DATWYLER

ASSURANCE IN GLP-1 DRUG DELIVERY:

A CHECKLIST TO ACHIEVE **COMPATIBILITY, COMPLIANCE, AND CONFIDENCE**

As GLP-1 receptor agonists transform the treatment landscape for obesity and type 2 diabetes, the need for reliable, high-performance drug delivery systems is on the rise. These therapies are often self-administered and require packaging that guarantees patient safety, efficacy, and ease of use. From chemical compatibility to supply chain resilience, every part of the delivery system is crucial. Use this checklist to guide the selection of elastomer components for GLP-1 primary packaging applications across seven key criteria.

1 FORMULATION COMPATIBILITY

GLP-1 drugs are chemically sensitive and prone to degradation through oxidation, aggregation, or interaction with packaging materials. Ensuring chemical compatibility is necessary to maintain formulation stability. Material and drug contacting components like plungers must meet these criteria to effectively preserve the potency of GLP-1 formulations. Look for:

- ☐ **Chemically pure compounds** – *like Datwyler's FM457* which offer ultra-low extractables to help minimize risk of peptide aggregation, oxidation, and immune reactions.
- ☐ **Material consistency** across all surfaces in contact with the formulation to ensure consistent drug stability and simplify regulatory filings. *For example, Datwyler's FM457 can be used for plungers and combiseals.*
- ☐ **Coatings that minimize drug interaction** by providing a robust, inert barrier between the compound and the drug product. *Ask about NeoFlex™ plungers.*
- ☐ **Anticipation of impending PFAS regulations for coated components** to prevent supply interruption or sudden reformulation. Explore the use of coated plungers containing polymeric PFAS. *Datwyler uses polymeric PFAS in its NeoFlex™ plungers.*

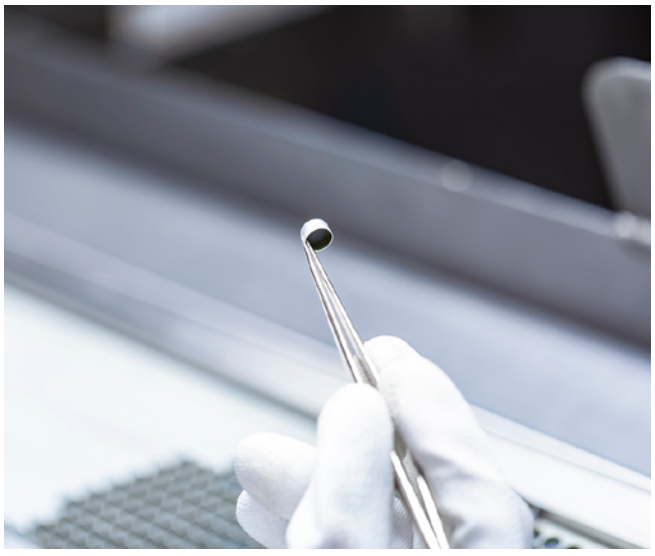
2 FUNCTIONAL PERFORMANCE

GLP-1 therapies are typically delivered in either a cartridge or pre-filled syringe, which most likely end up in a secondary delivery device, such as a pen or auto-injector. No matter how the drug is self-administered, the design of the packaging components can impact the reliability of dosing, product sterility—and ultimately, patient safety and adherence for self-administered therapies. Ensure the design attributes of components support optimal, consistent performance.

- **Plungers**
  - ☐ Check plunger performance metrics like low break loose and gliding forces to facilitate smooth movement for accurate, consistent dosing. Performance must stay in acceptable ranges across different temperatures.
  - ☐ Ensure the plunger stays in the 'sterile zone' during air transport — even in barrels with a large headspace. *Datwyler verifies limited plunger movement with vacuum chamber simulations.*
  - ☐ Ensure a leak-tight design. Plungers must maintain container closure integrity (CCI) to ensure sterility, efficacy, and stability throughout the product's shelf life.
- **Needle Shields**
  - ☐ Verify well-balanced removal force to maintain compatibility with auto injectors. Look for rigid needle shield designs (RNS), which ensure safe handling and help prevent needle stick injuries. *Datwyler's rigid needle shields achieve well-balanced removal forces for reliable performance and safety.*
- **Combination Aluminum-Rubber Seals (Combiseals)**
  - ☐ Ensure multi-piercing resealability that maintains sterility even after 50–100 piercings, compliant with applicable ISO standards. *Ask about Datwyler's ACS0003, ACS0006 combiseal models.*
  - ☐ Inquire about fragmentation resistance to prevent rubber particles from contaminating the drug product after needle piercing.

Datwyler components are tested with leading device manufacturers for consistent break-loose and gliding forces. To ensure device compatibility, align with ISO-standard for your device and as well as additional criteria or specs provided by your barrel and needle suppliers. Input any notes or questions in the cell below.

NOTES:



3 DEVICE AND OPERATIONAL COMPATIBILITY

Manufacturers of GLP-1 therapies must ensure the components are compatible with all partner operations and secondary delivery devices to facilitate seamless integration and speed time to market. This makes it critical to work with a supplier with machine expertise, supporting on standardization, testing, and engineering.

Device Compatibility

- [ ] Find a supplier offering components compatible with standard pen and auto-injectors on the market as GLP-1 drugs typically end up in a secondary delivery device. *Datwyler's NeoFlex™ plungers have been tested by device manufacturers and show superior compatibility due to consistent gliding performance.*

Operational Support

- [ ] Utilize supplier Ready-to-Use (RTU) components to further minimize contamination risk without the costly investment in on-site washing or sterilization options. *Datwyler offers components Ready-to-Use.*
- [ ] For filling lines requiring Rapid Transfer Port (RTP) bags, work with suppliers offering RTP packaging configurations that will help prevent product contamination while transferring components to the filling lines. *Datwyler offers RTP bag configurations that help you to remain compliant with regulations, such as Annex 1.*
- [ ] Explore opportunities for validated sterilization services. *Datwyler's FM457 and coated components are validated for both gamma and steam sterilization methods.*

Datwyler offers a wide range of support services. Add any areas that require operational support below.

NOTES:

4 REGULATORY AND QUALITY ASSURANCE

In a highly regulated environment, primary packaging for injectable drugs must meet stringent global standards. From DMF filings to validated sterilization processes, consider the quality systems and regulatory strategies that support compliance and reduce risk.

Consider what scope of support your organization needs from its suppliers and input any key factors or questions in the cell below.

NOTES:

Global Compliance

- [ ] Lock down supplier support in preparing comprehensive regulatory documentation with any available materials, like DMF filings, or assistance to ease that process. *Datwyler supports customers in their global market readiness across the most highly regulated markets: United States, Europe, China, and Japan.*

Contamination Control

- [ ] Set a high bar for contamination control measures across the component production chain. *Datwyler's FirstLine® manufacturing standard includes Grade C cleanrooms, camera inspection, and validated washing/sterilization processes striving for zero-defect delivery.*
- [ ] Confirm audit readiness. *Datwyler's contamination control strategy aligns with GMP and EU Annex 1 and components are produced according to ISO 15378.*

5 SUPPLY CHAIN RESILIENCE

The global demand for GLP-1 therapies is growing rapidly. To meet this demand, manufacturers must ensure continuity of supply and mitigate risks associated with sourcing and logistics. This section explores strategies that support a robust supply chain.

- **Dual Sourcing and Business Continuity**

  - ☐ Qualify dual sources to reduce risk of supply disruption and support regulatory flexibility. *Datwyler's global footprint ensures consistent quality and faster delivery with a market-to-market manufacturing model to support regional supply strategies that minimize lead times.*

  - ☐ Reinforce supply chains with disaster recovery and capacity planning. *All Datwyler sites have disaster recovery plans and equivalent equipment for uninterrupted supply.*

- **Evaluate supplier technical support and responsiveness**

  - ☐ Evaluate the breadth and depth of expert assistance and co-engineering support. *Datwyler maintains a global team to ensure quick, responsive service to customers around the world.*

  - ☐ Confirm hands-on regulatory expertise. *Datwyler's regulatory affairs team helps customers navigate complex global requirements and support filings across the US, EU, China, Japan, and India.*

Evaluate supply chain needs holistically. Do you need second source support across other applications beyond GLP-1 therapies? Add notes to the cell below.

NOTES:

6 LIFECYCLE MANAGEMENT

As GLP-1 therapies evolve, packaging must adapt to new formats, markets, and regulatory requirements. Lifecycle management strategies enable faster transitions and reduce requalification. Build agility into your packaging strategy with these considerations:

- **Platform Consistency**
  - ☐ Make selections that enable the reuse of data for regulatory filings when transitioning between vial, syringe, and cartridge formats. *Datwyler helps customers minimize time and cost by avoiding redundant testing across all healthcare packaging solutions.*

- **Future Proof Components**
  - ☐ See around the corner to anticipate and adapt to regulatory changes by ensuring materials and coatings selected to meet evolving standards.
  - ☐ Employ a two-by-two matrix strategy to enable qualification of multiple interchangeable components, increasing flexibility and reducing risk. *Datwyler specialists offer guidance to implement this approach.*

What other lifecycle management challenges do you foresee in production of your GLP-1 therapy?

NOTES:

Take your next step. Reach out to Datwyler if you'd like a consultation to put this criteria into action in your company's primary packaging strategy for GLP-1 therapies.

Contact us at healthcare@datwyler.com

DATWYLER