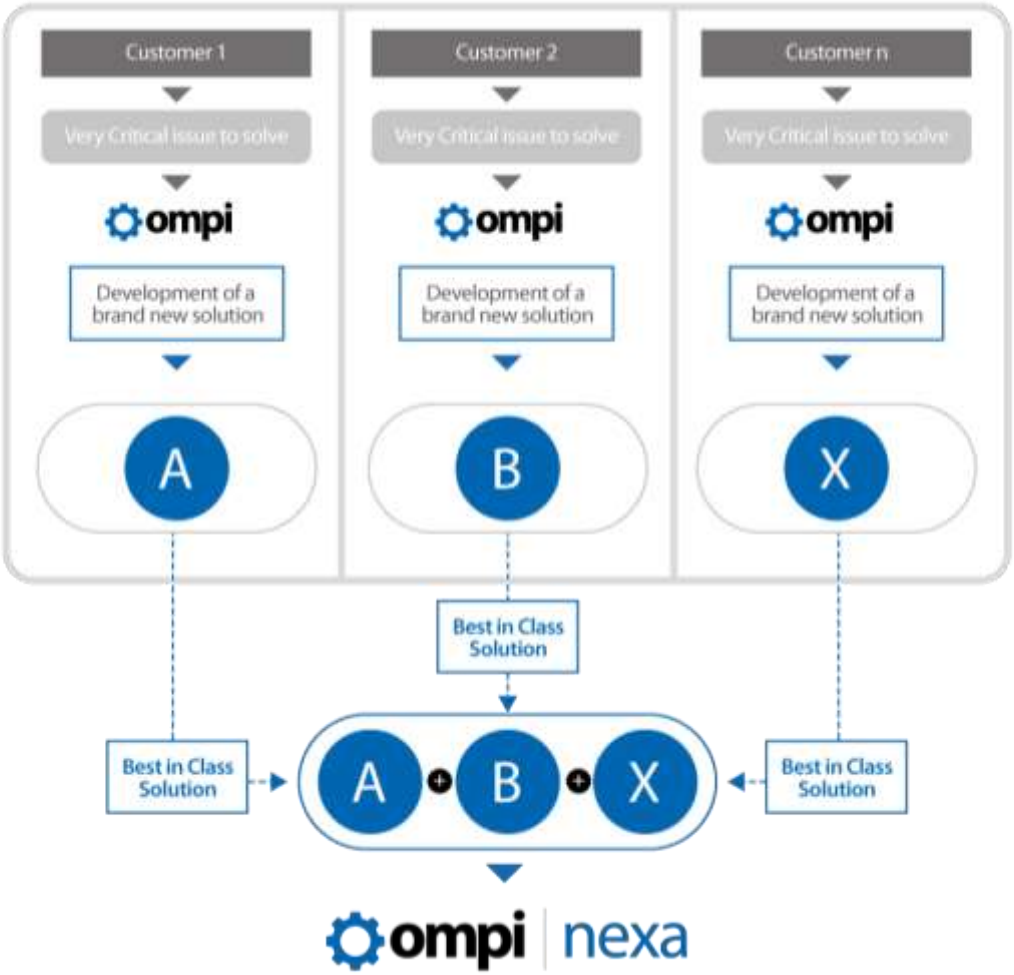
A Brand New Product Portfolio

Ompi Nexa | The sum of the ‘n’ best solutions

Ompi Nexa is the right option to guarantee:

- High compatibility between drug and container
- Unprecedented cosmetic performances

Optimize Total Cost of Ownership



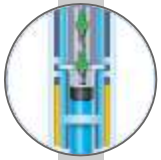
Ompi Nexa Syringes | Benefits

Ensuring your successful and timely launch for novel and existing drug.

Minimizing your Total Cost of Ownership via superior reliability

Increased compatibility between drug and container

Regulatory Expertise to support your launch



Increased Auto-Injector compatibility

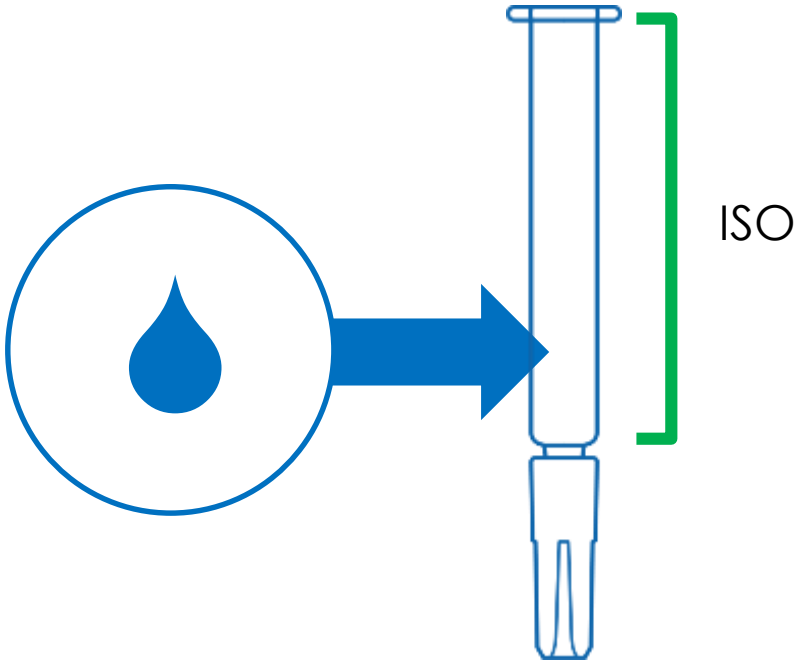
Minimizing risk of false rejects of filled syringes

Superior gliding performance

More proactive quality management

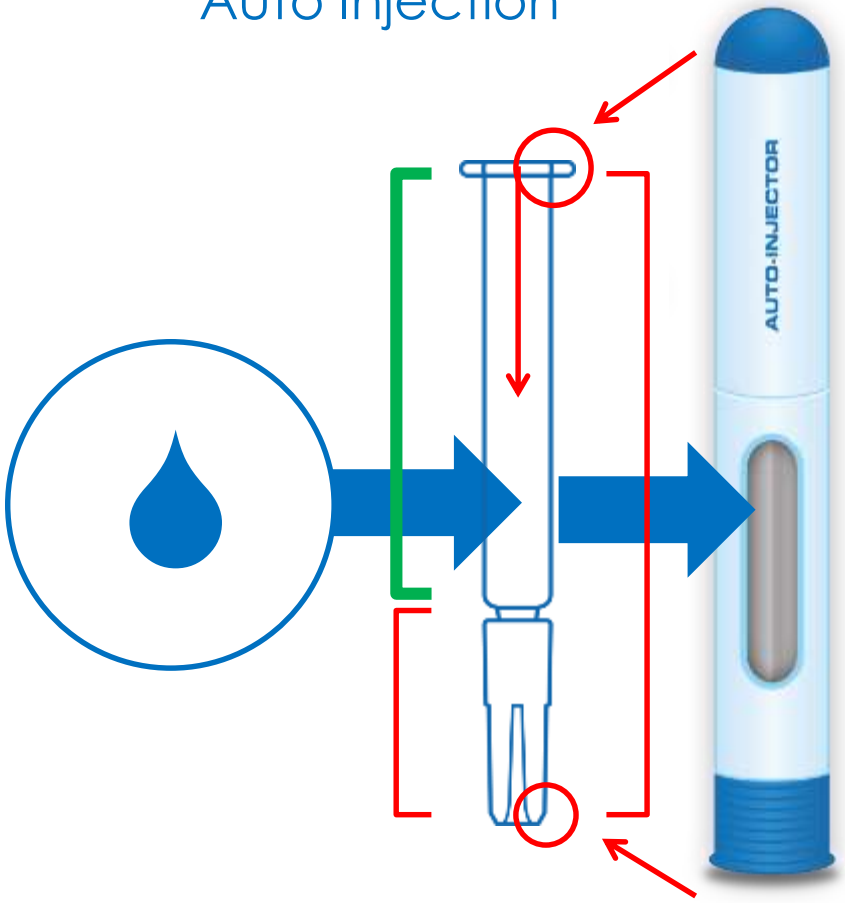
A big challenge (ISO 11040)

Manual Injection



Easy to manage,
less parameters to check

Auto Injection

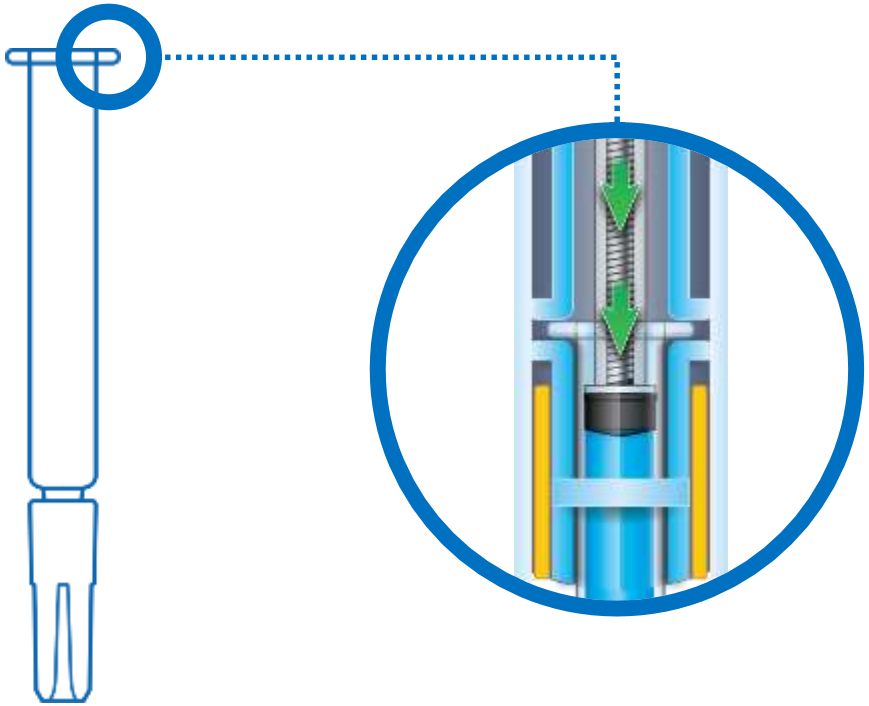


More parameters to manage,
More experience required

Compatibility with Auto-Injectors

- Flange shape & dimensions
- Shoulder radius
- Needle selection

Flange Shape & Dimensions



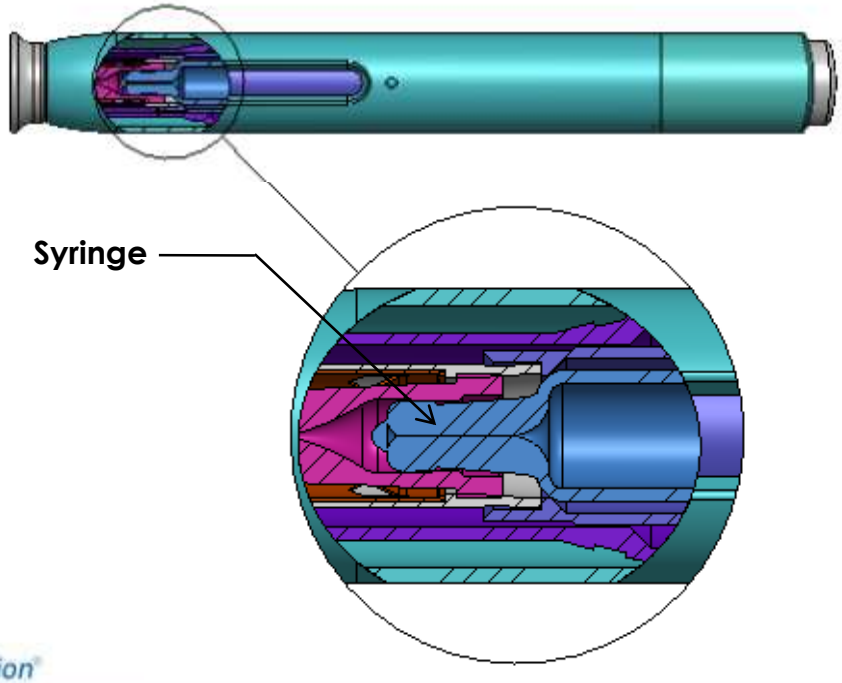
- Critical to the functionality of the system
- Sometimes submitted to high mechanical stress

Benefits of Optimized Flange

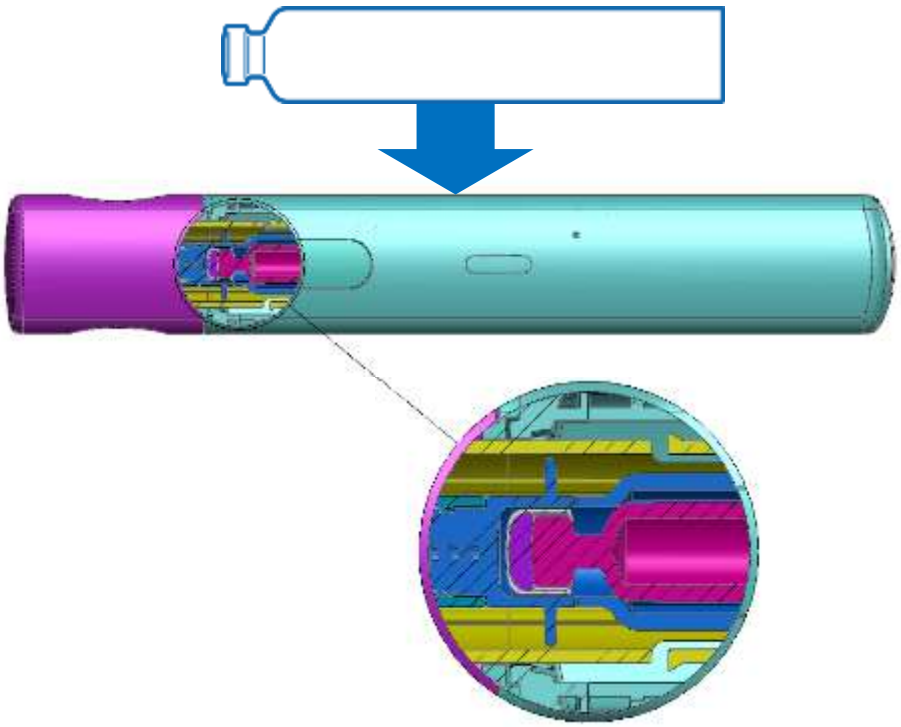
- Flange tailored on the AI syringe carrier
- Less issues during syringe assembly
- Faster development for new AI (through a joint collaboration between syringe manufacturer, AI manufacturer and PharmaCo because of the different flange designs available)

Shoulder Interaction

- Some AI's use the shoulder as a contact point for assembly & the functionality of the system
- This is becoming a critical part of the syringe barrel and for this reason must be characterized for the dimensional point of view



Shoulder Interaction

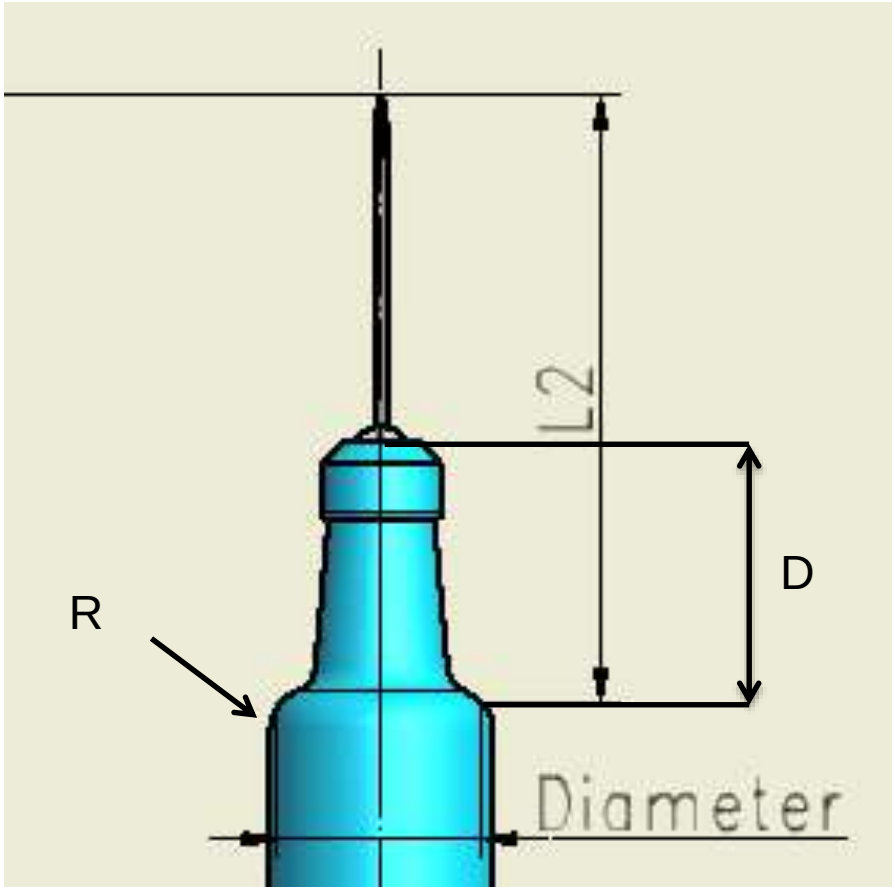


ISO 11040-4 does not specify shoulder area

The shape and the stability of the syringe shoulder depends on the forming process & ease of inspection.

Traditionally cartridge barrels have some additional dimensional parameters to better specify the area of interaction with the device

Shoulder Interaction



- Forming process capability
- 100% Camera inspection

$D \propto L2$

Benefits of Optimized Shoulder

- Optimized integration between glass container & AI
- Reduced risk of breakage due to the mechanical interface between syringe and AI
- Reduced tolerances for injection depth

AI: Needle / Barrel Dimensions

Friction force: Depends on stopper, syringe, siliconization and aging

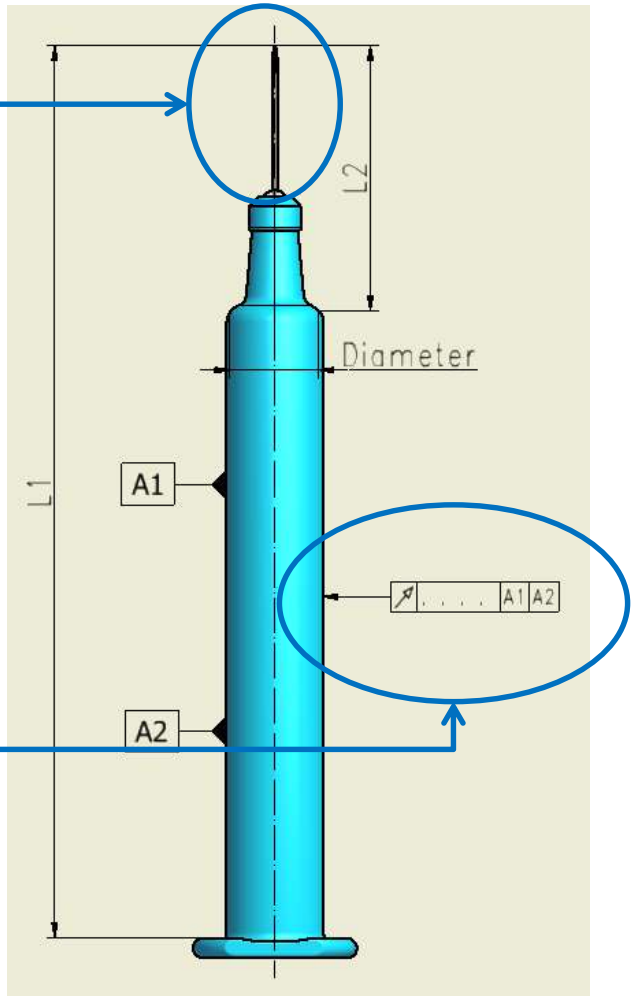
Viscous force: Depends on needle ID, viscosity, and injection speed

$$F_{\text{travel force}} = F_{\text{friction}} + 8\mu L \frac{SR_s^2}{R_n^4}$$

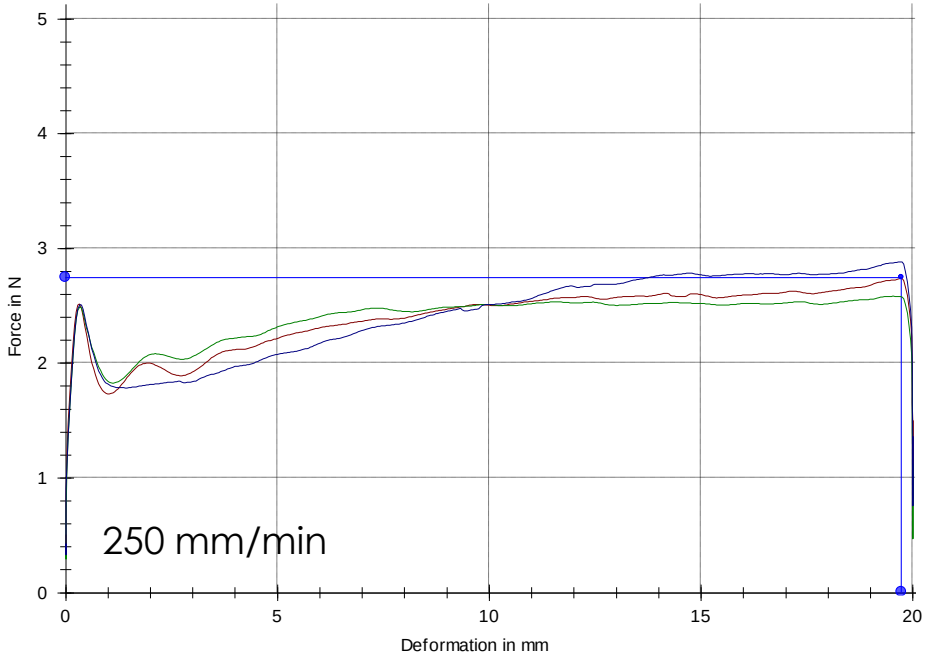
viscous force

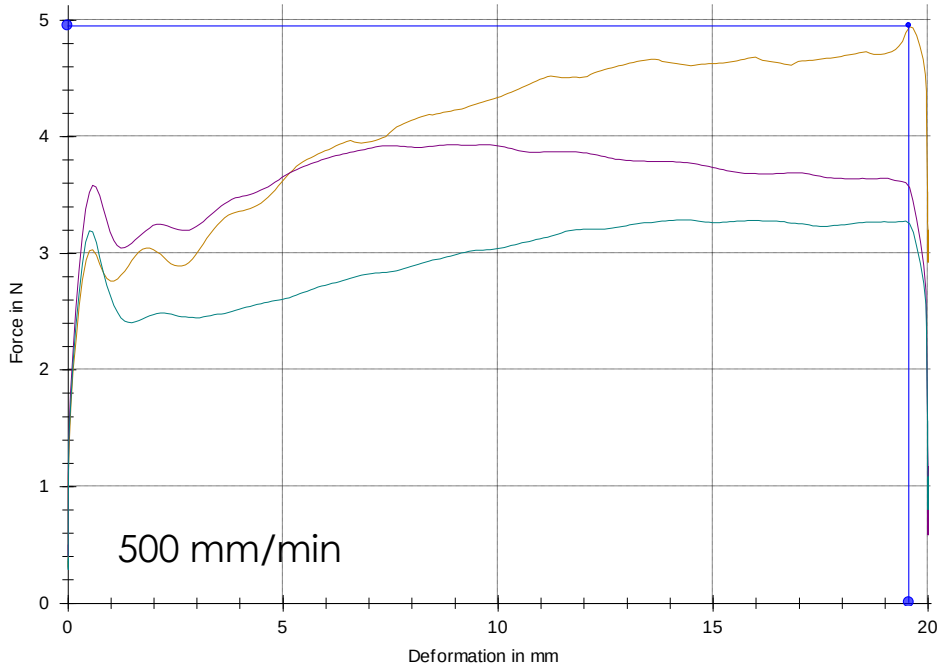
- μ = viscosity (Poise)
- L = needle length (cm)
- S = injection speed (mL /min)
- R_s = radius of syringe (cm)
- R_n = radius of needle (cm)

The needle ID has most significant effect on the injection force



AI: Needle Dimensions





Less variance at low speed

More variance at high speed

viscosity and testing speed (tbd)

Benefits of Injection Depth and Needle Dimensions

- Better integration into the AI
- Reduced variability on the injection time
- Better drug administration

Ompi Nexa Vials | Benefits

Optimizing yield and manufacturing efficiency during the industrial life of your drug

Reducing your Business impacts linked to Quality

Unprecedented cosmetic performance reducing your reject rates to the lowest level.

Reduce vial breakage risk during the industrial life of your drug

Increased compatibility between container and drug

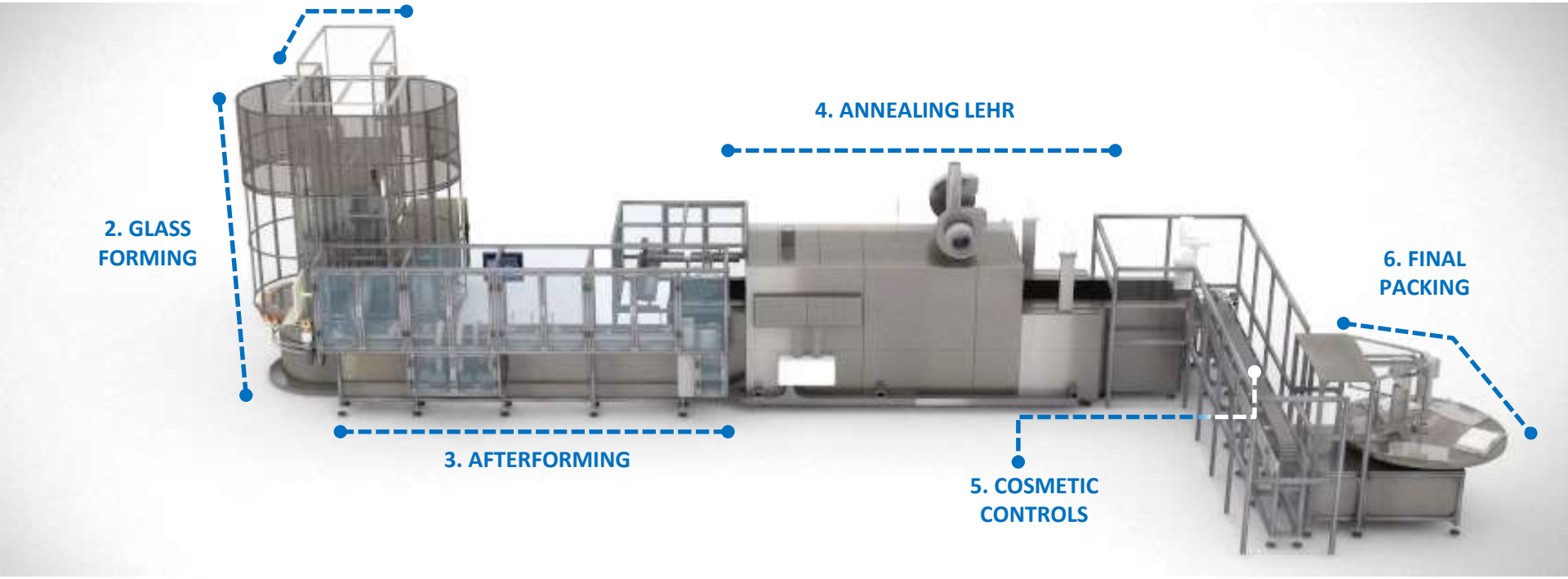
Making your primary packaging easy to manage.

More proactive quality management by extended data collection, to be shared with you.

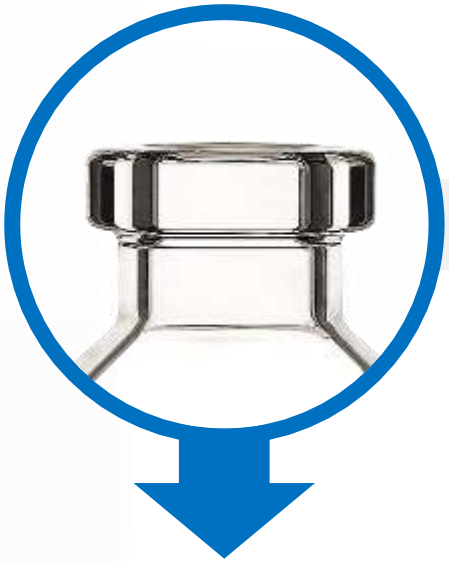
Forming process

Manufacturing process	Focus on the process
	Geometry and tight dimensions
	Mechanical resistance
	Cosmetic quality

Technology steps and main benefits for customers

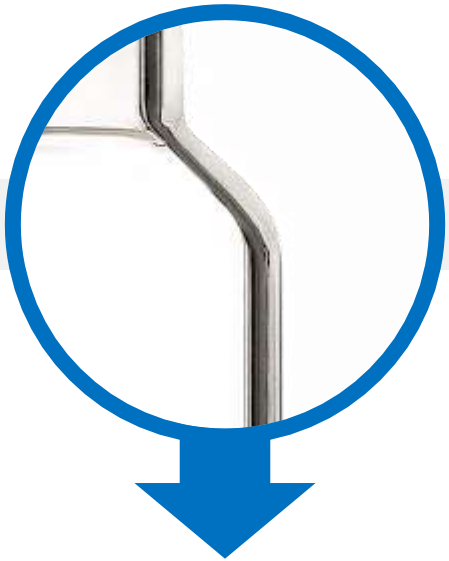


Tight Dimensional tolerances



NECK

Blowback repeatibility



SHOULDER

Optimized for Inspection, to reduce false rejects

BOTTOM

Freeze-dryed drugs

Handling: to preserve mechanical resistance

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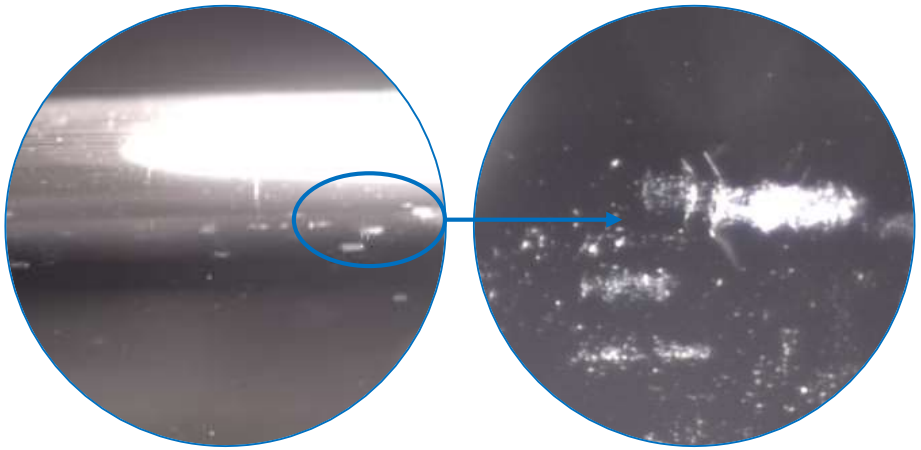
Accurate Handling

- To Avoid glass-to glass contact
- To Avoid/minimize metal-to-glass contact
- Soft handling of the vials
- Reduce particles generation

Ompi Nexa: increased mechanical performance



Cleaner+: the most advanced equipment for inspecting empty vials

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Camera and Inspection

- Multiple cameras

Cleaner+: the most advanced equipment for inspecting empty vials

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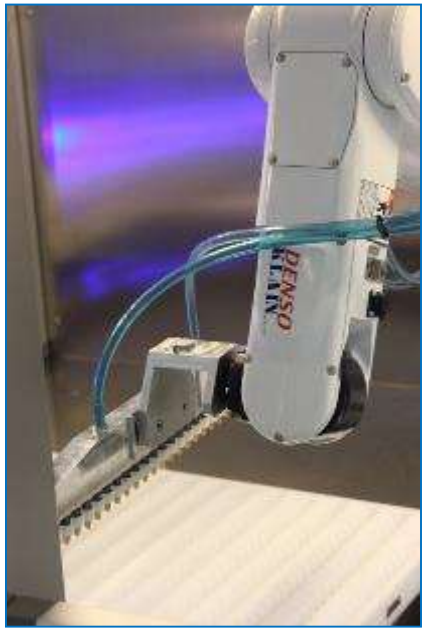

Handling and Automization

- Glass-to-glass contact prevented
- Fully automatic handling

Keys Take Away

- Do not forget what you learnt from the past: sometimes the sum of the improvements can be higher than expected
- Take in account the complete primary packaging process steps
- Assure a very high cosmetic quality
- Try to involve the primary packaging supplier in early stage for selecting the best option

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