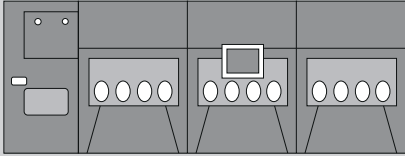
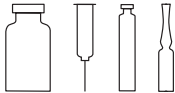
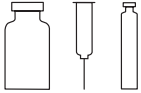
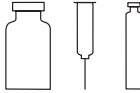
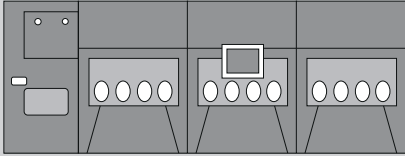

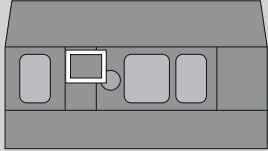





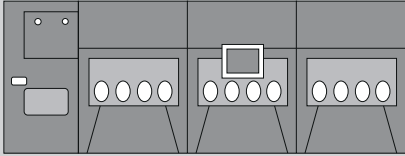

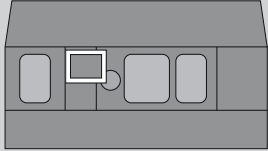
Flexible Filling and Process Infographic

System	<p>VARIOSYS®</p> 	Other flexible filling systems	Workcell system
Application packaging components	 <p>Vials, syringes, cartridges and ampoules</p> <p>+++</p>	 <p>Vials, syringes and cartridges</p> <p>++</p>	 <p>Selected vials, syringes and cartridges</p> <p>+</p>
Speed to the Market	<p>PO FAT Installed & Qualified</p> <p>6 months 6 months</p> <p>+++</p>	<p>PO FAT Installed & Qualified</p> <p>6 months 6 months</p> <p>+++</p>	<p>PO FAT Installed & Qualified</p> <p>6 months 6 months</p> <p>+++</p>
Process Flexibility	<p>1 hour</p> <ul style="list-style-type: none"> • Start-up including decontamination • Changeover between formats <p>+++</p>	<p>1 hour</p> <ul style="list-style-type: none"> • Start-up including decontamination • Changeover between formats <p>+++</p>	<p>1 hour</p> <ul style="list-style-type: none"> • Start-up including decontamination • Changeover between formats <p>+++</p>
Strategic Flexibility	<ul style="list-style-type: none"> • Scalable from preclinical to commercial • Simple to operate with one operator within small Grade C/D space • Deploy globally with standard design • Process transferable to high speed filling lines <p>+++</p>	<ul style="list-style-type: none"> • Scalable from preclinical to commercial • Simple to operate with one operator within small Grade C/D space • Deploy globally with standard design • Process transferable to high speed filling lines <p>+++</p>	<ul style="list-style-type: none"> • Scalable from preclinical to commercial • Simple to operate with one operator within small Grade C/D space • Deploy globally with standard design <p>++</p>

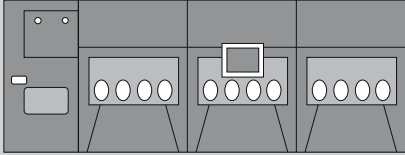

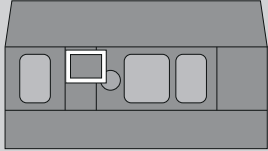
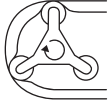
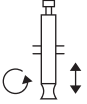



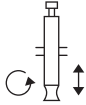
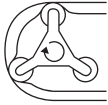
Flexible Filling and Process Infographic

System	<p style="text-align: center;">VARIOSYS®</p> 	<p style="text-align: center;">Other flexible filling systems</p> 	<p style="text-align: center;">Workcell system</p> 
<p>Multi-product Flexibility</p>	 <ul style="list-style-type: none"> • Batch of 15.000 piece per day < 5h <p style="text-align: center;">+++</p>	 <ul style="list-style-type: none"> • Batch of 15.000 piece per day < 5h <p style="text-align: center;">+++</p>	 <ul style="list-style-type: none"> • Batch of 15.000 piece =>10h • To match VarioSys® capacity and speed, multiple units must be purchased <p>(Requires multiple the validation, revalidation, maintenance, calibration, footprint, SOPs, personnel, etc. Multiple batch production records, compendial testing, product specific analytical testing, etc.)</p> <p style="text-align: center;">-</p>
<p>Vial Sourcing Flexibility</p>	<ul style="list-style-type: none"> • Can process vials in tubs, vials in trays, bulk vials and plastic vials • Vials can be molded, tubular with custom dimensions, or ISO standard <p style="text-align: center;">+++</p>	<ul style="list-style-type: none"> • Can process vials in tubs, vials in trays, bulk vials and plastic vials • Vials can be molded, tubular with custom dimensions, or ISO standard <p style="text-align: center;">+++</p>	<ul style="list-style-type: none"> • Can only process vials in tubs with standard ISO dimensions from alliance suppliers (alliance monopoly - no second source) <p style="text-align: center;">+</p>
<p>Flexibility of different vial stoppers</p>	<ul style="list-style-type: none"> • All stoppers up to Ø 20 mm on the market can be used • Can process unlimited stopper formulations & designs <p style="text-align: center;">+++</p>	<ul style="list-style-type: none"> • All stoppers up to Ø 20 mm on the market can be used • Can process unlimited stopper formulations & designs <p style="text-align: center;">+++</p>	<ul style="list-style-type: none"> • Limited availability of closures from two alliance suppliers (alliance monopoly - no second source) • Very limited formulations & designs <p style="text-align: center;">+</p>

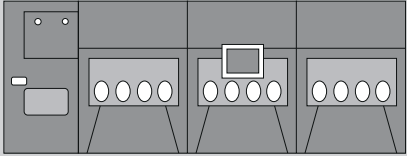
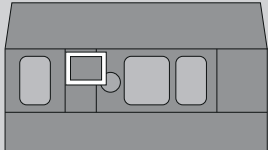
Flexible Filling and Process Infographic

System	<p style="text-align: center;">VARIOSYS®</p> 	<p style="text-align: center;">Other flexible filling systems</p> 	<p style="text-align: center;">Workcell system</p> 
Syringe and cartridge plungers	<ul style="list-style-type: none"> • Can process unlimited plunger formulations & designs • Can handle bulk plungers <p style="text-align: center;">+++</p>	<ul style="list-style-type: none"> • Can process unlimited plunger formulations & designs • Can handle bulk plungers <p style="text-align: center;">+++</p>	<ul style="list-style-type: none"> • Can only process plungers provided in a nest configuration manufactured by alliance supplier <p style="text-align: center;">-</p>
System of sealing of vials	<ul style="list-style-type: none"> • All crimp caps up to Ø 20 mm on the market can be used <p style="text-align: center;">+++</p>	<ul style="list-style-type: none"> • All crimp caps up to Ø 20 mm on the market can be used <p style="text-align: center;">+++</p>	<ul style="list-style-type: none"> • Snap on caps from 2 alliance suppliers (alliance monopoly - no second source) <p style="text-align: center;">+</p>
Closure transfer into the isolator	<ul style="list-style-type: none"> • The closures in bags are gamma radiated (caps and stoppers), steam sterilized (stoppers) or specially treated with a stopper processor. The transfer is done gently with a state of the art RTP system. Feeding of the closure directly out of the bag by disposable bag hopper system. <p style="text-align: center;">+++</p>	<ul style="list-style-type: none"> • The closures in bags are gamma radiated (caps and stoppers), steam sterilized (stoppers) or specially treated with a stopper processor. The transfer is done gently with a state of the art RTP system. <p style="text-align: center;">++</p>	<ul style="list-style-type: none"> • Stoppers with snap on caps are transferred with a VHP cycle. Are studies on closure VHP exposure available? <p style="text-align: center;">-</p>
CCIT (Container Closure Integrity Testing) on closures	<ul style="list-style-type: none"> • FDA approved industry standard <p style="text-align: center;">+++</p>	<ul style="list-style-type: none"> • FDA approved industry standard <p style="text-align: center;">+++</p>	<ul style="list-style-type: none"> • Not FDA approved, not industry standard, validation risk on customer <p style="text-align: center;">---</p>
Machine speed >50 p/min	<p style="text-align: center;">+++</p>	<p style="text-align: center;">+++</p>	<p style="text-align: center;">-</p>

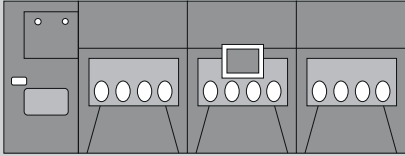

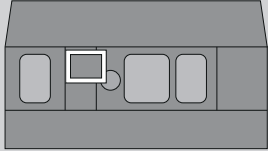
Flexible Filling and Process Infographic

System	<p style="text-align: center;">VARIOSYS®</p> 	<p style="text-align: center;">Other flexible filling systems</p> 	<p style="text-align: center;">Workcell system</p> 
<p>Introduction of „Ready to fill“ objects into the isolator</p>	<ul style="list-style-type: none"> • „No touch transfer“ or heat sterilization of vials <p style="text-align: center;">+++</p>	<ul style="list-style-type: none"> • „No touch transfer“ or heat sterilization of vials <p style="text-align: center;">+++</p>	<ul style="list-style-type: none"> • VHP in process this process results in residual VHP inside the tub and on the object surface. The VHP gas diffuses through the Tyvek and stays there. This is very critical, because VHP destroys the molecules of biotech drugs. <p style="text-align: center;">---</p>
<p>Filling systems</p>	<div style="display: flex; flex-wrap: wrap; justify-content: space-around;"> <div style="text-align: center;">  Peristaltic pump </div> <div style="text-align: center;">  Rotary piston pump </div> <div style="text-align: center;">  Time pressure </div> <div style="text-align: center;">  Powder dosing </div> </div> <p style="text-align: center;">+++</p>	<div style="display: flex; flex-wrap: wrap; justify-content: space-around;"> <div style="text-align: center;">  Peristaltic pump </div> <div style="text-align: center;">  Rotary piston pump </div> </div> <p style="text-align: center;">++</p>	<div style="text-align: center;">  Peristaltic pump </div> <p style="text-align: center;">+</p>
<p>IPC weight check</p>	<ul style="list-style-type: none"> • Vials in bulk 100% IPC without speed reduction • Nested components with 1-100% IPC <p style="text-align: center;">+++</p>	<ul style="list-style-type: none"> • Vials in bulk 100% IPC • Nested components with 1-100% IPC <p style="text-align: center;">++</p>	<ul style="list-style-type: none"> • Statistical IPC <p style="text-align: center;">+</p>
<p>Viable and non-viable monitoring</p>	<ul style="list-style-type: none"> • FDA approved industry standard <p style="text-align: center;">++</p>	<ul style="list-style-type: none"> • FDA approved industry standard <p style="text-align: center;">++</p>	<ul style="list-style-type: none"> • Viable monitoring without petri dishes (FDA approved?) <p style="text-align: center;">-</p>

Flexible Filling and Process Infographic

System	VARIOSYS® 	Other flexible filling systems	Workcell system 
No gloves	-	-	+++
Access in an emergency	<ul style="list-style-type: none"> • Gloves <p style="text-align: center;">+++</p>	<ul style="list-style-type: none"> • Gloves <p style="text-align: center;">+++</p>	<ul style="list-style-type: none"> • No gloves, designed to eliminate only 95% of causes for interventions <p style="text-align: center;">-</p>
Toxic application	<ul style="list-style-type: none"> • Vials are automatically de-nested in a separate chamber which is positive pressure, to the filling chamber • The nest is not exposed to toxic product • Isolator safe change filter cartridges on return air • External vial washing at outfeed • Manual WIP <p style="text-align: center;">+++</p>	<ul style="list-style-type: none"> • Filling of toxic product in the nest • Isolator safe change filter cartridges on return air • External vial washing at outfeed • Manual WIP <p style="text-align: center;">+</p>	<ul style="list-style-type: none"> • Filling of toxic product in nest and VHP out How to decontaminate nest, closure and vial? (VHP out does not neutralize all toxic substances) <div style="text-align: center; border: 1px solid gray; padding: 5px; background-color: #f0f0f0;"> <p>immunotherapies</p> <p>small-molecules</p> <p>gene therapies therapeutic peptibodies</p> <p>RNA peptides CAR-T Bispecific antibodies</p> <p>mAbs ADCs proteins fusion therapies</p> </div> <p style="text-align: center;">---</p>
Lyophilization Process	<ul style="list-style-type: none"> • Vials loaded on shelf via row-by-row in honeycomb configuration • Vials can be externally washed prior to exit of the isolator • cGMP lyophilization process is scalable to high speed, high capacity line • Lyophilizer can be mounted in a class C space • Line could be used for liquid filling or VHP cycle while the lyophilization process is ongoing <p style="text-align: center;">+++</p>	<ul style="list-style-type: none"> • Vials loaded on shelf via row-by-row in honeycomb configuration • Vials can be externally washed prior to exit of the isolator • cGMP lyophilization process is scalable to high speed, high capacity line • Not mounted in class C space, lyo chamber in unclassified area • Limited access to the line <p style="text-align: center;">+</p>	<ul style="list-style-type: none"> • Vials loaded on shelf while in the nest ≈50% less capacity as compared to row-by-row loading of the shelves • Process is not scalable • Not mounted in class C space <p style="text-align: center;">+</p>

Flexible Filling and Process Infographic

System	VARIOSYS® 	Other flexible filling systems 	Workcell system 
Future upgrade of processes	<ul style="list-style-type: none"> The production line can be reconfigured or expanded for capabilities any time after purchase order <p style="text-align: center;">+++</p>	<ul style="list-style-type: none"> The production line configuration is fixed at the time of purchase order <p style="text-align: center;">-</p>	<ul style="list-style-type: none"> The production line configuration is fixed at the time of purchase order <p style="text-align: center;">-</p>
Customer Investment	<ul style="list-style-type: none"> Always expandable and upscalable, can start with minimal configuration <p style="text-align: center;">+++</p>	<ul style="list-style-type: none"> Fixed configuration, upgrades possible <p style="text-align: center;">+</p>	<ul style="list-style-type: none"> Fixed configuration <p style="text-align: center;">-</p>
Production of biosimilar or generic products for clinical trials	<ul style="list-style-type: none"> Ability to exactly match vial, stopper, seal and seal color for clinical trial comparator studies <p style="text-align: center;">+++</p>	<ul style="list-style-type: none"> Ability to exactly match vial, stopper, seal and seal color for clinical trial comparator studies <p style="text-align: center;">+++</p>	<ul style="list-style-type: none"> No capability to exactly match vial, stopper, seal and seal color for clinical trial comparator studies <p style="text-align: center;">--</p>
Process flexibility	<ul style="list-style-type: none"> Customization and process adaption possible <p style="text-align: center;">+++</p>	<ul style="list-style-type: none"> Customization and process adaption possible <p style="text-align: center;">+++</p>	<ul style="list-style-type: none"> No customization and process adaption possible <p style="text-align: center;">--</p>
Commercial and project handling	<ul style="list-style-type: none"> Single source possible <p style="text-align: center;">+++</p>	<ul style="list-style-type: none"> Single source possible <p style="text-align: center;">+++</p>	<ul style="list-style-type: none"> Only single source possible <p style="text-align: center;">++</p>

VARIOSYS®

Smart system using the synergy of the three best-in-class suppliers