

# Pre-Designed Solutions (PDS) Provide Simpler, Safer, Faster & Cheaper Supply Chains for SUS

The growing adoption of SUS in all process steps & applications of commercial production drives the need for reducing complexity, enhancing quality, improving assurance of supply and reducing leadtimes.



# The Accelerated Adoption of SU in Commercial Production Calls for Business Simplification

SUS adopted in clinicals with massive customization & proliferation of SKU's\*

- > 5.000 components from 100's of suppliers
- > 20.000 SKU's created in the last 20 years
- > 70% of SKU's are specific to one customer

SUS growing in all Process & Application Clusters (PACs) of commercial production

Need to reduce complexity at suppliers & end-users to provide

- More robust quality
- Stronger assurance of supply and
- More cost effective supply chain

"Commercial single-use-based manufacturing, consumes much more equipment than at pre-commercial scales"

**BioPlan Associates, Inc.**

SUS	CAGR
Storage & shipping	>15%
Mixing	>20%
Freezing	>30%
Tubes & connectors	>10%
Sampling	>20%
Filling (DDS)	>20%

\* Stock Keeping Units

## PDS Established by 60 Experts Reviewing 4.000 Designs from 20 Years of Experience in Designing SUS

- > 1.200 PDS created to meet all functional and quality requirements of all PACs

PDS performance & AOS based on the complete control of our process from the resins to the final product

All outsourced components are

- Covered by quality agreement  
▶ **consistent quality**
- Secured by long term supply contracts  
▶ **change control & business continuity**
- Available off-the-shelf  
▶ **best delivery reliability**

PDS Bags & Components	USP <87> or USP<88> Class VI	Bioburden Endotoxin Particles	TSE-BSE EMA/ 410/01	Biphenol A free REACH	Noti- fication time
Flexsafe <sup>®</sup> , Flexboy <sup>®</sup> & Celsius <sup>®</sup> bags	Yes	Yes	Yes	Conform	48 months
Flexsafe <sup>®</sup> Pro Mixer	Yes	Yes	Yes	Conform	24 months
TuFlux <sup>®</sup> Transfer Sets	Yes	Yes	Yes	Conform	24 months
TuFlux <sup>®</sup> Tubes	Yes	Yes	Yes	Conform	24 months
Opta <sup>®</sup> connectors	Yes	Yes	Yes	Conform	24 months
Sartopore <sup>®</sup> filters	Yes	Yes	Yes	Conform	24 months
Fittings	Yes	Yes	Yes	Conform	24 months
Connectors	Yes	Yes	Yes	Conform	24 months

# Digital Finder Help You Select the Right PDS For Your Process Steps & Applications in 3 Clics

## Select Application

Storage 2D

Storage &amp; Shipping 2D&amp;3D

Mixing

Freeze &amp; Thaw

Filling

Transfer

Sampling

Select  
Process  
StepSelect  
Connections

### Media Formulation

Sterile Weld to BIOSTAT STR®  
and RM Single-use BioreactorsSterile Connection to other  
Single-use BioreactorsSteaming Connection to  
Stainless Steel BioreactorsSterile Connection  
Sterile Weld

### Buffer Formulation

Sterile Connection  
to Downstream SystemsSanitary or Aseptic Connection  
to Downstream SystemsSterile Connection  
Sterile WeldQuick Coupler Connection  
Tri-Clamp Connection

### Cell Harvest & Downstream Intermediates

Sterile Connection  
to Downstream SystemsSanitary or Aseptic Connection  
to Downstream SystemsSterile Connection  
Sterile WeldQuick Coupler Connection  
Tri-Clamp Connection

### Drug Substance Purification

Sterile Connection  
to Downstream SystemsSanitary or Aseptic Connection  
to Downstream SystemsSterile Connection  
Sterile WeldQuick Coupler Connection  
Tri-Clamp Connection

### Drug Product Formulation

Sterile Connection to  
Final FillingSterile Connection  
Sterile WeldAseptic Transfer  
to an Isolator

## Standard Components

Off-the-shelves

24 months change  
notification

## Standard PDS

Best Quality

Delivery performance

AoS &amp; Price

Optimized inventory

## PDS Provide Best Quality, Change Control, Business Continuity, Delivery Performance & Costs

PDS simplify your process design & provide best quality

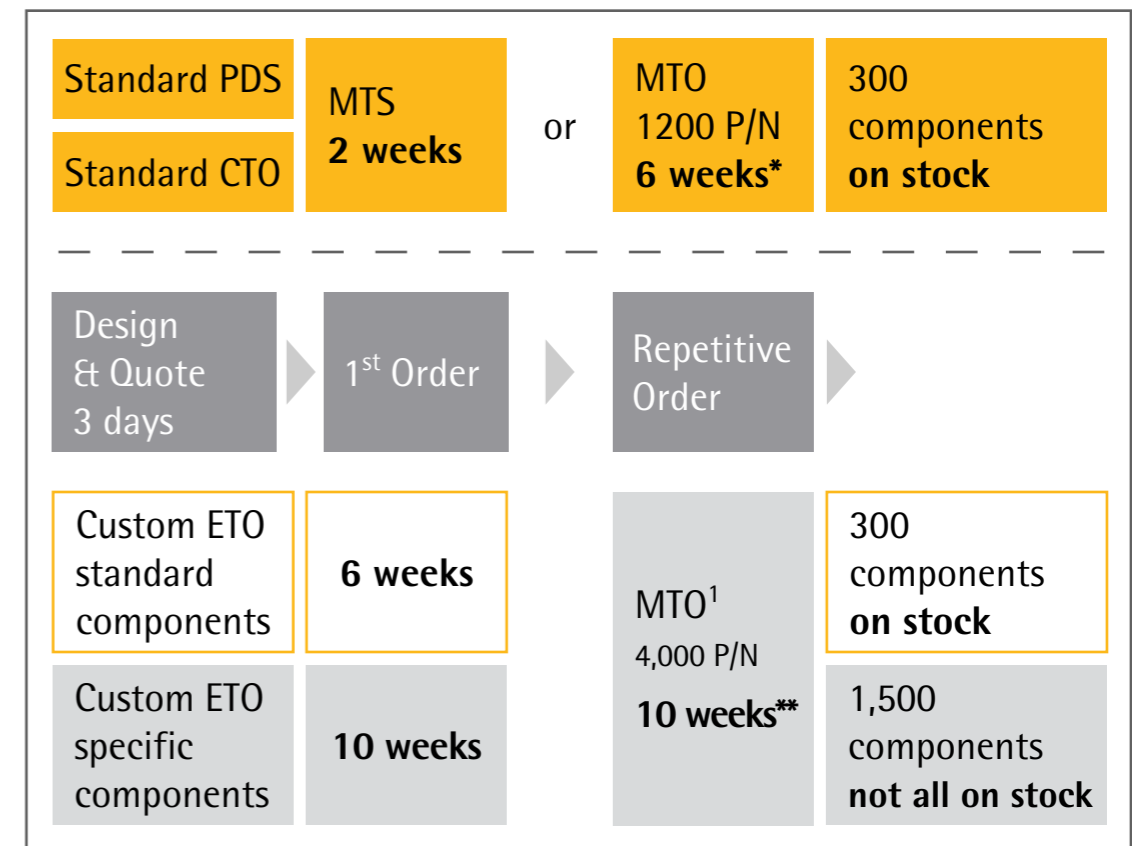
- Digital finder help select a PDS in < 5 min
- > 1.200 PDS qualified & QC tested for your PAC

PDS provide best change control & business continuity

- > 48 month change notification for bags
- > 24 month change notification for components

PDS reduce complexity, costs & leadtimes

- Reduce proliferation of your SKU's
- Optimize your inventory and costs
- Less P | N's & components on stock for best leadtimes



\* currently 8 weeks | \*\* currently 12 weeks

## PDS Offer Safer, Faster, Simpler & More Cost Effective Supply Chain for SUS

For you to fully benefit of the advantages of our SUS, we provide PDS **tailored, proven & quality controlled** for each of your PACs

With quality & supply contracts in place, we guaranty you the best level of **quality, change control & business continuity**

Using our PDS help you speed up your process design and reduce your number of SKUs, **your inventory management complexity and your costs**

PDS finally offer **best lead times** with **2 weeks for MTS** and **6 weeks for MTO**

Standard Vs Custom	AOS	PAC based QC	Lead time	Complexity & costs	Validation data
PDS	●	●	2 – 6 weeks	●	●
CTO	●	●	6 weeks	●	●
CUSTOM Standard	●	●	6 – 10 weeks	●	●
CUSTOM Specific	●	●	10 weeks	●	●



See attached files

Digital-Tool\_Celsius\_SP-1525-e\_EXT

Digital-Tool\_Flexboy\_2D-Bags\_SP-1524-e\_EXT

Digital-Tool\_Flexsafe\_SP-1517-e\_EXT

Pro Mixer customer presentation

Digital-Tool\_PDS\_SP-1523-e\_EXT

Digital-Tool\_TuFlux\_SP-1528-e\_EXT

Digital-Tool\_TAKEONE\_SP-1529-e\_EXT

Global\_PDS

Position-Statement\_PDS

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